Henk A. M. J. ten Have
Bert Gordijn
Editors

Handbook of Global Bioethics

Springer Reference

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With 54 Figures and 17 Tables

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Editors
Henk A. M. J. ten Have
Center for Health Care Ethics
Duquesne University
Pittsburgh, PA, USA

Bert Gordijn
Institute of Ethics
Dublin City University
Dublin, Ireland

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Preface

The *Handbook of Global Bioethics* is published at the right time for the progressive development of bioethics. Started as a discourse critical of medical professional ethics, the new discipline of bioethics emerged in the 1970s primarily in western countries. Concerns about the potential impacts of new scientific and technological advances were dominant. The main challenge was how to empower patients and citizens in light of the new diagnostic and therapeutic powers of medical practice and the sheer endless technological possibilities to improve health, eliminate disease, and extend life.

However, since the turn of the millennium, bioethics has entered a new, more expansive stage. Due to international cooperation, new information technologies, and transnational economic activities, bioethical issues have also been globalized. Bioethical challenges are now experienced in almost all countries. Yet the major questions facing global bioethics today are no longer related to the power of science and technology. Nowadays the most important bioethical questions are related to money and socio-economic conditions. Many people in a large number of countries do not even have access to the benefits of scientific and technological progress. They have treatable diseases but medication is not available. They need surgery but sanitary facilities are far away. They need medical care but cannot afford to pay. They cannot take care of their sick children because they have to work long hours away from home. They cannot properly feed themselves and their family. Thus the processes of globalization have called into existence a truly global bioethics, but at the same time the neoliberal market ideology has particularly created multiple new bioethical issues.

A landmark in the early stage of global bioethics was the Universal Declaration of Bioethics and Human Rights, adopted by all member states of UNESCO (United Nations Educational Scientific and Cultural Organization), in 2005. This political and legal document presents the first general framework of ethical principles for global bioethics that covers all cultures and countries. It has been used as the major reference document for this Handbook.

The Handbook aims to provide a geographic and systematic overview of global bioethics. Volumes 1 and 2 discuss many of the existing and emerging topics in the field. Volumes 3 and 4 present the current state of bioethics in a large variety of countries throughout the world. It is obvious that the Handbook can only give an early picture of the state of global bioethics, a discipline that will undoubtedly go

through a long process of maturation. Many issues will need to be more thoroughly addressed and new unexpected issues will arise. Therefore, this first edition of the Handbook will certainly need continuous updating. In this way it aims to orientate the reader in the ongoing developments within the new discipline of global bioethics.

A work of this magnitude could not have been accomplished without the support of many. First of all, we would like to thank our bioethics colleagues who were willing to spend time and intellectual effort in contributing. But we also thank all those who assisted in the development, reviewing, and processing of the content of this title. Particular thanks go to Aimee Zellers, Barbara Postol, and Jillian Walsh, graduate assistants, and Glory Smith, academic advisor in the Center for Healthcare Ethics in Pittsburgh.

July 2013

Henk A. M. J. ten Have
Bert Gordijn

About the Editors

Henk A. M. J. ten Have studied medicine and philosophy at Leiden University in Netherlands. He received his medical degree in 1976 from Leiden University and his philosophy degree in 1983. Dr. ten Have worked as a researcher in the Pathology Laboratory, University of Leiden (1976–1977), as a practising physician in the Municipal Health Services, City of Rotterdam (1978–1979), and as a Professor of Philosophy in the Faculty of Medicine and Faculty of Health Sciences, University of Limburg, Maastricht (1982–1991). From 1991 he was a Professor of Medical Ethics and the Director of the Department of Ethics, Philosophy, and History of Medicine in the University Medical Centre Nijmegen in Netherlands. In September 2003 Dr. ten Have joined UNESCO as Director of the Division of Ethics of Science and Technology. Since July 2010 he has been Director of the Center for Healthcare Ethics at Duquesne University in Pittsburgh, USA.

Dr. ten Have is involved in many public debates concerning palliative care, euthanasia, drug addiction, genetics, choices in health care, and resource allocation. His research has focused on ethical issues in end-of-life care. Dr. ten Have was the coordinator of the European Commission funded project, 'Palliative Care Ethics'. Over the last decade, he has been particularly involved in debates on global bioethics, emphasizing the need to create bioethics infrastructure (teaching programs, ethics committees, and legislation) in developing countries.

Dr. ten Have serves on numerous editorial boards. He is editor-in-chief of *Medicine*, *Health Care and Philosophy*. He was co-founder and secretary of the European Society for Philosophy of Medicine and Health Care. Dr. ten Have published *Medische Ethiek* (1998; 3rd revised edition 2009), a textbook for medical curricula (also translated in Lithuanian) used in most medical schools in Netherlands. His other books include *Palliative Care in Europe*. *Concepts and Policies* (IOS Press, Amsterdam, Netherlands, 2001), *Bioethics in a European Perspective* (Kluwer Academic Publishers, Dordrecht, Netherlands, 2001), *The Ethics of Palliative Care*: *European Perspectives* (Open University Press, Buckingham, UK, 2002), *Ethics and Alzheimer Disease* (Johns Hopkins University Press, Baltimore, 2004), and *Death and Medical Power*. *An Ethical Analysis of Dutch Euthanasia Practice* (Open University Press, 2005). In UNESCO Dr. ten Have has been involved in a wide range of international activities in bioethics, such as capacity building on the basis of the Universal Declaration of Bioethics and Human Rights, particularly the establishment of national bioethics committees and the promotion of ethics teaching (with a current priority for Africa and the Arab region). With UNESCO he published *Environmental Ethics and International Policy* (Paris, 2006), *Nanotechnologies*, *Ethics and Politics* (Paris, 2007), and *The UNESCO Universal Declaration on Bioethics and Human Rights*: *Background*, *Principles and Application* (Paris, 2009). In 2011, Dr. ten Have published as editor together with Ruth Chadwick and Eric Meslin *The Sage Handbook of Health Care Ethics*: *Core and Emerging Issues* (Sage Handbook Series, Sage, London). In the same year his book in Dutch, *Bioethiek zonder grenzen*: *Mondialisering van gezondheid*, *ethiek en wetenschap* (*Bioethics without Borders*: *Globalisation of Health*, *Ethics*, *and Science*), was published by Valkhof Pers in Nijmegen, Netherlands.

Dr. ten Have is a member of the Real Academia Nacional de Medicina (in Madrid, Spain) as well as of the Royal Dutch Academy of Science (in Amsterdam, Netherlands). From 2007 to 2010 he was an Honorary Research Professor in the School of Philosophy, University of Tasmania, Australia. In March 2008, Dr. ten Have was awarded the title of Doctor Honoris Causa by the Medical University of Pleven in Bulgaria. In September 2008 he received the Oscar M. Ruebhausen Visiting Professorship in the Department of Bioethics, Case Western Reserve University, in Cleveland, USA. In September 2008 Dr. ten Have was also awarded the Ethos Prize for Bioethics sponsored by Calouste Gulbenkian Foundation in Lisbon, Portugal.

Bert Gordijn is Professor and Director of the Institute of Ethics at Dublin City University in Ireland. He studied Philosophy and History in Utrecht, Strasbourg, and Freiburg in Breisgau. In 1995 Bert was awarded a doctorate in Philosophy from the Albert-Ludwigs-Universität Freiburg, followed by a doctorate in Bioethics from the Radboud University Nijmegen in 2003. He has been a Visiting Professor at Lancaster University (UK), Georgetown University (USA), the National University of Singapore, and the Fondation Brocher (Switzerland).

Bert has served on Advisory Panels and Expert Committees of the European Chemical Industry Council, the European Patent Organisation, the Irish Department of Health, and UNESCO. He is Secretary of the European Society for Philosophy of Medicine and Healthcare, and President-Elect of the International Association of Education in Ethics.

Bert is Editor-in-Chief of two book series—*The International Library of Ethics*, *Law and Technology* and *Advances in Global Bioethics*—as well as a peer reviewed journal, *Medicine*, *Health Care and Philosophy*, all published by Springer. His latest published books are *Biobanks and Tissue Research*: *The Public*, *the Patient and the Regulation*, published by Springer in 2011; *Scientific and Philosophical Perspectives in Neuroethics*, published by Cambridge University Press in 2010; and *Ethik in Klinik und Pflegeeinrichtung – ein Arbeitsbuch* (Third Edition) by Hermann Luchterhand Verlag in 2010. Bert's forthcoming books are *In Pursuit of NanoEthics* and *Disaster Bioethics*: *Normative Issues when Nothing is Normal*, both to be published by Springer.

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Contributors

Adamu Addissie School of Public Health, Department of Preventive Medicine, Addis Ababa University, Addis Ababa, Ethiopia

Ghiath Alahmad King Abdullah International Medical Research Center, King Saud bin Abdulaziz University for Health Sciences, Riyadh, Saudi Arabia

Silviya Aleksandrova-Yankulovska Department of Medical Ethics, Management of Health Care and Information Technologies, Medical University of Pleven, Pleven, Bulgaria

Zümrüt Alpinar Centre for Ethics/Institute of Biomedical Ethics, University of Zurich, Zurich, Switzerland

Roberto Andorno School of Law, University of Zurich, Zurich, Switzerland

Berna Arda Department of History of Medicine and Ethics, School of Medicine, Ankara University, Sihhiye, Ankara, Turkey

Vilhjálmur Árnason Department of Philosophy and Centre for Ethics, Department of History and Philosophy, School of Humanities, University of Iceland, Reykjavik, Iceland

Alireza Bagheri School of Medicine, Tehran University of Medical Sciences, Tehran, Iran

Robert Baker Philosophy Department, Union College, Schenectady, NY, USA

Gaia Barazzetti ETHOS-Interdisciplinary Ethics Platform, University of Lausanne, Lausanne, Switzerland

Nikola Biller-Andorno Institute of Biomedical Ethics, University of Zurich, Zurich, Switzerland

Alberto Bondolfi Faculté de théologie, University of Geneva, Geneva, Switzerland

Ana Borovečki School of Medicine, Andrija Stampar School of Public Health, University of Zagreb, Zagreb, Croatia

Alastair V. Campbell Centre for Biomedical Ethics, Yong Loo Lin School of Medicine, National University of Singapore, Singapore

Doutora Ana Sofia Carvalho Instituto de Bioética, Universidade Católica Portuguesa, Porto, Portugal

Leonardo de Castro Centre for Biomedical Ethics, National University of Singapore, Singapore

Don Chalmers Faculty of Law, University of Tasmania, Hobart, Tasmania, Australia

Jacqueline J. L. Chin Centre for Biomedical Ethics, Yong Loo Lin School of Medicine, National University of Singapore, Singapore

Yali Cong Department of Medical Humanities, Health Science Center, Peking University, Haidian District, Beijing, People's Republic of China

Julie Cousineau Centre de Recherche en Droit Public, Université de Montréal, Montreal, QC, Canada

Research Center, CHU Sainte–Justine Mother and Child University Hospital Center, Université de Montréal, Montreal, QC, Canada

Bahaa Darwish Department of Philosophy, College of Arts, Minia University, Minia, Egypt

Hubert Doucet Faculty of Theology and Religious Studies, Université de Montréal, Montreal, QC, Canada

Vilius Dranseika Department of Logic and History of Philosophy, Vilnius University, Vilnius, Lithuania

William English Fellow, Edmond J. Safra Center for Ethics, Harvard University, Cambridge, MA, USA

Donald Evans University of Otago, Otago, New Zealand

Berit Faber Faber Advisors Aps, Copenhagen, Denmark

Thomas Faunce College of Law and College of Medicine, Biology, and the Environment (Joint Appointment), Australian National University, Canberra, ACT, Australia

Lydia Feito Grande School of Medicine, Complutense University of Madrid, Madrid, Spain

Anoja Fernando Chairperson National Committee on Ethics in Science and Technology, National Science Foundation, Colombo, Sri Lanka

Volnei Garrafa Unesco Chair of Bioethics/Faculty of Health Sciences, University of Brasília, Brasília, Brazil

Eugenijus Gefenas Department of Medical History and Ethics, Vilnius University, Vilnius, Lithuania

Grant Gillett Bioethics Centre, Dunedin, New Zealand

Vasil Gluchman Institute of Philosophy and Ethics, University of Prešov, Prešov, Slovakia

Bert Gordijn Institute of Ethics, Dublin City University, Dublin, Ireland

Diego Gracia Complutense University of Madrid, Madrid, Spain

Nouzha Guessous Department of Medicine, Hassan II University, Casablanca, Morocco

Wika Hartanti Faculty of Medicine, Center for Bioethics & Medical Humanities, Universitas Gadjah Mada (UGM), Yogyakarta, Indonesia

Nicole Hassoun Department of Philosophy, Carnegie Mellon University, Pittsburgh, PA, USA

Johan Hattingh Department of Philosophy, Stellenbosch University, Stellenbosch, South Africa

Henk A. M. J. ten Have Center for Health Care Ethics, Duquesne University, Pittsburgh, PA, USA

Calvin W. L. Ho Centre for Biomedical Ethics, Yong Loo Lin School of Medicine, National University of Singapore, Singapore

Soraj Hongladarom Department of Philosophy, Faculty of Arts, Chulalongkorn University, Bangkok, Thailand

Samia Hurst Institute for Biomedical Ethics, University of Geneva, Geneva, Switzerland

Sarah-Louise Johnson Department of Philosophy, University of Birmingham, Edgbaston, Birmingham, UK

Vincent Chipiliro Jumbe Centre for Bioethics in Eastern and Southern Africa (CEBESA), University of Malawi College of Medicine, Chichiri, Blantyre, Malawi

Gregory E. Kaebnick The Hastings Center, Garrison, NY, USA

Lucie Kalousova Department of Sociology, Department of Health Management and Policy, University of Michigan, Ann Arbor, MI, USA

M. Volkan Kavas Department of History of Medicine and Ethics, School of Medicine, Ankara University, Sihhiye, Ankara, Turkey

Isabel Kazanga Centre for Bioethics in Eastern and Southern Africa (CEBESA), University of Malawi College of Medicine, Chichiri, Blantyre, Malawi

Gerrit K. Kimsma Department of Ethics, Philosophy and History of Medicine, Radboud University Nijmegen Medical Center, Nijmegen, HB, Netherlands

Lindsey N. Kingston Department of History, Politics, and International Relations, Webster University, Saint Louis, MO, USA

Julius K. Kipkemboi UNESCO Regional Documentation and Research Centre on Bioethics, Egerton University, Njoro, Egerton, Nakuru, Kenya

Júlia Klembarová Institute of Philosophy and Ethics, University of Prešov, Prešov, Slovakia

Katarína Komenská Institute of Philosophy and Ethics, University of Prešov, Prešov, Slovakia

Natália Kotorová University Hospital J. A. Reiman, Prešov, Slovakia

Evert van Leeuwen UMC St Radboud, Radboud University Nijmegen Medical Centre, Nijmegen, HB, Netherlands

Adela Blahová Lešková Institute of Philosophy and Ethics, University of Prešov, Prešov, Slovakia

Thérèse Leroux Centre for Research in Public Law, Université de Montréal, Montreal, QC, Canada

Hong-wen Li Department of Philosophy, Peking University, Beijing, China

Evariste B. Likinda Chief of Department of Surgery, University Hospital Centre of Mbandaka, Mbandaka, Equateur, Democratic Republic of the Congo

Fernando Lolas Center for Interdisciplinary Studies in Bioethics and Department of Psychiatry, Clinical Hospital, University of Chile, Santiago, Chile

Kristi Lõuk Centre for Ethics, University of Tartu, Tartu, Estonia

Darryl Macer Eubios Ethics Institute, Christchurch, New Zealand

Aaron L. Mackler Theology Department, Duquesne University, Pittsburgh, PA, USA

Ruth Macklin Department of Epidemiology & Population Health, Albert Einstein College of Medicine, Bronx, NY, USA

Gerard Magill Center for Healthcare Ethics, Duquesne University, Pittsburgh, PA, USA

Nur Azid Mahardinata Faculty of Medicine, Center for Bioethics & Medical Humanities, Universitas Gadjah Mada (UGM), Yogyakarta, Indonesia

Toivo Maimets Institute of Molecular and Cell Biology, University of Tartu, Tartu, Estonia

Pierre Mallia Bioethics Research Programme, Faculty of Medicine and Surgery, University of Malta, Msida, Malta

Lucinda Manda-Taylor Centre for Bioethics in Eastern and Southern Africa (CEBESA), University of Malawi College of Medicine, Chichiri, Blantyre, Malawi

Jean F. Martin Privat-Docent à l'Université de Lausanne, Membre de la Commission nationale suisse d'éthique, Echandens, Switzerland

Herjeet Marway School of Philosophy, Theology & Religion, University of Birmingham, Edgbaston, Birmingham, UK

Francis Masiye Centre for Bioethics in Eastern and Southern Africa (CEBESA), University of Malawi College of Medicine, Chichiri, Blantyre, Malawi

Jude M. Mathooko School of Management and Leadership, The Management University of Africa, Nairobi, Kenya

Alex Mauron Institute for Biomedical Ethics, University of Geneva, Geneva, Switzerland

Sheila A. M. McLean School of Law, University of Glasgow, Glasgow, UK

J. M. Mfutso-Bengo Division of Community Health, Centre for Bioethics in Eastern and Southern Africa (CEBESA), University of Malawi College of Medicine, Chichiri, Blantyre, Malawi

Jennifer E. Miller Fellow, Edmond J. Safra Center for Ethics, Harvard University, Cambridge, MA, USA

Emilio Mordini Centre for Science, Society and Citizenship, Rome, Italy

Christopher P. Morley Department of Family Medicine, Department of Public Health and Preventive Medicine, Department of Psychiatry and Behavioral Sciences, S.U.N.Y. Upstate Medical University, Syracuse, NY, USA

Kelli Mulder-Westrate Notre Dame Law School, University of Notre Dame The Law School, Notre Dame, IN, USA

Anton A. van Niekerk Centre for Applied Ethics, Stellenbosch University, Matieland, South Africa

Linda Nielsen Faculty of Law, Copenhagen University, Copenhagen, Denmark

Rudolf Novotný Faculty of Health Care, University Hospital, University of Prešov, Prešov, Slovakia

Fiachra O'Brolcháin Institute of Ethics, Dublin City University, Dublin, Ireland

Dónal P. O'Mathúna School of Nursing and Human Sciences, Dublin City University, Dublin, Ireland

Liudmyla Paliei Philosophy Department, The Shupyk National Medical Academy of Post-graduate Education, Kyiv, Ukraine

Augustine Pamplany Institute of Science and Religion, Little Flower Seminary, Aluva, Kerala, India

Eimantas Peicius Department of Social Sciences and Humanities, Lithuanian University of Health Sciences, Kaunas, Lithuania

Andres Peralta-Cornielle Professor Medical Ethics, O&M Dominican University, Medical School, Santo Domingo, Dominican Republic

Svitlana Pustovit Philosophy Department, The Shupyk National Medical Academy of Post-graduate Education, Kyiv, Ukraine

Juha Räikkä Behavioural Sciences and Philosophy, University of Turku, Turku, Finland

Ahmed Ragaa A. Ragab International Islamic Center for Population Studies and Research, Al-Azhar University, Cairo, Egypt

Jacob Dahl Rendtorff Department of Communication, Business and Information Technologies, Roskilde University, Roskilde, Denmark

David B. Resnik Bioethics, National Institute of Environmental Health Sciences, National Institutes of Health, Research Triangle Park, NC, USA

Mónica Rincón Children's Heart Foundation Cardiology Institute, Nueva Granada Military University, Bogota, Cundinamarca, Colombia

Miguel Angel Sanchez-Gonzalez School of Medicine, Complutense University of Madrid, Madrid, Spain

Bakhyt Sarymsakova Department of Health Policy & Management, Central Asian Bioethics Association (CABA), Kazakhstan School of Public Health, Almaty, Kazakhstan

Soenarto Sastrowijoto Faculty of Medicine, Center for Bioethics & Medical Humanities, Universitas Gadjah Mada (UGM), Yogyakarta, Indonesia

Doris Schroeder Centre for Professional Ethics, University of Central Lancashire, Preston, UK

Michael J. Selgelid Centre for Human Bioethics; School of Philosophical, Historical and International Studies, Monash University, Clayton, VIC, Australia

Stefano Semplici Department of Business, Government Philosophy, University of Rome 'Tor Vergata', Rome, Italy

Darren Shickle Academic Unit of Public Health, Leeds Institute of Health Sciences, University of Leeds, Leeds, UK

Jacques Simpore University of Ouagadougou UFR / SVT, Department of Biochemistry /Microbiology/Molecular Biology, Biomolecular Research Center, Pietro Annigoni, (CERBA / LABIOGENE), University of Ouagadougou, Ouagadougou, Burkina Faso

Alexandra Smatanová Institute of Philosophy and Ethics, University of Prešov, Prešov, Slovakia

O. Carter Snead Notre Dame Law School, University of Notre Dame The Law School, Notre Dame, IN, USA

Jeremy Snyder Faculty of Health Sciences, Simon Fraser University, Burnaby, BC, Canada

S. Yati Soenarto Faculty of Medicine, Center for Bioethics & Medical Humanities, Universitas Gadjah Mada (UGM), Yogyakarta, Indonesia

Jan Helge Solbakk Centre for Medical Ethics, Institute of Health and Society, Faculty of Medicine, University of Oslo, Oslo, Norway

Michèle Stanton-Jean Centre de Recherche en Droit Public, Université de Montréal, Montreal, QC, Canada

Florea Ştefan Faculty of Orthodox Theology, Valahia University Targoviste, Targoviste City, Romania

Godfrey B. Tangwa Department of Philosophy, University of Yaounde 1, Yaounde, Cameroon

Cameroon Bioethics Initiative (CAMBIN), Yaounde, Cameroon

Markos Tesfaye Department of Psychiatry, College of Public Health and Medical Sciences, Jimma University, Jimma, Ethiopia

Sarah Jane Toledano Department of Philosophy, University of the Philippines, Diliman, Quezon City, Philippines

E. Tuzaite Department of Medical History and Ethics, Vilnius University, Vilnius, Lithuania

Susana María Vidal Latin American and Caribbean Bioethics Programme. SHS. UNESCO Montevideo Office, Especialista de Programa. Programa para ALC de Bioética de la UNESCO Oficina Regional de Ciencia de la UNESCO Montevideo, Montevideo, Uruguay

Raymond De Vries Department of Medical Education/Department of Obstetrics and Gynecology, Department of Sociology, Center for Bioethics and Social Sciences in Medicine, University of Michigan, Ann Arbor, MI, USA

Heather Widdows School of Philosophy, Theology & Religion, College of Arts and Law, University of Birmingham, Edgbaston, Birmingham, UK

Erika Yu Department of Public and Social Administration, City University of Hong Kong, Kowloon, Hong Kong SAR

Haihong Zhang Department of Philosophy, Peking University, Haidian District, Beijing, People's Republic of China

Section I

Introduction

Global Bioethics

1

Henk A. M. J. ten Have and Bert Gordijn

Introduction

Bioethics is often regarded as a typically Western phenomenon. According to this view, its development began some forty plus years ago in North America and shortly later in Western Europe in response to emerging scientific and technological advances. It is strongly based on Western values and ethical principles. And, recently bioethics has been "exported to increasing numbers of developing countries" in an almost missionary effort to bring "salvation" to other parts of the world (Myser, 2011, p. xix). This view of today's bioethics is often advocated by anthropologists and sociologists interested in the cultural values and traditions of specific countries (De Vries & Rott, 2011). But it is also defended by some researchers, philosophers, and healthcare professionals in developing countries, arguing that Western bioethics has been imported in their countries without sufficiently taking into account the indigenous and traditional value systems (Chattopadhyay, 2011). This view on the development of bioethics will be called the "story of exportation." According to this story bioethics has originated in Western culture. It is nowadays being exported to other countries, thus imposing Western values on non-Western cultures in the process. Accordingly, bioethics is regarded as an exponent and promoter of "moral colonialism." Therefore, it is appropriate to talk about the "globalization of bioethics" or "globalizing bioethics" as a phenomenon that can be studied, analyzed, and explained as an interesting subject by anthropologists, sociologists, historians, and political scientists who pursue empirical studies and are interested in transformations of value systems, cultural and intellectual imperialism, and so forth. According to this view, any talk about "global bioethics" is suspect because it implies unsubstantiated claims of normative universality that basically amount to imperialistically exporting and

H.A.M.J. ten Have (✉)
Center for Health Care Ethics, Duquesne University, Pittsburgh, PA, USA
e-mail: tenhaveh@duq.edu

B. Gordijn
Institute of Ethics, Dublin City University, Dublin, Ireland
e-mail: bert.gordijn@dcu.ie

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imposing a dominant Western ethics upon other approaches in ethics in other cultures and traditions.

This view on bioethics is closely related to a particular view on its origin, i.e., the "story of invention." This view centers around the claim that modern bioethics is in fact an American invention. In *The Birth of Bioethics*, bioethicist Albert Jonsen describes how bioethics emerged in the 1960s in the United States. Jonsen's historic sketch of the transformation of the old medical ethics into the new bioethics reflects his own story. Like many other early bioethicists he had been drawn from theological and philosophical backgrounds to the new ethical discourse around medicine, healthcare, life science, and medical technologies. Those pioneers have developed bioethics as a new discipline, crafting the theoretical framework and core notions and principles, as well as developing a public discourse, bringing ethical debate and reflection to hospitals wards, classrooms, courtrooms, and television studios. But first of all, this history demonstrates how bioethics was first born in the United States. Dan Callahan, another founding father of bioethics cited in Jonsen's history of bioethics, has said it this way: "Bioethics is a native grown American product" (Jonsen, 1998, p. 377). From this point of view, bioethics in other countries came only later; there simply was no bioethics prior to its American invention. Naturally this later development makes bioethics in other countries less relevant and interesting. Thus, in his 431 page book Jonsen touches on developments outside the USA in only one chapter, entitled "Bioethics – American and elsewhere" (29 pages). In this chapter actually not less than 5 pages are devoted to bioethics outside the USA.

Jonsen extensively elaborates on the question of why bioethics has, and perhaps only could have developed in his country. At first sight, there might be historical reasons: critique of medical paternalism, the citizen's rights movement, the emergence of new technologies, liberalism with its emphasis on individual freedom, and the market ideology. However, according to Jonsen, the real explanation for the invention of bioethics should be sought at a deeper level: the American ethos. In Jonsen's view, this is a way of thinking about ethics that is difficult to understand if one has not lived through the American experience. It is obvious that from the perspective of this interpretation of bioethics it is difficult to conceive of a genuine global bioethics. It can only imagine globalization of bioethics as an extension of the bioethics that has been invented in the USA. However, that extension is intrinsically somewhat difficult because bioethics is so tightly connected to the American ethos. Thus, in this perspective bioethics in other parts of the world is indeed the result of importing US values and adapting them to the idiosyncrasies of non-US countries.

Both the story of exportation and the story of invention are in fact two sides of the same coin. They articulate the outsider and insider views, respectively. More important is that they both lead to similar conclusions. Protagonists of both stories will primarily articulate the differences between forms of bioethics: Asian bioethics and European bioethics, and also Mediterranean bioethics, French bioethics, and perhaps even Burgundian bioethics. They will point out the enormous cultural diversity. In the perspective of diversity, bioethics will be focused on differences

rather than commonalities. Global bioethics in this perspective will primarily address different traditions, religions, and cultures but is less interested in the question what they have in common. They can hardly promote any universally shared values that might make sense of global bioethics. For believers in the story of exportation this would be offensive as, from their point of view, such a conception of global bioethics can only be driven by an agenda that advances Western values to the detriment of non-Western traditions. It disregards other cultures and lacks respect for cultural diversity. For believers in the story of invention promoting universal values is irrelevant and hardly interesting as an essentially US derived bioethics will have to be modified according to local and regional specifics of other cultures in order to be successfully incorporated elsewhere.

Thus, for believers of the stories of exportation and invention, global ethics as based on universal values is either undesirable or impossible: it is either abusive or futile. Bioethics must always have a local origin and a local field of application. It cannot overcome its specific, localized origin. It must always remain characterized by its local nature. Thus, both stories lead to the same conclusion. If bioethics is indeed a Western product it should not and, in fact, cannot be disseminated in other countries, at least not in an unaltered state. Nowadays nobody wants to be regarded as an imperialist and neocolonialist, certainly not bioethicists.

This Handbook of Global Bioethics will follow another approach. Surely, bioethics has an important origin in the West. That being said, however, more historic research may be required to sketch a complete picture of bioethics' origins. Whatever the precise historic origins of bioethics, currently, it has turned into a truly global phenomenon. It has significance around the world, because people are not merely European or Asian, but citizens of the world and members of a global moral community. Bioethics is important for everybody everywhere, not because it is imported or imposed, but because it provides a universal framework to interpret and manage the ongoing changes, in which currently all countries and cultures are involved. However, the interpretation and application of this framework must always be informed by local circumstances. Thus, present-day bioethics must be conceived as characterized by both its global nature as well as its local characteristics. On this view, local traits and origins as such do not preclude universal validity. Whatever one might find out through historical research about the precise origins of the ideas that slavery and racial discrimination are wrong, these finding are not going to have any influence on the universality of these norms. The origin of norms does not affect their universality or lack thereof.

The Coining of "Bioethics"

The word "bioethics" was introduced in the intellectual discourse in the early 1970s. Warren Reich (1994) concluded that it had a "bilocated" birth, the word being coined more or less at the same time by Van Rensselaer Potter in his publications and by Andre Hellegers in the initial name of the Kennedy Institute.

It is clear, however, that Potter had already used the term in a journal publication in autumn 1970, months before his book *Bioethics: Bridge to the Future* was published (Potter, 1971). The book again preceded the opening of the Kennedy Institute with a half year. The term "bioethics" became quickly adopted and widely used. In 1973, for example, Dan Callahan published "Bioethics as a discipline" (Callahan, 1973). In fact it was an ideal term to designate a new movement, away from the traditional medical ethics, and referring to an innovative discipline that was open for experts from a broad range of other disciplines. The recent claim that the term "bioethics" was in fact coined long before the emergence of bioethics as a discipline is interesting, because it embarrasses the view that bioethics is an American invention. The German pastor Fritz Jahr introduced the term "Bio-Ethik" in a publication in 1927 (Sass, 2008). His concept of bioethics is broad, based on respect for both human beings as well as other living organisms in the universe, similar to the respect for life advocated by his contemporary Albert Schweitzer. However, calling him the founder of bioethics is exaggerated. After all, his work had been largely forgotten and the term he used had no impact at all. But at least he is forerunner, indicating that a new idea always has a long history as Jahr himself acknowledged that his view was rooted in the ideas of others (Goldim, 2009).

Van Rensselaer Potter (1911–2001) worked for more than 50 years as Professor of Oncology at the McArdle Laboratory for Cancer Research at the University of Wisconsin in Madison in the USA. Potter was an enthusiastic scientific researcher. Oncology, for Potter was essentially interdisciplinary; it cannot merely focus on individual and medical perspectives. In explaining cancer, it is necessary to go beyond the level of individual persons and beyond the medical perspective, since cancer is often associated with life style and environmental influences. In the 1960s, Potter started to publish on issues outside his initial scope of cancer research, such as on the concept of human progress, the interrelation between science and society, and the role of the individual in modern society. These publications are included as chapters in his first book on bioethics (Potter, 1971). This broadening of scope was due to limitations of the range of research in which he was fully engaged; studying cell mutations only provides a limited view of the complex problem of cancer. Potter noted that progress had been made but he was also aware that the goal of eliminating cancer was far away. He argued that we must be content with "small victories" without expecting a breakthrough anytime soon. There will be some limited progress at the individual level (in terms of alleviation of suffering and improved treatment) but much more can be accomplished at the level of populations (in terms of prevention of cancer, for example, through restrictions on smoking).

However, Potter pointed out that his long-term preoccupation with cancer research prevented him from realizing that there were more important problems. He acknowledged that it took a long time before he started to look around and take interest in "the major problems of our time" (Potter, 1971, p. 150). Although Potter did not systematically discuss them, he listed the priority problems as: population, war, pollution, poverty, politics, and the negative side effects of progress. He regarded these problems as jeopardizing the survival of humankind, and their

urgency induced in him a growing concern regarding the future. What was necessary, therefore, according to Potter, was a new science of survival, a new discipline that he called "bioethics."

In an interview in 1992, Potter indicates that the word "bioethics" just came to him, like a Eureka feeling (Reich, 1994). Interestingly, Potter himself had previously analyzed the Eureka feeling (Potter, 1975). When a new idea, concept, insight, action plan, or experimental approach is formed subconsciously and then erupts into our consciousness, the result is called a Eureka feeling. This feeling has three properties: (a) suddenness: it cannot be willed and it is unpredictable whether or when it will occur; (b) euphoria: it is accompanied by a feeling of elation, which invites action; and (c) fallibility: it has the inherent possibility of error – the new idea may be useful and survive or may be erroneous and will disappear. On the basis of his consideration of these properties Potter developed ". . .the idea of humility with responsibility as the basic bioethic" (Potter, 1975, p. 2304). This basic bioethics is nowhere more appropriate than for oncologists because of the multidisciplinary character of oncological problems. However, it has a broader validity for scientist and professionals in general. Because there is always the possibility of error, one ought not to assume that one's own area of expertise will provide all the answers. In order to make recommendations for public policy, one should develop a realistic understanding of biological knowledge, trying to steer a course between optimistic and pessimistic evaluations so that the most feasible policy will result. It is also necessary to be continuously aware of the limitations of such knowledge since there are always built-in error tendencies.

A New Discipline

For Potter, "bioethics" was the name of a new discipline that would combine science and philosophy. The goal of this discipline would be wisdom. Already in his first publication on bioethics, he defined wisdom as "knowledge of how to use knowledge" for human survival and for improvement of the quality of life (Potter, 1970, p.127). The knowledge to be brought together was, on the one hand, biological knowledge or the science of living systems (hence "bio"), and on the other hand knowledge of human value systems (hence "ethics"). Wisdom is action-oriented; it is a guide for action. When there are competing possible policy decisions and when it is uncertain what to do or what has priority, biological knowledge must be combined with value judgments. In these circumstances, one can only proceed with humility. But at the same time cautiousness requires assessment mechanisms and feedback so that one learns from experiences. Bioethics is a science (the science of survival) because it is using the scientific approach of testing ideas, i.e., confronting them in peer groups, in experiments, and with what has been learned from previous investigation. Ideas should be tested and verified. They can no longer be based on introspection or logic alone. What is new in bioethics is the interdisciplinarity of this approach. We should cross the boundaries between disciplines in order to look for ideas "that are susceptible to objective verification

in terms of the future survival of man and improvement in the quality of life for future generations," as Potter formulates the mission of bioethics (Potter, 1970, p. 132).

Already in the opening sentence of the Preface of his first book on bioethics Potter emphasized that he wanted to contribute to the future of the human species. He observed that part of the reason why the future was in danger was that the two cultures of modern society, viz., the sciences and the humanities, were not communicating. This idea had already been developed by the British physicist and novelist Charles Percy Snow in his widely read and discussed lecture "The two cultures" (1959). According to Snow, a common culture had been lost in modern Western society. This had made it difficult to solve the problems people were facing especially with regard to the future. With his book Potter intended to give a reply to this challenge. The creation of the new discipline of bioethics could provide a bridge between the two cultures.

Bioethics on the Wrong Track

Potter himself was positively surprised how quickly the word "bioethics" was disseminated in the ethical but also public discourse. However, he also saw that it was used to demarcate the activities of ethics experts from the traditional discourse of medical ethics without incorporating a really new approach as he had advocated. He complained that, although using the word "bioethics" suggested innovation, the ethical practice remained business as usual. Already a few years after he introduced the term "bioethics," Potter began to make a distinction between "medical bioethics" and "environmental bioethics" (Potter, 1975). The first term signified the bioethics movement as it was rapidly developing since 1970 under the leadership of the Kennedy Institute at Georgetown University. The orientation of this movement was completely at odds with Potter's original conception of bioethics. As an "outgrowth of medical ethics," it was focused on medical issues and medical technology (Potter, 1988, p.1). First, it was primarily concerned with the perspective of patients: how can their lives be enhanced, maintained, and prolonged through the application of medical technologies? Second, it was exclusively interested in the short-term consequences of medical and technological interventions as well as the prolongation of our current individual existence. Third, it was unrelated to social, cultural, and political environmental determinants of human life. In contrast, "environmental bioethics" was characterized by a long-term view and a concern with the continued existence of the human species. In addition, it was developing without any connection to medicine and healthcare (Potter, 1988).

Potter conceded that medical bioethics had a somewhat broader approach than traditional medical ethics. It focused, for example, on new technologies, particularly in the field of reproductive medicine, which generated intricate ethical questions. But it was still too narrow to address what were, in his view, the basic and urgent ethical problems of humankind today, for example, environmental pollution, overpopulation, poverty, violence, and war. He regarded these problems as threats

to the survival of humankind, and their urgency induced a growing concern regarding the future. In order to adequately address these problems, according to Potter, a much broader vision was necessary. That is why he had initially introduced the new term "bioethics." But now that this term was used in the conventional medical way, it did no longer evoke the need for a broader and more inclusive approach. Because bioethics, as it did not go beyond the medical perspective, was not generating new perspectives and new syntheses, Potter wanted to reemphasize the concern for the future of the human species by qualifying the terminology. According to Potter, medical bioethics needed to be combined with ecological bioethics, and other forms of ethics related to human life such as agricultural ethics. All these approaches in bioethics should be merged in a new synthetic and interdisciplinary approach called "global bioethics" (Potter, 1988).

The Coining of "Global Bioethics"

In the second part of the 1980s, Potter started to use the new term: "global bioethics." It aimed at bringing together the different approaches in bioethics in a unified, broad approach (Potter, 1987). His ideas were published in 1988 in his second bioethics book: *Global bioethics – Building on the Leopold legacy* (Potter, 1988). In this book, he strongly emphasized the ecological perspective in bioethics, inspired by his former university colleague Aldo Leopold, an American pioneer in wildlife conservation. Leopold had suggested that there are three stages in the development of ethics. In the first stage, ethics concerns the relations between individuals, in the second stage it focuses on the relations between individual and society, and the third stage, which does not yet exist, ethics would deal with the relations of human beings with their environment, i.e., land, animals, and plants. Potter was convinced that the rise of global bioethics heralded the emergence of Leopold's third stage of ethics.

In connecting bioethics with a global perspective Potter was in fact using ideas of Pierre Teilhard de Chardin (1881–1955), French Jesuit philosopher, geologist, and palaeontologist. In his early publications, Potter made references to Teilhard's work, explaining that he started to study his philosophy in 1964. He also published an article exclusively focused on Teilhard (Potter, 1968), which was later included in his 1971 monograph.

Teilhard anticipated what nowadays is called "globalisation." One of his main ideas was that humanity will develop into a global community. Teilhard devoted his life to reflection on the place of human beings in the universe and the grand scheme of evolution. Due to processes of "planetary compression" (intensified communication, travel, exchanges through economic networks) and "psychic interpenetration" (increased interconnectedness and a growing sense of universal solidarity) humankind will be involved in an irresistible process of unification, according to Teilhard de Chardin (2004). The emergence of a global community will occur, or so Teilhard argues, not because human beings will accept one single truth or will desire one single thing, but because they increasingly recognize their interdependency and their

common destiny. Shortly after the Second World War Teilhard wrote that even incidental recurrences of racism and nationalism lack importance in the overall process of cultural and social evolution of the planet; they are disastrous for individuals but compel us sooner or later to come together on the basis of human solidarity. This is what he has called the "planetization of Mankind" (Teilhard de Chardin, 2004, p. 108).

The challenge for Teilhard is to outline a new vision of the world that emerges from the accomplishments of science and that takes into account the role of human beings. For Teilhard the notion of evolution is the starting-point for such an endeavor. This notion is no longer only relevant for biology but it can clarify all dimensions of the human condition: matter, life, and mind. Furthermore, evolution is an ongoing process. It progresses through humankind, not in the sense that there will be a new biological species of super-humans but in that it creates more complexity and consciousness among human beings, an "ultra-human" phase. In Teilhard's view, humanity was becoming more unified, more interdependent, and increasingly cooperative. Humankind would evolve into a coherent whole, a cosmopolitan community. Nowadays, human beings have significant means at their disposal to facilitate communication, distances can be easily overcome, and borders between nations are becoming futile. As a result it has never been so easy to get to know other people. Growing unification within complex diversities and an increasing feeling of solidarity between human beings are stages in the process of evolution that will lead to a moral community of citizens of the world. The world population is growing while the surface of the earth remains the same; therefore, people are obliged to cooperate even more intensely: "We can progress only by uniting" (Teilhard de Chardin, 2004, p. 66).

Potter recognized that Teilhard, like him, was interested in the problem of human progress and the survival of humankind. They share the view that human progress is the goal of the universe, that we should try to bring about the best possible future and that the best way to do this is to combine the science of biology with human values. Given these concurring views it is remarkable that in Potter's first bioethics book there is no explicit mentioning either of the global scope of problems or the global nature of the search of solutions, the more so since the need for a global perspective in ethics had also been emphasized by Leopold. However, it is obvious that the global dimension had always been implicitly assumed by Potter. Bioethics' basic problems such as overpopulation and poverty are necessarily affecting the whole of humankind. Bioethics' goal of survival is global since what is at stake is the survival of humanity. Bioethics' methods are global in the sense that they combine all available intellectual resources for long-term approaches. Global bioethics in the vision of Potter unites two meanings of the word "global" (Potter, 1988). First, it is a system of ethics that is worldwide in scope. Second, it is unified and comprehensive.

Global Bioethics Today

Nowadays, Potter's vision remains in full force. Global bioethics is truly worldwide in that it goes beyond international bioethics. It is not merely a matter of crossing

borders, but it concerns the planet as a whole. Bioethical discourse is not limited to transnational territories (e.g., the European Union) but has become supra-territorial. Bioethics nowadays is relevant to all countries and takes into account the concerns of all human beings wherever they are. While bioethics may have primarily originated in Western countries, its reach and relevance are now planetary. On the one hand, the traditional issues of bioethics are confronted with new challenges. With the introduction of clinical trials in developing countries the concept of informed consent is confronted with different cultural traditions in which individual decision making is an unusual concept. On the other hand, the existence of global markets has created new problems such as organ trade, medical tourism, corruption, and bioterrorism. Even if such problems exist only in few countries, the way they are addressed will have consequences for other countries. Usually the transactions and interconnections between developed and developing countries can either exacerbate or diminish the impact of such problems on society and culture. Often national legislation or regulation will not be sufficient but international cooperation and action will be required. Problems like pandemics, malnutrition, hunger, and climate change require coordinated global policies and actions. Even if the moral values in specific countries and regions differ, a common ground has to be found as a world community.

Potter's second meaning of "global" refers to bioethics as more encompassing and comprehensive, combining traditional professional (medical and nursing) ethics with ecological concerns and the larger problems of society. This implies more than simply declaring that today's problems are global and affect everyone. First, it requires interdisciplinary cooperation. Global problems as poverty, climate change, and inequities in healthcare can only be addressed by obtaining and applying different types of knowledge. It is unavoidable to bridge the gap between science and humanities. Secondly, it requires that diverse perspectives must be used to explain and understand complex phenomena. Global problems can no longer be approached only from an exclusively Western or Eastern perspective. Healthcare will not be improved by simply importing and applying Western medication; we need to understand the existing value systems. Various methods and theories will therefore be used in global bioethics. It also needs input from empirical studies as well as philosophical analysis.

A Transcultural Moral Framework?

Both characteristics of global bioethics will probably not be disputed: bioethics has become worldwide and comprehensive. It has an interdisciplinary approach and applies a mixture of methods. Also, there are many new ethical issues on the agenda. Controversial, however, are the following questions: should global bioethics advance a transcultural framework of ethical values and principles? Are there any global values and principles in the sense that they are commonly shared among all human beings?

Warren Reich has pointed out that global bioethics utilizes a "comprehensive vision of methods" (Reich, 1995, p. 24). The global perspective of bioethics is not

a matter of geographical expansion, but rather, it refers to phenomena that have a global dimension – i.e., they are no longer dependent on the specifics of a particular culture or society – and that require global answers and remedies. Of course, this is not the same as arguing that there is an international set of fundamental values that is used everywhere. That we have similar bioethical problems in different countries does not imply that we follow the same ethical approach everywhere. The global dimension, however, invites us to rethink our usual approaches and ethical frameworks that are often connected to domestic values. It makes us aware of the "locality" of our own moral views, while challenging us to search for moral views that will be shared globally. As a result bioethics is increasingly connected with international law, particularly human rights law, which has a similar global vision.

Universal ethical theories that can transcend cultural differences are looked upon with suspicion. They incite some colleagues in developing countries to breathe new life into the "story of exportation" and advance accusations of "moral neo-colonialism." Other bioethicists doubt whether universal theories can ever do justice to cultural diversity (Verkerk & Lindemann, 2011; Widdows, 2007). Of course, there should be a theoretical debate about the question of whether a common framework of values and principles is possible or desirable as a basis for global bioethics. Apart from this debate, however, we are witnessing the fast development of global bioethics as an exponent of globalization. Globalization refers to a movement toward greater interdependence and integration, or "planetization" in the words of Teilhard.

Since the globalization of bioethics is only one component of a more encompassing process, it would be wrong to suggest that bioethics became globalized as an independent entity. The ongoing globalization of bioethics is inextricably bound up with the ceaseless globalization of medical research and healthcare. As soon as humanitarian aid programs are introduced or international clinical trials undertaken bioethical discourse automatically appears as well. This does not mean that a global bioethics is "imposed." After all, any international or global moral framework that is introduced in a new local context usually immediately engages with the ethical discourse at local level. This observation follows from current globalization studies demonstrating that there is a dialectics between global and local (see, e.g., Kirby, 2006). Many local events are shaped by events far away, while global events are often influenced by the local context and conditions. Globalization, therefore, is not simply a process in which one global culture gets to dominate local cultures. There is no antithesis between the global and the local. In contrast, they increasingly seem to gain access to each other. Instead of generating oppression of the local sphere, the emergence of a global space for moral frameworks and ethical discourse has created opportunities for local cultures to find universal expression. Many indigenous groups, for example, disadvantaged within their own countries, have been able to reframe their position with an appeal to human rights on a global platform (Kearney, 1995). The idea that global bioethics is a "colonizing" force does not take into account the interaction between global and local. In addition, it underestimates the power of existing local value systems.

This interpretation of global bioethics therefore depends on how we view globalization. If globalization is considered as an irresistible process that "reshapes, mutilates, and overturns the local," we would indeed be subject to external forces, hard to identify and control, and making our cultures homogeneous and transforming our specific identities and values. Globalization would therefore be primarily passively endured (Burawoy, 2001). In this view, global bioethics would present values and principles as "universal" in order to dominate local value systems.

In contrast, if one takes the dialectics of global and local levels seriously, much of globalization is "globalization from below." In this view, everybody takes part in globalization: "What we understand to be "global" is itself constituted within the local" (Burawoy, 2001, p. 150). Globalization is therefore not only experienced passively but in many cases actively produced by groups of citizens, agencies, and institutions at the local level. In this view, global bioethics does not refer to ethical values and principles that are transcending various cultures or are imposed on them from outside, but global values are produced in interactions with local value systems. The global ethical framework is emanating from the fast growing manifold interconnections between people worldwide.

Universal Principles and Local Traditions

In the debate on globalization of ethics, Kymlicka (2007) has suggested that global ethics is a two-level phenomenon: at one level there is a self-standing international human rights discourse defining a minimum set of standards agreeable to all. At a second level, there is a multiplicity of different ethical traditions. These "local" traditions define what is ethically required beyond and above human rights. The same distinction can be used for global bioethics. On the one hand, there is a set of minimum standards on which traditions and cultures agree; this is expressed in international human rights language and elaborated into specific bioethics principles. On the other hand, there are many efforts to articulate more specific bioethics standards in the context of specific religious and cultural traditions. Members of these traditions also bring their views in the global debate through constructive dialogues and sometimes negotiations, so that the dialectic of global and local also helps to construct and produce global bioethics. Thus, the universal principles of global bioethics are the result of continuous and multilateral articulation, deliberation, and production.

The way in which a shared global bioethical discourse can be established is demonstrated, for example, in the activities of the Parliament of the World's Religions. In 1993, approximately 200 leaders from more than 40 religious and spiritual traditions signed the statement "Toward a Global Ethics." This statement drafted by German theologian Hans Küng, declares that all traditions share common values such as respect for life, solidarity, tolerance, and equal rights (Küng, 1997). The document emphasizes that it is important to show what world religions have in common rather than to point out how they differ. Another example

is the Universal Declaration on Bioethics and Human Rights adopted by UNESCO member states in 2005 (Ten Have, Henk & Jean, 2009). The request to develop a common framework of ethical principles was explicitly made by developing countries. They were afraid that with the rapid evolution and globalization of medical science and research they would insufficiently benefit from the advances and suffer too many harms and risks. A major concern was that international medical research and healthcare endeavors would proceed along double standards so that people in developing countries would receive substandard care and be involved in clinical trials without the ethical protection that exists in developed countries. This call from developing countries to develop a global normative framework demonstrates that global bioethics principles are not necessarily imposed by rich and powerful countries on the rest of the world. Their development might very well be triggered and driven by less powerful countries instead. The 191 member states negotiated 2 years to reach consensus on the text of the Declaration. Many activities took place in very different countries. Expert conferences have been organized in countries such as Lithuania, Turkey, Indonesia, and Argentina. Regional conferences were convened on Latin America, the Arab region, and Africa. Experts from many countries filled out questionnaires or wrote commentaries and suggestions (Ten Have, Henk & Jean, 2009). Some issues remained highly contested. For example, it turned out to be impossible to reach consensus on certain specific ethical issues as abortion, euthanasia and stem cell research consensus. The solution was found with the above mentioned two-level approach. In the end official representatives of states but also of cultures, traditions, and religions could agree on 15 ethical principles of global bioethics. These principles include the four principles of Beauchamp and Childress but also other principles that seemed to play a more significant role in non-Western countries, such as solidarity, social responsibility, and benefit sharing.

One of the principles is that of respect for cultural diversity. This is the only principle that can never overrule any of the other principles. In other words: a healthcare practice that is violating human dignity can never be justified by referring to the principle of respect for cultural diversity. Let us clarify this by focusing on the debate about informed consent. Although there is wide consensus that informed consent is a fundamental principle, it is also argued that in different cultures informed consent takes shape in different ways. For example, in many African countries, a communitarian approach underlines the importance of the group or tribe. Thus, in healthcare and research decisions a group discusses the issue and the community leader takes the lead in decision making. In many Arab countries the head of the family tends to be crucial, and husbands are used to take important decisions rather than their wives. Nonetheless, the principle of informed consent requires that in the end the concerned individual needs to provide informed consent whatever the specific cultural context. According to the Declaration nobody is allowed to violate the principle of informed consent on the basis of the principle of respect for cultural diversity. However, differences can occur in the application of informed consent in specific contexts where "local" values and norms play a major role. For example, informed consent in North America requires

a lot of bureaucracy. Patients have to sign extensive documentation, while in certain other countries, specifically in the Arab region and Africa, a word is a word, and asking a signature a sign of distrust.

A Global Moral Community

The establishment of a global bioethical framework marks the beginning of a "global moral community." This is also demonstrated in debates on the new principle of protecting future generations and on intergenerational justice. The UNESCO Declaration on the Responsibilities of the Present Generations toward Future Generations (UNESCO, 1997) connects our responsibilities to posterity with the need to ensure the future existence of humankind. These are the same concerns as those advocated in Potter's conception of global bioethics. The notion of the global moral community is furthermore introduced in global bioethics through the principle of benefit sharing. This novel principle is important in the context of bioprospecting, i.e., the search and collection of natural substances that might be used for the development of new drugs. Natural resources are abundantly available in developing countries with rich biodiversity such as Brazil and Indonesia. In many developing countries, traditional medicine is based on such natural resources. These resources and the traditional knowledge of indigenous populations are increasingly being appropriated ("biopiracy") by Western companies to fabricate new profitable drugs without any compensation to the indigenous communities. Against this backdrop the principle of benefit sharing has been advanced in order to counteract this injustice.

These new debates in fact refer to a more fundamental discourse around the notions of "global community" and "world moral community." In this discourse, two interrelated claims are now gaining ground (Agius, 2005). One claim states that the global community includes not only human beings but the totality of biological nature, broadening up the traditional concept of community so as to include nonhuman species as well. After all, we all share dependency and vulnerability. In fact, this is Potter's view. He argues that ethics should extend the idea of community from human community to a community that includes soils, waters, plants, and animals. Humankind coexists with ecosystems; together they constitute the "entire biological community" (Potter, 1988, p. 78). The second claim is that the earth is not the possession of one particular generation; each generation inherits it and should not bequeath it in an irreversibly damaged state to future generations. Because of the interdependence of human life and the fragility of our planet, we need a new vision of community that encompasses past, present, and future generations.

Apart from its members, who are increasingly connected and related due to processes of globalization, the global moral community contains content as well: global values and responsibilities as well as global traditions and institutions. An example is the concept of the "common heritage of humankind." Introduced in international law in the late 1960s to regulate common material resources, such as

the ocean bed and outer space, the concept was expanded in the 1970s to include cultural heritage. This has led to the construction of a new global geography of symbols indicating that humanity itself can be regarded as a community. Cultural heritage is no longer only representative of a particular culture but of human culture in general. Labeling some cultural products as a world heritage produces a global grammar, in which diverse and local phenomena receive a universal significance and require global management. Such heritage is the expression of human identity at a global level. It is part of the quest of citizens of the world. It becomes an indicator of world culture. Regarding and categorizing cultural property as world heritage implies a global civilization project that seeks to create a new global community representing humanity as a whole, enable the identification of world citizens, and evoke a sense of global solidarity and responsibility. This process of creating the global community as a moral community was further promoted through the application of the concept of "common heritage" in global bioethics, first in the late 1990s in the field of genetics and promoted by researchers in genetics, followed in the 2000s by the adoption of Universal Declaration on Bioethics and Human Rights by almost all countries in the world (Ten Have, Henk & Jean, 2009). With such a universal framework global bioethics can now claim to represent a global geography of moral values, closely associated to universal human rights discourse. It enables humanity itself to be regarded as a moral community. It implies that citizens of high-income countries can no longer be indifferent to obscure clinical research practices or organ trade in low-income countries, since the same moral values and standards apply within the global community, although the application of principles is always modified according to local circumstances and local communities. Membership in the global community furthermore draws on a growing number of global institutions and movements (e.g., Doctors without Borders, Oxfam, fair trade, UNESCO). Thus, we are witnessing the rise of a global community of shared values. These values are the product of intensive and continuous negotiation, deliberation, and dialogue. They are reflected in a universal framework of ethical principles that will continuously be challenged, interpreted, and coproduced in local settings influenced by specific religions and cultural traditions. The dialectics between the universal and local normative frameworks will enrich and reinforce global bioethics.

Conclusion

This chapter has presented and criticized "the story of exportation" and "the story of invention," which regard global ethics as either undesirable or as futile. Instead, a more favorable and optimistic account of global bioethics has been advanced. Against the backdrop of Potter's original conception of global bioethics and along the lines of Kymlicka's conception of global ethics an account of global bioethics as a two-level phenomenon has been presented. On an abstract level, there is a set of minimum standards, on which different traditions and cultures agree. On a more contextualized level, there are efforts to articulate more specific bioethics standards in

the context of specific religious and cultural traditions. In addition, local specifics of cultures and traditions are important for the interpretation and application of universal standards. The two levels are interacting along bottom up and top down lines of communication. Global platforms and local contexts mutually help each other to construct and produce global bioethics. Thus, global bioethics is the result of continuous and multilateral articulation, deliberation, and production. It is both a herald and a witness of the rise of a global community of shared values, as revealed in this Handbook.

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History of Global Bioethics

2

Diego Gracia

Introduction

Globalization is a new term coined to express one of the most outstanding characteristics of human life in the end of the twentieth century and the beginning of the twenty-first. For the first time in the history of mankind, people are aware and know what is happening all over the world, no matter the distance or the differences of any kind. This phenomenon has been the consequence of the progress in telecommunications and the new capacity of managing and exchanging information through the world, due to new computer technology. This first technological and informational globalization made possible another one in the fields of economy and finances. The problems arising in many countries in the wake of the economic crisis that began in 2007 made many people aware of the need, going ahead in this process, to look for new ways of globalizing politics. This was also the moment in which the necessity of focusing on moral problems with a global perspective became evident. New terms, like "global ethic" and "global bioethics," appeared. These are not only new and specific fields of analysis and debate, but questions that affect the core of ethics, making it necessary to rethink and reconstruct the entire discipline.

Globalization, A Linguistic Novelty

"Globalization" is a new term. It proceeds from *globus*, the Latin translation of the Greek word *sphaîra*, round body, ball, sphere, or globe. The word was frequently used by scientists and in philosophical writings in antiquity, but without any moral connotation. On the contrary, the word *kósmos*, whose primary meaning was "order," and also "world order" or "universe," acquired in late antiquity the meaning of the realm of sin and death, as opposed to the spiritual kingdom of holiness and life (John. 12:31; 14:30; 17:9,16; 18:36. Eph. 2:2; 6:12.

D. Gracia
Complutense University of Madrid, Madrid, Spain
e-mail: dgracia@fcs.es

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New International Version). This moral meaning was even more evident in the words *mundanus*, mundane, and *mundanitas*, which in Medieval Latin meant *vanitas*, vanity, or *mundi amor*, mundane or worldly love. This negative moral meaning came to Western languages, giving in English the word "worldly," secular, sophisticated, or not spiritual. This is perhaps the reason why it was necessary to coin a new word with a more descriptive and positive meaning, deriving it from "globe" and not from "world"; the result being the term *global*. This word was frequently used in classical English. But the abstract noun *globalization* is new in the English language. It appeared for the first time in the third decade of the twentieth century, and it began to be generally used during the 1960s and 1970s. From English, it entered into other languages as *Globalisierung*, *globalisation*, *globalización*, etc. The French language has also the word *mondialisation*, and the same happens in Spanish, *mundialización*. In any case, the word globalization has today a specific meaning, different from that of *mondialisation* or *mundialización*. This meaning, completely new, appeared during the last decades, as a consequence of some important changes happened in science and technology, and also in the political and economic life of the societies.

The Global Village

The possibility of knowing in "real time" the things happening in other territories or on different continents has been remote during the major part of the human history. Only recently, due to the development of telecommunication, has the entire world become an integrated electronic network in which everyone is connected with all others. Human beings are now interconnected in a web of interdependency with changes and developments on one side of the world affecting the other. This revolutionary phenomenon was called by Marshall McLuhan "the global village." For the first time in history, the world has become one big village, in which all things are present and inextricably interconnected. McLuhan remembered that George Washington, two centuries ago, once remarked, "We haven't heard from Benjamin Franklin in Paris this year. We should write him a letter" (McLuhan & Powers, 1989, 80). In the information era, he stresses, the "real" world of things has been substituted by another that is "virtual," the world of information.

Globalization of Economy

The first globalization, prompted by the development of telecommunications, opened the door to other types that are more subtle. The second has happened in the field of economics and finance, with the integration of national economies into international or global ones, through trade, foreign direct investment, and capital flows. After World War II, Western politicians adopted Keynesianism as the way of building the new welfare state. It reigned, especially in Europe, until the crisis

of 1973. This crisis was interpreted by many as the death knell of the welfare state. As an alternative, many returned to the theories of the neoclassical school, lead in this movement by the economists of the Chicago school, based on monetarism, economic liberalism, little government intervention, and free markets. These ideas were implemented by politicians during the 1980s, when Margaret Thatcher (UK prime minister, 1979–1990) and Ronald Reagan (US president, 1981–1989) came to power. They also became the core principles of the main economic international agencies located in Washington (the International Monetary Fund, the World Bank, and the US Treasury Department) during the 1990s. After 1989, this economic ideology became generally known as the "Washington Consensus," an expression coined by John Williamson, an economist from the Institute for International Economics based in Washington. As a consequence, the General Agreement on Tariffs and Trade (GATT), and its successor, the World Trade Organization (WTO), promoted international agreements in order to lower the barriers to international free trade, facilitating the flow of goods, capital, services, and labor. Thus, the entire world has become, for the first time in history, a global free market.

This second process of globalization has also had a negative side. The economic collapse of the years 2007–2012 has generally been interpreted as the consequence of the drastic distinction by the neoclassical school between economy as a science and applied economy, in an attempt to make of Economics a value-free science, centered only on the so-called economic "facts," without any "value" compromise. Milton Friedman said in 1970 that the only social responsibility of business is to increase its profits; profit is the sole value to be taken into account. This oversimplification is seen as one the causes of the economic crisis, interpreted by many as a crisis of values (i.e., a moral crisis).

Today, it seems evident that in trying to be value-free, economics chose a value option, perhaps one that was not the most beneficial. There is no possibility of making human decisions without values. In avoiding value questions, economists transmitted to the public opinion the wrong idea that there is only one important value, the economic one – profit. This is what George Soros calls "market fundamentalism," most frequently seen during the last decades in Western countries. "The functions that cannot and should not be governed purely by market forces include many of the most important things in human life, ranging from moral values to family relationships to aesthetic and intellectual achievements. Yet market fundamentalism is constantly attempting to extend its sway into these regions, in a form of ideological imperialism. According to market fundamentalism, all social activities and human interactions should be looked at as transactional, contract-based relationships and valued in terms of a single common denominator, money. Activities should be regulated, as far as possible, by nothing more intrusive than the invisible hand of profit-maximizing competition. The incursions of market ideology into fields far outside business and economics are having destructive and demoralizing social effects. But market fundamentalism has become so powerful that any political forces that dare to resist it are branded as sentimental, illogical, and naive." (Soros, 1998, xxvi).

The theorists of the neoclassic school stressed that value questions do not pertain to scientific economics, but to another branch they call applied or normative economics, which is the realm of politicians and managers. But politicians were obliged by the same ideological bias to focus all their work around the economy and the economic problems of their societies, the main goal being to increase incomes and the welfare of their states. Hence, the essential role played by economics in the new politics, both national and international. To manage the economy of the new global situation, the politicians of the six major economies created in 1975 the so-called G6 (Group of Six), which became G7 in 1976, G8 in 1997, and G20 in 2009. It has been the main economic council of wealthy nations, but not a global economic forum. As a consequence, some anti-globalization movements appeared, in an attempt to avoid the negative consequences of the economic process of globalization. They have organized riots during the summits of the G6 and G20 (Mittelman, 2000).

As politicians are the agents of public policies, managers are the leaders of private corporations. Management has also been frequently conceived as a "value-free" activity. Some managers, on the contrary, have stressed the importance of values in the promotion of quality and excellence in organizations. Hence, the importance of value questions in some new business theories. Terms like *virtue*, *quality*, *excellence*, *stakeholders*, *good citizenship*, *corporate social responsibility*, and so on are beginning to play a new role in business ethics. Trying to promote these practices, the United Nations launched in 2000 the UN Corporate Social Responsibility Global Compact program, seeking to mainstream ten moral principles in business activities around the world in the time of globalization. The importance of the Global Compact is due to the fact that, today, most important private industrial corporations are transnational and, to some extent, global, unlike the governments, which are by definition national. This means that the economic power of industries is in some cases greater than that of nations and governments.

Lack of a Global Polity

In the globalization era, economies are inextricably interconnected, surpassing the national borders and territories in which politicians and governments can take decisions. The consequence is that the globalization process has shown problems that can only be managed and perhaps solved in the international arena. This means that the globalization of trade and the economy demand another more difficult process, the political one. This is, perhaps, the biggest issue of humanity's present situation, in which the global economy coexists with a political system based on an old idea of nationality.

There is a general consensus that politics must find new ways of managing global problems, first because international bodies have been, up to now, subordinate to national interests, and, second, due to the fact that there is neither a real, nor perhaps desirable, global government. An intermediate solution may be the so-called "global governance," a novelty that appeared after the fall of the national

security model prior to the collapse of the Soviet Union in 1991. Global governance tries to manage global processes through institutions such as intergovernmental organizations (IGOs), non-governmental organizations (NGOs), and private entities. The question is whether bodies like these are capable of limiting the individual power of states in a positive way, going beyond market laissez-faire and private economic interests, and then solving the collective problems of mankind. In any case, global governance remains weak relative to pressing current needs for global public policy. Some theorists try to avoid these problems through the promulgation of a Global Constitution as the basis of global governance. Going beyond the traditional Westphalian system, states should share part of their sovereignty with institutions and bodies at other territorial levels, and they must begin a major process to deepen democracy, making their organization more responsible. The main goal of the Global Constitution should be to make possible the convergence of the unsustainable development of developed countries and the unsustainable underdevelopment of the underdeveloped countries into "sustainable development."

Some political theorists think that political globalization is coming through the triumph of Western patterns of life. Francis Fukuyama, a supporter of the Reagan doctrine during the 1980s, published in 1992 a book entitled, *The End of History and the Last Man*. He argued in it that the triumph of Western culture is complete after the struggle of ideologies during the Cold War, the fall of the Berlin Wall, and the collapse of Marxism. Political and economic liberalism, he stresses, is the only theory with a future. Big confrontations will no longer be possible, making possible a new era he calls the "end of history." "What we may be witnessing is not just the end of the Cold War, or the passing of a particular period of post-war history, but the end of history as such: that is, the end point of mankind's ideological evolution and the universalization of Western liberal democracy as the final form of human government" (Fukuyama, 1989, 3).

A year later, the political scientist Samuel P. Huntington published an article titled, "The Clash of Civilizations" in response to Francis Fukuyama's vision. Three years later, in 1996, he expanded this theory in the book, *The Clash of Civilizations and the Remaking of World Order*. The question is, once more, how to conceived a global politic after the Cold War era. Fukuyama's answer is that human rights, liberal democracy, and a free market economy will be the pillars of the process of political globalization. Huntington, on the contrary, thinks that after the time of ideologies, only cultures and religions have the values capable of conducting the life of societies. These are, for the same reason, the true sources of social and political conflicts. Therefore, the fundamental source of conflict in this new world will not be primarily ideological or economic, but cultural. "Nation states will remain the most powerful actors in world affairs, but the principal conflicts of global politics will occur between nations and groups of different civilizations. The clash of civilizations will dominate global politics. The fault lines between civilizations will be the battle lines of the future" (Huntington, 1993).

One important source of conflict is religion, especially between those religions that defend the existence of an absolute truth, one only in the hands of its believers,

who have the duty of extend their message to the whole world as the only way of salvation. This is the case of Christianity, most common in Western civilization, and of Islam. Both messages and pretensions are incompatible and will lead to a violent confrontation between them. That is what Hizb ut-Tahrir has called "the Inevitability of the Clash of Civilisations."

Others think that these predictions are completely biased, because they focus the analysis on the extreme points of view of fundamentalisms, either political or religious. Hence, the importance of promoting respect and tolerance between different cultures and religions. Some proposals have been developed in this way by religious leaders, like the declaration promoted by the Parliament of the World's Religions on peace and global ethics in 1993; others include the Dialogue Among Civilizations promoted by the former Iranian president Mohammad Khatami, which was the basis of the declaration by the United Nations in 2001 as the Year of Dialogue among Civilizations, and the Alliance of Civilizations proposed at the 59th General Assembly of the United Nations in 2005 by the president of the Spanish government, José Luis Rodríguez Zapatero, and co-sponsored by the Turkish prime minister Recep Tayyip Erdogan.

Philosophers have made their own proposals, following, especially in Europe, the Kantian tradition of "cosmopolitanism" (Held, 1995). One of the most prominent defenders of this idea has been Jürgen Habermas, who translated the Kantian cosmopolitanism into a more pragmatic global constitutionalism (Habermas, 2008, 312–352). Human beings are living now in a "multilevel system" (with "states," "transnational" regimes such as the European Union, and "supranational" organizations like the United Nations) that establishes "a politically constituted world society without a world government" (Habermas, 2008, 316). In this situation, public action should be based on "negative duties of a universalistic morality of justice," legitimated by a thin "worldwide background consensus." Habermas thinks that this ideal is expressed today, at least, in the "shared moral indignation" of people in response to "egregious human rights violations and manifest acts of aggression [that] gradually produce[s] traces of cosmopolitan solidarity" (Habermas, 2008, 344).

Need for an Ethical Globalization

Political globalization cannot become real without an established "Global Civic Culture" (Boulding, 1988) or a "Global Civil Society" (Oliveira & Tandon, 1994). On the front line of this social movement is the "third sector" (Florini, 2000), which is nonprofit but at the same time neither governmental nor religious, and then a veritable "global associational revolution," "a massive upsurge of organized private, voluntary activity in virtually every region of the world" (Florini, 2000, 1). It tries to construct a society different from the purely economic one of the free market. In the words of the French Prime Minister Lionel Jospin, "Yes to a market economy, no to a market society." The third sector is the upsurge of a new culture

and a new set of values, beyond the economic profit, from one side, and the religious charity, from the other. And now the question is what kind of values are these?

There are, at least, two strictly different types of values, called "intrinsic" and "instrumental" (Gracia, 2011, 89–133). These are the most accessible today to human beings. The most important instrumental value by-and-large is the economic one. Money is only one instrument to achieve different things people value. In other words, money is a value-mean, not a value-end. It has no value by itself, but by the other things that can be achieved with it, which are appreciated by themselves, for instance, the beauty of a picture, or the friendship in a person. In fact, only instrumental values can be measured in monetary units; friendship or beauty are priceless.

The problem is that economic globalization has grown with the idea that economic profit is the only important value, and that priceless means worthless. This is the public opinion today, and is also prevalent in politics. "Elected representatives also frequently put their personal interests ahead of the common interest. Instead of standing for certain intrinsic values, political leaders want to be elected at all costs - and under the prevailing ideology of market fundamentalism, or untrammeled individualism, this is regarded as a natural, rational, and even perhaps desirable way for politicians to behave [. . .] The contradiction between politicians' personal and public interests was, of course, always present, but it has been greatly aggravated by prevailing attitudes that put success as measured by money ahead of intrinsic values such as honesty" (Soros, 1998, xxvi).

Money is the measure of all instrumental values. But some values, the most important in human life, are not instrumental. They are called intrinsic, because they are valuable by themselves, like friendship, love, justice, peace, pleasure, wellbeing, solidarity, life, and health. When one of them is lost, something valuable by itself vanishes. It cannot be imagined a true human world without love, or without beauty, or any other of these values. Technical instruments, like cars, phones, or pharmaceuticals, are needed, but only for the intrinsic values they are related to. A pill is a way of curing a headache. If the pill could not improve health, it could be said that it is completely useless, or worthless. Health is an intrinsic value, and the value of drugs is only instrumental.

The duty of all human beings is always the same, to add value, that is, to promote or implement values, to increase values or to do things more valuably. Ethics deals with all kinds of values, but especially with the intrinsic ones, because they are ends by themselves, the true ends of human life.

The Long Run to Moral Globalization

Human beings have always been aware that they have moral duties not only to themselves, promoting, for instance, their perfection and happiness, but also, and perhaps primarily, to others. But what they have understood by others, from a moral point of view, has been changing through history. In ancient times, it can be imagined that the moral world of human beings was reduced to families and

relatives; at the most, to their segmentary or tribal society. Outsiders were by definition strangers, rivals, and enemies, with which the only moral duty they had was to kill them or make them slaves.

The Greek perspective was to some extent similar. Only Greeks were endowed with the *logos* or reason needed to develop a fruitful moral life. All others were "barbarians," incapable of developing their lives as true human beings. Only in the *polis*, and not in the other minor social structures, was deliberation, the right method of moral thinking, considered possible. And in the *polis*, only some people were endowed with a true deliberative capacity, "for the slave has no deliberative faculty at all; the woman has, but it is without authority, and the child has, but it is immature" (Aristotle, Pol. 1260 a 12-14. Aristotle 1984, 53). The consequence was that there were some people entitled to take moral decisions, the true moral agents, while the others were by nature moral patients, that is, people only capable of obedience.

The first consequence of this historical analysis is that humankind has never understood all human beings as moral agents. On the contrary, it has been thought that only a small number of people were endowed with the true moral condition. The only moral virtue of all others was obedience, that is, moral slavery. Even during the Middle Ages, this moral slavery did not disappear; it was interpreted then in theological terms. The cause of this new spiritual slavery, as discriminatory as the old one, was sin (John 8: 34f; Rom. 6: 16). Sinners were degraded to the level of slaves, and deprived of nearly all human rights, in some cases even the right to life, while grace was taken as the way of liberation from the sinners' slavery, entering to a new one. "But you have been set free from sin and have become slaves of God" (Rom 6: 22). In this new slavery, people were not endowed with the capacity of deliberating about moral things, but reduced to the role of moral patients instead of moral agents, and obliged to blind obedience.

Only in modern times was moral agency asserted as an intrinsic propriety of all rational beings. This was the origin of the so-called "principle of universalization," coined by Kant. All human beings are by nature autonomous agents, and therefore slavery is always inhuman, either social or moral. There are two different and opposite sets in the world, the one with all rational beings and the other with all the other things. The first is called the "moral world" and the other the "natural world." The Kantian universalization covers, therefore, human beings but not the things of nature.

From the end of the eighteenth century, the time in which Kant coined the so-called moral principle of universalization to today, many things have happened. By "all human beings" Kant could only understand the "actual" people living on earth in a certain period of time. But there was little capacity to take into account the actual situation of people all over the world in Kantian times. The Kantian world covered little more than Europe. Only during the last decades, and due to the accelerated development of telecommunication, has it been possible to know what really happens anywhere and anytime. This is the first difference between the old "universalization" and the new "globalization." What Kant called "the kingdom of ends," the set of human beings, covers today for the first time all

human beings actually existing on earth. People's moral decisions must take into account all of them in order to think they are right.

From Ethical Universalization to Moral Globalization

But this is not the only way in which globalization goes beyond universalization. One of the most important consequences of scientific development is the increase in one's capacity of foresight. This foresight embraces not only the future of present human beings, but also the life of all others possible, that is, future generations. Future generations are only "virtual," not actual, but mankind is now aware, perhaps for the first time in history, that there are moral duties to them, making possible its existence with a quality of life at least equal to the one people enjoy today. The problem is to determine whether these duties are perfect or imperfect, that is, duties of justice or duties of beneficence. In the first case, these virtual human beings should be entitled to human rights, and therefore included in the moral set, the set of human beings. This is what has happened lately, with the development in the theory of human rights of the so-called "rights of future generations." In the second case, if they were not entitled with rights, one's moral duties would only be imperfect, or private duties of good will and beneficence. Things are currently going in the first direction more than in the second, and therefore moral globalization is taking into account not only all actual human beings but also the virtual ones, that is, future generations. They are human beings, although right now only virtual.

Globalization, therefore, differs from universalization at least in two points. First, it covers all human beings actually existing, and second, future human generations. But it also covers non-human nature. This is also the consequence of scientific development. During the last decades of nineteeth century, ecology appeared as a new discipline. Its main idea is that living organisms are inseparable of their surroundings. A living organism alone is an abstraction without reality. This is one of the consequences of the theory of evolution, defined broadly by Darwin in 1859. Therefore, it is necessary to think of human beings in their environments, without which they are not real.

An important consequence of this new approach is that things can no longer be divided in two opposite sets, one with human beings and the other with all other things. Human beings cannot be taken alone, without their environment. And if they are ends by themselves, natural things must participate in this condition at some extent. Therefore, they are not pure means, as supposed previously. Kant said that human beings are means and *not only* ends, which means that, in addition to their condition of ends, they are also means, like all other things. If this is so, then the opposite should be also possible, that is, that natural things are at some extent ends, and *not only* means. Natural things should be included, at least partially, in the same set of human beings. They are also, in some way, ends, and therefore subject to rights. This is the origin of the so-called animal and environmental rights.

Animal and environmental rights can be justified in ways different from the Kantian one. Many thinkers do not accept the application of the category of "end by themselves" to animals and things to any extent, due to the fact that they are neither rational nor adequate subjects of morality and rights. The only thing that can be said is that they have "value." This is another approach, more pragmatic and intuitive than the first. The more enforcing language of rights is substituted here with the language of values. Natural things are valuable only by the fact of being or existing, and living organisms more so. The simple fact of being is an intrinsic value, the value of being instead of not being, and the fact of being a living organism is another important intrinsic value. Kant said that human beings are endowed with an intrinsic value called dignity. But this is not the only one. There are many other intrinsic values, not only in human beings but also in pure natural things and living organisms. And due to the fact that these are endowed with intrinsic value, the defenders of this second approach think that human beings have the moral duty of respecting these values and promoting them as much as possible. Such duties are respective to intrinsic values inherent to these things, and then it can be said that these things are entitled to the right be respected, in order to safe their values. Another way of explaining that is saying that these non-human beings are endowed with rights that are respective to one's duties. This is, therefore, a different form of justifying the so-called animal and environmental rights. They have rights because they are entitled with intrinsic values.

There is another way, a third, of approaching the problems raised by the new ecological ethics. If the first approach was the Kantian, and the second one the axiological, this third is strictly utilitarian. It is necessary to take into account animals and nature in moral considerations due to the negative consequences of doing the opposite. Taking care of nature is also taking care of ourselves. Both are members of the same world, with a common future (U.N. World Commission on Environment and Development, 1987).

A consequence of these new approaches is that the classic Kantian categorical imperative – "Act so that you can will that the maxim of your action be made the principle of a universal law" – is now inconsistent, because it must be formulated in broader terms. Hans Jonas proposed these four alternative formulations: "Act so that the effects of your action are compatible with the permanence of genuine human life"; or expressed negatively: "Act so that the effects of your action are not destructive of the future possibility of such life"; or simply: "Do not compromise the conditions for an indefinite continuation of humanity on earth"; or, again turned positive: "In your present choices, include the future wholeness of Man among the objects of your will" (Jonas, 1984, 10–11).

One problem with this wide and totalizing approach is the impossibility that human minds can take into account in their moral deliberation process things so vague and indefinite as "the permanence of genuine human life through time," or "the indefinite continuation of humanity on earth," etc. Edward Norton Lorenz described the "butterfly effect" in 1969, and the impossibility of forecasting non-linear phenomena or predicting the future in chaotic systems. The most astonishing example of this is the inaccuracy of weather forecasting from more than

about a week out. In the era of non-linear phenomena and the chaotic approach to reality, what does "the indefinite continuation of human life on earth" mean?

Science is a system of prevision. In fact, these new problems are the consequence of one's better understanding of natural laws. This new capacity of foreseeing the future have many scientific and technological consequences, and also may influence in a definite way one's moral thinking. Now it is necessary to take into account in moral judgments the foreseeable consequences of one's actions. The problem is that natural systems are extremely complex, influenced by so many factors that human beings are incapable of taking control of all of them. Here certainty is very rare, and there is the need of working only with probabilities. This is the reason why in this field it is not possible to reach a lineal and determined conclusion, but only to choose a course of action that seems better than the others, in the balance of risks and benefits. This means that in this field the only thing that can be intended is to make wise, reasonable, or prudent decisions. A sage decision can be wrong, and time can also show that an unwise decision would have avoided many risks or harms. But the moral duty of human beings is to make wise and responsible decisions, not the avoidance of any mistakes. The opposite could be highly unwise and imprudent.

Towards a Global Ethics

The expression "global ethics" has, at least, two different meanings. In its first meaning, global ethics includes also virtual ethics and environmental or ecological ethics. This is the meaning in which the expression global ethics is frequently used. But it has another meaning. The question is whether it is possible to define some moral content that all human beings could agree upon. Anthropologists are aware of the diversity of moral norms in different cultural and religious traditions. They assume generally as a postulate the so-called "cultural relativism" also in the moral domain. Disagreement seems to be the norm in moral matters, which is why Huntington (1993) thinks that the clash between the major cultures and religions is unavoidable. Could it be possible, then, to formulate some universal moral principles? Are there some moral contents that can be called global?

The first attempt to answer to this question in a positive way came from the Parliament of the World's Religions in 1993, immediately after Huntington's proclamation. On 4 September 1993, the Parliament passed a "Declaration toward a Global Ethic," in which people of very different religious backgrounds for the first time agreed on a minimum of irrevocable directives that they were already affirming in their own traditions. The promoter of the Declaration was the Catholic theologian Hans Küng, who previously, in 1990, published a book entitled *Project Weltethos*. The German expression *Weltethos* means "global ethos" and not "global ethics," which in German would be said *Weltethik*. The difference is important, because the goal of the *Weltethos* movement is not to define specific duties or to construct an ethic, but to promote a basic attitude, a fundamental moral option that the world's religions have in common, drawing up a minimal code of

rules of behavior everyone can accept. The idea of Küng is that the new "world society" does not need a single unified religion or ideology, but "does need some norms, values, ideals and goals to bring it together and to be binding on it" (Küng, 1991). Some statements in the book have become famous: "There will be peace on earth when there is peace among the world religions," and "No world peace without peace among religions; no peace among religions without dialog between religions" (Küng & Kuschel, 1993).

The Declaration of 1993 was the origin of a wide international movement, organized around the *Global Ethic Foundation*, which appeared in 1995. The Parliament of World's Religions developed the content of the Declaration in its meeting of 1999 in Cape Town, South Africa, with the document *A Call to Our Guiding Institutions*. And Pope John Paul II gave the official Catholic judgment about globalization and global ethic in his address to the Pontifical Academy of Social Sciences on 27 April 2001. On the other hand, the core ideas of global ethic have been applied to specific fields, like science, education, politics, and economics. Promoted by Hans Küng, in 2009 a group of people signed at the United Nations the *Manifesto Global Economic Ethic: Consequences and Challenges for Global Businesses*.

In a secularized society and in a post-metaphysical era, other ways of justifying globalization that are alternative or complementary to the religious justifications appeared immediately. The main characteristic is that they do not look for "substantial" agreements but only for "procedural" consensus. Two of the most outstanding representatives of this trend are John Rawls in America and Jürgen Habermas in Europe. The first has developed a procedural way of reaching a rational consensus between all human beings on the basic content of the idea of justice. Although this procedure is strictly secular, religious "tolerance" is an essential precondition in order to achieve the agreement (Rawls, 1971, 180–181). Therefore, this secular approach to global ethics cannot be seen as opposed to the religious one, but complementary to it.

The perspective of Habermas is similar. The procedural way of reaching a global ethic is, in this case, through the symmetrical dialogue between all the people affected by the norm or decision at stake. And, as in the previous case, one of the presuppositions of this dialogue is tolerance, especially in religious matters (Habermas, 2008, 306). A secular and post-metaphysical global ethics cannot be indifferent in religious matters, but it needs to be tolerant. Without tolerance, the communicative ideal discourse becomes impossible.

All these questions have political consequences, and thus the importance of politicians in this debate. More than 30 of them, former heads of state or government, are trying to promote universal ethical standards in national and international politics, through the *InterAction Council*. This body develops proposals for action for government leaders, national decision-makers, heads of international organizations, and influential individuals around the world. In 1997, they proposed to the U.N., as a complement to the Universal Declaration of Human Rights (1948), a *Universal Declaration of Human Responsibilities*. At the same time, UNESCO promoted another *Declaration of Human Duties and Responsibilities*, proclaimed

in 1998, to commemorate the 50th anniversary of the Universal Declaration of Human Rights in the city of Valencia. Finally, the U.N. approved, on the 50th anniversary, a *Declaration on the Right and Responsibility of Individuals, Groups and Organs of Society to Promote and Protect Universally Recognized Human Rights and Fundamental Freedoms* (53/144, 9 December 1998).

There is a growing amount of literature and documentation on global ethics. To collect it, UNESCO began and supports the Global Ethics Observatory (GEObs), a system of six databases with worldwide coverage.

Globalization and Bioethics

"Bioethics" is a recent movement. It appeared as such half a century ago. As Warren T. Reich has stressed, it had a "bilocated birth," in Madison, at the University of Wisconsin with Van Rensselaer Potter, and in Washington, DC, at Georgetown University, with André Hellegers. Potter gave to the word *bioethics* an environmental and global significance, whereas Hellegers understood it more narrowly as the ethics of medicine and biomedical research. The Hellegers/Georgetown approach came to be the more widely accepted, while Potter's idea of bioethics remained largely marginalized (Reich, 1995). In any case, it was into Potter's tradition that the concept of "global bioethics" appeared. Eighteen years after coining the word *bioethics*, Potter (1988) introduced the term *global bioethics* as a way of unifying medical and ecological ethical issues in the one, more inclusive field (Reich, 1995, 25).

In 1971, Potter published a book entitled *Bioethics: The Bridge to the Future*. The metaphor of the bridge is important, because Potter conceived bioethics as the way of balancing new scientific facts, especially in the life sciences, with reflection about the values at stake. The goal of bioethics is to make up these two types of knowledge in a wider vision, reaching a way a new wisdom (Potter, 1971, 2). Only this new wisdom can assure, in the Potter's view, the survival of humankind, which is why he defines also bioethics as "the science of survival" (Potter, 1971, 1).

Because bioethics was born and developed during its first decades in the United States, many people assumed that the "four bioethical principles" of the Georgetown model could be asserted as "global," and therefore exportable to the rest of the world. But critical voices began to appear. Sociologists (Fox & Swazey, 2008) and anthropologists (Turner, 2003) denounced this attempt at globalization as disrespectful with the values of other cultures (Schroeder, 2005). "Moral pluralism and cultural difference have not been central topics of concern in the first decades of American academic bioethics [...] Bioethics has only concerned itself with issues of cultural pluralism quite recently" (Marshall & Koenig, 2004, 253).

There have been two different agencies of the United Nations interested in the promotion of dialogue between different cultures in order to make bioethics into a true global discipline. One is the World Health Organization (WHO), which in 2002 established an Ethics and Health Unit, expanded in 2003 to foster the

development of programs on ethical issues in biomedicine and science in both clinical and research setting worldwide, particularly in resource-poor nations. It is also part of the international consortium that supports the Global Forum on Bioethics, promoted by the Fogarty International Center at the National Institutes of Health of the United States.

The second large international agency engaged in the development and promotion of global bioethics is UNESCO, through its Unit on Ethics in Science and Technology, and more specifically through the International Bioethics Committee (IBC). This committee approved in 2003 a Report on the Possibility of Elaborating a Universal Instrument on Bioethics. Two years later, the Universal Declaration on Bioethics and Human Rights was adopted by UNESCO's General Conference. The aim of the Declaration is "to provide a universal framework of principles and procedures to guide States in the formulation of their legislation, policies or other instruments in the field of bioethics." The sixteen principles are declared as universal, and the procedures are related to the establishment of independent, multidisciplinary, and pluralistic ethics committees at institutional and/or local, regional, national, and international levels.

This Declaration tries to be an extension of the Universal Declaration of Human Rights of 1948. And, as in those days, criticism immediately appeared, due to the difficulty of determining moral principles as "universal." For some authors, this is once more the attempt to extend the Western moral tradition to other places with different cultures and values. One of the most outstanding critics has been the American bioethicist H. Tristram Engelhardt, Jr. (2006). His libertarian thesis is that in the postmodern world a general consensus about values is impossible. (Engelhardt, 2006, 3, 6) Another strong criticism came from the British bioethicist John Harris. He questions the wisdom and utility of a declaration that neither distinguishes moral judgments from judgments about moral issues, nor provides any evidence that consensus was informed consensus (Harris, 2008).

The Declaration has had opponents and defenders. Some other authors looked for ways of articulating universal principles with cultural particularities (Finkler, 2008), using especial methodologies to solve the antinomy (Zieler, 2009), and stressing the need of deepen the way opened by the Declaration in the future (Williams, 2005).

In all these cases, "global bioethics" is understood as a set of universal or global moral principles. But there are other meanings of the expression. One is less theoretical and more operational. The question is whether bioethics has become a global field of inquiry, or, on the contrary, whether it is in a phase previous to the actual constitution of a global scientific domain. This has been the topic analyzed by Søren Holm and Bryn Williams-Jones in their paper "Global bioethics: myth or reality?" (Holm & Williams-Jones, 2006). The conclusion reached is that moral globalization is in the process of being real, but it is not yet (Borry, Schotsmans, & Dierickx, 2006). Therefore, global bioethics is still a topic in process of becoming a discipline. Bioethics is a young product of the Western culture, requiring time and dedication to become a true global body of knowledge and practices.

Concluding Remarks

Globalization is a recent phenomenon and is far from being completed. It began with the revolutionary changes in telecommunications that happened during the second half of the twentieth century and continued with the globalization of the financial and commercial markets in the beginning of the 1980s. The great economic crisis experienced by the Western world since 2007, without any precedent in the history of mankind, is generally interpreted as the consequence of the achievement of a global market, without the counterweight of an effective political and moral globalization. The ideology of profit as the main goal, or the only one, in human actions, is one of the causes, perhaps the most important, of the present disaster. There are two types of human values, some intrinsic and others instrumentals. The first are the most important in human lives, and these cannot be measured in monetary units. Ethics deals primarily with these intrinsic values, and then the importance of its culture. When, on the contrary, only the instrumental values are at stake, or when they take precedence, then what Habermas calls "strategic action" or "instrumental rationality" comes forward. That is, perhaps, what is happening at present.

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Structure of the Compendium

3

Henk A. M. J. ten Have and Bert Gordijn

Introduction

This Compendium of Global Bioethics, as volume of the *Handbook of Global Bioethics*, is the first comprehensive systematic treatment of the major normative issues in contemporary global bioethics to date. The global issues, problems, and principles addressed in this work represent a genuinely new stage in the development of bioethics, especially since they are pertinent to developing and developed countries. This new stage in bioethics is furthermore promoted through the ethical framework presented in the *Universal Declaration on Bioethics and Human Rights*. This declaration is the first political statement in the field of bioethics, adopted unanimously by all member states of UNESCO in 2005. The declaration is distinct from other international documents such as the Declaration of Helsinki in formulating a commitment of governments. Being part of international law (though not binding as a convention), it presents a universal framework of ethical principles for the further evolution of bioethics at a global level. This chapter explores the roots and the development of the Universal Declaration. In addition, it shows how its principles inform the structure of the compendium. This may help to understand and comprehend the approach that is followed in most of the chapters of the compendium.

The Growth of Global Bioethics

Most developing countries still have a limited infrastructure in bioethics, lacking expertise, educational programs, bioethics committees, and legal frameworks. Due to the global nature of science and technology, however, there are similar bioethical questions emerging as in developed countries where bioethics has already existed

H.A.M.J. ten Have (✉)
Center for Health Care Ethics, Duquesne University, Pittsburgh, PA, USA
e-mail: tenhaveh@duq.edu

B. Gordijn
Institute of Ethics, Dublin City University, Dublin, Ireland
e-mail: bert.gordijn@dcu.ie

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for a long time. As a result, developing countries endeavor to develop and apply bioethics principles that are coherent with their own value system. They recognize the importance of bioethics but do neither have the capacity nor the facilities to fully engage in it. At the same time, they aim to have a bioethics framework in their country that would not be regarded as extraneous but would be considered as suitable for their own country and culture. For this reason, they have appealed to UNESCO as an impartial global organization to set universal ethical benchmarks for the analysis and assessment of the issues within bioethics. They wanted to work together in this international political platform toward identifying basic principles and shared values regarding science, technology, and health care to be put to use in the global bioethics conversation.

When the United Nations Educational, Scientific and Cultural Organization (UNESCO) was established more than 60 years ago, its constitution declared that peace must be founded upon the intellectual and moral solidarity of humanity. Julian Huxley, the first director general, pointed out that, in order to make science contribute to peace, security, and human welfare, it was necessary to relate the applications of science to a scale of values. Guiding the development of science for the benefit of humanity therefore implied "the quest for a restatement of morality [. . .] in harmony with modern knowledge" (Huxley, 1946, p. 41).

Since its foundation, UNESCO has been concerned with moral issues in relation to science. From the 1970s onward, the emergence of the life sciences, in particular, has led to the international examination of bioethical questions. In order to match the increasingly global scope of the bioethics debate, UNESCO established the International Bioethics Committee (IBC) with a work program and budget for international activities in 1993. The program was expanded in 1998 with the foundation by UNESCO of the World Commission on the Ethics of Scientific Knowledge and Technology (COMEST), which addresses other areas of applied ethics such as environmental ethics, science ethics, and technology ethics. Since 2002, UNESCO has been coordinating the activities of several international bodies in the area of bioethics through the Inter-Agency Committee on Bioethics of the United Nations (with, among others, FAO, OECD, and WHO). In the same year, the 191 member states decided that ethics should be one of the five priorities of the organization.

Against this backdrop, it is hardly surprising that UNESCO was considered by states to be the most appropriate international forum for the elaboration of a framework of bioethical principles, the more so since the organization has demonstrated its ability to fulfill a constructive standard-setting role in the field of bioethics. Over the past two decades, UNESCO, being the only specialized instance within the United Nations system that combines education, culture, science and social sciences in its field of competence, has developed a bioethics program that reflects the multidisciplinary and transcultural dimension of the discipline. UNESCO has been engaged in carrying out actions to involve countries around the world in order to bring out fundamental principles acceptable to all, without loosing sight of respect for cultural diversity. The success of the Universal Declaration on the Human Genome and Human Rights, adopted in 1997 (and furthermore adopted by the General Assembly of the United Nations 1 year later), and the International Declaration on Human

Genetic Data, adopted in 2003, has reinforced UNESCO in its standard-setting action in the field of bioethics and has convinced states to place confidence in the organization's capability to develop a more general bioethics declaration.

Constructing Consensus

In October 2001, the general conference (the general meeting of all member states), supported by the Round Table of Ministers of Science, invited the director general of UNESCO to examine the possibility of developing "a universal instrument on bioethics." The feasibility study drafted by the International Bioethics Committee (IBC) concluded that it might be possible to find common ground in divergent bioethical positions by focusing on basic principles (Ten Have & Jean, 2009). Some of these principles had already been identified in previous declarations. The study also stressed the necessity to develop a universal instrument because of rapidly developing scientific practices increasingly extending beyond national borders. Consequently, it was deemed desirable that developed and developing countries alike achieve a consistent set of principles informing their regulations and policies.

Two years later, in October 2003, the general conference provided a mandate to submit a draft declaration within 2 years. In the meeting, then French President, Jacques Chirac, made a vigorous plea for a universal normative framework, preferably a convention, to guide the progress of the life sciences and to protect the integrity and dignity of human beings. Taking into account the short time frame, the variety of cultures and traditions to be take into account, and the controversial nature of many bioethical issues, the subsequent process of drafting, entrusted to the IBC, was based on extensive consultations with many organizations (e.g., FAO, WHO, WIPO, Council of Europe, National Bioethics Committees, and international bioethics societies). Throughout the process of elaborating the text, several drafts were published on the website of UNESCO. The work of the IBC drafting group was conducted in as public a way as possible in order to facilitate consensus formation and early identification of any dissenting views.

Dealing with bioethics in an intergovernmental organization such as UNESCO implies a linkage between science and politics. Each normative instrument needs to reflect the scientific and ethical state of the art. But in the end, every draft is submitted for approval to the member states which then decide if they wish to adopt it. Thus, the draft text developed by the independent scientific experts of the IBC was subjected to political negotiations among the experts who represented the various governments of the UNESCO member states. As a result, the cogency of the final text may have been diminished, in some respects, due to textual adaptations to create maximum adherence by all of the governments involved. In order to facilitate the opportunities for compromise, the work of the independent IBC was connected at an early stage with that of governmental experts. Several amendments to the IBC text were made by the governmental experts. The Declaration, as adopted, represents the IBC draft as so amended. After 2 years of intense work, the members states adopted, unanimously and by acclamation on 19 October 2005, the Universal Declaration on Bioethics and

Human Rights, thus solemnly affirming the commitment of the international community to respect a certain number of universal principles for humanity in the development and application of science and technology.

Universal Declaration on Bioethics and Human Rights

The Universal Declaration aims to define the universally acceptable norms, principles, and procedures in the field of bioethics, in conformity with human rights as ensured by international law. It is thus conceived as a group of general provisions and principles that allow for a better evaluation of the implication of ethical issues at stake and to provide assistance in decision-making in this field. It does not pretend to resolve all the bioethical issues. In order to achieve its goals, the Universal Declaration incorporates a linkage to international human rights law as is reflected in its full title. Thus, it anchors its ethical principles in the international rules that govern respect for human dignity, human rights, and fundamental freedoms. By drawing on the 1948 Universal Declaration of Human Rights, it clearly enshrines bioethics in international human rights law thus applying human rights discourse to the specific domain of bioethics.

One of the contentious issues in the elaboration process was the scope of bioethics. At least three views were advanced stating that bioethics had to do with (1) medicine and health care as well as associated technologies; (2) the social context, such as access to health, solidarity, and justice; and (3) the environment. In different parts of the world, different conceptions, definitions, and histories of bioethics were prevalent.

The scope of the adopted text of the Declaration is an obvious compromise between these views. It addresses "ethical issues related to medicine, life sciences and associated technologies as applied to human beings, taking into account their social, legal and environmental dimensions" (Art. 1a).

The aims of the Declaration are multiple. However, the most important aim is to provide "a universal framework of principles and procedures to guide states in the formulation of their legislation, policies or other instruments in the field of bioethics" (Art. 2i). One characteristic of present-day bioethics is that it is not merely an academic discipline; it is also a subject of public policy. This is why the Declaration primarily addresses states. But at the same time, since the bioethical principles identified are founded on human rights and fundamental freedoms, the Declaration also aims "to guide the actions of individuals, groups, communities, institutions and corporations, public and private" (Art. 2). The ethical principles that should guide governments cannot be different from the ones guiding professional conduct.

Ethical Framework for Global Bioethics

The heart of the Declaration is to be found in the 15 principles that are listed. The principles express the different obligations and responsibilities of the moral subject

("moral agent") in relation to different categories of moral objects ("moral patients"). The principles are arranged according to a gradual widening of the range of moral objects: the individual human being itself (human dignity, benefit and harm, autonomy), other human beings (consent, privacy, equality), human communities (respect for cultural diversity), humankind as a whole (solidarity, social responsibility, sharing of benefits), and all living beings and their environment (protecting future generations and protection of the environment, the biosphere, and the biodiversity).

Fundamental ethical principles in the UNESCO Declaration:

1. Human dignity and human rights
2. Benefit and harm
3. Autonomy and individual responsibility
4. Consent
5. Persons without the capacity to consent
6. Respect for human vulnerability and personal integrity
7. Privacy and confidentiality
8. Equality, justice, and equity
9. Nondiscrimination and non-stigmatization
10. Respect for cultural diversity and pluralism
11. Solidarity and cooperation
12. Social responsibility and health
13. Sharing of benefits
14. Protecting future generations
15. Protection of the environment, the biosphere, and the biodiversity

Some of the principles are already widely accepted (e.g., autonomy and consent). Other principles have been endorsed in previous declarations (e.g., sharing of benefits). Innovative within the set of principles in the Universal Declaration on Bioethics and Human Rights is the balance struck between individualist and communitarian moral perspectives. The Declaration recognizes the principle of autonomy (Art. 5) as well as the principle of solidarity (Art. 13). It emphasizes the principle of social responsibility and health (Art. 14), which aims at reorienting bioethical decision-making toward issues urgent to many countries (such as access to quality health care and essential medicines especially for women and children, adequate nutrition and water, reduction of poverty and illiteracy, improvement of living conditions and the environment). Finally, the Declaration anchors the bioethical principles firmly in the standards governing human dignity, human rights, and fundamental freedoms.

The section on the application of the principles (Arts. 18–21) is also innovative because it addresses the spirit in which the principles ought to be applied. It calls for professionalism, honesty, integrity, and transparency in the decision-making process; the setting up of ethics committees; appropriate assessment and management of risk; and ethical transnational practices that help in avoiding exploitation of countries that do not yet have an ethical infrastructure. The Universal Declaration thus opens perspectives for future action and reiterates the need to place bioethics within the context of reflection open to the political and social world. Today,

bioethics goes far beyond the code of ethics of the various professional practices concerned. In addition, it involves and promotes reflection, as advocated by Potter, on the future of humankind and on the evolution of society and science (see ▶ Chap. 1 on "Global Bioethics" in this volume). The Universal Declaration paves the way for a new agenda of bioethics at the global level.

Rationale of the Compendium

Although the Universal Declaration constitutes a nonbinding instrument in the eyes of international law, its value and its strength are in no way diminished. For the first time in the history of bioethics, all states of the international community are solemnly committed to respect and implement the basic principles of bioethics, set forth within a single text. Also through the Universal Declaration, bioethics finds its place on the agenda of states. Furthermore, characterized by the transparency and active participation of all the actors concerned, the elaboration process of the Universal Declaration, involving extensive consultations, has already largely contributed to the renown of the text and its general acceptance. The innovative dimension of the Declaration is that it constitutes for the first time a commitment of governments to a set of bioethical principles. Previous international declarations, although sometimes very influential, such as the Declaration of Helsinki, have been adopted by professional organizations (such as the World Medical Association).

The Universal Declaration on Bioethics and Human Rights should therefore not be seen as the fruit of the reflection of just a few but as the result of a long and sustained common effort in which numerous actors have been involved, representing a wide range of countries in the world. It should also be regarded as the beginning of a long process implementing and applying the principles stated in the Declaration. First, it is important to make sure that scientists, healthcare professionals, and policy-makers all over the world are informed about the existence and the contents of the Declaration. Second, it is necessary to exchange experiences about possible ways of application of the principles in different settings. These aspirations have determined the structure of the Compendium for Global Bioethics. Taking the ethical principles of the Declaration as guides, the contributions in the compendium will explore how these principles are interacting with cultural and religious traditions and how they are helpful in analyzing many of the new issues on the agenda of today's global bioethics.

Structure of the Compendium of Global Bioethics

The first section of this compendium presents an introduction into global bioethics as well as an overview of its history. These chapters not only explain what is involved in using the terms "bioethics" and "global bioethics" but they also locate today's emerging global bioethics issues and discussions within an historical context.

The second section elaborates the 15 ethical principles adopted by UNESCO. These principles can be seen as foundational for global bioethics. It goes without saying that, in a global context, they are to be interpreted and applied differently according to the specifics of the manifold social and cultural local contexts. Against this backdrop, the authors in Section 2 proceed in roughly the same way: they explain the principle, present the various arguments pro and con, discuss the practical possibilities and problems in applications, and sketch the interrelations with other ethical principles. In this way, each of the ethical principles is explained in a similar manner, allowing a comparative assessment of strengths and weaknesses.

The third section presents the most significant cultural perspectives on the problems and practices of global bioethics. These perspectives influence the way in which ethical principles are specified and weighed. Application of the ethical principles always takes place within specific contexts that are influenced by culture and religion. The authors in this section discuss how the framework of ethical principles presented in Section 2 can be regarded and worked with from the specific perspectives of African, Arab, Asian, European, Latin-American, North-American, and Pacific cultures.

Section four focuses on religious perspectives. It follows the same methodological approach as the previous section. Only this time, the ethical principles are addressed from the perspectives of the world's major religions: Buddhism, Catholicism, Confucianism, Hinduism, Judaism, Orthodox Christianity, Protestantism, Islam, and Taoism.

The fifth section of the compendium presents the major ethical issues and challenges of current global bioethics. The emergence and significance of these issues have primarily been triggered by the globalization of science, research, technology, and health care. The authors use the framework of ethical principles, presented in Section 2, in order to analyze and discuss the specific issue at stake thereby demonstrating the practical use of the principles. Naturally, often, only a selection of the Declaration's principles will apply to the moral issue or dilemma at hand. Sometimes, the analysis is also still rather tentative, since a fair number of issues, such as bio-piracy, corruption, disasters, indigenous medicine, immigrants and displaced persons, malnutrition, and hunger, are rather new in bioethics as a topic of scholarly research.

The compendium concludes with an outlook focused on the future of global bioethics. Since global bioethics is a relatively young field, many issues and questions are still open for analysis and debate. Also, the debate will be enriched by the experiences with bioethics in an increasing number of countries. This section will outline the priorities for future research and development of global bioethics.

Conclusion

This chapter has presented the rationale for the Compendium of Global Bioethics. It has argued that present-day global bioethics is characterized by a common

framework of ethical principles defined in the UNESCO Universal Declaration on Bioethics and Human Rights. The various sections of this compendium are elaborating the ethical principles, examining the principles in various cultural and religious contexts, and applying the principles of topical issues in contemporary bioethical debate.

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Section II

Principles of Global Bioethics

Human Dignity and Human Rights

4

Roberto Andorno

Introduction

"Dignity" is defined as "the state of being worthy of honor or respect" (Oxford Encyclopedic English Dictionary). When this concept is associated with the adjective *human*, it is used to denote that all human beings possess equal and inherent worth and therefore ought to be accorded the highest respect and care, regardless of age, sex, socioeconomic status, health condition, ethnic origin, political ideas, or religion.

Inherent human dignity should be distinguished from *moral dignity*, which is a synonym of "honor." While the former plays a central role in the legal instruments relating to bioethics, the latter has less relevance in this field. On the one hand, the inherent dignity, as it is inseparable from the human condition, is the same for all, cannot be gained or lost, and does not allow for any degree (Spiegelberg, 1970). Even the worst criminal cannot be stripped of his or her inherent dignity and has therefore the right not be subjected to inhuman or degrading treatments or punishments.

On the other hand, moral dignity does not relate to the *existence* itself of persons but to their *behavior*; it is the result of a virtuous life, that is, of a life lived in accordance with moral principles. This is why moral dignity is not possessed by all individuals to the same degree (e.g., an honest citizen has more dignity than a pickpocket). While this is a kind of dignity that people may occasionally exhibit, lack, or lose, the dignity in which all humans are said to be equal is a characteristic that belongs permanently and inherently to every human as such (Gewirth, 1982, p. 27).

The concept of intrinsic human dignity operates in modern times as the bedrock of the international human rights system that emerged in the aftermath of the Second World War. It plays also a key role in the international policy documents relating to bioethics that have been adopted since the end of the 1990s. Human dignity can be characterized as the "shaping principle" of international bioethics

R. Andorno
School of Law, University of Zurich, Zurich, Switzerland
e-mail: roberto.andorno@rwi.uzh.ch

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(Lenoir & Mathieu, 2004) or as the "overarching principle" of the global norms governing biomedical issues (Andorno, 2009). Far from representing a shift merely in style, the higher profile accorded to human dignity in bioethics is seen as a true shift in substance that deserves to be carefully considered (Beyleveld & Brownsword, 2002, p. 29).

This chapter aims, first, to briefly present how the notion of human dignity has been conceptualized over centuries of philosophical thought; second, to stress the foundational role it currently plays in international human rights law; third, to emphasize its even more crucial role in the international policy documents relating to bioethics; fourth, to present the reasons for the recourse to human rights in the formulation of global bioethical standards; and finally, to briefly address the challenge to the universality of human dignity and human rights posed by cultural diversity.

Human Dignity in the History of Philosophical Thought

The notion of human dignity has been the subject of many centuries of philosophical inquiry. Most of the explanations emphasize the rational capacities and the free will that characterize human beings and make of them something absolutely unique among living beings. Ancient Greek philosophers, in particular Plato and Aristotle, came to the conclusion that the core of every human individual is not just pure matter, but a *spiritual principle*, which they called *soul (anima, psyché)*. They argued that, since human beings are capable of spiritual activities (understanding, self-understanding, loving, self-determining by judging and choosing, expressing themselves through arts, etc.), they are essentially *spiritual beings* (Aristotle, *On the Soul, III*). Precisely thanks to their spiritual component, human beings were regarded as radically unique among living beings and were thought to share in the divine nature (Plato, Laws, V; Timaeus, 90). The modern idea of human dignity was nevertheless not yet clearly present in ancient Greek philosophy, which justified slavery, a rigid hierarchical social order and a sharp distinction between Greeks and other peoples. However, its thoughtful reflections on the spiritual dimension of human beings provided an invaluable basis for the later developments of Stoic and Christian philosophy and theology, which adopted a *universal* perspective.

Stoicism insisted particularly on rationality as the constitutive element of human dignity, because the human person is the only living being who is able to live according to nature through its reason, which means living a virtuous life. Virtue is possible because human reason shares in the divine reason that governs all things and in this way is able to know the natural law. Roman Stoic philosophers seem to have been the first to use the term dignity (*dignitas*) to indicate the intrinsic and universal worthiness of human beings. Cicero explicitly employs it to refer to the excellence and dignity (*excellentia et dignitas*) that all human beings possess by the simple fact of sharing in the common rational nature (*On duties*, I, 105).

Similarly, Christian thinkers stressed the special dignity of all human beings on the grounds of their spiritual soul, which is the seat of intellect and free will.

Certainly, in this tradition, the intrinsic worth of all human individuals is ultimately a consequence of their being an "image of God" (Gen. 1, 26) and of the belief in the redemption by Jesus Christ of every single human being. But these theological explanations of human worthiness presuppose that the ultimate internal principle of every human being is *spiritual* and not merely corporeal. This philosophical assumption is explicit in the thinking of theologians, according to whom the likeness to God is to be found mainly at the level of the soul, not of the body, because God is a purely spiritual being (Thomas Aquinas, *Summa Theologica*, I, 93). However, the Christian tradition, following Aristotle, holds that every individual has an integrated bodily and spiritual nature. This implies that, although the soul is the core of every human being, it is connaturally related to the body, with which it makes up the substantial unity of the person.

During the Renaissance humanism, the emphasis on human dignity became more persistent, more exclusive, and ultimately more systematic than it had ever been during the preceding centuries. Italian Renaissance philosophers such as Marsilio Ficino and Giovanni Pico della Mirandola, based on both ancient Greek philosophy and on biblical sources, insisted on the intrinsic moral worth of human beings on grounds of the spirituality and immortality of the soul, on its central position in the cosmos, and on man's freedom and creativity capacities. Pico della Mirandola's *Oration on the Dignity of Man* (1486) describes the moment of the creation of the human being, following both the biblical and Platonic accounts. He claims that when the creation of the universe had been completed, God decided to add a being capable of meditating on the reasons of the world, loving its beauty, and admiring its greatness. Thus, he undertook the creation of the human being. But, since all gifts had already been distributed among the other creatures, he decided that the being for which nothing had been left as its peculiar property might in turn have a share of all the gifts that had first been assigned singly to the other living beings. Hence, according to Pico della Mirandola, human persons have no clearly determined essence or nature. They are neither celestial nor earthly, neither mortal nor immortal. On the contrary, they are free to choose good or evil, to develop or not the capacities they are endowed with. They may live like a plant, an animal, a celestial being, or may even be united with God himself. For this reason, the human person can be metaphorically described as a "chameleon." Human dignity consists in the freedom of choice that characterizes the human being in comparison to other living beings because the different possibilities open to the human person include the highest one.

At the end of the eighteenth century, Immanuel Kant developed one of the most influential accounts of human dignity in the history of philosophy. For the German philosopher, the intrinsic human worthiness is grounded on the capacity for practical rationality, especially the capacity for autonomous self-legislation under the categorical imperative: "Autonomy is then the ground of the dignity of human nature and of every rational nature" (*Groundwork of the Metaphysics of Morals*, 1996, p. 85). The Kantian approach puts the emphasis on the freedom to conceive and follow the moral law, which is a specific capacity of human beings. Kant holds that it is only from this *moral* perspective, and not on *ontological* terms, that human

dignity can be justified. Having maintained that there is nothing in the world that "could be considered good without limitation except a good will" (p. 49), he points out that the value of the good will cannot be grounded empirically, that is, it cannot depend upon its having good effects or being oriented to attain certain purposes. The value of the good will, to be really unconditional, must be contained *within it*. This is only possible insofar as the moral action is oriented by a purely formal imperative, which can only consist in acting for the sake of *duty alone* (i.e., from respect of the moral law). This imperative must have a categorical nature, which means that it should represent certain actions as rationally required in themselves for everybody and without reference to any further end or goal. Therefore, the categorical imperative must be purely formal. Kant concludes that there is only one categorical imperative and it is this: "Act only in accordance with that maxim through which you can at the same time will that it become a universal law" (p. 73). In his view, the only way to make sense of the human will as a ground of a universal moral law is to conceive human beings as *ends in themselves*. This idea is expressed in the second formulation of the categorical imperative: "So act that you use humanity, whether in your own person or in the person of any other, always at the *same time as an end*, never merely as a means" (p. 80). Kant presents "dignity" as exactly the opposite of "price": while "price" is the kind of value for which there can be an equivalent, "dignity" makes a person irreplaceable. Therefore, the notion of human dignity expresses a requirement of *non-instrumentalization* of persons.

Although the concept of human dignity has been especially developed in the Western world, it is important to note that it is not strange to other cultural traditions. For instance, according to Chinese scholars, it has a correlate in the teachings of Confucianism (Zhang, 2000). The great Confucian philosopher Xunzi (third century BC) said that "Water and fire have essences (Qi), but not life; herbs and trees have life, but no knowledge; birds and beasts have knowledge, but no sense of justice (*Yi*). Man has an essence, life, knowledge and, in addition, a sense of justice; thus he is the noblest on earth" (*Kingly Government*, Ch. IX, cited in Zhang, 2000, p. 309). Xunzi believed that, although people are not innately good, they are all born with the *capacity* to *become* good (a "kingly person"), and this is what makes of each individual something special. Another great Confucian philosopher, Mencius (fourth century BC), developed a theory of human nature, claiming that the uniqueness of human beings lies not in their bodies, which they share with animals, but in their moral faculties assembled in their heart-mind (*Xin*). In this way, Confucianism has given substantive content to the notion of dignity in classic Chinese philosophy by establishing the moral ideals of humanity (*Ren*) and righteousness (*Yi*), as exemplified in the moral character of the Confucian gentleman (*junzi*), the prototype of the virtuous man (Zhang, 2000).

Also the Islamic tradition emphasizes the very special place of human beings on earth. According to the Qur'an, the sacred text of Islam, God gave to the human being the best shape and form (95:4), breathed into him his spirit (15:29; 38:72), gave him intellect and freedom (16:78; 23:78), bestowed dignity on the progeny of Adam (17:70), placed him even above his angels (2:31), and made him his *Khalifah* (representative) on earth (2:30; 33:72). Because of this, it is commonly interpreted

that the sacred text of Islam assigns dignity to all human beings, regardless of color, sex, race, or religion. Dignity arises from the mere fact of sharing in the human condition and is not restricted to those who believe in Islam (Hashim Kamali, 2002; Sachedina, 2009).

Human Dignity in International Human Rights Law

Immediately after the horrors of the Second World War, the international community felt it necessary to strongly emphasize the notion of human dignity in order to prevent "barbarous acts which have outraged the conscience of mankind" from ever happening again (Preamble of the Universal Declaration of Human Rights of 1948, thereafter UDHR). Three years before the UDHR, the United Nations Charter, which is the foundational treaty of this major intergovernmental body, had already reaffirmed the member states' "faith (. . .) in the dignity and worth of the human person" (Preamble). The UDHR served as the cornerstone of the new international human rights system, which was grounded on the "recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family" (Preamble). From the very beginning, the declaration puts forward that "all human beings are born free and equal in dignity and rights" (Article 1).

According to international law, the relationship between human dignity and human rights is the one between a foundational principle of equal respect for every human being and the concrete norms that are needed to flesh out that principle in social life. Human dignity is the foundation of human rights; rights *derive* from human dignity. Human dignity is not a kind of super-right, or a collective term to refer to rights, but rather the ultimate source of all rights. The notion of human dignity attempts to respond to the question, "why do human beings have rights?" And the answer is that they are entitled to rights precisely because they possess intrinsic worth.

At present, the entire international human rights system is based on the assumption that people do really have inherent dignity. In modern political thought, the state's raison d'être is precisely to promote and secure respect for dignity and rights. The validity of human dignity and human rights is thought of as not conditional upon their explicit recognition by states. Rather, both the international community and individual states are *obliged* to recognize that people do have basic rights (i.e., that they have equally valid claims to basic goods) because these latter derive from the dignity which is inherent in every human being. Hence, it can be said that, ultimately, the notion of human dignity points to a requirement of *justice* toward every individual. In the words of Rawls, this requirement presupposes that "each person possesses an inviolability founded on justice that even the welfare of society as a whole cannot override" (Rawls, 1971, p. 3).

Certainly, the practical efficacy of promoting human rights is significantly aided by their legal recognition by states. But the ultimate validity of basic rights is characteristically thought of as not *conditional* upon such recognition (Nickel, 1987). In other words, legal systems do not present the notion of human dignity

as a merely theoretical hypothesis or as a legal fiction but as the *indispensable basis for the fair functioning of human society*.

It is noteworthy that human dignity is not explicitly defined by international law. Rather, its meaning is "left to intuitive understanding, conditioned in large measure by cultural factors" (Schachter, 1983, p. 849). This is not surprising given the foundational nature of this notion, as well as the extreme difficulty of finding a precise definition of such a basic concept that satisfies everyone, especially in a transcultural context. This is also explained by the fact that lawmakers are reluctant to provide rigid definitions, which may lead to unsolvable difficulties in the implementation of legal norms. In this regard, they prefer to follow the old Roman dictum: *omnis definitio in iure periculosa est* ("every definition in law is perilous").

Despite this lack of definition, international law offers a helpful guidance for a better understanding of the notion of dignity when it provides, first, that dignity is "*inherent*. . . to all members of the human family" (UDHR, Preamble); second, that all human beings are "free and *equal* in dignity and rights" (UDHR, Article 1); and third, that "these rights *derive* from the inherent dignity of the human person" (1966 International Covenants on Civil and Political Rights, and on Economic, Social, and Cultural Rights, Preambles):

(a) The term "inherent" means "involved in the constitution, or essential character of something," "intrinsic," "permanent or characteristic attribute of something." The idea expressed in this term, when it is accompanied by the adjective "human," is that dignity is *inseparable from the human condition*. Thus, dignity is not an accidental quality of some human beings or a value derived from some particular personal circumstances such as the fact of being young or old, man or woman, and healthy or sick but rather something that all human beings possess *by the mere fact of being human*.
(b) The second important consequence of the meaning that "human dignity" has in international law is that basic rights are *equal* for all: if human dignity is the same for all and the ground of human rights, then all human beings possess equal basic rights. This is the reason why discrimination, that is, the unjust distinction in the treatment of different categories of people is directly contrary to human dignity.
(c) The third statement of international law stressing that rights *derive* from human dignity has also an important practical consequence: if basic rights are not given by authority, but are preexisting values which are inherent in every human being, then they cannot be legitimately taken away by government (Schachter, 1983, p. 853).

Human Dignity in International Norms Relating to Bioethics

Having been firmly established since 1948 as the bedrock of international human rights law, the notion of human dignity began gradually also to play an important role in the field of bioethics. Interestingly, the emphasis on human dignity in

modern bioethics is closely related to the same dramatic events that led to the development of international human rights law. The drafting work of the UDHR was indeed largely inspired by the discovery of the horror of concentration camps, including the revelation that prisoners were used for brutal medical experiments (Baker, 2001). The Second World War was "the crucible in which both human rights and bioethics were forged, and they have been related by blood ever since" (Annas, 2005, p. 160).

The increasing recourse to human dignity in bioethics can be schematically divided into three stages. The first stage, which took place immediately after the end of the Second World War, was focused on issues relating to medical research on human subjects, in particular, the requirement of free and informed consent of participants. This trend crystallized in 1947 in the famous Nuremberg Code formulated by the trial that condemned the Nazi physicians. Although the principles included in the Nuremberg Code do not explicitly refer to human dignity, it is clear that they are immediately inspired on this notion. The *nonnegotiable* nature of the code principles puts in evidence that the idea of an unconditional human worthiness was in the mind of the judges that formulated them. In this respect, it has been stressed that "never before in the history of human experimentation, and never since, has any code or any regulation of research declared in such relentless and uncompromising fashion that the psychological integrity of research subjects must be protected *absolutely*" (Katz, 1992, p. 227). According to Principle 1, "voluntary consent of the human subject is absolutely essential," and "the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice (…); and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision." The code also requires that research "should be so conducted as to avoid all unnecessary physical and mental suffering and injury" (Principle 4), that it should not be conducted "where there is an a priori reason to believe that death or disabling injury will occur" (Principle 5), and that "the degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment" (Principle 6). Consistent with the focus on medical research during this first period, the only provision of the International Covenant on Civil and Political Rights of 1966 which directly relates to bioethics states that "no one shall be subjected without his free consent to medical or scientific experimentation" (Article 7). Twenty years after the Nuremberg Code, this article is still like an echo of that historical trial decision.

The second stage in the recourse to human dignity in the field of biomedicine started in the end of the 1970s. It went beyond the domain of medical research and began to cover very different medical practices and techniques that operate at the edges of life, both at the very beginning (assisted reproductive technologies, preimplantation genetic diagnosis, embryo research, etc.) and at the very end (futile treatments, assisted suicide, euthanasia). Human dignity began also to be invoked to criticize some practices that are regarded as new forms of commodification of the human body, like organ selling and surrogate motherhood. In this varied context, it is not surprising if the term "dignity" was sometimes used to support different and

even opposed views (such as in the debate on assisted suicide). This broader and multifaceted function of human dignity is visible in the intergovernmental instruments adopted since the end of the 1990s. Two of the most important ones from a global perspective are the Universal Declaration on the Human Genome and Human Rights and the Universal Declaration of Human Rights and Bioethics, which were adopted by representatives of virtually all countries at the UNESCO General Conference in 1997 and 2005, respectively. The latter one is probably the best example of the key and multifaceted role that human dignity plays in bioethics. The promotion of respect for human dignity is the main purpose of the declaration (Article 2.c); the first principle governing the whole field of biomedicine (Article 3); the main argument every form of against discrimination, including, for instance, genetic discrimination (Article 11); the framework within which cultural diversity is to be respected (Article 12); and the highest interpretive principle of all the provisions of the declaration (Article 28).

The Council of Europe's Convention on Human Rights and Biomedicine of 1997 is another good example of the central and overarching role that human dignity is beginning to play in the biomedical field. According to its Explanatory Report, "the concept of human dignity . . .constitutes the essential value to be upheld. It is at the basis of most of the values emphasized in the Convention" (Paragraph 9). The Preamble refers three times to dignity: the first, when it recognizes "the importance of ensuring the dignity of the human being"; the second, when it recalls that "the misuse of biology and medicine may lead to acts endangering human dignity"; and the third, when it underlines the need to take the necessary measures "to safeguard human dignity and the fundamental rights and freedoms of the individual with regard to the application of biology and medicine." The purpose itself of the convention is defined by appealing to the notion of human dignity (Article 1). Although this is a regional, not a global instrument, its potential impact on a global scale should not be overlooked as it is the only intergovernmental legally binding instrument that comprehensively addresses the linkage between human rights and biomedicine.

Certainly, even with the formal recognition of human dignity as a fundamental principle, there is not always unanimity between countries, and within countries, about the concrete implications of this notion, especially regarding those medical practices that operate at the edges of life. Nevertheless, this does not necessarily mean that a universal conception of dignity does not exist but suggest only that a universal understanding of dignity does not exist *at the margins* (McCrudden, 2008, p. 711).

The third stage in the increasing recourse to human dignity in bioethics started at the end of the 1990s and marked a significant shift in comparison to the previous ones. The notion of human dignity began also to be invoked to articulate concerns about biotechnological developments that may impact on humanity as a whole. What is at stake in this new context is not only the dignity of existing *individuals* but also the value attached to the existence and integrity of the human species as such. It is important to note that a purely human rights approach is powerless to face these new challenges because rights are only enjoyed by *existing* individuals, not by humankind as a whole or by future generations. This is why the new instruments

relating to bioethics directly appeal to the notion of human dignity, and not to human rights, when they condemn practices such as human reproductive cloning or human genetic engineering. Three examples illustrate this trend: the Universal Declaration on the Human Genome and Human Rights of 1997, which emphasizes the need to preserve the human genome as a "heritage of humanity" (Article 1) and expressly labels human reproductive cloning and germline interventions as "contrary to human dignity" (Articles 11 and 24, respectively); the UN Declaration on Human Cloning of 2005, which calls on member states "to prohibit all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life" (Paragraph d); the Council of Europe's Convention on Human Rights and Biomedicine of 1997, which prohibits germline interventions on the ground that "they may endanger not only the individual but the species itself" (Explanatory Report to the Convention, Paragraph 89); and the 1998 Additional Protocol to the same convention, which bans human reproductive cloning on the grounds that it is "contrary to human dignity" (Preamble).

The Recourse to Human Rights in Global Bioethics

The emerging global instruments relating to bioethics combine the recourse to human dignity as an overarching principle with the integration of the new commonly adopted standards into a human rights framework. Moreover, these instruments present themselves as an extension of international human rights law into the specific field of biomedicine. Several reasons explain this strategy.

One reason is that, since biomedical activities are directly related to the most basic human rights such as the right to life and to physical integrity, it is logical to have recourse to the umbrella of human rights norms to ensure their protection. In spite of all its evident weaknesses, the existing human rights system, with its extensive body of international standards and wide range of mechanisms and international courts, is an invaluable tool for promoting respect for the most fundamental human goods *also* in the biomedical field.

A second advantage for appealing to a human rights framework in this field is that it facilitates the formulation of universal standards, because international human rights law is based on the principle that basic rights transcend cultural diversity and political borders. Human rights are conceived as entitlements that people have simply by virtue of their humanity and not by any particular condition or circumstance. In other words, human rights are held to be universal in the sense that "all people have and should enjoy them, and to be independent in the sense that they exist and are available as standards of justification and criticism whether or not they are recognized and implemented by the legal system or officials of a country" (Nickel, 1987, p. 561). In such a sensitive field as bioethics, where diverse sociocultural, philosophical, and religious traditions come into play, the universalistic nature of human rights is of crucial importance.

A third reason for the recourse to human rights in bioethics is that the notion of human dignity, which is the cornerstone of global bioethical norms, is unable alone

to provide concrete responses to most challenges raised by biomedical advances. Human dignity is not a magic word that, when uttered, will immediately solve all the complex dilemmas posed by medical technology. This is why the abstract principle of human dignity normally operates through other much more concrete notions (informed consent, bodily integrity, nondiscrimination, privacy, confidentiality, etc.), which are usually formulated using the terminology of "rights."

A more pragmatic reason for casting the bioethical standards into human rights terms is that there are few, if any, mechanisms available other than human rights to function as a global normative foundation in biomedicine (Thomasma, 2001). Moreover, the human rights framework provides "a more useful approach for analyzing and responding to modern public health challenges than any framework thus far available within the biomedical tradition" (Mann, 1996, p. 924). The human rights strategy allows "a well-tested and long-established common language, rhetoric and institutional practice to be applied in order to achieve consensus both on the nature of the problem and, ideally, on the form of possible solutions to it" (Ashcroft, 2010, p. 644).

This increasing use of a human rights framework to deal with bioethical issues does not mean that "human rights will subsume bioethics" (Faunce, 2005) or render bioethical discussions at the academic and professional level useless. Insofar as bioethics is a part of the ethics, it cannot and will never be entirely encapsulated in legal form. Though ethics and law interact in various ways and may significantly overlap with one another, they will always remain as two different normative systems. Legal instruments only attempt to establish a minimal ethics, inasmuch as it is necessary to ensure respect for the most basic human goods. In doing so, the law leaves a broad range of issues open for discussion and to the prudential judgment of the various stakeholders involved in medical practice and research controversies.

Human Dignity, Human Rights, and Cultural Diversity

A common objection to the very idea of human dignity and human rights applying universally is that they embody a Western liberal-individualistic perspective and are therefore alien to other cultures. Attempting to impose respect for human rights standards on non-Western countries would be tantamount to cultural imperialism. This objection can be overcome by considering that, although the current notion of human dignity was systematically developed in the West, it has close correlates in non-Western cultures, as it was mentioned above.

Understandably, each culture articulates the idea of intrinsic human worth using its own conceptual tools, but the crucial point is that this notion is present, in some way or another, in all of them. Concerning the much more modern notion of "human rights," it is a fact that it has its immediate origins in the insights of the European Enlightenment philosophers and in the political revolutions of the end of the eighteenth century, notably, the American and French Revolutions. Nevertheless, this historical circumstance is not a good enough reason to discard the idea that

people have inherent dignity and, as a consequence, equal rights. The relevant question is whether or not this idea deserves to be promoted, no matter where it was conceptually developed for the first time. Merely pointing to moral diversity and the presumed integrity of individual cultures does not, by itself, provide a philosophical justification for cultural relativism nor a sufficient critique of universalism.

It may happen that certain practices that could be seen as cultural traditions of a particular society enter in conflict with human rights principles: lapidation, female genital mutilation, child labor, the "honor killing" of women who are regarded as having brought dishonor upon the family, discrimination against people of lower castes, etc., are the most known examples. These practices, even if accepted by large part of a particular community, are regarded by the international community as incompatible with basic human rights and therefore do not deserve to be given due regard on the ground that they reflect the cultural specificities of a society. In such cases of clear conflict between the supposed cultural values of a society and human rights principles, these latter should prevail. In this regard, the 2005 Universal Declaration on Bioethics and Human Rights, while recognizing that cultural diversity should be given "due regard," makes it clear that such respect is subjected to the condition that it is not "contrary to human dignity, human rights and fundamental freedoms" (Article 12).

In addition, it is a historical fact that international human rights law was developed by representatives of the most diverse countries and cultures. Thus, it is hard to claim that it intends to impose one *cultural* standard. Rather, it can be said that it seeks to promote a minimum legal standard of protection for all human beings, regardless of their specific cultural background. Certainly, in many Western nations, there has been an excessive emphasis on rights and freedoms for the *individual*, sometimes to the detriment of duties and of family and community values, which are of paramount importance to most non-Western (mainly Asian and African) societies. However, it would be equally fair to say that international law has made substantial efforts over the last decades to be more attuned to the communal and collective basis of many non-Western countries. This was done, in particular, through the development of the "second generation of rights" that are included in the abovementioned International Covenant on Economic, Social, and Cultural Rights of 1966, which emphasizes the notion that the individual has not only "rights" but also "duties to other individuals and to the community to which he belongs" (Preamble). The protection of the family, which is recognized as "the natural and fundamental group unit of society" (Article 10), the special protection awarded to children and young persons, the promotion of just and favorable working conditions, and the improvement of education and of public health, have a special place in this document. This tendency toward a broader understanding of human rights has been even further developed in the last few decades through the so-called rights of solidarity, which include the right to development, to peace, to self-determination, and to a healthy environment.

Hence, although human rights remain philosophically grounded within an individualist moral doctrine, it must be acknowledged that serious attempts have been made by the international community to adequately apply them to more

communally oriented societies. This more socially oriented tendency can also be found in the intergovernmental instruments dealing with bioethics. For instance, the 2005 Universal Declaration on Bioethics and Human Rights insists on the importance of developing "new approaches to social responsibility to ensure that progress in science and technology contributes to justice, equity and to the interest of humanity" (Preamble); of taking into account "the special needs of developing countries, indigenous communities and vulnerable populations" (idem); of promoting "solidarity and cooperation" (Article 13); and of fostering the sharing of benefits resulting from scientific research within each society and between societies (Article 15).

In sum, human dignity and human rights, which are by definition universal, are not necessarily in conflict with respect for cultural diversity. This is also valid in the field of bioethics. The circumstance that bioethical issues are closely linked to the deepest sociocultural and religious values of every society is not an obstacle to the formulation of universal norms but, quite to the contrary, can be regarded as a valuable asset in the efforts to develop global bioethical principles. Precisely because bioethics is close to the most cherished aspirations of people, and people are essentially the same everywhere, the development of some minimal common standards in this area is feasible. Human dignity plays in this regard a unifying role by reminding that all human beings are entitled to basic goods and have therefore equal basic rights. From this perspective, human dignity plays the role of a precious bridge between cultures.

Conclusion

Since 1948, the notion of human dignity operates as a central organizing principle of the international human rights system. It also plays a crucial role in the emerging global norms relating to bioethics, which present themselves as an extension of international human rights law into the field of biomedicine. The recourse to dignity in this specific area reflects a real concern about the need to promote respect for the intrinsic worth of human beings and the urgency to preserve the identity and integrity of the human species against potentially harmful biotechnological developments.

However, human dignity alone cannot solve most of the dilemmas posed by biomedical advances. This explains why international norms addressing bioethical issues combine, on the one hand, the appeal to human dignity as an overarching principle with, on the other hand, the recourse to human rights, which provide an effective and practical way forward for dealing with bioethical issues at a global level.

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Benefit and Harm

5

Donald Evans

Introduction

Article 4 of the Universal Declaration on Bioethics and Human Rights (UNESCO, 2005) states that:

> In applying and advancing scientific knowledge, medical practice and associated technologies, direct and indirect benefits to patients, research participants, and other affected individuals should be maximized and any possible harm to such individuals should be minimized.

There are two layers of difficulty involved in any attempt to apply this article in either research or practice in health care. The first concerns the fundamental problem of identifying precisely what should count as a benefit or harm in a given situation. The second is to identify the ethical limits of the injunction to maximize the potential benefits and to minimize the potential harms involved in each of these enterprises. In each of these contexts, it is important to identify the relationship between this article and others in the declaration.

What is a Health Benefit?

Let us first consider the former problem by asking the question "What is a health benefit?"

At first glance, it does not seem to be problematic to identify health benefits. We are all only too familiar with the common reasons we have for going to see our doctor. Perhaps we have an unexplained pain, or we are short of breath, or we simply feel dreadful and find we have no energy to do anything. We expect the doctor to diagnose some kind of problem associated with disease, either trivial or serious. We are told that we have an infection or that our condition demands further investigations which will involve sophisticated detective work to determine

D. Evans
University of Otago, Otago, New Zealand
e-mail: Donald.evans@otago.ac.nz

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whether we are developing a malignant tumor, or rheumatic joints, or a stomach ulcer, or whatever. There is an orthodox nosology to which doctors refer when conducting these investigations. It is tempting, therefore, to conclude that to be healthy is to be free from any of the diseases detailed in that list and being unhealthy is to suffer from one or more of them.

Once we have determined the disease state of a person, then it seems we have also identified their health needs. Absence of disease means no health needs and, therefore, no possibility of health benefits; presence of disease means there is a need for treatment, if there is one, leading to either the cure or the palliation of the effects of the disease each of which counts as a health benefit.

A Narrow Concept of Health

Attractive though the above story is, it is only part of the truth. A cursory glance at the practice of medicine will show that health benefits are available to people who do not presently suffer from any disease. These are provided by prophylactic treatments or disease prevention programs such as vaccination against whooping cough. To be protected from the onset of a disease clearly constitutes a health benefit. Indeed, it has been argued by health economists that these are the cheapest forms of health benefits to achieve. Most people would also prefer that their health practitioners enable them to avoid suffering diseases rather than have to treat those diseases when they occur. However, conceding this point does not move us far from the disease model of health in that the range of health benefits is still exhausted by either the treatment or the avoidance of disease.

If we look more closely at health care delivery, we will see that non-disease conditions are also part of the remit of medicine and surgery. The most obvious treatments which go beyond the disease-related conditions are bodily dysfunctions arising from traumas such as broken legs and brain injuries. Restoring proper physical functioning by treating the results of non-disease events is clearly part of the remit of health care provision. But the practice of health care professionals might go way beyond restoring normal bodily functions in the face of such events. When such restoration is impossible, health care professionals might still have a role in providing health benefits to those who suffer impairments of function. For example, the provision of prostheses to people who have suffered the loss of arms or legs in accidents is doing nothing to restore normal bodily functioning nor to treat or ameliorate the affects of disease. It is to treat a social dysfunction insofar as the new limb enables its wearer to engage in a wider range of social activity and the affairs of life than would otherwise be possible. No one would hold that this was not to provide a health benefit. Such an extension of the definition of health benefits demonstrates that simply widening the disease model of health to one related to physiological function is also inadequate. Here, the social context of a physical condition becomes significant.

Further reflection will soon bring us to a consideration of mental health problems. There are very few people who would assert that such problems always

originate from or are explicable in terms of physiological functioning. Even though there has been vigorous debate among psychiatrists and philosophers about the application of terms like illness to mental conditions, it is generally accepted that many behaviors and psychological phenomena fall under the umbrella of health (Szasz, 1961). Indeed, mental health is a major segment of health care delivery. While there are some advocates for physiological explanations of mental problems, including genetic determinists, most practitioners disagree. Indeed, to take an extreme example, even personality disorders which figure in the Diagnostic and Statistical Manual of Mental Disorders (DSM IV) are not so explained. If, for example, an apparent psychopathy can be explained by the existence of a brain lesion, a physiological explanation, then it is described as a pseudo-psychopathy (Walton, 1973).

The WHO Definition

Given the apparently limitless extension of the boundaries of health and consequently of needs and benefits indicated above, can we find some kind of general description which would secure a manageable range of benefits which health care should aim for? The World Health Organization, fully aware of the dangers of imposing narrow limits on the notion of health, has provided a definition which has been influential for many years. It is as follows: "Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" (World Health Organisation [WHO], 1946).

This definition certainly takes account of the extensions of health beyond the boundaries imposed by disease-related and physiological dysfunction-related conceptions. It takes the psychological and social dimensions of people's conditions seriously. Insofar as this is the case, the definition is valuable. However, it is limited in its usefulness by the sheer immensity of the range of circumstances and conditions for which, by implication, health authorities should be regarded as responsible. These would include the benefits of the provision of adequate defense capabilities to provide for the security of the population of a country and for the benefits of the provision of education to a population. A later suggested amendment includes "the ability to lead a socially and economically productive life" (ACT Health, 2009). However, the amended definition merely tempers the criticism at the ethical cost of discounting the interests of a large group of potential patients, viz., those who will never be able to live an economically productive life, from the cohort of possible recipients of the benefits of health care and research. In addition, the amended definition might tempt us to consider that there are universal objective measures of health and consequently of health benefits. This would oversimplify the task of identifying and measuring health benefits.

So how do we proceed when we want to identify a health benefit? It seems that the general definitions of health tend to be either too wide or too narrow to fit all cases. It might, therefore, be helpful to look at the arguments that have been made for and against the identification of a particular condition as a candidate for being

a health need and for the identification of the relevant concomitant health benefits which attach to the treatment of that condition by means of the application of a new biotechnology.

The Case of Infertility

Is infertility a health need? (Evans, 1996) Are the benefits afforded by infertility treatment health benefits? Should scarce health funds be used for providing treatments for infertility?

For centuries, the inability of couples to produce their own children was blamed on the female partner who was described as barren. We now know that in at least half of the cases of infertility, the problem lies with the male partner rather than the female and is usually connected to an inadequate production of sperm. This knowledge has come as a great relief to many women who suffered misplaced guilt, anxiety, and social disapproval for not being able to become mothers. But such a relief is a small comfort to them when nothing can be done to address the issue of their childlessness.

In limited numbers of cases, women with disease conditions which caused their infertility could be treated for those diseases, or the results of them, and their fertility could be restored. Tubal surgery is still performed for this purpose. Such treatments enjoy limited success. But they also leave unhelped couples whose infertility is not explained and those whose infertility is due to their male partner's physiological problems. The technological breakthrough of in vitro fertilization (IVF) in the late 1970s afforded clinical hope for these couples. Professor Robert Edwards has reported that by the year 2002 more than a million children had been born as a result of the use of this technology and that by 2012 he estimates that ten million people will be alive who were born by these means (personal conversation, October 22–24, 2002). But the provision of these services has been the subject of continued dispute among health care providers in numerous parts of the world (Evans, 1995).

The problems can be seen to arise from the difficulties presented by the temptation to assume that health is fundamentally constituted by the absence of disease. This is clearly demonstrated in a research paper which compared the behavior of a number of health providing authorities in the United Kingdom (Redmayne & Klein, 1993). Half of them refused to purchase IVF treatments while the other half did purchase them. The reasons for their choices are illuminating. The predominant reason given by the non-purchasers of IVF services was that couples with unexplained infertility were not ill and that their infertility was not a disease. Even some of the purchasers gave reasons which also embodied the assumption of the need to relate the treatment to disease in that they purchased the services as a prophylactic designed to ward off the onset of stress and mental illnesses which often arise from infertility.

Others paid lip service to the importance of social aspects of the condition but in such a way as to bar it from treatment. The view was that the condition of

childlessness constituted a social need rather than a health need. It is the case that the use of IVF does not really constitute a treatment of infertility as such but rather that of childlessness. This is because the treatment leaves the couple as infertile as they were before that condition was circumvented to achieve a pregnancy. But to disengage such physiological conditions from the context in which they occur, as these non-purchasers did, is a sure way to misidentify health needs and benefits.

It is not difficult to make a case for regarding infertility as a health need in certain circumstances and, hence, to regard its clinical circumvention as a health benefit. It is acknowledged by all that the condition is a source of much unhappiness and stress causing suffering for many couples. It is also clear that it constitutes a physiological dysfunction. The function of procreation is a fundamental physiological function at the species level. But it is also an extremely important function at the personal level for the vast majority of people for whom living in and rearing families is a major constituent of emotional well-being. For the infertile couple who long for a child, the dysfunction is socially debilitating. We have already noted that other dysfunctions such as the loss of limbs are standardly treated by health care professionals because of their socially significant consequences. So why not infertility or, rather, childlessness? Until the advent of IVF and the subsequent research on the early stages of human development and reproduction, there was little that could be done to address the condition for most couples. Thus, they could not then be said to have any need for clinical treatment. But now that we do have clinical means to circumvent their infertility and enable them to achieve a pregnancy in many cases, they can be said to have a clinical need. This is tantamount to saying that they have a health need and that the successful bringing to birth of a child constitutes a health gain.

It now begins to look as though the amended WHO definition of health does, after all, serve the purpose of identifying what shall count as a health benefit; if we add the rider that where a clinical intervention can achieve the possibility of a socially productive life, then it achieves a health benefit. However, this is not quite so. One might be tempted to read it as suggesting that wherever infertility is found, then it represents a physiological dysfunction which calls for treatment. But this would be a mistake. It is possible to argue that no physiological condition in itself constitutes a health need. That is, until the condition is cast in the context of the life of the person or persons concerned, we cannot know whether it is a health need or not. This is easily demonstrated in the case of infertility or childlessness. It is ironic that in many areas where IVF services are not accessible to patients, contraceptive and sterilization services are available. Of course, in some cases, sterilization, for example, is thought to be an important clinical treatment to avoid the possibility of diseases unrelated to reproduction. But in most cases, it is offered in order to produce a desirable biological dysfunction for the patient concerned. For those patients, their fertility is seen as constituting a health need and the state of childlessness, whether temporary or permanent, is seen to be a desirable condition. Thus, in the process of identifying possible health benefits, it is important to consider the particular circumstances of each patient in question in order to see whether the apparently general rule in fact applies.

Above All, Do No Harm

It will not be surprising to learn that the task of identifying harms in health care delivery suffers from the same difficulties as the identification of benefits. The conclusions reached in the use of reproductive technology above apply equally to the following case of identifying harms. Let us imagine that a surgical procedure to remove an ovarian cyst is carried out successfully on a patient. In the course of the procedure, one of her fallopian tubes is inadvertently damaged and scarred. This damage results in infertility. Has a harm been visited upon that patient? The answer to this question is that it all depends on the patient. If the patient considers that she has completed her family and that she will not want any further children, then the inability to conceive will not constitute a harm for her. Of course, it might turn out that she will change her mind about this given the possible circumstances which could develop in her life. In such an event, she would come to consider that the surgical error did harm her. In other words, we are obliged to consider the context of the surgical mistake in the life of the patient before we can determine whether it was harmful or not.

We have seen that the application of a general rule for identifying a health need crucially masks the variety of possible perceptions of harm and benefit. Some situations are even more complex and demanding of the clinician than those we have considered. Indeed, this variety can sometimes challenge the most basic assumptions about what constitutes a health care intervention and a lack of imagination or willingness in a health professional; to contemplate such challenges can vitiate the critical determination of what treatment is indicated for a given patient.

The juxtaposition of three recorded clinical cases each involving what might be naively considered as the same intervention graphically illustrates this point (Evans, 2008). The intervention which was either contemplated or executed in each case was the amputation of a limb, viz., a leg.

C was a paranoid schizophrenic patient who was detained in Broadmoor Special Hospital following his arrest on the charge of attempting to murder his fiancée and his subsequent diagnosis. After some 30 years of detainment there, he developed a gangrenous foot which was diagnosed as life threatening. The hospital authorities wished to proceed with an amputation but this was challenged by the patient. A delusion that he was an important surgeon might well have clouded the issue of whether he was competent to determine whether he should be so treated. Such a condition would lead one to think that he mistakenly thought that the clinical decision was flawed. However, when asked by the court why he did not want the amputation, he declared that he would rather be dead with two feet than alive with one. In other words, he considered that the procedure would so undermine his dignity that his subsequent life would be undesirable. This had nothing to do with the likely outcome of the procedure in clinical terms. That is, it was not a question of his being correct or mistaken. Thus, Judge Thorpe declared that he was competent to decide for himself. C's decision was based on his perception of what was an acceptable life. On this, the court considered him to be the authority (Re C, 1994).

The one-legged man was a combatant in the trenches in Northern France in the 1914–1918 War. He was the victim of shell fire which so seriously injured his leg

that it was amputated in a field hospital following which he was repatriated to England. He has been immortalized in a short poem entitled "The one-legged man" (Sassoon, 1961). Now living in the English countryside in peacetime, he reflects on the loss of his limb:

> Safe with his wound, a citizen of life,
> He hobbled blithely through the garden gate,
> And thought: 'Thank God they had to amputate!

Life was sweet and highly desirable. He would, without doubt, prefer to be alive in his own land with one foot than dead in the trenches of Northern France with two.

Now how much sense is there in asking which of the two, the old soldier or C, was correct? The answer is plain; there would be no sense in it. This was not a matter of the calculation of empirical odds for them. It was rather a matter of fundamental differences in their valuation of a certain kind of existence. One would need to know more about each of them than their clinical conditions as diseased or injured men in order to understand whether the procedure was indicated for them or not.

The significance of the absence of a general rule for determining what constitutes a harm or a benefit to individual patients might go even deeper in determining what is an indicated treatment for a patient. Consider the case of a proposed amputation for a patient whose leg was neither diseased nor injured.

From the age of 8 years, Kevin Wright had felt that his healthy left leg was not part of him. This unease resulted in considerable emotional pain and distress which defied treatment by medications or behavioral therapy. In desperation, he sought the amputation of the limb. This request seemed to be totally unacceptable to a number of surgeons who were approached. Robert Smith, a Scottish surgeon, thought more carefully about the case. He was able to reject some descriptions of the motivations for requesting the procedure by examining his medical record and engaging in extensive conversations with him. He concluded that the patient's desire was not motivated by some sexual deviation, by a desire to be dependent, nor by a tendency to self-mutilate for gratification. He embraced the diagnosis of body dysmorphic disorder (BDD) in the case and proceeded with the amputation. Following the procedure, the patient claimed that the surgeon had made him complete (Taylor, 2000).

The Balance Between Benefit and Harm

There remain some interesting issues to consider around the question of identifying and avoiding harms in health care. If the hippocratic oath which asserts the primum non nocere (above all do no harm) principle is to be adhered to in practice, how can any surgical procedure be attempted or indeed any medication be prescribed when we can never know with certainty what the effects in total of that intervention will be in a given patient? In another context, the wound inflicted by the surgeon in an abdominal operation would constitute a grievous bodily harm. Similarly, the

administration of cytotoxic drugs in other situations than in treatments of malignant disease would constitute poisoning. What justifies them in surgery and chemotherapy is the net balance of benefit over the harm which the treatments inevitably involve. Indeed, any clinical intervention has to be undertaken only after the completion of a risk of harm/benefit calculation. If a patient does not stand the chance of benefiting overall from an intervention, then that intervention is not indicated for him. That is, where the risk of harm outweighs possible benefit, the treatment is not indicated.

These calculations are often very difficult to make for, not only will the variety of perceptions of harm and benefit mentioned earlier come into play, but also the empirical and conceptual uncertainties of the possible outcomes will confound the procedure.

With respect to the former uncertainty, it has been said that every administration of a drug is an experiment. How one patient will react will not always be a reliable guide to how another will react. One patient with the same disease as another might respond well to a drug whereas the other will remain unhelped. Or one might suffer unpleasant adverse events whereas the other will tolerate the medication well. While there is hope that the new technology of pharmacogenomics will increase our levels of confidence in matching medicines to patients and remove much of the trial and error element of prescribing, it will never eliminate uncertainty.

With respect to conceptual uncertainty, we might consider the difficulties of making risk of harm/benefit calculations in withdrawing or continuing intensive care treatments. In such circumstances, it is often difficult to distinguish between whether it is of benefit to a patient to withdraw life prolonging treatment as to ask whether it is harmful to continue life support where it precludes the possibility of a death with dignity. In such situations, we might be tempted to describe any choice equally as being beneficial or harmful.

Acute and Elective Procedures

Another context in which harms and benefits have to be recognized and weighed is in the classification of clinical cases as acute or elective. No health service is able to treat all patients as soon as they present themselves with a health problem. Access to services is managed by means of a distinction between acute and elective treatments. These classes are defined in terms of the possible harms which are likely to result from not treating the patient immediately. There are two categories of harm involved in the distinction. The first is that failure to treat as soon as possible could result in death. The second is that failure to treat immediately could lead to irreparable damage. Thus, it makes no sense to place a case of the rupture of an aortic aneurism on a waiting list as time is of the essence if that life is to be saved, whereas treatment of a standard abdominal rupture could be delayed without risk. Similarly, it is dangerous to delay treating a patient suffering from septic arthritis whereas treating a case of osteoarthritis could be delayed beyond the immediate future. There might be graded waiting times also depending on the rate at which

gross damage could occur. Thus, for example, one might distinguish between immediate, urgent, semi-urgent, and routine cases where septic arthritis would rank as immediate, seropositive RA as urgent, inflammatory polyarthritis as semi-urgent, and osteoarthritis as routine. This possibility of ranking certain conditions will be examined in more detail in the next section.

Once again, there will be difficult cases arising in these categorizations. For example, some might regard any cancer diagnosis as potentially life threatening and, therefore, as an acute condition. However, it is known that whereas some cancers are aggressive and the earliest intervention offers the only chance of recovery, others are more gradual. Yet even in these cases, postponement of the provision of care beyond a short time frame is dangerous because of the possibility of the development of systemic problems and secondary metastases. Certainly, in the mind of the sufferer, delays will appear to be grossly neglectful and the possibilities of good outcomes become more and more remote.

In contrast, chronic diseases which involve joint damage such as hemophilia and rheumatoid arthritis might not be threatening in the way that malignant tumors are but, nevertheless, they can result more or less quickly in catastrophic disability. Protection against the deterioration of joints by the avoidance of bleeds through the prescription of Factor 8 or steroids and antimetabolites to counteract connective tissue disease is also called for promptly. Insofar as these kinds of classification are feasible, it is possible to grade degrees of harm and benefit. However, we have to be careful not to be too ambitious in scoring relative harms and benefits. The temptation to extend the process is often demanded by attempts to manage resource allocation and access to health services. This runs up against both empirical and conceptual difficulties.

Maximizing Benefit and Minimizing Harm

Let us now turn to the second feature of Article 4 (UNESCO, 2005), which enjoins us to maximize benefit and minimize harm insofar as they can be identified.

It is plausible to claim that in times of scarcity of health care resources, one ought always to seek to achieve the maximum benefit from the investment of every health dollar. It seems that any other approach will applaud the achievement of less benefit than was possible and result in the denial of care to some patients (Mooney, 1986). This view is in line with many of the approaches of health economists who operate on a utilitarian model of determining correct allocation decisions (Mill, 1910). Mill's guiding principle is often called the greatest happiness principle in that it asserts that whatever action achieves the greatest happiness of the greatest number of people is the right action to perform. Any other action is less than optimal in terms of its rightness as it fails to achieve the maximization of happiness. Before we apply this theoretical structure to the health care setting, it is important to note that Mill himself recognized problems in its application. They were largely concerned with making the calculations called for to determine which action would maximize happiness. We shall see that this problem is more than an empirical

difficulty. It is a conceptual problem attaching to the nature of goods or benefits which are the measure of the rightness of an action and to the correlative harms. This is a problem which we have earlier discussed in the health care setting.

The search for one measure of goodness was designed to facilitate the utilitarian calculations. Happiness was his choice. But he recognized that different people have different views as to what happiness is. The tongue-in-cheek proposal of convening a committee of experts in happiness to adjudicate the matter is amusing. These experts, having experienced all the pleasures, would be in an authoritative position to tell us which were the best pleasures. Of course, such a proposal is nonsense. Some pleasures are antithetical to others such that they cannot all be experienced by the same person. There are no experts in happiness and the view of such a committee would be a view from nowhere.

But this lesson has not been learned in health care management where efforts are still made to find a single measure in terms of which to cast health needs and to rank them. Concepts such as the restoration of normal ranges of opportunity have been candidates for this role (Daniels, 1985). The truth is, however, that these are also views from nowhere. Both the identification of health goods or benefits and the aggregation of health benefits to discover the maximal outcome from health expenditure are not simply difficult to achieve, they are misconceived. We have seen the problem of finding a universal identifier of health benefits and harms, so let us now consider the problem of trying the aggregate health benefits and harms. Even if we agree on the identification of health benefits, how can we perform the calculations needed to tell us which is the most efficient way to spend health resources in order to maximize outcomes?

Two kinds of calculations have been designed to assist in the task. One is misleading, the other is useful. The misleading concept is of horizontal aggregation. This consists in attempts to find a common measure, such as the one mentioned above, in terms of which one might cash any given health condition and, hence, use this common currency to compare the outcomes of given investments. But the endeavor fails to recognize the incommensurability of harms and, consequently, of benefits in health. It is not difficult to illustrate the impossibility of achieving such a goal. Imagine trying to ranking the following five conditions in terms of their worseness – that is, endeavor to answer the question which condition would you least like to suffer from and which next and so on. Here is the list: blindness, a grossly disfiguring facial disease, the shortening of one's life by 25 years, serious mental illness, and constant intractable and intense physical pain. It is simply not possible to think of a currency in terms of which we could form such preferences. How much more difficult would it be to decide between the value of one person's blindness, another's mental illness, and another's shortening of life? Health managers have to make macro-decisions about expenditure in all these fields. But it is dangerous to pretend that we can put a management tool in their hand to make definitive determinations of relative need between such patients. Thus, there is a conceptual problem in aggregating or ranking all health conditions.

Yet if we want to achieve equity in health care provision by treating people according to their degree of need, then we must to be able to compare the needs of

some persons to those of others. This is possible using the second model of aggregation, viz., vertical aggregation. It embodies the principles involved in the previous example of arthritis. While ranking is not possible across conditions which are dissimilar, save in respect of the acute/elective kind of distinction, it is possible within specific health services such as surgical intervention for hernias, varicose veins, Dupuytren's contracture, cataracts, and so on enabling clinicians to compare the severity of the condition of one patient with that of another and to perform a fair calculation of relative health needs between them. While this is not an exact science, some contrasts are clear. For example, where a patient's vision is so defective that reading is impossible and even leading an independent life is ruled out by the condition, the need will be seen as greater than that of patients who do not need to live independently and for whom reading is not an important activity. The social limitations imposed on the sufferers by their condition such as the ability to continue employment or carry out weighty family duties can also be built into this assessment. In these ways, patients who do not count as acute cases might still be ranked above other patients on the basis of their degree of need for an intervention.

Clinicians have worked hard in many disciplines to produce reliable tools for ranking their patients within the confines of specific conditions in this manner in order to inject more equity of access to services than is afforded by crude waiting list systems (Derrett, Devlin, Hansen, & Herbison, 2003). It is, therefore, important to note that measurements of need and, consequently, of harm and benefit are possible when related to individual patient narratives. But this does not involve the maximization of benefit. On this model, less benefit might be achieved overall from a given investment of resources but the allocation will be better insofar as it is fairer (Evans, 2008). Maximization models discriminate against minority groups, the chronically ill, the dying, the mentally ill, and the elderly among others, insofar as all calculations employing measures which involve multipliers such as the degree and duration of benefit militate against the interests of both those whose health problems afford less prospect of extremely good outcomes and those whose longevity is compromised.

Interrelation of Article 4 with Other Articles in the Declaration

While we have noted that maximization of benefit as such is an ethically questionable goal in the allocation of health care provision, there are important senses in which maximizing the provision of benefit and minimizing the occurrence of harm is an ethical requirement. Article 4 does not in any way throw doubt on this claim. It is rather concerned to describe the intent of clinicians, researchers, and institutions in the area of health to aim for a proper balance of benefit over harm in the clinical encounter. It is not so much concerned with the issue of who should be afforded the privilege of such an encounter as with the predominant motivation of clinicians vis-à-vis their relationship with each individual patient for whom they are providing care. The wording is clear in its application to patients where

it specifies that in *applying* scientific knowledge in medical practice and associated technologies, direct and indirect benefits to patients should be maximized and any possible harm to such *individuals* should be minimized. We have already noted that the notion of an "indicated treatment" is based on such individual calculations.

However, the article has wider connotations related to the issues of maximization of benefit and minimization of harm which become clearer when we see its relationship to other articles in the declaration.

The article mentions the concepts in relation to the conduct of research in health care. Here, we need to be precise for it might appear that the wording enjoins that research participants as such are to enjoy the maximization of benefit and the minimization of harm. The latter idea is the sine qua non of good research involving human participants (Nicholson, 1986; Evans 2012). However, the former idea, viz., that research procedures should maximize health benefit to participants is incoherent. Research protocols are designed to determine whether a novel treatment is safe and, then, whether it is effective. No benefit can be promised to research participants for the very research question being posed in a trial is whether the novel procedure can count as a treatment at all. Until this question is answered, no promises of benefit can accompany the administration of the novel drug or the execution of the novel procedure which is being researched.

However, there is an important sense in which the maximization of benefit is applicable to the research enterprise. This sense becomes clear when the relation between Article 4 and other articles in the declaration are recognized. For example, Article 15 deals with the issue of the sharing of the benefits of research (UNESCO, 2005).

> Benefits resulting from any type of scientific research and its application should be shared with society as a whole and within the international community, in particular with developing countries.

This extension of as wide a range as possible treatments to as many people as possible is not a maximization policy in terms of who shall be refused treatments (as resource allocation models are), but rather a response to the fundamental needs of as wide a group of sufferers as possible, vast numbers of whom are not even candidates for their health needs to be addressed at all at present. These needs will in turn also have to be graded between individuals for their application, but until they are recognized and addressed, for example, in relevant research, no allocation decisions are even called for.

This is a program of the maximization of benefit if it is anything. It can take a number of forms. For example, special consideration should be given to those who participate in the research. In the past, some groups, especially from developing countries, who have participated in the research phase of the development of drugs, have been denied access to those drugs when they have been marketed. Such barriers should be removed. In addition, maximization of the benefits of research also entails the provision of quality care on the widest basis including access to diagnostics and novel therapeutic modalities and the sharing of expertise and

knowledge. These are but part of the declaration's intent to link ethical behavior in health care practice and research to human rights. There are further elaborations on the theme in Article 14 on social responsibility and health (UNESCO, 2005).

> Taking into account that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition, progress in science and technology should advance access to quality health care and essential medicines, especially for the health of women and children, because health is essential to life itself and must be considered to be a social and human good.

While the ethical encouragement to provide the benefits of research to as many citizens of the world as possible is laudable, there are major obstacles to its achievement. These obstacles include national interests and the interests of investors in health research. Article 15, as we have noted, strongly suggests that these barriers are not justified insofar as they deny fundamental human rights to large proportions of the world's population. This is not to say that these interests are improper. It is, however, to say that though they are justifiable and even essential, there should be room for accommodation of the interests of humanity in general in programs of health care research and delivery. This can be illustrated in the role which university research plays in health research (Evans 2012).

Researchers have always been jealous of their discoveries and have wished to protect them from misappropriation. Isaac Newton so feared that his methods and results in his enunciation of the Laws of Motion would be copied that he slept in his laboratory at Cambridge to watch over them. He later accused Leibniz of plagiarizing them. Similarly, there was a dispute over whether Louis Pasteur plagiarized the results of Bechamp's research in his discovery of the germ theory of disease. Preserving due credit for research results is an ethical enterprise. However, things have moved beyond that in the academy where such protections have been hardened into intellectual property rights (IPRs) which effectively privatize the knowledge so providing funds for the University by licensing the use of this property by other researchers and practitioners in exchange for royalty payments. The owners of the knowledge can make the knowledge available to those who are both willing and able to pay for it and deny it to the rest. The academy has met the market. This is far from a maximization of the benefits of the research though it is a maximization of the profits of the owners of the knowledge.

If this is true of the university which has traditionally been much involved in public good research, then what hope is there of maximizing the benefits of that knowledge discovered and patented by multinational companies? There is need for the establishment of ethical guidelines in business to ensure that room is left for the exploitation of the products to meet the dire needs of vast numbers of human beings in the developing world. The 10/90 gap identified by the Global Forum for Health Research has shown that only 10 % of the monies invested in health research are related to the health needs of 90 % of the world's population. Consider the graphic example of the likely developments of nanotechnology as discussed by Singer, Salamanca-Buentello, and Daar (2005).

The authors consider the question of the likely future direction of the development of the technology in the context of the rival pressures of the market, on the one hand, and the fundamental needs of vast numbers of citizens of developing world on the other hand.

The needs involved are overwhelming. Eighty percent of the diseases in the developing world are water related. 1.5 billion people currently lack access to clean water. It has been estimated that 3.4 million deaths per annum result from the use of water contaminated by bacteria, viruses, oil, and heavy metals. Nanotechnology offers solutions to this contamination. Singer et al. (2005) list three possible tools nanotechnology might offer to achieve this highly desirable extension to the benefits of progress in science.

1. Intelligent membranes can be produced to make affordable and portable filter systems which will remove most contaminants including bacteria and viruses. These materials are 10,000 times more capable of binding bacteria and toxins than activated carbon.
2. Nanomagnets with various coatings can be designed to deal with specific contaminants, including oil, from water. Such dustlike preparations could be spread over wide areas and gathered up affording almost 100 % effectiveness. These nanomachines could be recycled and used over and over.
3. Magnetite nanoparticles combined with citric acid could remove heavy metals from water.

But will the development of this technology move in this direction under pressure from the desperate needs of so many human beings or will it succumb to the pressures of the marketplace? Singer et al. (2005) starkly pose the question.

> Will nanotechnology produce the nanodivide? Resources might be directed primarily to nanosunscreens, nanotrousers, and space elevators to benefit the 600 million people in rich countries, but that path is not predetermined. Nanotechnology could soon be applied to address the critical food, water, and energy needs of the five billion people in the developing world.

Conclusion

The identification of health benefits and harms is crucial in the delivery of effective health care services; though it is a complex activity. It is also crucial in the allocation of those services to patients. However, it is important to remain aware of the limitations which attach to this activity both in clinical practice and health care management. Maximization of benefits as a tool for the rationing of health care offends the ethical principle of equity (Article 10). However, to ignore the responsibility to maximize the use of medical and technological innovations also offends against the fundamental right of human beings to the enjoyment of the highest attainable standard of health without distinction of race, religion, political belief, economic, or social condition (Article 14). Actions are called for to temper obstacles to the sharing of medical and technological knowledge as demanded by Article 13 and 14 of the declaration. Solidarity among human beings and international cooperation toward that end are to be encouraged.

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Autonomy and Individual Responsibility

6

O. Carter Snead and Kelli Mulder-Westrate

Introduction

The Universal Declaration on Bioethics and Human Rights is an extraordinarily ambitious document. It seeks to "provide a universal framework of principles and procedures to guide States in the formulation of their legislation, policies or other instruments in the field of bioethics" (Universal Declaration, Art. 2(a), 2005). Few, if any, intergovernmental instruments match its breadth in terms of subject matter covered ("ethical issues related to medicine, life sciences and associated technologies as applied to human beings, taking into account their social, legal and environmental dimensions") (Universal Declaration, Art. 1, 2005). It is also notable for the unusually vast audience to whom it is addressed. Not only is it meant to offer advice to member states but also "to guide the actions of individuals, groups, communities, institutions and corporations, public and private" (Universal Declaration, Art. 2(b), 2005). The Declaration has received some attention from scholars and policy makers, both positive and negative. UNESCO itself has taken steps to circulate and promote it, including by publishing commentaries on its various provisions, authored by invited contributors, including the International Bioethics Committee itself. But one aspect of the Declaration has not yet received the attention it deserves, namely, its treatment of autonomy as an ethical principle. Whereas autonomy has been accorded pride of place as the dominant ethical principle in mainstream bioethics for decades, the Declaration offers a strikingly different approach. That is, it subordinates autonomy to other goods such as human dignity, solidarity, and protection of the vulnerable. In this way, the Declaration recovers and restores the original key animating good for public bioethics that gave rise to this new species of law and policy in the first instance. It marks an important return to the foundational principle of respect for persons.

This chapter will elaborate on this countercultural feature of the Declaration and offer an argument that it is a salutary development for public bioethics. To that end, it will proceed in the following manner. First, it will supply a necessarily

O.C. Snead (✉) • K. Mulder-Westrate
Notre Dame Law School, University of Notre Dame The Law School, Notre Dame, IN, USA
e-mail: Orlando.C.Snead.1@nd.edu; osnead@nd.edu; kmulderw@nd.edu

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compressed account of the shift from respect for persons to respect for autonomy as the dominant ethical norm in public bioethics. Next, it will argue that this singular emphasis on autonomy has impoverished public bioethics as a form of governance (and a field of inquiry). This chapter will then explain how the Declaration represents a turnaway from this approach, toward the embrace of a suite of goods squarely situated within the concept of respect for persons, richly understood.

Brief History: From "Respect for Persons" to "Respect for Autonomy"

The origins of bioethics in its scholarly and public forms are complicated and contested (Jonsen, 2003, offering a compelling account of this history; Snead, 2010, offering an extended discussion). As a field of interdisciplinary scholarly inquiry, bioethics seems to have emerged in the middle of the twentieth century (late 1960s) in large part as a reaction to the simultaneous increase in technical skills on the part of physicians (enabled by extraordinary advances in biomedical science) and *decline* in the humanistic dimension of medical practice. As doctors became more technically proficient, they also became (or were widely perceived as becoming) more humanly distant from their patients. The almost priestly role of the physician (who had historically ministered to the whole person and her family) gave way to a narrowed emphasis on the technical mastery of interventions aimed at correcting clinical pathologies. As a result, patients increasingly felt neglected as participants in their treatment. Worries about paternalism proliferated. In response, an interdisciplinary array of physicians, theologians, philosophers, legal scholars, and social scientists convened meetings and founded centers to explore these and related matters. These events, according to Albert Jonsen (and other commentators) marked the beginning of bioethics as a field of scholarly inquiry (Jonsen, 2003).

The birth of *public* bioethics (i.e., the *governance* of medicine, science, and biotechnology in the name of ethical goods), however, emerged in response to a very different series of events. Unlike the scholars and commentators described above, public officials charged with making, enforcing, and interpreting the law were not "driven by a desire to tame the imperialism and arrogance of medicine" (Schneider, 1994b, p. 1076, describing the theoretical foundations of bioethics and the role of autonomy as its dominant norm). Instead, they were moved to action in the face of a series of grave abuses of the weak and vulnerable by scientific researchers. Such abuses occurred at the hands of Nazi scientists in concentration camps (later prosecuted for crimes against humanity in a trial that culminated in the publication of the Nuremberg Code), by researchers who (from 1963 to 1966) deliberately injected children at the Willowbrook School for "mentally defective persons" with the hepatitis virus, by investigators who (in 1963) intentionally and without consent injected living cancer cells into patients at New York City's Jewish Chronic Disease Hospital, and by researchers in 22 separate clinical studies whose unethical practices were documented by Harvard's Dr. Henry K. Beecher in his groundbreaking 1966 article in the *New England Journal of Medicine* (Davis, 2008).

But two events in particular prompted members of the United States Congress to convene hearings in 1973. First, lawmakers in Congress were spurred to respond by reports of the Tuskegee Syphilis Study, in which scientists from the US Public Health Service enrolled 399 poor black men suffering from syphilis in a research project aimed at studying the progress of the disease in its untreated form. For 40 years, the researchers systematically deceived these men and their families about the nature and purpose of the project. Worse still, the researchers did not administer antibiotics to the subjects, even after the drug became established as an effective treatment for the disease in 1947 – 15 years after the study began. Second, lawmakers in Congress were animated by reports of experimentation on unborn children slated for abortion in protocols that involved temporary life support followed by direct killing in especially gruesome and painful fashion (Jonsen, 2003, pp. 94–95). Jonsen quotes one researcher as saying "I don't think it is unethical. It's not possible to make this fetus into a child, therefore, we can consider it as nothing more than a piece of tissue."

It is notable that in all of the aforementioned instances of abuse – from Nuremberg forward – the researchers involved attempted to defend their actions on the grounds that they had not created the underlying tragic circumstances facing the various subjects, nor would their interventions materially harm them further. The subjects were already destined to suffer from dread diseases or to be killed in any event. By their lights, the researchers were merely trying to salvage something useful from an unfortunate circumstance. Understandably, these arguments have been widely rejected and criticized. It is one thing to accept the unavoidable death or suffering of another. It is another thing entirely to appropriate and instrumentalize the circumstances and (as in the cases of some of the researchers described above) intentionally infect or even kill the otherwise doomed subject for the sake of research.

In response to these two particularly troubling examples of unethical and abusive conduct by researchers, Congress passed the National Research Act of 1974, which, among other things, established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (Pub. Law No. 93–348). This development marked the first time an organ of government was created with explicit charge to "do bioethics" in the name of the state.

Given the constellation of research scandals to which the National Commission was a response, it is not surprising that an anchoring norm of its iconic 1979 *Belmont Report* was the principle of "respect for persons." This principle entailed a twofold protection for persons in the context of biomedical and behavioral research. First, the Commission asserted that respect for persons includes respect for their autonomy and self-determination (to be realized through legal mechanisms such as informed consent). Second, it claimed that respect for persons imposes an obligation "to protect those with diminished autonomy," including persons who are "immature and the incapacitated" (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979; Lysaught, 2004, pp. 665–680). Thus, while the National Commission proposed a principle for public policy that protected self-determination (in a way that aligned with the

aforementioned concerns about medical paternalism), it likewise attended to worries about the vulnerable class of persons whose diminished cognitive abilities render them unable to defend their own interests. In this way, the Commission cast an admirably wide net of protection for people in a domain where the risks of extraordinary forms of abuse had already been tragically demonstrated.

In short order, however, prominent and influential voices moved to constrict the circle of protection constructed by the National Commission. As both M. Therese Lysaught and F. Daniel Davis have shown, in a series of high-profile commentaries and textbooks, the principle of respect for persons was replaced by a new, more limited principle – respect for autonomy (Davis, 2008; Lysaught, 2004). Lysaught details how this change of course emerged in particular in Beauchamp and Childress's first edition of *Principles of Biomedical Ethics* (1983).

Beauchamp and Childress's *Principles of Biomedical Ethics* has perhaps become the single most influential work on bioethics and departs significantly from the *Belmont Report*. Beauchamp and Childress restyled *Belmont*'s "respect for persons" simply as the principle of autonomy or *respect* for *autonomy*. Whereas the *Belmont Report* presupposed an inverse relationship between autonomy and protection, Beauchamp and Childress took the opposite view. In the framework set forth by the *Belmont Report*, the moral imperative to protect individuals from harm increases as their autonomy diminishes: "Respect for the immature and incapacitated may require protecting them as they mature or while they are incapacitated. *Some persons are in need of extensive protection, even to the point of excluding them from activities which may harm them*" (Lysaught, 2004, p. 669 quoting the *Belmont Report* 1979, p. B.1 3, emphasis added). Moreover, in the *Belmont Report*, the obligation to protect the vulnerable extends to all human beings, not merely those capable of individualized choice (Lysaught, 2004, p. 678). By contrast, Beauchamp and Childress distinguish autonomous and nonautonomous individuals, privileging only the former as full "persons" entitled to robust care and protection (Lysaught, p. 676). For Beauchamp and Childress, "respect" thus becomes something like "noninterference" and is defined almost solely by informed consent (Lysaught, p. 676). This form of respect is not due "to persons who are not in a position to act in a sufficiently autonomous manner" (Beauchamp & Childress, 1983, p. 64). The *Belmont Report*'s framework for protecting the vulnerable under the heading of "respect for persons" drops from consideration altogether.

Moreover, with the rise of autonomy to pride of place among bioethical principles, the concept of "personhood" itself became truncated to include only those human beings capable of rational choice. Ruth Macklin confirmed as much when she famously equated "human dignity" with autonomy. She argues that dignity (and the respect and protections that it entails) is owed only to those whose actions and thoughts are "chosen, organized and guided in a way that makes sense from a distinctly individual point of view" (Macklin, 2003, pp. 1490–30 quoting the Nuffield Council on Bioethics, Genetics and Human Behaviour). In a similar vein, Steven Pinker has argued that human dignity is "stupid," "a mess," dangerous, and should be abandoned in favor of a single-minded focus on respect for autonomy (Pinker, 2008).

This startling shift from respect for persons to the narrower respect for autonomy seems to emerge, in part, from a desire to push the boundaries of scientific research, especially with regard to abortion and embryo research. Lysaught argues persuasively that the shift to autonomy alone was meant to enable the endorsement of activities that "traditionally would have been strong candidates for violating 'respect' – for example, destroying embryos, creating embryos for research, creating embryos through cloning, and creating chimeras" as "morally licit" pursuits (Lysaught, 2004, p. 667 discussing National Bioethics Advisory Commission, 1999, internal citations omitted). The shift to autonomy likewise seems to be driven by the aspiration to identify an ethically "thin" principle that would command broad appeal in a pluralistic culture and thus provide a suitable basis for public policy.

The Consequences of the Hegemony of Autonomy in Public Bioethics

The consequences of this shift to autonomy as the singular lodestar of public bioethics have been profoundly deleterious. As Carl Schneider points out in his article, *Bioethics with a Human Face*, the notion of autonomy alone does not capture the whole truth of what it means to be human. He argues, "A powerfully stated and too-often simple autonomy paradigm has become the central feature of bioethical thought and law. Yet, despite the undoubted and true importance of that paradigm, its reiteration has become stale, flat, and unprofitable, and its simplicities have become too costly" (Schneider, 1994b, p. 1076).

The inadequacy of autonomy as the sole normative paradigm for bioethics becomes particularly apparent when one considers the profound vulnerability of patients in the clinical setting (Lysaught, 2004, p. 678). Patients seeking care surely desire information and the opportunity to give consent to treatment. But, first and foremost, they are asking for help. To entrench autonomy as the only normative polestar in this domain threatens to reorient the doctor-patient relationship itself. Carl Schneider warns that:

> If doctors and patients meet clad in the armor of their rights, both of them will lose as well as gain: 'The physician who is now instructed to obey the 'informed consent' of his patient, no matter how harmful he feels that action to be for the patient, is not only permitted but positively enjoined to separate himself from his patient, to respect his patient's "autonomy" by suppressing his own identifications, his self-confusions, with that patient.' (Schneider, 1994a, pp. 16–22 quoting Burt, 1977, p. 32)

As Charles Bosk writes, "The dark side of patient autonomy [is] patient abandonment" (Schneider, 1994a, pp. 16–22 quoting Bosk, 1992, p. 158). A simplistic emphasis on autonomy alone is "particularly injurious in bioethics, a field that treats people in their least rational moments, in their most emotional travails, in their most contextual complexity" (Schneider, 1994a, pp. 16–22 quoting Bosk, 1992, p. 158).

Further, the narrowed definition of "person" that results from a sole focus on autonomy radically constricts the circle of protection for the weakest and most vulnerable members of the human family. As Gilbert Meilaender has correctly

observed (quoting Philip Abbott): "There are very few general laws of social science but we can offer one that has a deserved claim: the restriction of the concept of humanity in any sphere never enhances respect for human life" (Meilaender, 1998, pp. 108–109). The very victims whose plight motivated public officials to intervene in the practice of medicine and scientific research in the first instance – the unborn, the socially marginalized, the cognitively disabled, the elderly suffering from dementia – are deemed "sub-personal" under the autonomy-only paradigm of public bioethics. It is a paradigm that stands humankind's best moral traditions their heads – perversely privileging the claims of the strongest over those of the weakest.

Even aside from the grave concerns about the weak and vulnerable, the autonomy paradigm reflects an impoverished moral anthropology even for those capable of robust free choice. It conceives of persons as radically individualistic disembodied wills whose activities are reducible to bargained-for exchanges with other wills. Left ignored are bonds of kinship, community, and the *unchosen* obligations that characterize such relationships. The human good of solidarity is missing from this framework.

Restoration and Retrieval in the Universal Declaration on Bioethics and Human Rights

One of the signature achievements of the Universal Declaration on Bioethics and Human Rights is a turnaway from this inhumane paradigm, back toward a richer conception of human beings and their obligations to one another. The Declaration is grounded in a humanly robust moral anthropology – one of human dignity and solidarity – and situates autonomy within this framework. It rejects that conception of personhood that over time has become conflated with autonomy and decouples these notions. It recognizes that persons are not simply autonomous beings. In fact, the Declaration eschews the term "person" as an exclusionary category; rather, it uses the term "human beings" to orient the document and then uses "persons" in an expansive fashion. Furthermore, the Declaration mentions "persons" incapable of autonomous decision-making, so the cognitively impaired and cognitively immature are included in the Declaration's notion of personhood.

Most obviously, Article 5 ("Autonomy and Individual Responsibility") signals a return to the original conception of autonomy (as a subsidiary good), found in the *Belmont Report*. It urges respect for autonomy but reminds the reader that individuals bear responsibility for the choices they make and must pay due regard for the good of others. More importantly, Article 5 restores the injunction to protect "persons not capable of exercising autonomy," by ensuring that "special measures be taken to protect their rights and interests."

By acknowledging that there are "persons" who lack the capacity to exercise autonomy, Article 5 also strikes a blow against the use of "personhood" as a term of exclusion, about which Meilaender cautioned above. Likewise, Article 6 ("Persons without the Capacity to Consent") calls for special protections for "persons who do not have the capacity to consent." Thus, on their face, these provisions reject the

notion that the capacity to exercise autonomy or to give consent is a necessary prerequisite to membership in the community of persons. By extension, all of the attendant protections of human dignity and human rights accorded to "human beings" in the Declaration are equally applicable to persons lacking the capacity for intentional, self-aware action.

A related virtue of the Declaration is its global use of the phrase "human beings" to describe the principal focus of its protections. By opting for this term, the Declaration offers its protections to the widest possible array of subjects and strengthens its human life-affirming provision even further. And these protections are significant. First, the preamble recognizes that human beings have a responsibility to protect one another. Additionally, the preamble provides that "all human beings, without distinction, should benefit from the same high ethical standards in medicine and life science research." Article 10 ("Equality, Justice and Equity") affirms explicitly the principle that "all human beings" are equal in dignity and rights and are to be treated justly and equitably. Article 8 ("Respect for Human Vulnerability and Personal Integrity") declares that in the development and application of science, technology, and medicine, "individuals and groups of special vulnerability should be protected and the personal integrity of such individuals respected." Finally, protection of future generations is declared to be an explicit aim of the instrument. This is made more concrete by Article 16 ("Protection of Future Generations"), which provides that "the impact of life sciences on future generations, including on their genetic constitution, should be given due regard."

Human dignity – not autonomy – is the most prominent ethical principle featured throughout the Declaration. The Declaration includes many provisions that serve to elevate the importance of human dignity and highlight the respect for human life. First, the preamble establishes human dignity as the very lens through which science and technology should be understood. It provides that "advances in science and their technological applications should be examined with due respect" for human dignity. The first "aim" of the Declaration relating to the development of ethical principles (Article 2[c]) declares that the purpose of the instrument is to "promote respect for human dignity." Similarly, the very first "principle" of the Declaration (Article 3), titled "Human Dignity and Human Rights," provides that "Human dignity, human rights and fundamental freedoms are to be fully respected." The Declaration forcefully asserts in several of its provisions that human dignity may not be ignored or transgressed. Indeed, the Declaration makes clear that full regard for human dignity is itself an explicit limitation on the application of other worthy principles. For example, the preamble recognizes the importance of "the freedom of science and research" and affirms the benefits that flow from "scientific and technological developments," but firmly reminds the reader that such activities should take place in a context that gives proper recognition to human dignity. Similarly, Article 12 ("Respect for Cultural Diversity and Pluralism") celebrates the virtues of diversity and pluralism but explicitly notes, "Such considerations are not to be invoked to infringe upon human dignity." Finally, the Declaration concludes (in Article 28) with the following injunction: "Nothing in this Declaration may be interpreted as implying for any State, group or

person any claim to engage in any activity or to perform any act contrary to … human dignity." Simply put, the concept of human dignity infuses the entire Declaration. The instrument literally begins and ends with statements underscoring its importance. There is no principle that animates the Declaration to the same extent.

The Declaration also strongly affirms the centrality and importance of respect for human life. Most obviously, it is tremendously significant that an explicit aim of the Declaration is "to promote respect for human dignity and protect human rights, by ensuring respect for the life of human beings, and fundamental freedoms, consistent with international human rights law" (Universal Declaration, Art. 2(c), 2005).

Conclusion

The Universal Declaration on Bioethics and Human is anchored in the concepts of human dignity and solidarity and affirms the central importance of basic obligations of human beings to one another in virtue of their shared humanity. Although the Declaration is by no means perfect, its provisions reject the notion that respect for autonomy should remain the key animating principle in bioethics. In this way, the Declaration signals a vital recovery and return to the foundational anchoring norm of respect for persons.

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Persons Without the Capacity to Consent

7

Eugenijus Gefenas and E. Tuzaite

Introduction

Implementation of the doctrine of Informed Consent (IC) into the practice of health care has been one of the major ethical and legal shifts in the history of twentieth century medicine. The essence of this shift has been the replacement of the paternalistic ethos of the doctor-patient relationship with respect to personal autonomy based health care decision making. As a result, the principle of IC has become a basic rule to be followed in all health care related interventions with competent patients. Although there are still many problematic issues related to the implementation of IC into health care practice with capable persons (Stanton-Jean, Doucet, & Leroux, 2012), a particularly complex situation may arise when health care decision making involves persons without the capacity to consent, such as minors, people with learning disabilities, or those suffering from severe mental disorders. The complexity of this field of decision making can be attributed to the need to harmonize the traditional approach of protecting the best interest of this particularly vulnerable group of patients with the paradigm of health care based on the principle of personal autonomy and self-determination. The major international guidelines and legal instruments reflect the importance of this issue. The Universal Declaration on Bioethics and Human Rights (UDBHR) by UNESCO devotes a separate Article 7 to set general principles protecting the rights and interest of persons without the capacity to consent (UNESCO, 2005). Similarly, at the European level, the Council of Europe Convention on Human Rights and Biomedicine (The Oviedo Convention) provides an even more elaborated normative framework aiming at the protection of persons not able to consent (Council of Europe, 1997a). This instrument provides separate guiding principles with respect to different categories of incapable persons: those suffering from mental disorders, being in emergency situations, and, what is very important for this discussion, those who had their wishes expressed in the past before becoming incapable (previously expressed wishes). This chapter aims at

E. Gefenas (✉) • E. Tuzaite
Department of Medical History and Ethics, Vilnius University, Vilnius, Lithuania
e-mail: Eugenijus.Gefenas@mf.vu.lt; Egle.Tuzaite@mf.vu.lt

H.A.M.J. ten Have, B. Gordijn (eds.), *Handbook of Global Bioethics*,
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analyzing the general framework of decision making with regard to persons unable to consent as well as presenting some areas of practice, where decisions are particularly complex.

Conceptual Framework of Decision Making and Incapable Persons

The concept of capacity or incapacity is closely linked to the concept of competence. In health care context being competent means the capacity to make autonomous health care decisions. A person loses his or her competence and becomes incapacitated when s/he loses such a capacity and is unable to (1) posses a set of values and goals; (2) communicate and understand information, and (3) reason and deliberate about one's choices (US President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, 1982). Two different meaning of a loss of competence can be distinguished. First, a narrow legal definition means a loss in court of a person's legal right to function in a particular area. Second, a broader and more common clinical use of the term means that a person can still have a legal right but is unable to make their health care decisions (Wettstein, 2005). This broader definition of competence is very important for this discussion because rather often the decisions with regard to persons unable to consent are made without their legal capacity being removed.

Different Meanings of Personal Autonomy and Protection of Incapable Persons

The system of protection of incapable persons has been recently developed within the new paradigm of medical ethics based on the principle of respect for personal autonomy. However, within the bioethics literature some interpretations of this principle have been criticized as providing insufficient background for complex health care related decisions. This criticism has been mostly directed toward a so-called minimalist-libertarian account of personal autonomy, which limits the relationship between the care giver and the cared person to noninterference rather than promoting and facilitating the decision making of the person concerned. This interpretation of personal autonomy can be criticized as reducing the relationship between health care providers and patients to simple contractual relationship of two "strangers." As such, this model neglects the caring attitude of health care provider, which is crucial when dealing with vulnerable patients.

Therefore, the alternative interpretation of personal autonomy going beyond the minimalistic-libertarian approach seems to be more relevant in many health care situations, particularly when incapable persons or other vulnerable patients are involved. This account of autonomy is emphasizing authenticity of a decision-making process (Welie, 1998). Autonomy as authenticity is implemented when decision making is based on the values and life story of the person. This is

especially relevant when people who are close to the patient and familiar with his or her personality can make choices that are congruent with the patient's values and life story. This helps to base important decisions not only on the rational and explicitly stated information but also on motivation and signs, which are not explicitly expressed by the incapable person. This component of decision making becomes increasingly important in the course of decreasing cognitive capacities of the person.

The modern system of legal protection of incapable persons has been developed following the broader interpretation of personal autonomy rather than the minimalist-libertarian one. The authenticity based account of personal autonomy allows developing a more flexible set of measures assisting a person who is starting to lose decisional capacity. Such a system of legal protection is elaborated in some international recommendations based on a set of principles to be followed when it is necessary to organize protective measures for an incapable person (Council of Europe, 1999). First, the protection provided for a person concerned should be based on respect for the wishes and feelings, including previously expressed wishes, which is of paramount important when decision-making capacity of the person is getting increasingly compromised by the disease. Second, prominence should be given to the welfare and interest of the person to counteract the sometimes existing tendencies to use assets of the person to benefit other parties. Third, the principle of subsidiary or minimum necessary intervention should be followed, which means that protection has to be established, if and only if it is unavoidable in the circumstances. It also means that preference should be given for any less formal arrangements that might be used rather than formal ones, and for any assistance that might be provided by family members. Finally, the proportionality of the measure to be applied means that protection needed should correspond to the degree of capacity of the person concerned and tailored to the individual circumstances of the case (Council of Europe, 1999). All the mentioned principles are important to understand the limits of the traditional system of protection. The problem is that some countries still have a rather traditional approach toward the protection of incapable persons. This approach can be characterized as rather rigid. In this traditional system, the measure applied deprives a person concerned of almost all legal capacity to make decisions and is coupled with the appointment of the guardian who is supposed to represent the incapable person in all the matters of life. As a result, it is mainly based on deprivation of legal capacity rather on the attempt to involve the incapacitated person into his or her own care-related decision making, which is a key feature of the alternative modern approach based on a broader concept of personal autonomy (Gefenas, 2004).

Normative Principles of Protecting Incapable Persons in Health Care Context

There have also been some more specific principles developed with regard to medical interventions on persons not able to consent. In the European context,

the Oviedo Convention provides a rather comprehensive framework for these principles summarized in its Article 7 (Council of Europe, 1997a). References will be made to this and other legal instruments and guidelines to make this framework explicit.

First of all, another person or a body substituting the decision making of the incapable person should be introduced when such a necessity arises following the subsidiary rule mentioned above. It means that the authority to consent is being transferred to somebody who represents the interests of the person unable to consent. For example, the intervention on the minor may only be carried out with the consent of his or her parents. In cases of incapable adults, the substituted decision makers should be legal representatives or any person or body provided for by law. It should also be noted that before making a decision, the representative should get the same information that would have been given to the person concerned if s/he was capable.

Second, the guidelines require to involve the person himself, as far as possible, into the process of his or her health care decision making. This principle is relevant to both minors as well as adults whose capacity starts to diminish due to a mental disorder. In case of minors, it helps to ensure that their opinion is to be regarded as an increasingly determining factor in proportion to their age and capacity for discernment. This means that in certain situations and depending on the nature and seriousness of the intervention as well as the minor's age and ability to understand, the minor's opinion should increasingly carry more weight in the final decision. This principle is also enforced by the Article 12 of the United Nations Convention on the Rights of the Child (United Nations [UN], 1989). The involvement of the person who has lost or is losing the decision making capacity in respect to health care can also be achieved by referring to his or her previously expressed wishes, life goals and values. This is an especially important issue in the context of this discussion and it will be addressed in a separate section.

Third, the general framework also usually specifies the type of intervention to be authorized in terms of risk/benefit ratio. For example, according to the Oviedo Convention the only interventions to be authorized on behalf of incapable persons are those that are supposed to bring them direct benefit. In general, the higher the benefits of the intervention, the more stringent capacity criteria are required from the person whose capacity is being questioned to refuse such an intervention, for example, in case of refusing potentially life-prolonging interventions. This tendency has been called "sliding scale" of competence evaluation (Wettstein, 1995).

Complexity of Implementation and Remaining Controversies

Although a consensus has been achieved with regard to the general principles mentioned above at the international level, this general framework is not always easily applied in practice. The difficulties arise because sometimes these principles can contradict each other or because their interpretation contains some level of unavoidable ambiguity. For example, the requirement to take into account

previously expressed wishes can come into conflict with the views of representatives or medical staff with regard to the best interest of the person concerned. In other cases, such as decisions on reproductive choices of minors, it is not always clear if the representative should have a final word on the issue or the teenager can make her own choice. The following most controversial areas of decision making will be analyzed in this chapter:

- Recent tendencies to implement previously expressed wishes in practice
- Complex reproductive choices by minors and people with learning difficulties
- Compulsory hospitalization and treatment of people with mental disorders
- Research on incapable persons

Previously Expressed Wishes

As has already been noted, previously expressed wishes are one of the most basic means to implement the principle of respect to personal autonomy in the field of health care with regard to people unable to consent. This is why the concept of previously expressed wishes is included into the international ethical and legal guidelines presented in this chapter. Article 7 of the UDBHR by UNESCO does not explicitly mentions this concept; however, it refers to the need to involve a person concerned to a greatest extent possible in the decision-making process. At the same time the Article 9 of the Oviedo Convention makes it explicit that "[t]he previously expressed wishes relating to a medical intervention by a patient who is not, at the time of the intervention, in a state to express his or her wishes shall be taken into account" (Council of Europe, 1997a).

Advance Directives

The concepts of "document of prior instructions" or "advance directives" have been used to refer to implementation instruments of previously expressed wishes of incompetent patients (Council of Europe, 2011). This section will only focus on the advance directives which deal with those health care and treatment options that the person would like to receive while s/he is still alive and will not deal with the decisions about the use of body and organs after death.

Two major models (or their combination) of advance directives can be distinguished in this context. These are living wills and continuing powers of attorney (World Health Organization [WHO], 2004). Living wills are written legal documents which allow people to convey their wishes about the life-sustaining procedures ahead of time. They usually include instructions on withholding or withdrawing the treatment. For example, a person can express his/her wishes by signing the, "do not resuscitate" (or DNR) order when admitted to the hospital. However, living wills are not limited to treatment refusals. They can also be used to advance a wish that a particular type of treatment will be continued (Council of Europe, 2011).

On the other hand, the model of continuing powers of attorney is based on the choice of a person who is supposed to make health care decisions on behalf of someone who loses the ability to do so. Usually attorneys are relatives or close friends and it can be argued that this model has a significant advantage comparing to the living will because it can provide a "personal voice" clarifying the patient's preferences. This is especially important in those cases when written instructions are ambiguous, or there are unexpected developments in the situation that have not been addressed by the patient (Council of Europe Steering Committee on Bioethics (CDBI) [CDBI], 2008). It can also be noted that this model provides the granter an opportunity to appoint one more person to supervise how the attorney performs his/hers duties (Council of Europe, 2009).

The increasing importance given to advance directives in both legal instruments and academic literature is related not only to the changing paradigms of health care provider – patient relationship, where the paternalistic culture has been gradually replaced by the value of personal autonomy and the practice of informed consent. The importance of integrating previously expressed wishes into the clinical decision making and the need to introduce the practice of advance directives also reflect intensive technological advancements of modern medicine and life-sustaining technologies. These developments not only help to save human lives. They can also contribute to the continuation of physical survival of patients for prolonged periods of time without their capacity to make decisions about their own health care for the rest of their lives.

Implementation Difficulties

It should be noted, however, that the changes in ethical and legal paradigms have not yet been fully implemented in many countries in the world. In this respect, the situation is somewhat better in the USA, where the percentage of people with an advanced directive is far higher than in European countries, where only a tiny minority of the Council of Europe's 800 million citizens actually have advance directives (Council of Europe, 2011). For example, in the USA the advance directives have been expressed by around 22 % of all patients (raging from 32.1 % of surgery patients vs. 17.7 % of medicine patients), living wills being the most frequently chosen type of advance directives (Morrell et al., 2008).

In many European countries, it is still unusual to base clinical decision making on previously expressed wishes. Many states are just starting to recognize the importance of advance directives. For example, in some countries such as Austria, Belgium, Finland, Germany, Hungary, the Netherlands, Spain, Switzerland, and the United Kingdom advance directives are made legally binding. More specifically, in Austria it is obligatory to take the advance directives into account if a few criteria are met: the physician's consultation has been provided, the procedure of advanced directive has been supervised by a lawyer, the refused treatment is described in detail, and the document has been signed not more than 5 years ago (CDBI, 2008). However, in many other European countries specific provisions concerning the

advance directives are not legally binding or there is a lack of laws on this particular matter. It is argued, that the reason for such a slow integration of previously expressed wishes into the legislation of some European countries has been the advisory character of the provision of the Article 9 of the Oviedo Convention, which only states that patient's "wishes shall be taken into account" rather than being followed. In other words, according to this article European countries are not required to assign the advance directives a legally binding status (CDBI, 2008). More details on the advisory nature of this provision are provided in the Explanatory Report of the Oviedo Convention, which states that "[. . .] taking previously expressed wishes into account does not mean that they should necessarily be followed.[. . .] when, for example, they were expressed long time before the intervention or medical technology made a significant progress since the time when the advance directive was signed" (Council of Europe, 1997b).

There can also be other obstacles to build an efficient system of advance directives. For example, in some countries patient autonomy is taken more seriously, while in the other countries the paternalistic model of decision making still prevails. Furthermore, the economic situation in the country can also play an important role. This is especially the case when the most basic health care services are hardly available for the country's population. For example, it has been argued that in transition European countries, like Ukraine, interest in this kind of arrangements is very limited due to the fact that people are mostly preoccupied with access to basic services in the context of severe scarcity of health care services available (Council of Europe, 2011).

Previously Expressed Wishes in the End of Life Care

The importance of advance directives should be particularly emphasized in end of life care situations with persons unable to consent. Here there are two interrelated issues to be discussed: first, involvement of patients and their relatives in particular medical end of life decisions (MELDs) that might have a life-shortening effect; second, controversy of associating the advance directives with euthanasia.

According to the EURELD study conducted in six European countries, rather often MELDs are shared neither with patients nor with their relatives. For example, in Italy and Sweden, countries representing culturally rather different regions of Europe, MELDs were not discussed with the patient or with the relative in more than 50 % of cases (van der Heide, Deliens et al., 2003). It should be stressed that these figures applied to both competent and incompetent patients and showed how important advance directives can be in these highly sensitive and stressful situations. The reason why the doctors try to escape from communicating and sharing their decisions with relatives or patients can be their reluctance to overburden relatives (in case of incompetent patients) or the consideration that even competent patients would not be able to fully comprehend the situation. The advance directives seems to be a relevant solution to overcome both of the mentioned obstacles as this would make possible a decision making respectful to personal autonomy of the patient.

The association between advance directives and euthanasia should also be addressed. It has been pointed out that this association is unfortunate because active termination of life is forbidden in the vast majority of European countries (Council of Europe, 2011). In addition, as has been shown by the EURELD study, administering, supplying or prescribing drugs with the explicit intent to hasten the death on patient's explicit request (which are the most common criteria of active voluntary euthanasia), appeared to be also one of the least frequent types of decision. It occupied a very small portion of MELDs as reported in the studies available, e.g., 1 % of deaths or less in Denmark, Italy, Sweden, and Switzerland as compared to nontreatment decisions such as withdrawing or withholding medication (or forgoing hydration and/or nutrition), which in some countries (e.g., Switzerland) reached as much as 28 % of all death cases (van der Heide et al., 2003). Therefore, the introduction of advance directives can help to ensure that no form of unconsented medical end of life treatment decision is taking place, which is still the existing practice in many countries as shown above. It can also enable a person to explicitly express the wish to not take or omit some actions with the intention to shorten his or her life.

There have been important recent European developments that can bring positive changes in this field. First, the Council of Europe Committee of Ministers issued a special Recommendation CR/Rec (2009)11 on the principles concerning continuing powers of attorney and advance directives for incapacity. This document laid down basic principles on the role of attorney, the procedure of her/his appointment and the circumstances when her/his rights come into force (Council of Europe, 2009). Second, and more specific to this discussion on advance directives in the field of health care, the Council of Europe is adopting a Resolution and Recommendation on "Protecting Human Rights and Dignity by taking into Account Previously expressed Wishes of Patients" (Council of Europe, 2012). Hopefully, this can be an important impetus to further encourage the European countries to take steps in this field.

Reproductive Issues in Minors and People with Learning Difficulties

As has been already shown in the previous sections of the chapter, it is currently accepted that minors and people with learning difficulties should be involved in the decision making about their health care as much as this is possible in the circumstances. However, the involvement of people unable to consent in the decision making on their reproductive health issues can be more complicated because of societal taboos surrounding the sexuality of the intellectually disabled. As has been noted, due to this reason even studies concerning their contraception and moreover their sterilization may be difficult to carry out and when carried out, biased by low participation rates (Servais et al., 2004). However, the denial of the problem does not eliminate it. On the contrary, if the issue of reproductive choices fell beyond the scope of legal regulations and public discourse, nobody can guarantee that the best interests of the incapable people are really served and their rights are protected.

Use of Contraception and Termination of Pregnancy in Minors

The complexity of reproductive health policies in relation to minors arises predominantly because of the tension between the rights of the minors and those of their legal representatives. According to Article 16 of the United Nations Convention on the Rights of the Child every child has the right to privacy (UN, 1989). This right can also justify those cases when legal representatives are not asked for authorization of the minor's decision and the practice of teenage contraception seems to be particularly relevant case to be discussed in this context. For example, the issue of prescribing contraceptives without authorization of legal representatives became widely discussed in the UK in the 1980s when Mrs Gillick wrote to her area health authorities forbidding medical staff to give contraceptive or abortive advice or treatment to any of her four teenage daughters without her consent. This case culminated in the well-known Gillick judgment of 1985 when the House of Lords ruled (by the narrowest of majorities) that doctors can in certain cases prescribe contraceptives for girls under 16 without parental consent (Dyer, 1985).

The supporters of Mrs. Gillick position usually argue that the policy of confidential counseling allows teenagers to engage in risk taking behavior and insist that information about the use of contraceptives should be disclosed to the parents because the minor's ability to give a valid informed consent can be compromised by the minor's immaturity and the lack of life experience. This may make minors vulnerable to exploitation and external coercion and therefore decision making in such a sensitive field should be overtaken by legal representatives who are believed to act according to the best interests of the minors.

The opponents of this position may respond that the involvement of parents into the counseling procedure do not necessarily increase the welfare of the minor. For example, if the family relations are complicated and parents or guardians are informed about their child's request for contraception, this can make teenagers life in the family unbearable due to excessive control exercised upon the social environment of the child. Furthermore, it seems that confidential consultations have the potential to reduce the unintended pregnancy and abortion rates because some surveys have shown that as many as 59 % of teenagers would discontinue use of specific sexual health care services if their parents were informed that they were seeking prescribed contraceptives (Reddy, Fleming, & Swain, 2002).

The role of health care professionals seems to be very important in this context because they can act as moderators between teenagers and their parents in this complex and controversial area of personal relationships. In fact, sensitive and professional counseling can resolve raising tensions and encourage communication between the parties involved. Due to this, physicians are strongly recommended to help adolescences to see the potential advantages of improved communication with their parents (Ford, English, & Sigman, 2004).

However, despite the importance attributed to the confidentiality issue in health care provider – minor relationship, the health care providers do not necessarily share the same opinion. In some countries, physicians do not regard the confidentiality as the issue of utmost importance in the field of adolescences' medicine.

The study carried out among Swiss doctors revealed that maintaining minors' confidentiality was ranked considerably lower than such issues as psychosomatic/functional symptoms, eating disorders, or depression-anxiety and was not considered to be a priority topic in adolescent medicine training (Kraus, Stronski, & Michaud, 2003). Furthermore, a resent Lithuanian study in this field showed that when consulting on general sexual issues, more than 70 % of the Lithuanian general practitioners stated that they would respect their minor patients' confidentiality. However, nearly the same percentage said they would inform parents in cases of sexually transmitted infections or pregnancy (Jeruseviciene et al., 2011).

The termination of teenagers pregnancy is probably the most sensitive and controversial issue in this discussion. Whose decision must be followed in case of disagreement between the pregnant minor and her parents? A tendency to give priority to the opinion of the minor has been observed in many European countries and the USA. However, there are opposing views expressed toward this prevalent tendency as well. For example, in Britain teenage girls are allowed to have an abortion without their parents consent, however, some time ago a mother whose daughter secretly had a chemical abortion publicly criticized this law claiming that if she had known what was happening she would have been able to change her 14 years old daughter mind (Mother angry at secret abortion, 2004). On a state level some countries, such as Slovakia, enforced the legislation to require parental or guardian consent in case of termination of pregnancy in minors. This shows a fundamental and hardly commensurable disagreement between the worldviews of those who hold different positions on this matter (Gefenas, 2012).

Sterilization of People with Learning Difficulties

Policies to regulate reproductive choices of incapable adults have a long and controversial history. The racial hygiene politics and eugenics movement in Nazi Germany is probably the best known, but not the only example of such a policy in the twentieth century. In fact, during the whole post–World War II period till about the 1980s, the sterilization laws were in force in many countries of the world. For example, in 1997, one of the most influential Swedish newspapers disclosed information about a sterilization program carried out between 1935 and 1975 leaving more than 60,000 Swedes being sterilized including people with learning difficulties. The sterilization law existed in Denmark as well. From 1934, when this particular law was adopted, until 1968, 5,579 mentally disabled people were sterilized in this country (Broberg & Roll-Hansen, 2005).These policies were largely associated with eugenic intentions to reduce the incidence of learning disability in general population, which appeared to be based on a mistaken belief that this goal can be achieved by eliminating the opportunities for intellectually disable people to reproduce (Howard & Hendy, 2004). Even though the understanding of mental disability has undergone significant changes in recent years, the issues concerning the reproductive health of incapable people remain controversial and difficult to handle.

In many countries, women with learning difficulties are still rarely involved in decisions about their contraception arguing that these issues are too complex for them to understand. In this situation, the reproductive questions have been dealt with in a paternalistic manner and contraception presented as a preventive measure to assure that in the case of the sexual assault the unintended pregnancy is avoided. Sterilization of mentally disabled people is regarded to be the most reliable method of contraception. Although it is regarded as the last measure which should be taken only if the more conservative methods of birth control do not work, it is rather widespread and mainly applied to sexually active women. Although it is difficult to single out a concrete disability which could increase the possibility of sterilization, people with Down syndrome seems to be the group most often exposed to contraceptive sterilization. This is probably due to the fact that this genetic condition can be transmitted to the offspring with 50 % of probability. In addition, women with Down syndrome are commonly considered as very social and affectionate, which also make them more vulnerable in intimate relationship (Servais et al., 2004). However, the level of capacity of people having this syndrome can be very diverse, which makes the decision on their sterilization sensitive.

The comparison of sterilization rates of people living in social care institutions versus those staying with their family members in the community helps to reveal some prevalent tendencies in this field. It might seem that opportunities to control fertility of people living in institutions are more favorable than for incapable people staying in the community. This feature can be explained by the fact that nowadays intellectually disabled people are more integrated into the society which provides them with more opportunities to start sexual activities. At the same time, however, this makes them more vulnerable to sexual offenses. It can be predicted therefore that sterilization rates should be higher for noninstitutionalized population of incapable people. However, the Belgian study revealed the opposite tendency where living in an institution was associated with an increased probability to be sterilized (Servais et al., 2004). This tendency seems to point to the need to revise the existing institutional policies as they might better serve the interests of the institutional employees rather than the interests of the incapable persons themselves.

Compulsory Hospitalization and Treatment of People with Mental Disorders

Coercive measures applied to people suffering from mental disorders are another ethically sensitive issue to be addressed. Images of chaining psychiatric patients to the walls of the asylums or medicating political dissidents with high doses of neuroleptics can hopefully be regarded as historical examples not to be repeated in modern psychiatry. Indeed, methods of treatment and the models of patient-doctor relationships showed in the Oscar wining movie “One Flew Over the Cuckoo’s Nest” are hardly imaginable in contemporary society. Nowadays, it is universally accepted that people with mental disorders, including those unable to consent to particular health care interventions, are entitled to the same civil, social,

political, and cultural rights as the rest of the population. However, even in the twenty-first century, reports on keeping psychiatric patients in net beds or just chaining them to their beds are published (Sailas & Wahlbeck, 2005; WHO, 2008). There is still disagreement among different representatives of the society and professionals about the proper use of restraints and coercive measures in general. Therefore, this section surveys the most important principles guiding coercive measures to be applied to psychiatric patients with limited capacity.

Basic Normative Framework

The major changes in the field have been brought by integrating psychiatric practice with basic human rights principles in the second half of the twentieth century. The Universal Declaration of Human Rights (UN, 1948) can be considered to be the first international human rights instrument paving the way to more specific documents enforcing the rights of people with mental disorders, such as Convention on the Rights of Persons with Disabilities (UN, 2008) or the Council of Europe Recommendation Rec(2004)10 concerning the protection of the human rights and dignity of persons with mental disorder (Council of Europe, 2004a). The latter document provides a detailed normative framework on involuntary measures applied in the field of psychiatry. According to this document two basic conditions should be satisfied in order to apply coercive measures, such as involuntary hospitalization, with regard to people with mental disorders. First, involuntary hospitalization is only justified when the existence of mental disorders is recognized or its assessment is required to determine whether a mental disorder is present. Second, it must be very likely that mental disorders can cause a risk or a serious danger to the person concerned or a serious danger to other persons (Article 17, part i & ii). In addition, the Council of Europe Recommendation (Article 17, part iii) also emphasizes that the intention of the involuntary placement should always include a therapeutic purpose. Two specific distinctions are important in this context, namely, the distinction between involuntary hospitalization and involuntary treatment, as well as the distinction between formal versus informal involuntary hospitalization.

Distinction Between Involuntary Hospitalization and Involuntary Treatment

Although it is often thought that the need of compulsory hospitalization also includes mandatory treatment, the forced hospitalization does not necessarily imply the involuntary medication. A person involuntarily admitted to the institution should be provided with several treatment choices and should be free to choose any of them. Among these choices and despite being forcibly admitted to the hospital the person should retain the right to refuse the medical treatment proposed. The Explanatory Memorandum to Recommendation Rec(2004)10 (Article 17, paragraph 133) states that “therapeutic purpose” of hospitalization should not be equated with medical

treatment. For example, a person diagnosed with schizophrenia can choose to experience hallucinations (such as hearing voices) instead of taking medications because of their short and long-term side effects (Council of Europe, 2004b).

The distinction between forced placement and forced medical treatment has not been made until the late 1970s. Due to the human rights movement in psychiatry this approach has remarkably changed in the USA and Europe leading to a clear separation between involuntary hospitalization and involuntary treatment. It should be noted, however, that some European countries still do not define in their laws involuntary placement and treatment as separate modalities, which seems to also imply that in these countries the decision of forced hospitalization means an approval for forced medication of psychiatric patients against their expressed resistance (Dressing & Salize, 2004).

Formal Versus Informal Involuntary Hospitalization

One more issue to be addressed here is the inconsistency between legal regulations for involuntary placement and application of these regulations in practice. This inconsistency can be analyzed as a distinction between formal involuntary hospitalization and so-called informal involuntarily hospitalization, where patients sign the admission forms for voluntary hospitalization, however, cannot leave the institution whenever they want. This can be demonstrated by remarkable variation between frequency of compulsory admissions into psychiatric institutions in the European Union countries. The frequency of involuntary hospitalizations can vary from 218 involuntary placements per 100 000 population in Finland, 175 in Austria, 114 in Sweden to 11 in France or just 6 in Portugal (Salize & Dressing, 2004). Due to the fact that the ratio of persons with mental disorders in population in Europe cannot be so different, one possible explanation of this phenomenon is that admissions to the hospital are formalized in a significantly different way. Health care providers can avoid compulsory admission due to complex legal procedures, such as obligatory court's hearing or search for patient's representative. Scarce personnel and financial recourses at the health care institution can also be the reason of escaping the formalities of mandatory hospitalization. The problem is that these tendencies raise a question about the safeguards to protect patients' rights in these complex situations because de facto involuntary patients are left without the safeguards, which should be provided for them in the institutions for mentally disordered people unable to consent (European Committee for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment (CPT) Standards & CPT/Inf/E [CPT], 2011).

Research on Incapable People

Conducting research activities on participants who are not capable to understand and consent to these activities is nowadays regarded as one of the most complex and controversial areas of research ethics. After all, modern history of research ethics

has emphasized the fundamental importance of informed consent. This principle has been placed on the top of the list of ten requirements of the Nuremberg Code – the first international instrument condemning the Nazi experiments and paving the way for the development of research ethics. In addition, as has been already shown above, the principle of informed consent has replaced traditional paternalism and marked a paradigm shift in the history of medical ethics and health care provider-patient relationship.

The problem is that research on persons unable to consent has to actually "bypass" this basic research ethics benchmark, which since the Nuremberg Code has been incorporated into the most important research ethics guidelines and legal instruments. Therefore, some alternative mechanisms of protecting incapable research subjects had to be developed. The historical overview of the evolution of these alternative models of protection reveals some complex features of establishing what is nowadays regarded as widely accepted ethical and legal algorithm to conduct research on incapable persons. The Article 7 part B of the UDBHR by UNESCO is a good example of this algorithm. It is important to note that this framework of research on incapable persons is also enforced by other important international instruments such as Article 17 of the Oviedo Convention and the Guideline 9 of the International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS). Although there exist some differences between the mentioned documents, the convergence of the main provisions is remarkable as compared to the regulations in some other areas of health care on persons unable to consent presented in this chapter.

It can be useful to briefly explain this two-step model of involving incapable persons into research project. As the first step, the guidelines require to limit research to only those projects where:

- The results of the research have the potential to produce real and direct benefit to the health of incapable research participant.
- Research of comparable effectiveness cannot be carried out on individuals capable of giving consent.
- The necessary authorization has been given specifically and in writing.

In case it is not possible to comply with the first step criteria, the second step of the framework is formulated as an exceptional scenario for research that does not have the potential to produce results of direct benefit to the health of the person concerned. Such a research can only be allowed if the following additional conditions are met:

- The research has the aim of contributing, through significant improvement in the scientific understanding of the individual's condition, disease, or disorder, to the person concerned or to other persons in the same category of disease or disorder.
- The research entails only minimal risk and minimal burden for the individual concerned.

In all circumstances the person concerned must not object to the participation in the project.

Two important features of developing the current ethical framework of research on incapable persons will be discussed. First, the liberalization tendency in the post-Nuremberg evolution of the research ethics codes: after an earlier absolute ban of

research on persons unable to consent, there are now provisions of research without the direct benefit. Second, a possible explanation will be provided for the emergence of the current ethical framework of research on incapable persons by referring to balancing or rather compensating the inability to get informed consent with other ethical principles and safeguards (Gefenas, 2007).

Two Steps of Liberalization

It can be claimed that modern research ethics started as a reaction to the horrors of Nazi human experiments, where adults and children became involuntary victims of activities, to which they would have never consented. The Nuremberg code responded to these atrocities in a radical way – it only legitimized research on those who were able to give informed consent. Paradoxically, this would have stopped the development of treatment and diagnostic interventions for many categories of patients unable to consent. That is why the Declaration of Helsinki made a step toward the softening of this very strict position in 1964 and introduced a distinction between so-called therapeutic research and nontherapeutic research (World Medical Association, 1975). This distinction made it possible to conduct so-called therapeutic research or research with the direct benefit for incapable people assuming that authorization from their representative was secured.

This was not, however, a sufficient condition allowing conducting early phase research where benefits for individual research participants can only be very limited. Therefore, the second step toward the liberalization of this type of research was introduced in the 1990s when research without direct benefit to the persons concerned was allowed by international codes and legal instruments under strict protective conditions described above.

Balancing Approach

The first liberalization tendency was followed by the attempt to "compensate" the impossibility to apply the principle of informed consent with other ethical principles and values involved in ethical decision making. Careful consideration of the risk and benefit ratio has been the most important one for this discussion: there is always a correlation between the capacity to consent and a justifiable risk/benefit ratio in the documents presented in this chapter.

For example, the level of risk that is tolerated in research on capable persons is higher than that allowed in research on incapable or other vulnerable groups: The Oviedo Convention only allows research with "real and direct benefit" on incapable people, while allows a higher level of risk by introducing the concept of "acceptable risk" in nontherapeutic research on capable persons. Similarly, the CIOMS Guidelines say that the risk presented by such intervention must be reasonable in relation to the knowledge to be gained (see Guideline 8). However, the CIOMS guideline 9 requires following the "low-risk" standard with incapable research participants.

Minimal risk or low-risk standard is probably one of the most important and complex principles to be followed in the field of research on incapable persons because it reveals both the conceptual differences between different definitions as well as variations in applying these definitions in different societies. For example, according to Article 17 of the Oviedo Convention the "minimal risk" standard is defined as "a very slight and temporary negative impact on the health of a person concerned." Paragraph 100 of the Explanatory Report to the AP to the Oviedo Convention provides examples of the interventions that might be considered as those not exceeding the minimal risk standard. These examples are among others: taking saliva, urine; taking small additional tissue samples during operation; taking a blood sample (capillary, peripheral vein); sonographic examinations, one X-ray exposure, or one exposure using magnetic imaging without a contrast medium.

The CIOMS guidelines introduce even more complex and liberal scale of balancing. Guideline 9 refers to the "low-risk standard": the risk that should not exceed the risk attached to routine medical or psychological examination of incapable persons. However, CIOMS Guideline 9 also provides a more liberal standard, the so-called slight or minor increase above such risk when there is (a) overriding scientific and medical rationale for such an increase and (b) research ethics committee's (REC) approval. The Commentary to Guideline 9 explains that there is no agreed definition of what the "slight or minor increase" is. However, it says that its meaning is inferred from the RECs' reports that provide such examples as, additional lumbar punctures or bone-marrow transplantation.

There are also other complexities that arise when conducting research on persons unable to consent. For example, the requirement to take into account the objection of the person concerned can beg the question what type of objection should be considered as a sufficient ground to stop or not to start participation in the research project. Research in emergency situations can also be mentioned as raising additional concerns. First, because in the emergency situations it can be very difficult to find a representative (e.g., a family member) who is supposed to authorize the involvement of the person in the research project. Second, because emergency medicine research also raises discussion on the alternative models of consent replacing the "real time" IC procedure. For example, different options have been proposed for these "modified" forms of consent in the emergency medicine research. One option can be "advance" consent given before the intervention when the person is still capable to make decisions. Another and more practicable option can be "retrospective" consent, which is given when a person regains the decision making capacity. However, this type of consent also raises serious concerns because it is given after a person has already started or completed participation in the research project.

Concluding Remarks

It should be acknowledged that since the second half of the twentieth century, there has been a significant progress in the protection of rights of persons unable to consent to medical interventions. Massive sterilization campaigns including among

others people with mental disorders or learning disabilities, chaining psychiatric patients as a means of restraint, "treating" political dissidents with damaging doses of psychotropic medications and sticking them the label of "sluggish schizophrenia" – all these will hopefully remain sad historical medical practices and will never return to the field of medicine.

The positive changes in attitudes and practices with regard to people unable to consent have been mainly achieved in the process of developing international and national regulations based on fundamental human rights instruments adopted in the post–World War II period. In some areas, such as research on incapable persons or the involuntary measures in the field of psychiatry, these regulations reached a remarkable level of convergence. It should be noted, however, that despite the mentioned positive developments, there are still many problematic open question. Many countries are still rather slow to follow with the implementation of some important internationally established principles. For example, respect for previously expressed wishes and advance directives have not yet been implemented in the national regulations of many countries. In addition, despite the presence of relevant regulations, there are still some controversial practices going on, such as the use of coercive measures in psychiatry or sterilization of some groups of population, which should attract more attention and studies in order to develop strategies of how to better protect the interests of the most vulnerable group of people – persons without or in a process of losing their decisional capacities.

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Respect for Human Vulnerability and Personal Integrity

8

Sheila A. M. McLean

Introduction

Article 8 of the UNESCO Declaration on Bioethics and Human Rights (2005) reads as follows:

> In applying and advancing scientific knowledge, medical practice and associated technologies, human vulnerability should be taken into account. Individuals and groups of special vulnerability should be protected and the personal integrity of such individuals respected.

This article, therefore, is concerned with two concepts – special vulnerability (seemingly, an effort to distinguish "mere" vulnerability from a higher level of vulnerability), and respect for personal integrity (which is often used almost interchangeably with the concept of human dignity). In 2011, UNESCO's International Bioethics Committee (IBC) issued a report on this article.

As the IBC puts it:

> The specific task of this Article is to address special vulnerabilities that occur, whether as a consequence of personal disability, environmental burdens or social injustice, in the contexts of health care, research and the application of emerging technologies in the biomedical sciences. Article 8 enjoins everyone to exercise vigilance in protecting the well-being of individuals and groups in these contexts. As the Declaration (taken as a whole) confirms, every human being has a claim to our care that must be respected. (para 5)

Importantly, Article 8 of the Declaration, ". . . .entails both a 'negative' duty to refrain from doing something and a 'positive' duty to promote solidarity and to share the benefits of scientific progress. There is an integral relationship between respect for the integrity and dignity of persons on the one hand and the vulnerability of persons on the other." (para 3) This is, therefore, a dynamic article of the Declaration, encouraging action to fulfill its aims, specifically in the context of healthcare delivery, even when that action might be construed as failing to do something. However, arguably, the concepts at the heart of Article 8 are not

S.A.M. McLean
School of Law, University of Glasgow, Glasgow, UK
e-mail: Sheila.McLean@glasgow.ac.uk; s.mclean@lbss.gla.ac.uk

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unproblematic, and it is necessary, therefore, before going further to spend a little time considering precisely what is meant by both "vulnerability" and "personal integrity."

Vulnerability

While its meaning may seem self-evident, in fact, various efforts have been made to define what is meant by the concept of vulnerability, and no consensus on its precise content has emerged from the wealth of literature and commentary associated with these efforts. However, despite this, it is sometimes easy to identify situations in which people are vulnerable. Schroeder and Gefenas (2009), for example, offer one relatively straightforward example where vulnerability seems evident: the old lady walking with difficulty, followed by a group of drunken youths bent on trouble. Unless the old lady is a black belt, or armed with a lethal weapon (and perhaps even then!), it is easy to identify her as vulnerable in this setting. She is weaker and less able to defend herself from imminent attack and lacks the ability to escape from this potentially dangerous situation. She is, therefore, vulnerable both as a result of personal attributes (her difficulty in walking) and her situation (that is, the context in which she finds herself).

However, not all attempts to describe vulnerability are quite so straightforward. While vulnerability as a concept appears in a number of international reports and guidelines, its precise ambit remains unclear. The International Ethical Guidelines for Biomedical Research Involving Human Subjects Prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO), for example, refer to vulnerable people in the context of human subject research in guideline 13. In the commentary on this guideline, vulnerability is described in the following way:

> Vulnerable persons are those who are relatively (or absolutely) incapable of protecting their own interests. More formally, they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests. (Council for International Organizations of Medical Sciences [CIOMS], 2002, available at: http://www.cioms.ch/publications/guidelines/guidelines_nov_2002_blurb.htm)

The most recent (2008) version of the World Medical Association's Declaration of Helsinki also refers to vulnerable individuals and populations, indicating that certain groups or populations who are potential research subjects may be "particularly vulnerable": for example "those who cannot give or refuse consent for themselves and those who may be vulnerable to coercion or undue influence." (Article 9) For Merry, "the conception of vulnerability hinges on the idea of agency. The vulnerable person is one who has little choice or capacity to escape pain and injury" (Merry, 2007, p. 195)

Although the concept may be difficult to describe in detail or to place boundaries around – and clearly other examples either within or outside of the research context could be found – there is an apparent consensus that vulnerable individuals, groups, and populations (however defined) are worthy of special protections. Whatever the source or cause of vulnerability, its presence demands the highest standards of care

and protection of human rights. This requirement is strengthened when individuals or groups are regarded as being especially vulnerable, and it is with these people that Article 8 of the UNESCO Declaration is specifically concerned. Of course, if defining vulnerability itself is problematic, ex hypothesi defining "special vulnerability" is every bit as challenging.

Interestingly, unlike some of the commentaries and guidelines already discussed, the IBC specifically declined to attempt a definition of vulnerability, or special vulnerability, preferring instead to provide examples of situations within the healthcare enterprise in which "special" vulnerability can be clearly identified. As the report says, "attempts to define vulnerability in general risk drawing the concept too widely or too narrowly, thereby triggering disputes rather than resolving them. . .." (para 7). This approach has the benefit of not focusing on the minutiae of definitional specifics, but rather concentrating on the concrete (but by no means exhaustive) examples the report describes. States and other agents/organizations can use these examples as templates for triggering appropriate responses and assisting in devising the protections that, it seems universally to be agreed, need to be put in place in certain circumstances and for specific individuals/groups/populations.

Personal Integrity

As has been seen, Article 8 specifically rolls together two concepts, the second of which is respect for the personal integrity of those who fall into the category of "special vulnerability." Unfortunately, perhaps, while widely used in human rights instruments and bioethical literature, this concept also can present definitional problems. Indeed, it is common to see the concept of "personal integrity" subsumed within, or accepted as a necessary facet of, human dignity. Both concepts recur in human rights instruments, and the literature that focuses on them. Indeed, Article 1 of the (UN) Universal Declaration of Human Rights says "All human beings are born free and equal in dignity and rights. . .," and Sulmasy (2008) reports that dignity is mentioned five times in the Universal Declaration. However, the Declaration does not explain what dignity actually is. Like vulnerability, however, it is a concept that seems to attain form and content by experience and implicit understanding. Just as there are obvious situations in which people would be widely recognized as vulnerable, so too the conclusion to Article 1, that exhorts people to "act towards one another in a spirit of brotherhood," serves to put some flesh on the bones of the concept, by emphasizing the importance of respect, equality, and solidarity.

Merely by belonging to the human species, people are entitled to respect, and it is this that triggers the attribution of human rights; perhaps the most significant political tool of the twentieth and twenty-first centuries. Definitional difficulties aside, as Sulmasy argues, "People do not have dignity because they have rights; they have rights because they have dignity. . .. All human rights depend upon the concept of dignity" (Sulmasy, 2008, p. 25) As one important aspect of human dignity, respect for personal integrity is integral to the attribution of human rights,

thereby offering the protection of "negative" rights, such as freedom from discrimination and exploitation, as well as "positive" rights, such as the right to self-determine.

Vulnerability Revisited

As has been noted, attempts to define vulnerability have proved problematic, yet as a concept it is in widespread use. Indeed, as Coleman says, "Even if there is no consensus on what vulnerability actually means, calls for 'protecting the vulnerable' seem to have an intuitive ethical appeal, and are therefore likely to continue" (Coleman, 2009, p. 14) Although, in Fox's words, the concept can be described as "plastic," nonetheless, it can serve as a trigger for important and sometimes essential protections (Fox, 2002). The International Bioethics Committee's decision not to focus on definition, but rather to provide relevant (albeit not exhaustive) examples, arguably successfully navigates the choppy definitional waters and provides a practical template for the implementation of Article 8. Focusing on outcome rather than definition allows for attention to be paid to the fundamental underpinnings of respect for persons in general and for the vulnerable in particular. Running the two concepts together, according to the IBC report, ". . ..reinforces this commitment by linking it to respect for personal integrity and the need to protect vulnerable individuals and groups" (International Bioethics Committee [IBC], 2011, para 1).

It is widely accepted that vulnerability is universal. At some time in life, everyone is vulnerable, irrespective of social status, intelligence, authority, or economic power. However, for many, the state of vulnerability is transient or contextual rather than inherent. While not unimportant, such states can often be overcome, or at least they pass in time. However, it is to those individuals, groups, or communities for whom vulnerability is not a transient state that attention is particularly important. It was to address the isolation, discrimination, and powerlessness of these individuals and groups that the IBC document was drafted, and it is to these individuals and groups in particular that the responsibility of seeking to rectify wrongs and obviate harms is owed.

Importantly also, people must be vulnerable *to* something. Vulnerability, then, is not merely a passive, but also an active, notion; political systems, socioeconomic or health-related circumstances to name but a few can individually or collectively conspire to attack or constrain capacities, life choices, and experiences. People are then, for example, vulnerable *to* disrespect, discrimination, stigmatization, and lack of agency.

While each and every person may be vulnerable at some time(s), some commentators have preferred to identify vulnerability by group characteristics. Thus, it is often claimed, for example, that children, pregnant women, the elderly, and people with disabilities are all ex hypothesi to be thought of as vulnerable. To be sure, this categorization may reflect both historical and contemporary realities. There is little doubt that women are disproportionately

disenfranchised, even in modern times, in some cultures and countries. Children all too often are at risk of exploitation – sadly, even by their own parents. The treatment of the elderly in some societies leaves much to be desired in terms of respecting them, and people with disabilities often identify disrespectful treatment in healthcare settings.

However, when commentaries, international statements, and guidelines direct special attention to groups or populations, the potential downside is the temptation to characterize all members of a discrete group as necessarily vulnerable. This is by no means uncontroversial, of course. Grady, for example, notes that:

> . . ..current concepts of vulnerability are usually applied to whole groups of people, without distinguishing between individuals in a group who might truly have a compromised capacity to protect their own interests from those who do not. Considering all poor people, pregnant women, members of ethnic or racial minorities, and people with terminal illness as inherently vulnerable in research has been particularly controversial. (Grady, 2009, p. 19)

While Grady's comment was made in specific reference to the healthcare research context, it resonates throughout life and transcends the clinical or research setting.

Thus, while there may be cases where all members of a group are vulnerable (perhaps, for example, in human population, genetic research on poor and isolated communities), it is important that the concept is sufficiently nuanced to ensure that the protections triggered by it are targeted appropriately and not indiscriminately merely because a person is a member of a group. This goes back to the question of definition, since it might be thought that it is the ability to describe those encapsulated by the concept that allows for strategic interventions to be made. However, problems emerge from this effort. Hurst expresses the impact of this definitional deficit concisely and clearly:

> Broadly, we agree that the vulnerable should be afforded some kind of special attention, or protection. Defining vulnerable persons or populations, however, has proved more difficult than we would like. This is both a theoretical and a practical problem. On a theoretical level, uncertainty as to what we mean by vulnerability is unsatisfactory because although we agree that this notion has a strong pull, we cannot account for this pull, justify it, or define its limits. On a practical level, we cannot know who should be afforded the protection due to vulnerable persons, or what form this protection should take. Contradictory definitions can lead to confusion for those who are supposed to protect the vulnerable, and wrong definitions may be acted upon. (Hurst, 2008, p. 191)

It is evident from this that translating aspiration into practice can be as challenging as finding a definition of vulnerability itself, and ultimately it is the imperative actually to *provide* the appropriate protections that is, or should be, at the heart of national and international endeavors. While, however, it may be difficult concisely and definitively to describe just *who* is vulnerable, it may be more straightforward to describe *when and where* people are vulnerable and what they are vulnerable to. One situation in which people may be thought of as especially vulnerable, and where their right to respect for personal integrity may be challenged, is in the provision of healthcare and its associated technologies.

Vulnerability in Healthcare, Research, and Technological Advances

The IBC report specifically divided the provision of healthcare into three discrete, albeit sometimes overlapping, areas: the routine clinical relationship, the research setting, and biotechnological advances. For ease, this essay will follow that pattern in what follows. However, it should be noted that special vulnerability and threats to personal integrity or human dignity can arise outside of the healthcare setting as well as within it.

The Clinical Context

People who are, or perceive themselves to be, unwell are dependent on healthcare professionals for diagnosis, prognosis, and – where appropriate – treatment. Irrespective of context, the sick person is vulnerable. That vulnerability has far-reaching consequences for his/her ability to self-determine. For this reason, laws have been developed over centuries that seek to secure protection of the individual's right to respect by focusing on the responsibility of healthcare providers to ensure that individual patients are well-informed, and ideally active, participants in any decisions made about their treatment and care. These laws, underpinned by the concepts of autonomy and respect for personal integrity, are intended to redress, to the extent possible, the imbalance between the healthcare professional and the patient, an imbalance based on characteristics such as context, knowledge, and authority. In combination with the law, professional guidelines increasingly stress the need to respect patients and their decisions, and to take care in ensuring that the dignity and rights of patients are respected.

If "average" patients can be described as vulnerable in their interaction with healthcare, there are others who can be described as being especially vulnerable and for whom the basic rules of law and professional guidelines offer insufficient protection. Although it has been argued to be inappropriate to make generalized assumptions about people simply because of their membership of a group, advocates, for example, for the elderly and people with disabilities, often argue that there is systemic disrespect within healthcare systems for these particular groups of people who are often regarded as inherently vulnerable. Inadequate funding may be routed into their care in general, they may be treated as "second-class citizens" even when care is available, and their specific needs may be neither adequately identified nor met. The principles articulated in Article 8 reinforce the need for action in such cases and, because they are directed at individuals as well as states, reinforce the obligations of solidarity and compassion that are owed to those who are especially vulnerable.

The dependent role of the patient in respect of healthcare providers seems self-evident. Irrespective of economic status, intellect, or any other characteristic, in a very real sense, individuals surrender something of themselves to the authority of healthcare professionals when they are, or believe themselves to be, ill. They are,

therefore, vulnerable to being ill informed, misled, or becoming passive recipients of, rather than active participants in, healthcare decisions that affect them. However, although it is clear that people can be described as vulnerable even in the standard therapeutic interaction, it is on the area of research that much commentary and activity has been focused, not least because in this setting the traditional, beneficent relationship between healthcare professional and patient is fractured by the very nature of human subject research. The primary aim in research is to identify potentially beneficial treatments for future patients, even if the individual research subject may also benefit. The research protocol, in order to be scientifically valid, must to some extent distance the researcher from the subject in a manner that does not exist in a good therapeutic relationship.

The Research Context

The need to undertake human subject research is generally accepted. Without it, medicine would not progress; novel treatments and technologies would not emerge, to the detriment of human health. While the law of consent also applies to the research context, and may even require that more information needs to be provided in this setting, concern remains that people invited to participate in human subject research are particularly vulnerable. Striking an appropriate balance between individual interests and rights and those of the wider society – current or future – is a challenge whose significance cannot be underestimated. Yet it is also a balance that is difficult to achieve. The importance of potential benefits may obfuscate the fact that research subjects may be exploited in the name of the greater good, even if that exploitation poses minimal risks to the subject.

There are a number of factors that may generate special vulnerability in the research context. These may be individual to the research subject or patient themselves; they may relate to the quality of the information provided by researchers; they may be socioeconomic or specific to the kind of research being proposed. These factors, according to Grady, may be more important than the subjects' identification with a specific group, reinforcing the claim that simple categorization as belonging to a particular community may be insufficiently nuanced to act as a rule of thumb for triggering special protections. Indeed, one consequence of such thoughtless homogenization has historically been not the inclusion, but rather the exclusion, of certain groups from engagement in the research enterprise. For example, particularly in the aftermath of the thalidomide case, pregnant women were routinely deemed unsuitable for involvement as research subjects, even though they too are entitled to the benefits of medical research. The International Ethical Guidelines for Biomedical Research Involving Human Subjects devised by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO) declare in Guideline 13 that "Special justification is required for inviting vulnerable individuals to serve as research subjects and, if they are selected, the means of protecting their rights and welfare must be strictly applied." However, it must also

be borne in mind that people can also be rendered vulnerable by their *exclusion* from research.

It has already been indicated that the law in many jurisdictions has developed so as to attempt to provide protection for patients, primarily through the law of consent. Naturally, consent is also an important feature in medical research. However, it can be questioned to what extent the law of consent is able to offer the most appropriate level of protection to those who are especially vulnerable in the research setting. It is the nature of research that an hypothesis is being tested; by definition, the outcome is not known. This makes it more difficult for an open, full, and honest discussion of possible harms and benefits of the research to be undertaken, and requires a level of trust between research subject and researcher that is arguably even greater than in the standard clinical setting.

Yet, for some individuals and groups, the apparent protections of the law of consent may be more apparent than real and the necessary trust may not exist. Sadly, examples of research misconduct do exist and have been reported on; more than basic legal rules is, therefore, required. Broadly speaking, the additional protections recommended for vulnerable groups lie in, and are dependent on, procedural requirements. For example, the Declaration of Helsinki says that:

> Medical research involving a disadvantaged or vulnerable population or community is only justified if the research is responsive to the health needs and priorities of this population or community and if there is a reasonable likelihood that this population or community stands to benefit from the results of the research. (Article 17)

These additional criteria are designed to add another level to the protection ostensibly afforded by laws on consent. Of course, however, they are not always applied, nor are they always easy to apply. For example, in the case of human population genetic research which has been referred to already, the research is neither generally designed to benefit the specific population nor is it the case that the community will benefit without a genuine commitment to benefit sharing. The subjects of this research may agree to participate based on misconceptions, pressure, or lack of awareness of the implications of participation. Given the nature of the targeted populations, they may be poor, ill educated, and isolated; in other words, they are especially vulnerable. Lack of education, lack of healthcare resources, and poor understanding of the research enterprise as a whole, coupled with ancient cultural traditions, may mean that even the most scrupulously designed research project fails to protect the personal integrity of these vulnerable groups. Their vulnerability may stem from a wide range of sources, not least that their lack of authority in the face of the global research enterprise may cause them to engage in a particular project without fully understanding what may be lost by their involvement, or because they simply feel powerless to refuse. As Grady argues, "Individuals may have difficulty rejecting unfair offers and protecting their own interests if they do not recognize the offer as unfair, if they accept an unfair offer as better than nothing, or they feel as if they cannot refuse" (Grady, 2009, p. 21). In addition, and in apparent contrast to the requirements of the Declaration of Helsinki referred to above, there may be no benefit for the group or its individual

members; indeed, there may be no intention or expectation that any such benefit will flow from their involvement.

Outside of what might be seen as a somewhat extreme example, the research context requires careful attention to the actual or potential vulnerability of research subjects and to respect for their personal integrity. The fact that research will generally be conducted in an effort to benefit future (albeit sometimes current) patients should not be permitted to obfuscate the possibility that subjects are exploited. Nor is this risk necessarily affected by the *nature* of the research. For example, while invasive research with potentially limited benefits might trigger careful consideration and mandate special protections by way, for example, of strict adherence to a high level of information sharing and additional requirements imposed by ethical review bodies, less intrusive research might be treated more casually, especially where the potential benefits are significant.

Research design must be sensitive to the fact that any intrusion – physical or emotional – can be harmful. Every protocol, therefore, must pay special attention not just to the possible vulnerability of the subject but also to the impact of the research itself on the respect to which each person is entitled. Sacrificing this for the greater good, while it may sometimes be tempting, disregards the commitments contained in Article 8.

Equally, it may be that potential benefits may override respect for personal integrity and ignore or minimize human vulnerability where the situation seems urgent. Again, the greater good may be used as a justification for circumventing some of the requirements of best medical research. For example, in situations where certain diseases are prevalent, it may be tempting for researchers and/or companies to test developing vaccines in protocols that, for one reason or another, have not been, or would not be, approved by the relevant ethical review committee in the country leading the research. Very often, as is the case with population genetic research, the researchers will come from a developed country and the subjects will be from one that is developing, creating additional levels of vulnerability in the target group to those which exist in any case because of disease prevalence.

Of course, medicine is expected, and needs, to progress and research is an integral part of that. Nor is it intended to imply that the vast majority of research is not conducted both for good reasons and also in clear, respectful, and scientifically valid protocols. However, there is an obligation on researchers, and those who authorize the project, to bear in mind not just the scientific validity of the project, but also any special vulnerability of the target individuals and/or groups, and ensure that special attention is paid to the need to ensure that their rights are respected.

Technological Advances

Over the course of the last century and a half, medicine and its potential have developed almost beyond recognition. The development of anesthesia and antibiotics, for example, has saved uncounted millions of lives. More recently, advances

in assisted reproduction and human genetics have changed the face of medicine yet again. While for the moment, these developments have more relevance for the developed world than elsewhere, the issues raised by them are emblematic of the problems that can be generated by scientific advances and their applications. Medicine is now capable of doing more than palliating or curing; it can circumvent established problems, as well as use the human body – particularly its genetic components – as a source of information of potentially wide-ranging importance and effect.

For many individuals and couples, the ability to reproduce – to establish a family – is a fundamentally important desire. As the causes of infertility became better established, and as the number of people reporting themselves as having fertility problems continued to rise, the devastating individual effects of the inability to conceive or carry a pregnancy to term became clearly identifiable both in individual terms and – sometimes – in community terms. While in some parts of the world, overpopulation is a serious threat to well-being, in (mostly) western countries, the inability to found a family is seen by some as a personal and social evil, or at least as the thwarting of a powerful desire. While arguments historically abounded about whether or not satisfying the desire to have a child was the proper business of medicine, that debate seems largely to have been resolved. The advances in assisted reproduction and associated technologies (ARTs) have placed this aspect of fertility control firmly within the medical domain.

For largely psychological, and sometimes social, reasons, people who find themselves in need of assistance to found a family feel themselves disadvantaged. In some communities, they may even be stigmatized. Two primary sources of vulnerability emerge from this. From the perspective of some feminist writers, women become vulnerable to pressure to conform by having children and are victims of social norms that prevent them either from coming to terms with childlessness or seeing themselves as "full" members of the community if they fail to breed (Sherwin, 1992; Corea, 1988; Rowland, 1992). Proponents of this school of thought would maintain that medicine's focus on facilitating women's reproductive role is a male-driven conspiracy to keep women within the constraints of their traditional role as carers and home makers, making their full integration into social, economic and political life more difficult. Not only are they vulnerable to this pressure, but they are also disrespected by the coercion to take advantage of ARTs that arises from societal expectations.

On the other hand, those who require assistance to reproduce may see themselves as vulnerable in a very different way. The availability of the technology to facilitate reproduction may be limited by state regulation regarding "fitness to parent" or by financial constraints. For these people, the inability to participate on an equal footing with those who do not need assistance is what renders them vulnerable and disrespects their dignity.

In this situation, women are rendered vulnerable by virtue of their overwhelming desire – some would say need – to have access to the technology that allows them to become a parent. With the best will in the world, this leaves open the opportunity for exploitation – that is, it may encourage women to engage in practices that they

would otherwise not agree to. For example, schemes have been developed that allow women to circumvent the restrictions on availability of ARTs, which may be seen as ethically problematic. In some situations, women who are unable to afford the services they seek may be given free treatment if they volunteer to share their eggs with other infertile women. This may result in the stranger becoming pregnant, but the egg donor remaining childless, with all of the psychological sequelae that may flow from this. For those for whom having a child is an overriding goal, it is *prima facie* unlikely that they would willingly give away some of the opportunities they may have to do so. Yet they may see themselves as having no option but to do this, given that the alternative is no treatment – no chance at all of becoming a parent. While affecting a relatively small number of women, a variation on this scenario was regarded as sufficiently important to be used as one of the examples proffered in the IBC's report on Article 8.

Not mentioned in the report, but arguably of additional concern, is the question whether or not the assisted reproduction revolution is also implicated in the creation of a new group of vulnerable people – namely, the children born as a result of its application. While there is no evidence to support their claims, opponents of assisted reproduction often use these children as a reason to limit its availability. The argument is that children born into unconventional families, which assisted reproduction now permits, will necessarily suffer psychologically, and may also be stigmatized, for example, by being born into a same sex family or as the result of a surrogacy arrangement.

The other so-called medical revolution that raises issues about vulnerability and respect for personal integrity – perhaps even more acutely – arises from the rapidly developing area of human genetics. While advances in this area have the potential to explain the causes of ill health or disability, to develop treatment and perhaps ultimately cures for these conditions and to prevent the birth of children destined to suffer, as yet, it must be said, the much vaunted benefits have yet to emerge in significant numbers. Nonetheless, healthcare professionals, scientists, researchers, and multinational companies continue to press ahead with research and development. There are, obviously, both medical and financial benefits to be obtained.

While awaiting the therapies and cures that were so confidently predicted at the beginning of this revolution, vast amounts of genetic information are stored either for anonymized research purposes (such as in so-called biobanks) or in medical records. At a general level, the mere possession of this information is argued to render people vulnerable. Since it is now known just how many conditions have a genetic basis, and predictions can be made about future health status, inappropriate disclosure of the information may lead to stigmatization and discrimination. On the other hand, there is a lobby suggesting that disclosure of this kind of information in certain contexts is not inappropriate, but is rather entirely relevant.

For example, it can be, and has been, argued that employers and insurers have a right to information about the actual or potential health status of those whom they employ or are invited to insure. In terms of employment, it is argued, employers would be able to make more informed decisions about who to employ or retain based on predictable health-related information. Of course, this makes the

assumption – often not accurate – that genetic information is predictive rather than probabilistic. Certainly, in some cases, genetic information can predict with some certainty that disease will eventuate – for example, in the case of Huntington's disease – but more often than not all it conveys is a possibility or probability that a condition will emerge. Even in cases such as Huntington's disease, the mere presence of the disease gene does not predict the time of onset of the condition, yet this information may be used negatively in employment decisions.

For insurers, it might also seem to make sense that they are informed about genetic predispositions. After all, health-related information is routinely required for health and life insurance, and, it may be argued, genetic information is merely another type of medical information. In addition, family histories are also generally taken in these situations and this too allows insurers to identify patterns of illness which may be inherited. This kind of argument raised early fears of the creation of a "genetic underclass" of people who would be uninsurable (and possibly also unemployable). Should this eventuate, these would become the "new vulnerable": unable to participate fully in the life of a modern society and their privacy rights ignored.

Admittedly, such fears have not become a widespread reality, but it is arguable that the potential remains. Even if no underclass emerges, individuals may feel themselves challenged psychologically by the mere fact that genetic information exists in their respect. With whom will that information be shared? To whom might they have an obligation to disclose it? Do people have an obligation to their families and/or future generations to seek this information in the first place? These are realistic situations which may compel people to discover information about themselves that they would otherwise not wish to have, in breach of what has been termed a "right not to know," or to have information shared with relevant third parties that they would prefer to maintain in privacy.

Conclusion

Despite the relative vagueness of the concepts of vulnerability, special vulnerability, and personal integrity, Article 8 of the UNESCO Declaration nonetheless moves some way toward serious reflection of the national and international obligation to protect those who are in a weak position in the healthcare setting, either as a result of personal characteristics, socioeconomic factors, or any other indicator of disadvantage. This is important, not because there is an assumption that healthcare professionals, scientists, researchers, or even global corporations necessarily act in bad faith or for impure motives; rather, its significance lies in the explicit recognition that the very nature of the enterprise predicts a power imbalance between "consumer" and "provider" that is institutional. The responsibility, therefore, lies on providers, agencies, companies, and states to ensure that – to the extent possible – protections are built into the system. Where the vulnerability is special, the obligation is greater, and specific consideration needs to be made as to how to minimize or obviate vulnerability and ensure that people's rights are respected. The Article

emphasizes that everyone is vulnerable at some times and in some situations, but focuses specifically on those whose position is particularly in need of protection. In tandem with the IBC's report on this article, this is a clarion call to action to protect rather than exploit those whose agency is diminished by their life experiences and the lethargy or lack of respect from third parties and/or organizations such as the state that create or increase their inability to self-determine.

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Privacy and Confidentiality

9

Jean F. Martin

Introduction: The context

Regarding the themes of this chapter, there have been, under the auspices of several organizations, developments that constitute a substantial background. To quote some:

The UNESCO Universal Declaration on Bioethics and Human Rights. This Declaration (UDBHR), adopted in 2005 by the UNESCO General Conference, is of particular importance (UNESCO, 2005b; ten Have and Jean, 2009). It says:

> ***Article 9: Privacy and confidentiality***
> *The privacy of the persons concerned and the confidentiality of their personal information should be respected. To the greatest extent possible, such information should not be used or disclosed for purposes other than those for which it was collected or consented to, consistent with international law, in particular international human rights law.*

An Early Effort: The Declaration on the Promotion of Patients' Rights in Europe (1994). This Declaration was elaborated under the auspices of the WHO Regional Office for Europe in collaboration with governments and interested bodies. In the resulting publication, Dr. J.E. Asvall, Regional Director, writes: "Well informed patients are beginning to assert rights in their private dealings with professionals in the health field. Until the beginning of the 1970s, the health professional-patient relationship was defined primarily by the rules of medical ethics. During the last two decades, the relationship was gradually redefined in terms of a contract (. . .) It has been demonstrated that well informed patients make better partners in their care, and have quicker and more complete recoveries (. . .) Patients' rights are a reflection of the importance of human rights" (WHO, 1995, p. 8).

J.F. Martin
Privat-Docent à l'Université de Lausanne, Membre de la Commission nationale suisse d'éthique, Echandens, Switzerland
e-mail: jean.martin@urbanet.ch

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The set of principles set forth in the Declaration include

> In the section "Human Rights and Values in Health Care": the right to respect of the patient's person as a human being; the right to respect for his or her privacy; the right of patients to be fully informed about their health status, including the medical facts about their conditions and alternatives to the proposed procedures. It further said that information may only be withheld from patients exceptionally, that patients have the right not to be informed at their explicit request, and to choose who, if anyone, should be informed on their behalf (WHO, 1995, pp. 38–39).
>
> In the section "Confidentiality and privacy": All information about a patient's health and all other information of a personal kind must be kept confidential, even after death; confidential information can only be disclosed if the patient gives explicit consent or if the law expressly provides for this; consent may be presumed where disclosure is to other health care providers involved in that patient's treatment; all identifiable patient data must be protected; patients have the right to access their medical files and technical records, such access excluding data concerning third parties; patients have the right to humane terminal care and to die in dignity (WHO, 1995, p. 41 and 43).

The Council of Europe Convention on Human Rights and Biomedicine (The so-called Oviedo Convention) was adopted in 1997. It includes in particular:

> ***Article 10: Private life and right to information***
> *Everyone has the right to respect for private life in relation to information about his or her health.*
>
> *Everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be so informed shall be observed.*
>
> *In exceptional cases, restrictions may be placed by law on the exercise of the rights contained in paragraph 2 in the interests of the patient.*

> ***Article 2:***
> *"Primacy of the human being," of the same Convention, is worth noting as well: "The interests and welfare of the human being shall prevail over the sole interest of society or science." Article 2, paragraph 2, of the UDBHR has, with minor editorial changes, the same content.*

Privacy

Privacy is a major feature of medical care, particularly in the Western World, with roots in the Hippocratic Oath as it has arrived to us. Today, the right to privacy is, among other things, a consequence of the autonomy attributed to (adult, normally competent) individuals, their right to conduct their lives as they see fit.

Regarding the already-mentioned UDBHR, this issue is described as follows in a Memorandum of the International Bioethics Committee that developed it (Stiennon, 2009, p. 166): "A right to privacy restricts access to personal and medical information and provides a claim of non-interference in various private

spheres (. . .) Confidentiality refers to a special and often fiduciary relationship, such as that between researcher and research subject, or doctor and patient, and provides that the shared information shall not be disclosed to third persons, unless a strictly defined, compelling interest justifies disclosure." It goes on to mention international legal instruments that have recognized the importance of privacy.

Groups Whose Privacy Is Not Protected in Their Own Society

In Ancient Rome, to take a historical example, only a minority were Roman citizens and could participate in decisions of a political nature. The Roman *pater familias* exerted a right of life and death on members of his household (wife, children, and slaves). The latter had thus no autonomy or real power over their own lives, including as regards privacy. Similar situations are numerous today still; it is necessary to recall how often the autonomy and right to privacy of entire groups are not recognized and much less guaranteed. This is especially true for women (in past centuries their testimony was not accepted in courts or did not have the same weight as that of men). In fact, they remained *legal minors* in several respects (civically, politically) in European countries until the twentieth century and, in a number of regions, remain so today.

One point is of particular importance in medical ethics and bioethics: because of their inferior social status, formally or informally, women encounter significant difficulties in exercising their autonomy and privacy in matters of sexuality; their right/freedom to choose when and with whom to have sexual relationships, when and in which circumstances to bear children, is not at all universally accepted. This makes them vulnerable to various types of pressures and to violence. Moreover, contraceptive needs often include an element of urgency for the woman who might thus be, in various ways, at the mercy of the care provider and/or of others.

The Cultural Dimension

It is important to recognize how in different societies traditional rules interfere with privacy as understood elsewhere. UNESCO's International Bioethics Committee, in its *Report on Consent* – discussing Articles 6 and 7 of the UDBHR – says under the title "Communal and individual consent": "In many societies, the community is the entity in terms of which the individual is identified. The leaders make decisions on behalf of the community and its members and these are not questioned (. . .) There is a difficulty in aligning the autonomy of individual as embodied in Article 5 of the Declaration with certain cultural settings. The expression of individual wish that goes against these decisions can be difficult or impossible (. . .) The distribution of responsibilities and the decisional hierarchy in the family unit are such that the choice to be treated or not is not necessarily made by the person concerned. Health professionals must ensure that individuals should

not be subjected to coercive treatment, involuntary exclusion from available treatment or unwilling participation in research." (IBC, 2008, pp. 35–36).

Further, the Report says: "One of the most complex situations arises in societies where communal forms of decisionmaking may prevail. Seeking consent from an individual is indispensable even if his/her community is consulted [respectively informed, as regards privacy] (...) although it is important to observe and respect values of different cultures, these values should not infringe on fundamental freedoms." (IBC, 2008, p. 49).

Respect of Privacy by the Health Care Provider

Over the centuries, health care has been marked by a strong tradition of paternalism by care providers. In many societies, the priesthood and medicine were fulfilled by the same persons or were closely related functions. To be noted, however: paternalism is not always authoritarian or rigid, it may be benevolent and empathetic; admittedly there is, within limits, some reasonable use of paternalism.

One should know that the principle of patient autonomy is absent in Hippocratic writings. It is mostly since the emergence of modern bioethics, in the l960s and1970s and in Anglo Saxon countries first, that the diseased person has been seen as the *subject* of health care rather than its *object*. In the former quite asymmetrical state of affairs, privacy was not much of a concern. A few decades ago, in hospitals in Europe and elsewhere, even in university ones, it was customary to see consulting rooms with lines of patients queuing to be seen by the doctor at the end of the line, who would ask questions in front of others; adopting often in the conversation the "tu" when addressing them (in Latin and German languages, "tu" is the "you" used when talking to a child or person of inferior status). These manners were seriously encroaching on the privacy of the patients, and indeed on their dignity. Quoting from the above-mentioned WHO European Office Declaration on patient's rights: "Patients admitted to health care establishments have the right to expect physical facilities which ensure privacy, particularly when health care providers are offering them personal care" (WHO, 1995, p. 42).

Such behavior might not have been basically ill-meant but corresponded to a power/authority relationship in medical care. The spontaneous provision of sufficient and understandable information to patients and the requirement of their informed consent, which are pillars of today's bioethics, were not given much attention – at best they were envisaged at the free, arbitrary, judgment of the physician. Things are changing, not always as rapidly as one would wish, however. There is a major need, in the training of all health personnel as well as in their practice, to underline the importance of attentive and tactful respect of patient privacy – and especially of his or her modesty.

This is an essential component of adequate care today, as expressed, for example, in the above-mentioned WHO Declaration on the Promotion of the Rights of Patients in Europe: "There can be no intrusion into a patient's private or family

life unless and only if, in addition to the patient consenting to it, it can be justified as necessary to the diagnosis, treatment and care. Medical interventions may only be carried out when there is proper respect shown for the privacy of the individual. A given intervention may be carried out only in the presence of those persons who are necessary for it" (WHO, 1995 p. 41).

It is important here to mention the issue of sexually suggestive or loaded behaviors by care providers, which is rightly receiving more and more attention. It is a fact that, due to the singular encounter situation, there might be temptation to express inadequate words or gestures, especially sexual in nature. Contrary to the autonomy of the patient, which does not appear in it, the prohibition of such inappropriate contact is expressly mentioned in the Hippocratic Oath**:** "In every house where I come I will enter only for the good of my patients, keeping myself far from all intentional ill-doing and all seduction and especially from the pleasures of love with women or with men" (English translation of the original by Michael North, National Library of Medicine – in Wikipedia, January 2012).

Such abuse of the care situation is strictly unacceptable. A number of professional bodies have included relevant dispositions in their deontological codes. For example, the Québec College of Physicians Code of Deontology:

> ***Article 22:***
> A physician must refrain from taking advantage of the professional relationship established with the person to whom he is providing services.

More specifically, the physician must, for the duration of the professional relationship established with the person to whom he is providing services, refrain from having sexual relations with that person or making improper gestures or remarks of a sexual nature (www.cmq.org – January 2012).

The deontological Code of the Swiss Medical Association says at article 4: In his professional activity, the physician does not exploit the dependence of the patient; it is particularly prohibited to misuse his authority on the patient, emotionally, sexually or materially" (www.fmh.ch – January 2012).

Of course, what is said here of sexually connoted behaviors holds true as well for any gestures or words that might be demeaning, insulting, scornful, or racist.

Finally, let us mention special needs, for example, when there is a particular risk of violence or escape by people under police custody or imprisoned. All efforts have to be made nevertheless to ensure maximum possible privacy and respect of the patient's dignity.

Privacy of the Care Provider

The professional is entitled to respect of his or her own privacy. Physicians and others, however, have a professional duty to be physically and mentally fit for their tasks.

None of them should drink alcohol when working; surgeons should not have any difficulty that might alter their dexterity. The author of this chapter had in his official capacity to ask two psychiatrists with serious bipolar syndrome to stop their practice.

An increasingly important issue is whistle-blowing. "Traditionally health care professionals have been reluctant to blow the whistle on an incapacitated colleague. This may have been out of misguided loyalty or fear of repercussions for themselves. Even when a colleague's infractions are serious, reporting such behaviours will not necessarily find peer support," writes in 1996 a practicing physician involved in medical ethics (Hébert, 1996 p. 62). Yet there is today no excuse for covering up inadequate abilities or professionalism. In the jurisdiction where this author worked, a legal provision, adopted in 2002, says that health professionals are obliged to inform the health authority of facts raising suspicion of abuse or malpractice by other professionals (Vaud, 2002).

In a recently published Casebook by the UNESCO Ethics Education Programme (UNESCO, 2011a), two situations regarding physician privacy are discussed (Cases 1 and 2 – the book describes real situations). The first case is about an accidentally cut obstetrics/gynecology resident, in whom immediate blood testing shows HIV seropositivity. Several hundreds of hospital patients had been involved with this doctor during their treatment. The question is to evaluate whether this physician's colleagues and patients have to be informed of his status and how. The second story is of a gynecologist who did not disclose to a patient that he was suffering from epilepsy. The disease, however, was adequately medicated and kept under control.

Such situations usually are delicate, do not have ready-made answers and need to be considered in depth under their various facets, by the professional concerned, by responsible deontological and public authorities, by the employers.

Privacy and Research

The rules and principles within a research endeavor are basically the same as those for the provision of health care. Any element touching on the participant's privacy has to be carefully explained. Any invasion of privacy, as the case may be, should be agreed upon by participants and strictly limited to what is imperative for the study purposes. There must be assurances that the participants may withdraw at any time from the research, without having to give motives. Also all research projects should be submitted to appropriate ethical review.

Relevant articles of the World Medical Association Declaration of Helsinki on ethical principles for medical research involving human subjects (1964, amended last in Seoul, Korea, in October 2008):

> ***Article 11:*** *It is the duty of physicians who participate in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects.*

Article 23: *Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information and to minimize the impact of the study on their physical, mental and social integrity.*

A Particular Ethical Issue in Research with Data Anonymization

A delicate situation is raised in research in which (with the consent of the participants) data are anonymized: "Even after rendered anonymous or encrypted, data related to samples might still be associated to the ethnic or geographical origin, socio-economic level and lifestyles of specific populations" (Stiennon, 2009, p. 169). Furthermore, in some studies, it appears ethically necessary to be able to go back to the provider of (anonymized) samples, when, for example, the sample examination uncovers information of major importance for him. However, if such "back-tracking" is possible for a reasonable, well-meaning purpose, concerned professionals and institutions should make all necessary efforts to prevent that it may be unduly used.

Confidentiality

Medical Confidentiality

The notion of confidentiality in medical care goes back in the West to the *Hippocratic Oath*: "All that may come to my knowledge in the exercise of my profession or in daily commerce with men, which ought not to be spread abroad, I will keep secret and will never reveal" (English translation of the original by Michael North, National Library of Medicine – in Wikipedia, January 2012). Said oath regained visibility and vigor in eighteenth century Europe. During the Middle Ages, European medicine was hardly organized and there is no clear indication of a confidentiality duty then, although such a duty was present in Islamic and Jewish medicine (Morais, 2001, p. 725).

In Anglo-Saxon societies, confidentiality is mainly a deontological rule without legal protection (British common law gives a right to professional confidentiality to the barrister only). This flexible conception has been influenced by eighteenth century medical personalities such as J. Gregory and T. Percival. The latter said, "confidentiality must be strictly observed when circumstances demand it", but, if called to testify, "the physician must tell the truth, all the truth and only the truth" (Morais, 2001, p. 725).

This is very different from the French approach: in France, the 1810 Napoleon Code provides a basis to the "secret médical," imposed to any person who by virtue of his or her profession is depository of secrets entrusted to him or her. The Québec legal disposition is of the same vein. Medical confidentiality is more than a moral duty, it is a legal obligation. It is considered an element relevant to "public order"

and its violation is sanctioned by the Criminal Code. Several authors think that this particularly stringent definition is due to some assimilation of the "secret médical" to the Catholic confession confidentiality – "secret de la confession" (Hoerni & Bénézech, 1996). In Switzerland, the "secret médical/professionnel" is also ruled by the Criminal Code but the faculty of being lawfully freed from the obligation to keep confidentiality is more easily obtained, and in more circumstances, than in France (Martin & Guillod, 2000).

Medical confidentiality has in modern times followed three different routes: one, as said above, is *deontological* (professional ethics). One of its expressions is the Geneva Declaration (1948), the forerunner of today's Helsinki Declaration. The second one is the *legal* one (the French model). One might note that deontological texts, elaborated and applied by a professional body, do not have the democratic legitimacy law has – today an increasing number of rules linked to bioethical issues are inscribed in public law and regulations.

Since the 1970s and the emergence of modern bioethics, confidentiality tends to follow a third route, the *human rights* one – similar to major evolutions in public and community health thinking. Below, we mention that the late Jonathan Mann, then head of the WHO AIDS program, championed the importance of human rights in the struggle to contain the epidemics. Would all concerned human beings be free to exercise their rights (especially autonomy, capacity to refuse unwanted relations), the spread of HIV/AIDS would not have been the same.

Goal of the Confidentiality/Secrecy

Fundamentally, the overarching objective of medical confidentiality is the *protection of the patient's interests* (and not the protection of the provider's – see below). It exists to protect the sick person from undue curiosity from a variety of others.

It is considered a cornerstone of good therapeutic rapport between the person cared for and the caring one. Louis Portes, a French physician who was (in the mid-twentieth century) president of the *Ordre national des médecins*, had the famous sentence: "There is no medicine without trust, no trust without confidence and no confidence without secret" (Hoerni & Bénézech, 1996, p. 12). The French doctrine insists strongly on the notion that, would patients not be fully confident about the strict secrecy of what happens in the therapeutic encounter (*colloque singulier*), they would not readily come for treatment anymore.

In principle, the doctor and other professionals have to be released from the confidentiality obligation *before they can talk to any other person* about the patient health condition. This holds true also for the patient's loved ones, wife/husband, partner, or children. The recognition of that principle has become more effective in recent decades. The consent of the patient needed before informing others usually does not require a formal procedure like a signature. Instead, it might be governed by common sense – as many things ideally should be in the relations between care givers and patients. In routine situations (fracture, appendectomy, common cold…), one

can often assume a tacit agreement that the provider informs family and loved ones. Yet, every time that there might be an unwelcome breach of the patient's privacy (information allowing to deduct questionable contacts or behaviors, e.g., sexually transmitted disease; this is an issue also in psychiatric care), the provider has to ensure that the patient gives clear and explicit consent, or mandate, to inform others. These aspects have been very significant, during the first decades of the AIDS epidemic.

Secret of the Doctor or "Secret of the Patient"

This is a significant terminological question. In German-speaking regions, one speaks today of the secret of the patient ("Patientengeheimnis"), which comes closer to the actual meaning of medical confidentiality, that is, to protect the person's privacy and data.

Over the last decades, a major evolution in a number of countries has been the recognition, and inclusion in the laws, of patients' rights. These imply the duty for the provider to inform the patient, spontaneously, without delay, and in a sufficiently complete fashion, about the medical observations made, laboratory and other para-clinical exam (imaging, etc.) results, about diagnosis and the various possible therapeutic avenues with their advantages and disadvantages, and about prognosis. This information is a *sine qua non* condition in order to obtain a valid informed consent from the person. Another patient's right is access to the medical file (in principle, to all that is in the file).

In this modern context, it is said that "the patient is the master of the confidentiality/secret," the health professional being the one who maintains it and stores it. Doctors who would refuse to their patients access to their medical data arguing that they are entitled to deny access "based on the medical confidentiality" would be grossly perverting the legal and deontological principle. After all, the patients should decide about the secret and its keeping or opening. Regarding their own medical data, they are to say to whom it may be given/transmitted, how and when. Case study 3 of a UNESCO Casebook in ethics education (UNESCO, 2011a) presents an actual example.

The Particular Situation of Teenagers Having Competency, the Capacity to Consent/Judge

Different systems have here different ethical and legal provisions. In several countries where the legal age of majority is 18 or 20, it is considered that teenagers have, some years before that age, the ability – the "strictly personal right" as the Swiss Civil Code has it – to request, accept, or refuse medical care, even without information being given to their parents or legal guardians, or against the will of their parents/legal guardians (see Martin, 2009). This allows, in Switzerland, for example, a 15-year-old girl to consult on her own a gynecologist to request

a contraceptive prescription, or even an interruption of pregnancy, without information of the concerned adults or against their will. Case 7 of the UNESCO Casebook on Benefit and Harm (UNESCO, 2011b) deals with that issue: the law, in the actual situation described, does not recognize any rule of absolute parental authority until a fixed age.

That "psychological/social age of competency" is not fixed by law, in general, it is a matter of appreciation by the care provider, in view of his or her professional experience. Understandably, it depends of the specific situation and in particular its severity.

The above has much to do with the principle of autonomy but is fully relevant regarding confidentiality. While for younger children the care provider has to thoroughly inform the parents, the provider has to be careful to protect the youth's privacy. By the same token (see preceding section), the youth is the one who decides about "secrecy" regarding their own medical data and the provider must have the patient's consent before informing others.

Shared Confidentiality Among Members of the Care Team

The need to share data among a variety of persons involved in the patient's treatment (the care team) is undisputable and now well recognized. The realization of this need required a change in mores and habits among the professions over the second half of the twentieth century. Physicians has been earlier rather possessive of the information they had ("information is power"...).

Stiennon notes, "Scientific and technical development has resulted in the need to accommodate the imprescriptible duty of confidentiality. Indeed, confidentiality is complicated by the fact that the flow of information is in the very interest of the patient. New confidentiality problems have also arisen from the computerisation of health administration. In the management of health problems and the prevention of diseases, government can intervene in the confidentiality domain" (Stiennon, 2009, p. 168).

In a time of high sensitivity to appropriate protection of personal private data (medical data are particularly sensitive), the desirable practice of "shared secrecy" has limits to be observed. The main one it that each member of the team has access only to the information needed in order to fulfill adequately his/her role/mission in the diseased person's treatment. Shared confidentiality shall not mean that everybody on the team can peruse any part of the file. This represents challenges and demands strict measures (passwords, etc.) in an age of computerized medical documents – see also what is said above of the respect of patient privacy by care providers.

Waiving Confidentiality When Others' Interests Are Seriously at Stake

There are situations where it appears desirable or necessary, as the case may be, to give others information covered by medical confidentiality. Flowing from the principle that

the patient is the master of the secret, the golden rule is to first obtain consent before the data is forwarded to others who have a significant interest in being informed.

Both the public authorities (health authority especially) as well as private individuals might have such an interest. The following examples are meant to illustrate this point:

- A number of communicable diseases need to be brought to the attention of the health authority in order to take appropriate treatment, control, or prevention measures.
- It is today generally considered necessary that violence and ill-treatment of persons, especially minors and others who are under the responsibility, rule, or pressure from others (including parents and close ones) and not in a position to adequately defend themselves and their interests, should be reported to an appropriate service or authority.
- The patient might be a danger for himself/herself but also for others, especially in psychiatric situations. In most countries there are legal texts allowing hospitalizing (committing) persons even without their consent.
- There might be cases where the declarations or behavior of a patient raise the fear that he might seriously harm others. The care provider has then to judge to what extent the danger is such that information should be conveyed to persons or offices concerned.
- There are countries where by law physicians or other care providers have to report to the appropriate authorities, if they come to know of a crime (in others, and by analogy with the confidentiality duty of ecclesiastic persons, this is not the case).

From an ethical point of view, one should generally oppose a duty of health professionals to denounce persons having committed a delict or crime (while the professional keeps the faculty, if they deems it necessary, to be freed – according to the relevant legal or deontological rules – from the confidentiality duty in order to give information to concerned third parties). In 1832, the famous French surgeon Dupuytren, asked by the police to give the names of rioters, answered famously "I don't know rioters in my wards, I see only wounded persons."

This issue is similar to the one raised by the ethical principle that physicians should not participate in any way, in acts of torture or other harsh and inhuman treatments, including the death penalty.

Confidentiality and Public Health: The Balance to be Struck Between the Individual's Interest and Privacy and Possible Community Interest and Wellbeing

In a book providing explanations about the UNESCO Universal Declaration on Bioethics and Human Rights, aimed at worldwide understanding and application of its principles, Jeanine-Anne Stiennon writes, "In practice, the rights and freedom of individuals are in conflict with the exigencies of the 'common good' and with the potentialities of information technology. Examples are : screening of pathogenic

agents or diseases, genetic or immunological typing, identification of potential offenders, codes of public health, interdependent social situations (social services, social insurance, preventive medicine, hygiene, and psychiatry) The interests of certain economic sectors linked to the exploitation of data are also involved" (Stiennon, 2009, p. 167).

In the future, deciding when medical confidentiality (may) have to be opened to others, private or public, will present many questions and challenges. They are to be dealt with by considering carefully the private and public interests concerned. The next sections provide illustrations.

Practical Issues and Examples in Today's World

A Major Challenge: Confidentiality and AIDS at the Outset

AIDS was described in 1981, first as a medical rarity and enigma, and became a worldwide public health problem around 1985. Public health authorities had then to ponder a number of difficult ethical questions, as it became apparent that it was an infectious disease, transmitted mainly through quite private behaviors (sexual intercourse, intravenous drug use), which raised alarms in the public.

There were demands for the promulgation of certain legal obligations in order to limit the spread of the disease. There were discussions in the 1980s and early 1990s about compulsory and universal testing (for HIV seropositivity) in the population, of exclusion of seropositive children from kindergartens or schools, of limitation of the freedom of persons living with AIDS to move around and even of their internment in closed institutions or camps. Several countries (including the United States) required an HIV test before delivering a visa! The problems were made more acute as medicine remained practically helpless for several years. There were many fears that one could catch that terrible disease unknowingly ("without deserving it").

With society faced with a dangerous communicable disease, it was logical that professionals were required to report whether they had seen cases, how many, in which types of patients (in order to advance epidemiological research, among other things). But did public health surveillance require that the names of the patients be known? With the possible exception of particular situations, the answer is no.

Medical confidentiality was at stake from another perspective, too: what was the physician to do about the (most reasonable) wish to make sure that partners of a person with HIV seropositivity be informed of that fact – at a time when full-blown AIDS killed in 1 or 2 years. The French medical profession never admitted that it was understandable, and in a way morally compulsory, to inform at least the regular partner (entitled to expect that his/her consort not be sexually nomadic), and that medical secrecy had to be waived. French physicians went on with a rigid legal view of confidentiality, arguing that if giving such a information, even to a directly endangered person, was accepted, then the seropositive patient

would lose all trust in the health system and not seek care anymore. That might very well be true, argued others, but what about intentionally letting another person be at a mortal risk? In Switzerland, ways were devised to achieve the goal of informing regular partners; first through efforts to convince the patient to allow information to be given, then if necessary by asking the relevant authority to waive medical confidentiality.

In the UNESCO Casebook on Benefit and Harm (UNESCO, 2011b), cases 27, 28, and 30 focus on situations that went before courts in relations with HIV seropositivity having been hidden, either from the patient or from an interested third party, or on the contrary disclosed to others without the consent of the patient.

It was not easy thus for public health professionals and decision-makers to strike the right balance in a novel situation, with a number of unknowns regarding the spread of the disease. As forceful intrusions in the private sphere of individuals were talked about, one had to evaluate when and to what extent it was legitimate to invade privacy. Should there be compulsory testing? If so, of the whole population? Or, in certain groups like children in school? What about patients entering hospitals, as clinicians also were afraid? Should it be routine in persons with multiple sexual partners, in IV drugs users? In retrospect, one may say that, thanks to courageous positions by the WHO (including the late Jonathan Mann, a great advocate of human rights issues in AIDS and in public health in general), by National AIDS and Bioethics Commissions and other bodies, and by public health professionals, one could in most places avoid unjustified authoritarian measures which would have seriously jeopardized privacy and confidentiality.

Privacy and Genetic Testing

Progress in medicine, especially in genetics, poses new challenges, for example in respect to Huntington disease (known as Woody Guthrie's disease in the US), a dominant hereditary disease leading to early dementia (in the forties) and death, for which there is no therapy. Today, it is possible from childhood on to know whether a person carries the responsible gene, which represents a first ethical difficulty: may one propose to young persons that they be tested when, should the result be positive, it would mean a terrible burden for the rest of their (rather short) life. For these reasons, it is considered unethical to propose testing before the legal age of consent. In any case, prior enlightened and tactful genetic counseling is indispensable, after which the decision to test or not is taken in all liberty by the person.

Confidentiality – or disclosure – comes into play in relation with the children of a person tested positive. Should they be informed that one of their parents is a carrier, is going to die prematurely with dementia, and might have passed on to them the Huntington disease gene, which they might later on transmit to their own offspring? The person tested positive has the right to refuse that their close relations be informed but one readily sees that this opens serious questions. Similarly, one would have to ponder these questions in relation to the fiancé of a young person who has tested positive.

Similar challenges and difficulties are encountered as a result of other current advances in genetics. In the recently published UNESCO Casebook on Benefit and Harm (UNESCO, 2011b), case 26 describes a situation of a woman found with a genetically transferable disease where physicians did not take measures to have her threatened children informed.

In 1997, UNESCO adopted the Universal Declaration on the Human Genome and Human Rights (UNESCO, 1997). Articles related to privacy and confidentiality include:

> *Everyone has a right to respect for their dignity and for their rights regardless of their genetic characteristics.*
>
> *The right of each individual to decide whether or not to be informed of the results of genetic examination and the resulting consequences should be respected.*
>
> *Genetic data associated with an identifiable person and stored or processed for the purposes of research or any other purpose must be held confidential in the conditions set by law.*
>
> *In order to protect human rights and fundamental freedoms, limitations to the principles of consent and confidentiality may only be prescribed by law, for compelling reasons within the bounds of public international laws and human rights.*

Medical Confidentiality and Daily Life

Other questions are common and may touch everybody's existence. Thus, employers have a (legitimate, per se) interest to have employees who enjoy good health. Should they be allowed to get information out of the medical file of applicants for a job? No, in principle. According to the above-mentioned golden rule, job applicants have the right to ask their doctors to inform any others, including a prospective employer, but one is well advised to be careful here; one would want to be sure that there is no undue pressure involved. Is the employer even allowed *to ask* health-related questions (about physical or mental conditions) to the candidate? This is much debated.

On the other hand, there are cases where such queries are logical: one very much wants a bus driver or a pilot to have good vision. One may understand as well that, before offering an expensive additional training to a collaborator, the employer wishes to have a reasonable assurance that the person will not in the short term be limited by medical conditions. Yet, there is here a contradiction with the notion of equal chances for all which we would like to maintain and promote.

Medical Confidentiality and Health Insurance

In countries with universal social security and/or health coverage mandated by law, it is unacceptable that risk factors linked to health or disease be invoked to reduce or

diminish what the legal mandate fixes. But the situation is very different where there is no such coverage, as well as regarding complementary insurance on a private basis: in many countries those who can afford it contract additional coverage to get better than basic care. Then the insurer may ask questions – and demand answers – before agreeing to an insurance policy. In fact, in that private industry (including life insurance), the name of the game, the researched goal is to propose to the customers the most advantageous premium, as figured on the basis of the risks they represent – or not – to get sick or die prematurely. Insurers are advised to learn as much as they can about an applicant, in order to offer a low premium to good risks and high premiums – or offer a refusal – to bad risks. There is no consideration here of social solidarity, which is in principle the rule for universal coverage. Applicants may of course refuse to provide information or allow their physician to transmit medical data, but in that case they will most probably not have any proposal by the insurance.

Such situations have been frequent, and difficult, in respect to HIV/AIDS. When effective anti-retroviral therapies were introduced, a number of young seropositive persons were able to pursue professional careers, in which they often needed to contract life insurance, for example, to get loans from banks. In those circumstances, physicians faced serious dilemmas when answering insurers' questionnaires.

Medical Confidentiality and Duties of the Public Hand

Within any health care system today, there are strong pressures to contain the cost of care. Authorities and bodies supervising insurance programs ask for medical data justifying the prescriptions and acts performed, aiming at ensuring that money is efficiently used, and for the purposes it is supposed to serve. The goal is to eliminate unnecessary procedures, redundancy, and waste, wherever they may be. From a social ethics point of view, this is legitimate; we all have an interest in the relevant and economical use of means made available by the community. Confidentiality should certainly not serve to hide any wasteful use of resources. On the other hand, this objective should not allow excessive curiosity by others, which would be contrary to the interest of a patient and their treatment. A reasonable balance is to be found between what the insurer might ask and undue breach in the privacy of the care relationship.

There are requests for medical data that are justified by other tasks of the State, where one expects the authority to take adequate measures. For example the control of the driving capacity: there is a clear public interest in reducing the number of dangerous drivers on the road – be they dangerous because of drinking, some physical or mental problem, or other reasons. The right to privacy and confidentiality of the individual is thus superseded by the desirable security in traffic. Either one agrees to be medically examined and the conclusions are transmitted to those in charge of road safety or one should accept not to drive anymore.

In summary on this point: confidentiality is established to protect/preserve the privacy and interests of the patient. However, there are situations that make it necessary to waive the confidentiality when others' or the community's interests are seriously endangered.

Privacy and Confidentiality Are Threatened by Difficulties in Communication and Integration

It is increasingly recognized, all over, that persons living in an area where they were not born, and of which they do not know the socio-cultural mores and language, are for that reason quite vulnerable. They are migrant workers who, legally or not, moved to the new country, or refugees and asylum seekers, or people displaced within their own country. They are at a much greater risk of not being able to explain what their health problem is nor to understand recommendations of health personnel, and consequently not to be treated adequately. In the UNESCO Casebook on Benefit and Harm (UNESCO, 2011b), case 3 describes difficulties rising from such misunderstanding.

These situations demand the collaboration of interpreters, or cultural mediators when the problem is to understand the way things work in the new residence. In several countries there are valuable efforts in this direction. As regards our topic, one should be aware of a potential side effect of this basically useful development, that is, the threat to the patient's privacy through the presence and intervention of a third person. The interpreter or mediator, though knowing the person's language and culture, might be reluctant to render exactly declarations which he or she finds awkward or even offensive (because "these are things which are not said or done in our original culture"). Also, a woman might very well not be willing to talk of a gynecological problem through a male interpreter. An adult might not accept translation by a youth. Interpreters must be aware of and respect the confidential character of what happens in the care relationship. They must understand that they have to transmit the message neutrally, without modifying it. Furthermore, the translation might simply be inaccurate or the health provider might misunderstand. There are here growing challenges in today's increasingly diverse and mobile societies.

Confidentiality and the Health Status of Persons Assuming High Office or Other VIPs

On several recent occasions, there have been rumors, concerns, and questions around the health of elected officials, including heads of State (e.g., President Georges Pompidou in France in the 1970s). The issue is to evaluate whether there is a *public interest* of the concerned citizens to be informed when a person with major political duties is hampered in his or her capacity to carry out the responsibilities they have been elected to. Does the public have a right to know, and if yes, to what extent? The main opinion today is that there is such a right. How rapidly it should be done and with which degree of detail should be evaluated in the particular case. Whether the same might hold true too for members of the "people crowd," movie stars, singers, writers is of less momentous importance. There, the potential unfortunate consequences of not knowing appear more related to the fans' sorrow or of a commercial nature. Contrary to the situation of major political decision makers, the reasons to request a "right to know" do not appear compelling at all in these cases.

To What Extent Is the Intervention of the State Legitimate in Highly Private Situations, for Example, at the End of Life?

There is an ongoing and necessary ethical debate about the extent to which the public authority is entitled to take compulsory measures vis-à-vis certain diseased persons (e.g., with psychiatric or addictive conditions). When, how, and in which circumstances might the State pretend to know better than the individual what is good for him or her? This is an important issue regarding the individual's right to privacy.

Until a few years ago, France had a law mandating premarital medical examination. As a measure ordered by the State, it came to be considered an inappropriate intrusion in the private life of individuals and was abolished. Needless to say, engaged people who freely decide to undergo a premarital examination show responsibility and are perfectly welcome. But, then, they are well advised to agree beforehand that the physician(s) are authorized to transmit possible pathological information both to the person concerned and to his or her partner. Case 30 of the UNESCO Casebook on Benefit and Harm describes the unfortunate consequences of a situation where the sick member of the couple did not inform his partner of the finding and where the doctor had not been given the mandate to inform her (UNESCO, 2011b).

Suicidality presents another illustration. Health care providers and society generally, have a general "mandate" to prevent suicide. However, putting an end to one's own life is also, in a way, a right. Almost all countries that earlier criminalized suicide (attempts) have abrogated such laws. Further, there is agreement that some suicides are understandable, "reasonable," given heavy and painful life circumstances – with a high degree of dependence, despondency, and no hope for recovery. One may talk of "stock-taking suicide," In some states in the US and in several European countries (Belgium, Luxemburg, Netherlands, and Switzerland), people with intractable suffering have the right to seek assistance for a suicide (though no right to require that it be given), and such assistance by third parties is not punished. The need there is to define a reasonable balance between the measures that public health might take to prevent suicide (e.g., of young persons under the effect of transitory stress or misfortune) and possibly undue and authoritarian limitations of the right of persons to decide over their own lives – their privacy.

About the Right Not to Know

Sigmund Freud is said to have told his physician, when the latter announced that he had diagnosed a cancer of the tongue, "Who authorized you to tell me that?" The right not to know is a generally recognized right. It follows from the principles of autonomy of the person, of consent (or refusal) and is linked to privacy. The patient is free to say, "Doctor, I trust you to do the best for me, whatever the diagnosis and available treatments, but I don't want to be informed" (especially, one assumes, in the case the findings and prognosis are severe). There are, however, cases where this raises questions. As mentioned above, the AIDS epidemic,

particularly when no therapy was available, generated much discussed ethical dilemmas. One is confronted with comparable issues in relation with less symbolically loaded communicable diseases as well as with hereditary conditions.

There might be other dilemmas for the physician and care team: suppose the discovery of a severe condition with bad prognosis in a young 40-year-old entrepreneur full of perspectives and projects. It is this patient's right not to be informed; yet he might have wife and children and the consequences of an announced death may be less devastating in several respects than if unannounced. Not knowing the threat to his life, he might engage in new investments that might become wasted; his business might lose much of its worth would he insist on managing it with a severely altered health. While the care provider's mission is not to take responsibility for all aspects of the patient's life, he is concerned with his general wellbeing.

Summarizing: patients are entitled not to know and to leave their close ones in ignorance but, in situations like the one described, for the professional to think of ways to discuss the possible consequences of deliberate ignorance is at least legitimate.

And After Death?

An important point is that the requirement for medical confidentiality is not cancelled by the death of the patient. Ethical and legal provisions remain the same, as well as the possibilities to be released from it – as mandated by law or if specific circumstances demand it (with no possibility then to follow the above-mentioned "golden rule" of the patient's consent as he or she is no longer in a position to give it).

Conclusion and Perspectives

The whole domain of privacy and confidentiality in health care and research has been marked in recent decades by the emphasis put on human rights. First, with the emergence of charters and laws about patients' rights, whereby the former deontological rules, elaborated and applied (arbitrarily as the case may be) by a profession, were replaced by public law – with therefore a democratic legitimacy.

Future challenges are, in particular, at the interface between traditional confidentiality, with the primary goal to protect the patient's interests, and the consideration of the interests of third parties. In some cases, these third parties are family members and close ones, in others cases they are persons the patient comes into contact with – in areas as diverse as communicable diseases, ill-treatment and battering of others, especially children, or traffic safety – or the community at large (public health problems).

There are delicate questions around the right not to know and whether to hide from concerned close ones information that is of importance for their own lives.

With increased emphasis on the respective rights and duties of patients and care providers, the latter might now more than in the past insist on protecting their own privacy. On the other hand, whistle blowing about incompetent professionals is now asked for. Others whose privacy is in jeopardy (unwillingly or sometimes willingly) are persons in very visible and looked upon positions: elected officials, people of the business or media worlds. For some of them, a legitimate public interest to know may be invoked.

In research, the widespread use of computerized banks, including biobanks, results in storage of ever larger amounts of data and samples of many sorts. This poses challenges in terms of informed consent for their use – when, for example, a new study is envisaged, which was not foreseen when they were collected, as well as questions in terms of privacy. Use of anonymized material has its own delicate issues.

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Non-discrimination and Stigmatization

10

Nouzha Guessous

Introduction

Justice and equality are two founding principles of universal human rights. Any attempt to infringe these principles is considered as an infringement of human dignity.

The equality principle implies the duty of equal treatment of any individual or group irrespectively of their particular characteristics. Based on the uniqueness of every human being and the duty of respect for human diversity, the nondiscrimination principle aims to ensure that no criteria or situation produce effects, which systematically disadvantage persons or groups possessing those characteristics or living under those situations. Historically speaking, slavery and all kinds of racism and xenophobia demonstrated dramatically the possible harms of discrimination.

Thus, the principle of nondiscrimination has been introduced from the very beginning of international attempts to institutionalize the human rights philosophy at a universal scale.

Obviously, as bioethics is an extension of human rights philosophy to the field of medicine, life sciences, and associated technologies, the nondiscrimination and nonstigmatization principles have been affirmed and considered as guiding principles in all discussions, documents, and legislations.

UNESCO has called on the nondiscrimination and nonstigmatization principle in almost all documents related to bioethics including the Universal Declaration on Bioethics and Human Rights (UDBHR) adopted in 2005.

Article 11 of the UDBHR states: "No individual or group should be discriminated against or stigmatized on any grounds, in violation of human dignity, human rights and fundamental freedoms."

This article addresses two issues: discrimination and stigmatization. Both deal with infringement of the equality principle and are considered as violations of human dignity, human rights, and fundamental freedom.

N. Guessous
Department of Medicine, Hassan II University, Casablanca, Morocco
e-mail: nouzhaguessous@gmail.com

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The application of this article either in research or healthcare practice will have to deal with a major difficulty related to the fundamental problem of identifying precisely what is to be considered as discrimination. Some practices can be perceived differently from one context and culture to another. Thus, this article in the UDBHR is closely related to Article 12 on respect for cultural diversity, and the main concern is to identify ethical limits so that this article could not be invoked to justify any discrimination and stigmatization of persons or groups.

Finally, in each of these contexts, it is important to identify the relationship between Article 11 and others in the declaration.

Some Definitions

Discrimination

The word "discrimination" comes from the Latin "discriminare" which means to "distinguish between."

To discriminate socially is to make a distinction between people on the basis of class or category or individual character without regard to individual merit, which is an infringement of the ethical theory of egalitarianism based on social equality.

Distinction between people based on individual merit (such as personal achievement, skill, or ability) is generally not considered socially discriminatory.

In contrary, distinctions between people based on race, social class or caste, nationality, ethnicity, religion, sex, sexual orientation, height, age, social conditions, physical or mental disability, diseases or genetic characteristics, or any other ground are generally considered in the whole corpus of human rights law as discriminatory and as a violation of human dignity, human rights, and fundamental freedoms.

Nondiscrimination

The concept of nondiscrimination is a social as well as a legal concept of long standing within human rights law. It requires the equal treatment of an individual or group irrespective of their particular characteristics. It is used to define and legally prohibit any criteria that may produce effects which systematically disadvantage persons possessing those characteristics.

The general aim of this principle is that in any decision or practice, no one shall be subjected to discrimination based on any grounds, including physical, mental, or social conditions, diseases or genetic characteristics, nor shall such conditions or characteristics be invoked or used to stigmatize an individual, a family, or a group.

Positive or Reverse Discrimination

There are several examples of discriminatory policies or acts that benefit a historically and sociopolitically nondominant group (typically women and minorities but sometimes majorities), at the expense of a historically and sociopolitically dominant group (typically men and majority races). Originally called "positive or reverse discrimination," international bodies are now used to call it "affirmative action policies." Such actions can be in any field to facilitate the access of vulnerable people to their rights including those related to health.

However, whether a given example of discrimination is positive or negative is often a subjective judgment.

Stigmatization

The word "stigmatization" is related to the word "stigma." Among other definitions (Rivard, 2009), stigmatization is defined by the Oxford English Dictionary Online as a "distinguishing mark or characteristic (of bad or objectionable kind)." The verb "to stigmatize" is defined as to "call by a disgraceful or a reproachful name; to characterize by a term implying severe censure or condemnation."

The concept of "stigmatization" is a social rather than a legal concept.

According to the *Encyclopedia Britannica*, "stigmatization" is a discrediting process which strikes an individual who is considered as "abnormal" or "deviant." He or she is reduced to this single characteristic in other people's eyes or opinions for whom this "label" justifies a range of social discriminations and even exclusion. The social impact of stigmatization shows a number of negative behaviors toward stigmatized people that can end in real discrimination as regards, for example, access to social services such as healthcare and education, employment and professional advancement, income level, and domestic life.

In the field of health, the concept of stigmatization has been frequently used in the work of WHO, especially in relation to HIV and AIDS, but also in contexts like mental health, genetic characteristics, diseases, or any other situation where a single physical or biological or a health character may be looked at as "bad" with a range of social and even legal negative impacts.

In the field of bioethics, UNESCO recognizes stigmatization as a distinguished kind of discrimination that may have a serious impact on the right to health and benefit of scientific research. It refers to any characteristics that may interfere negatively with a person or a group and infringe his/her/their right to access and benefit from the progress of "medicine, life sciences and associated technologies." In this perspective, stigmatization is a violation of human dignity, human rights, and fundamental freedom.

For some authors, the concept of stigmatization amounts to limited or indirect kind of discrimination but not as understood in international law (Rivard, 2009).

International Human Rights Instruments on Discrimination and Stigmatization

The *Universal Declaration of Human Rights* (1948) clearly stated the equality among humans by proclaiming in Article 1 that "All human beings are born free and equal in dignity and rights." Equality is therefore the basic fundamental principle of human rights philosophy. The same declaration stated in Article 2 that "Everyone is entitled to all the rights and freedoms set forth in this Declaration, without distinction of any kind," thus starting the concept of nondiscrimination among humans in any issue.

Article 7 specifically addresses the issue of discrimination "All are equal before the law and are entitled without any discrimination to equal protection of the law. All are entitled to equal protection against any discrimination in violation of this Declaration and against any incitement to discrimination."

The recognition of this principle was historically extended to all kind of domains and rights including socioeconomic and political rights. It is stated in many national constitution laws as well as in several regional and international instruments approved via intergovernmental organizations.

Many other conventions have further addressed discrimination in socioeconomic, political, and cultural rights, and others addressed issues of discrimination based on specific grounds: racial, sex and age. The *International Convention on the Elimination of All Forms of Racial Discrimination* of 21 December 1965 and the *Convention on the Elimination of All Forms of Discrimination against Women* of 18 December 1979 are the two major examples.

Without any attempt to create new human rights with new grounds of discrimination, or to duplicate the entirety of established international law, every specific instrument of bioethics has been embedded within this larger body of international human rights law.

Discrimination and Stigmatization in International Instruments on Bioethics

The twentieth century is sadly full of examples of harmful practices in the field of health and medical and scientific research based on several grounds of discrimination. The most famous drama occurred during the Holocaust and gave birth to the Nuremberg Code (1948) followed by several other professional, national, regional, or international instruments.

Within its mandate as defined by its constitution, UNESCO has been engaged in the ongoing global debates under the broad rubric of bioethics, beside a number of other international and regional organizations such as the World Health Organization, the World Intellectual Property Organization, the World Medical Association, and the Council of Europe. UNESCO aims mainly to provide guidance to member states for the elaboration of their laws and regulations.

UNESCO's work in the field of bioethics called on the established standard-setting corpus and other international human rights instruments adopted by the United Nations and specialized agencies of the United Nations system as well as the other international and regional instruments, international and national legislation, regulations, codes of conduct, guidelines, and other ethical texts in the field of science and technology.

The concept of stigmatization could appear as a label of the UNESCO input. It was added as a principle to the general body of international human rights law as UNESCO declarations in the field of bioethics were the first international instruments related to human rights to use this concept.

Nevertheless, UNESCO consider that "questions of bioethics, which necessarily have an international dimension, should be treated as a whole, drawing on the principles already stated in the Universal Declaration on the Human Genome and Human Rights and the International Declaration on Human Genetic Data and taking account not only of the current scientific context but also of future developments" (10th paragraph of the preamble of the UDBHR).

Nondiscrimination and Stigmatization in UNESCO Declarations

To date, UNESCO produced three declarations that dealt with bioethical issues:

1. The *Universal Declaration on the Human Genome and Human Rights* (UDHGHR) adopted by the General Conference of UNESCO in November 1997
2. The *International Declaration on Human Genetic Data (IDHGD)* adopted by the General Conference of UNESCO in October 2003
3. The *Universal Declaration on Bioethics and Human Rights (*UDBHR) adopted by the General Conference of UNESCO in October 2005

The preambles of the three declarations endorse the main related international, regional, and professional instruments of bioethics and human rights.

- *The UDHGHR* dealt with discrimination in Article 6: "No one shall be subjected to discrimination based on genetic characteristics that is intended to infringe or has the effect of infringing human rights, fundamental freedoms and human dignity."

Article 2 makes a direct link between genetic data and the risks of discrimination by proclaiming that

> "(a) Everyone has a right to respect for their dignity and for their rights regardless of their genetic characteristics.
> (b) That dignity makes it imperative not to reduce individuals to their genetic characteristics and to respect their uniqueness and diversity."

However, the UDHGHR did not call on the concept of stigmatization.

- *The IDHGD* dealt with the two concepts of discrimination and stigmatization in paragraph (a) *of* Article 7: "Every effort should be made to ensure that human genetic data and human proteomic data should not be used for purposes that discriminate in a way that is intended to infringe, or has the effect of infringing

human rights, fundamental freedoms or human dignity of an individual or for purposes that lead to the stigmatization of an individual, a family, a group or communities."

The paragraph 6 of the preamble recognizes that genetic characters may clearly expose an individual or a group to discriminatory actions both in their general life and in the issues of health and life sciences. They also may be cause of stigmatization: "Human genetic data have a special status on account of their sensitive nature since they can be predictive of genetic predispositions concerning individuals and that the power of predictability can be stronger than assessed at the time of deriving the data; they may have a significant impact on the family, including offspring, extending over generations, and in some instances on the whole group; they may contain information the significance of which is not necessarily known at the time of the collection of biological samples; and they may have cultural significance for persons or groups."

Thus, Article 3 on "person's identity" states: "Each individual has a characteristic genetic make-up. Nevertheless, a person's identity should not be reduced to genetic characteristics, since it involves complex educational, environmental and personal factors and emotional, social, spiritual and cultural bonds with others and implies a dimension of freedom."

- *The UDBHR* went further to proclaim nondiscrimination and nonstigmatization as universal principles of bioethics and human rights in Article 11.
- *Additional UNESCO documents* dealt with nondiscrimination and nonstigmatization. Further to the adoption of the UDBHR, the UNESCO Division of Ethics of Science and Technology has published a Bioethics Core Curriculum set out to introduce the bioethical principles of the Universal Declaration on Bioethics and Human Rights to university students. The primary target group of the core curriculum is medical students. Available on the UNESCO website, the core curriculum consists of two sections.

Section 1 provides the core contents with objectives, syllabus, and teacher manual for each unit of the curriculum.

Section 2 contains the proposed study materials for each unit of the curriculum.

The core curriculum is organized in units. Unit 11 is dedicated to the nondiscrimination and nonstigmatization principle.

Grounds of Discrimination and Stigmatization in Bioethics

In the field of healthcare and bioethics, some groups need more protection such as infants and elderly people, AIDS patients, psychiatric patients, and depressed patients.

The list of grounds of discrimination differs markedly from an international human rights instrument to another, starting from the UDHR. Arguably, the drafters of the UDBHR declined the proposal of identifying major grounds that are pertinent to the field of bioethics, in favor of a wording that makes it clearly embedded within

the established international law of human rights. This is why the enumeration of specific grounds has been dropped from the fourth draft of the declaration. This was based on the fact that any list would either be incomplete or even be seen as a way of creating new grounds of discrimination (Rivard, 2009).

This implies that the identification of the most pertinent grounds to the field of bioethics will be up to the implementation step and according to specific contexts of UNESCO member states.

1. Poor and vulnerable individuals and groups may be discriminated in the sense of suffering of deep inequalities in their right to access to healthcare services. A common argument in favor of positive actions toward those vulnerable persons is that it can correct some of these inequalities, while some opponents claim that it can create dependence and a sense of entitlement. Nevertheless, it can create a sense of discrimination for those who are excluded from the programs.

Case Study: Positive Discrimination for Poor Minorities
In a poor multiethnic country with limited health and economic resources, the government decided to give priority for primary healthcare to poor nomads of the desert minorities. For instance, specific funds will be allocated for the prevention, diagnosis, and care of trachoma and infantile diarrheal diseases.
(From Nouzha Guessous experience)

2. Advances in medical technology have the potential to create disproportionate disadvantages for some social groups, either by being applied in ways that harm members of these groups directly or by encouraging the adoption of social policies that discriminate unfairly against them with significant individual, social, and legal consequences.

For instance, reproductive medicine has developed techniques that enable parents to choose the sex of their child which raises the concern of discrimination against girls and women in societies where male children are valued more highly than female children. Similar concerns have been raised about the increasing use of abortion as a method of birth control in overpopulated countries where there is considerable social and legal pressure to limit family size. On the basis of cultural and/or socioeconomic background, in several parts of the world, there is a strong preference for male children. Prenatal diagnosis (PD) through chorionic villus sampling and direct fetal sexing or early ultrasonography are means to determine the fetal sex allowing couples to abort a fetus of a nondesired gender. PGD technology is used for this purpose as well, although only by a small elite that can financially afford it. According to the European Society of Human Reproduction and Embryology (ESHRE) 2002 Report, 70 % of the participating centers oppose the idea of embryo sexing and authoritative clinical geneticists have made a plea to limit PGD to medical indications.

In the 2003 report on preimplantation genetic diagnosis (PIGD), the UNESCO-IBC concluded as follows: "It is recommended that PGD be limited to medical indications. Therefore sex gender selection for non-medical reasons is considered to be unethical" (IBC-UNESCO, 2003).

Sex Selection in India

Prenatal testing and termination is the main problem in India, where its use has led to the ratio of girls to boys declining to 927 girls to 1,000 boys in 2001. In some regions, the ratio is as low as 800 per 1,000.

Sex selection is the exercise of sexism at the most profound level, choosing who gets born, and which types of lives are acceptable. In traditional patriarchal societies, such as in India and China, the preference for boys has led to huge imbalances in the sex ratio in the population. Worldwide, there are estimated to be 100 million missing women as the result of sex selection. Indian communities in the USA and the UK are now being targeted by clinics which have no scruples about exploiting these traditional prejudices for profit. In Western countries, there seems to currently be a preference among the majority white communities for girls, but the choices that are being made are still based on rigid, sexist, gender roles. Even in the case of "family balancing" (where a family has one or more child of one sex and wants a child of the opposite sex), which the HFEA views as relatively acceptable, rigid gender expectations are clearly operating. In how many cases where parents are "desperate for a girl" will they be hoping for a loud tomboy that grows up to be an engineer? Society must continue to fight sexist gender, not allow them to dictate who is born.

(From http://www.hgalert.org/sexselection.PDF)

3. Gender discrimination extends to many other areas both in the access to healthcare and to benefit from research. As women live longer in many parts of the world, elderly women might find themselves abandoned by their families, subject to inadequate healthcare, and disregarded by society. The prevalence of some diseases among mid-aged women may induce national positive actions to the exposed population.

Case Study: Positive Discrimination of Low-Income and Uninsured Women to Prevent Breast and Cervical Cancer

The national program for early detection of breast and cervical cancer in country A was designed to reduce disparities in mortality due to cancer by targeting primarily low-income and uninsured women.

The program has delivered notable improvements in access to screening for low-income women minority groups that could not benefit from the diagnosis campaigns in the 2000s with an emphasis on overrepresentation of women originating from rural areas.

This result was obtained at the expense of an underrepresentation of other women.

(From Nouzha Guessous experience)

4. Dominant moral and cultural habits and even legal dispositions may deprive adult women their personal authority to make important life and healthcare decisions.

Case Study: Discrimination and Stigmatization on Cultural-Based Grounds

MZ, aged 20, has come to Dr. NG for testing of her status for pregnancy and for sexually transmitted infections. She explains that her brother's friend has been sexually abusing her 1 week before. She further explains that, when she complained to her parents, they angrily denied the possibility and accused her of flirting and being sexually provocative. MZ lives with her family in a small village where the community is religiously devout, so any sexual scandal involving police or other authorities would be very stigmatizing. MZ asked for a prescription of an emergency postcoital contraception. She was very scared and asked that her parents not be informed of her visit because this would confirm their suspicions of her immorality.

(From Nouzha Guessous experience)

It may also deprive women from their right to equal access to healthcare services.

Case Study: Discrimination on Moral Grounds

In community A, any sex outside marriage is very strongly condemned, particularly for women. Furthermore, this community lives in a village with very limited health resources and is both poorly staffed and equipped in hospitals and delivery facilities. One evening, two women, Ms. KW and Mrs. MZ, came for delivery, with Ms. KW arriving shortly before. Ms. KW was known in the village as a sex worker and that she was pregnant as a single mother meaning that the father of her child was unknown.

Given the lack of resources, the administrators of the delivery hospital decided to give priority to Mrs. MZ as she was legally married and to refer Ms. KW to another maternity ward, approximately 2 h drive on non-asphalted road from village A.

(From Nouzha Guessous experience)

5. Migration and situations of war or civil conflicts also affect women especially. They are often vulnerable to abuse and to be deprived from their right to be part of the process for conflict resolution and reconciliation. The report of IBC on the principle of respect for human vulnerability and

personal integrity (IBC-UNESCO, 2011) provides an account of the principle of respect for personal integrity (Article 8 of the UDBHR) and the need to protect those who are especially vulnerable. As one of the most important examples of special vulnerabilities, IBC more specifically deals with the position of women, in particular migrant women and women affected by war who are especially vulnerable to the risk of being unwanted, uncared for, abused, and rejected (IBC-UNESCO).

6. In the field of genetics, the use of relatively simple tests for determining a patient's susceptibility to certain genetically transmitted diseases has led to concerns that the results of such tests, if not properly safeguarded, could be used in unfair ways by health insurance companies, employers, and government agencies. In addition, through genetic counseling, prospective parents can be informed about the chances that their offspring will inherit a certain genetic disease or disorder; this will enable them to make more informed decisions about reproduction. This is viewed by some bioethicists and some NGOs as contributing to a social atmosphere considerably less tolerant of disability than it ought to be. The same criticism has been leveled against the practice of diagnosing, and in some cases treating, congenital defects in unborn children.

Genetics Privacy and US Legislation

In 2008, the "Genetic Information Nondiscrimination Act" (GINA) passed by the US Senate prohibits US insurance companies and employers from discriminating on the basis of information derived from genetic tests. GINA protects Americans from discrimination based on information derived from genetic tests. It forbids insurance companies from discriminating through reduced coverage or pricing and prohibits employers from making adverse employment decisions based on a person's genetic code. In addition, insurers and employers are not allowed under the law to request or demand a genetic test.

(From http://www.ornl.gov/sci/techresources/Human_Genome/elsi/legislat.shtml)

Special attention should be paid to the so-called research on the genetic bases of behavior. It is controversial though it is still in its infancy because of its potential to encourage the adoption of crude models of genetic determinism in the development of social policies, especially in the areas of education and crime prevention. Such policies, it is claimed, could result in unfair discrimination against large numbers of people judged to be genetically disposed to "undesirable" forms of behavior, such as aggression or violence.

7. Medical research in general is also a domain where groups of population or patients may be subject to discrimination. The Tuskegee experiment is one of the most famous cases.

Case Study: The Tuskegee Experiment

In 1932, the US federal government of Alabama launched into a medical study called "The Tuskegee Study" of untreated men with syphilis. At that time, penicillin was proved as an efficient treatment. The study selected 412 poor African Americans men infected with the disease and faked long-term treatment, while really only giving them placebos and liniments. The premise of the action was to determine if blacks reacted similar to whites to the overall effects of the disease. The experiment lasted 40 years and was only discontinued in 1972 when a Senate investigation was initiated. The survivors of the study did receive treatment and financial compensation after the Senate investigation.

(Based on the true story of the decades – long Tuskegee experiment, a movie, Miss Evers' Boys (Director: Joseph Sargent), was adapted from the 1992 stage play written by David Feldshuh).

Limitations of the Principle of Nondiscrimination and Stigmatization

Article 26 of the UDBHR specifies the general framework of these limitations. "The Declaration is to be understood as a whole and the principles should be understood as complementary and interrelated." This implies that if a bioethical issue or problem emerges, it is usually the case that several principles are relevant to the issue or problem and need to be balanced in order to reach a justified conclusion about what to do.

Article 27 specifies the limitations on the application of the principles. It mentions several conditions in which application may be limited by law:

- "in the interests of public safety,
- for the investigation, detection and prosecution of criminal offences,
- for the protection of public health,
- for the protection of the rights and freedoms of others.
- Any such law need to be consistent with international human rights law."

Therefore, when public health is at risk, exceptions or restrictions to the nondiscrimination principle can be necessary either by "affirmative" actions in favor of some key persons or groups or by "negative" actions that may infringe upon individual rights. These exceptions must be publicly discussed and applied with transparency and according to the national law. They also must be subject to revision according to developments of the situation and scientific knowledge.

Interrelation of Article 11 with Other Articles in the Declaration

As with the entire Declaration on Bioethics and Human Rights, the understanding and the implementation of this article requires to be built in the context of the entire instrument, as stated in Article 26 above mentioned.

The provisions of Article 1 pertaining to the scope of the declaration cover those of Article 11 on nondiscrimination and nonstigmatization.

The injunction against discrimination and stigmatization is in reference to the resolution of "ethical issues related to medicine, life sciences and associated technologies as applied to human beings" with consideration of "social, legal and environmental dimensions." It applies to states, individuals, and organizations.

To be coherent with the declaration, Article 11 is to be read and implemented as a theoretical and practical continuation of Articles 3 (human dignity and human rights) and Article 10 (equality, justice, and equity). Whatever it may be built on, discrimination is against human dignity and human rights in general, and it infringes the principles of equality of all humans and of their right to justice and equity.

Article 12 (respect for cultural diversity and pluralism) is closely related to the issue and risks of discrimination and stigmatization based on cultural considerations, rules, and habits. Therefore, it clearly affirms that "such considerations should not be invoked to infringe upon human rights and fundamental freedoms."

Stigmatization on cultural grounds: Circumcision of girls

In some communities, a girl who is not "circumcised" may be stigmatized.

Mothers usually maintain such tradition under the justification that if they do not circumcise their daughter, these later will be considered negatively by members of her wider family and by her young peers and that she will not be eligible for marriage. This is facilitated by the fact that there are usually no legal prohibitions in the jurisdiction that ban the practice in the communities where the circumcision is practiced.

Because of the risks of such intervention, some mothers bring their daughter to medical doctors. They argue that if the medical doctor does not agree to perform the circumcision, the grandmother or a traditional birth attendant will undertake the procedure herself by customary unsafe and risky means responsible of severe bleeding and infection.

Finally, the duties of nondiscrimination and nonstigmatization are necessary for the comprehension and implementation of the principles of solidarity and cooperation (Article 13), social responsibility (Article 14), and sharing benefits among humans (Article 15).

Conclusion

In bioethics like in human rights philosophy, the principle of nondiscrimination is based on the understanding that discrimination is socially constructed rather than "natural." This recognizes the need and paves the way for concerted action against inequality and the institutional mechanisms which perpetuate it. It also aims to fight against any discrediting process which stigmatizes an individual or a group who is reduced to a single characteristic in other people's eyes or opinions for whom this

"label" considered as "abnormal" or "deviant" justifies a range of social discriminations and even exclusion.

This is to be understood, implemented, protected, and promoted, at national and international level, in accordance with the whole set of principles in the UNESCO Universal Declaration on Bioethics and Human Rights.

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Respect for Cultural Diversity and Pluralism

11

Ruth Macklin

Introduction

Our world is culturally, politically, and ethically pluralistic. Several major world religions, with numerous adherents, exist side by side in many countries, along with numerous smaller religious groups. Ethnic and cultural groups abound, with a wide variety of norms and customs. Countries – and even states or provinces within countries – have different political and economic systems, each with its own structure of laws and regulations. But it is not only in these respects that our world is pluralistic. Pluralism refers also to the ways different nations order the relations between state, religion, and citizens. Some nations, such as the United States of America, have a constitutionally protected separation between church and state. Others, such as Iran and Israel, have an official state religion, with formally recognized, state-supported religious laws and institutions, observances, and parochial education. The growth of multicultural societies and an increasingly globalized world have prompted a call for cultural sensitivity and respect for different traditions. With vastly increased immigration from developing to industrialized countries, nations that were predominantly homogeneous in the past have had an influx of immigrants from Africa and Asia. It is, therefore, uncontroversial to urge respect for cultural diversity and recognition of pluralism in a globalized world.

All cultures comprise members who adhere to their norms and practices to a greater or lesser extent, and individuals may have overlapping cultural identities. They may be members of an ethnic minority within a religious majority in a population. Alternatively, individuals may be members of an ethnic or a racial majority but a religious minority. The fundamental ethical principle, "respect for persons," implies that such respect includes recognition of the beliefs people hold and the actions they perform in conformity with their membership in a culture.

Several paragraphs in this chapter are extracted from my book, *Against Relativism: Cultural Diversity and the Search for Ethical Universals in Medicine*. New York: Oxford University Press, 1999.

R. Macklin
Department of Epidemiology & Population Health, Albert Einstein College of Medicine, Bronx, NY, USA
e-mail: ruth.macklin@einstein.yu.edu

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The UNESCO Universal Declaration on Bioethics and Human Rights makes reference to cultural diversity in Article 12, entitled "Respect for cultural diversity and pluralism." Article 12 states: "The importance of cultural diversity and pluralism should be given due regard. However, such considerations are not to be invoked to infringe upon human dignity, human rights and fundamental freedoms, nor upon the principles set out in this Declaration, nor to limit their scope." The caveat in this last sentence sets out the task for anyone seeking to comply with the UNESCO Declaration and at the same time express respect for cultural diversity. It requires determining which cultural norms and practices related to human health and medicine in our diverse world do not deserve respect or adherence because they violate human rights or universal ethical principles.

Several contexts related to bioethics exist where respect for cultural diversity may arise. The first is within a multicultural country or city characterized by large numbers of recent immigrants from other countries or cultures. Clinicians and biomedical researchers residing in the city or country face an immigrant population with values, beliefs, and practices that medical personnel may not have encountered previously. One example is the prohibition in some traditional cultures for a woman to undergo a medical examination by a male physician. A second context is that of multinational research, in which the sponsor is typically from an industrialized country or the pharmaceutical industry and the research participants are from a developing country with different cultural norms or values. A third context is that in which physicians from industrialized countries bring medical students or residents to a developing country to provide humanitarian aid and often at the same time, education and training for the students in a different cultural setting. Similar dilemmas or quandaries of cross-cultural conflict may arise in all three settings, and some situations may be unique to one or the other context.

Culture, Ethical Principles, and Moral Rules

Despite a very general understanding of the concept of "culture," it remains ambiguous and often means different things to different people. One critic of the sloppy use of the term writes that "most of the time, *culture* is a lazy, trendy substitute for a more specific word." The anthropological use of the term "refers to the total way of life of a discrete society, its traditions, habits, beliefs, and art. . ." (Clausen, 1996, p. 2). A culture, in this sense, is defined by certain features that differentiate it from other cultures.

Although it is indisputable that different nations, cultures, religious, or ethnic groups adhere to different norms of behavior, it is possible to provide an ethical analysis of social practices by seeing how they conform to fundamental ethical principles such as those embodied in the UNESCO Universal Declaration and to human rights provisions in United Nations treaties and covenants. However, this is no easy or straightforward task. Ethical principles require interpretation in their applications to specific actions or practices. The same is true for human rights provisions. Moreover, ethical principles and human rights are not the only features

that require interpretation in an ethical analysis of respect for cultural diversity. The very notion of what constitutes an ethical principle may be open to debate. Here are two illustrations.

The well-known "four principles" of bioethics – respect for persons, nonmaleficence, beneficence, and justice (Beauchamp & Childress, 2008) – are widely known in bioethics outside of "Western" countries, although they have been given various interpretations in different cultural settings. Yet, debates can arise over what should count as an ethical principle. For example, on occasion, one hears reference to the phrase, "respect for tradition," implying that it is an ethical principle. Does "respect for tradition" qualify as an ethical principle? If it does, is it on a par as a fundamental principle with "respect for persons" or the ethical imperative to strive to bring about more benefits than harms? "Maintain respect for tradition" is a customary norm in many societies and operates as a conservative force for maintaining the status quo. It also functions as a practical and possibly also a moral maxim for anthropologists conducting fieldwork. It is evident that "respect for tradition" can conflict with one or more of the well-known four principles, especially respect for autonomy.

Some traditions are ethically neutral yet are intimately bound in cultural practices. These include ceremonies of various sorts at weddings and funerals; nonharmful rituals that may include prayers, dancing, chanting, and rites of passage; and adhering to dietary laws like kosher and halal. Most of the time, these sorts of activities are ethically neutral; that is, they do not give rise to harms or wrongs to those involved. Ethics deals with how people treat one another, how governments or nongovernmental institutions treat people, and whether human beings are harmed or wronged by these treatments. Adherence to a cultural tradition may be neutral; it may harm people or it may benefit them; it may support human rights or violate them. But "respect for tradition" as a norm does not by itself constitute an ethical principle.

A second illustration of a debate over what constitutes an ethical principle is an ongoing contrast between so-called "Western" and "Eastern" principles. The guest editors of a journal issue devoted to a discussion of this pair of principles wrote: "Much has been made of the fact that the so-called Western principles of 'autonomy, nonmaleficience [sic], beneficence, justice' do not address 'compassion' and professional 'competence' as has been the case in all healing traditions for centuries" (Sass & Zhai, 2011, p. 1). Presumably, the principle that embodies the concept of compassion goes as follows: "physicians should treat their patients with compassion." If that is a moral principle, it does not seem to be uniquely "Eastern." Physicians everywhere and throughout history have been enjoined to behave compassionately (as the authors of the article acknowledge). An article that appeared in an online publication of the American College of Physicians is entitled "Why compassion is such an important part of practice." The first sentence of the article states: "Amid the daily demands of teaching and practice, it's sometimes easy to lose sight of our primary purpose as physicians: providing compassionate care to our patients" (American College of Physicians, 2011). Nevertheless, "treat patients with compassion" cannot properly be considered a general ethical

principle. It is, rather, a norm of medical practice, a moral rule for physicians in caring for patients. Arguably, it is a specific example of a rule that falls under the general ethical principle, *respect for persons*. In any case, it is no more Eastern than it is Western. Alternatively, as one author notes, "compassion is more of a virtue than a principle to Confucianism" (Cheng-Tek Tai, 2011, p. 25).

The other example of a so-called "Eastern" principle that these same authors refer to is "physician competence." This can also be cast as a moral rule: "Physicians should be competent in the practice of medicine and not exceed the skills they can competently exercise in treating patients." Arguably, this moral rule falls under the principle of beneficence: "Act so as to maximize benefits and minimize harms (to patients)." An incompetent physician is unlikely to maximize benefits but is perhaps equally likely to maximize harms. Nothing peculiarly "Eastern" or "Western" characterizes this moral rule. In any case, like "compassion," it is not a general ethical principle but rather, a moral rule subsumed under a more general principle (Beauchamp & Childress, 2008). It would be difficult to find a so-called Eastern ethical *principle* that does not have an equivalent "Western" formulation, or else is better construed as a moral rule that can be subsumed under a more general principle.

According to one position, a rigid categorization of "Eastern" and "Western" values fails to accord with the realities of today's globalized world (Joseph, 2011). A fusion of ethical principles is one possibility, leading to greater harmony. But uncertainty or even occasional harm can occur when respect for autonomy is conjoined with cultural sensitivity. The case of a Hindu woman seeking a cesarean section is illustrative. The woman, a devout Hindu, asked her obstetrician for an elective cesarean section so the baby could be born on an auspicious day in the Hindu calendar. This required that the C-section be performed earlier than at the time of a full-term pregnancy. In many traditional societies even today, physicians make the decisions and patients willingly comply (this was, of course, also true in Europe and North America for most of medical history). But in this case, adhering to the principle of "respect for persons" and at the same time showing cultural sensitivity, the obstetrician acceded to the patient's request based on her faith-based reasons. The operation was performed at 35 weeks and resulted in harms: the baby had immature lungs, required a prolonged stay in the hospital, and at great financial cost to the parents (Joseph, 2011).

Increasingly, scholars in bioethics question whether "Eastern" and "Western" principles of ethics are mutually exclusive or even readily identifiable as such (Widdows, 2011). For example, a "Western" view in bioethics not unlike the "Eastern" value that put individuals in the context of family or community is the idea of "relational autonomy" in feminist theory. The difference between these values seems to be more one of emphasis than of radically different ethical principles.

Pluralism

Just as the concept of culture can be vague or ambiguous, so too does confusion exist regarding ethical "pluralism." According to one author: "What we might call

'social pluralism' is the view that diverse and often mutually inconsistent ethical outlooks should be respected and that there may not be any single moral principle or set of principles, however basic, that all moral agents must acknowledge. Human rights, for example, may be widely acknowledged in the West, but not in other parts of the world; hence, from a social pluralist's point of view, for Western governments to try to impose standards of human rights upon non-western societies is inappropriate" (Callicot, 1995, p. 685). This author is mistaken in claiming that non-Western governments do not recognize human rights. The difference between acknowledgment of human rights by Western governments and some others lies in *which* human rights they recognize and acknowledge, not whether they recognize human rights at all.

A somewhat different concept of pluralism has been proposed in the context of multinational research. The authors of an article in the second edition of the *Encyclopedia of Bioethics* contrast ethical universalism and ethical pluralism: "Some contend that all research, wherever it is conducted, should be justified according to universally applicable standards. Those opposed to this position, while sometimes accepting certain standards as generally applicable, argue that most standards must be adapted to accommodate the mores of particular cultures; they argue for ethical pluralism. Pluralists commonly refer to the universalist position as 'ethical imperialism,' while universalists often call that of their opponents 'ethical relativism'" (Christakis & Levine, 1995, p. 1781). Although intended to be helpful in distinguishing two widely held views regarding ethics in the conduct of multinational research, this paragraph is rife with confusion. It refers to "universally applicable standards" and to "the mores of particular cultures." Nowhere are ethical principles mentioned. Are "universally applicable standards" ethical principles? If so, do pluralists reject one or more of the well-known ethical principles that govern research? And if so, do they propose to replace ethical principles with the mores of particular cultures? Do they maintain that cultural mores are on a par with general ethical principles? Without knowing what the "ethical standards" are, which mores, in particular, might override such standards, and where ethical principles enter the picture (if at all), we cannot understand what the pluralists will or will not endorse.

This conceptual confusion calls for clarification in what is meant by "ethical standards." Are all ethical aspects of research with human subjects properly considered *standards*? Should standards be universally applicable or are variations permissible according to economic, political, or cultural differences among nations? When different ethical standards exist and are potentially applicable, which ones should researchers adhere to? It is useful to distinguish between *substantive* and *procedural* ethical requirements in research. Substantive ethical requirements are those embodied in the fundamental principles of bioethics: respect for persons, beneficence, and justice. These substantive requirements are the ones that constitute ethical *standards* and should be applied universally. Examples are the requirement to obtain informed consent individually from each adult participant and the need to disclose complete information about the research maneuvers to be performed and the expected risks of those interventions. Procedural requirements,

on the other hand, may vary according to cultural and other differences in multinational research. Examples are the requirement that informed consent documents be signed and the composition of ethical review committees and their rules of procedure. Attention to the distinction between substantive and procedural ethical requirements shows that the same ethical standards can be applied across national borders, while permitting differences in specific procedures in order to respect cultural variations.

Even more problematic than confusion over the meaning of "ethical standards" is the use of the terms "ethical imperialism" and "ethical relativism" by the authors of the encyclopedia article. The charge of ethical imperialism is clearly a condemnation; it implies that the perpetrator is acting like a colonial power in imposing a governmental system or way of life on a conquered or subordinate state or population. "Ethical relativism," when used in this context, refers to a philosophical doctrine: the view that whatever a culture *believes* is ethically right *is*, therefore, ethically right for that culture. One application of ethical relativism holds that rules governing research practices may vary according to the cultural norms accepted in the country in which the research is carried out. Respect for diversity underlies this form of ethical relativism, which rejects the notion that a single set of ethical standards for research should prevail in our culturally diverse world. Ethical relativism has defenders and critics. However, no one is likely to come to the defense of "ethical imperialism," since the very concept of imperialism is one of denigration.

These same authors are clearer when they provide examples of the contrast they intend between universalists and pluralists. Again, addressing multinational research, they invoke the *Declaration of Helsinki*: "Pluralists call attention to the fact that the *Declaration of Helsinki* reflects a uniquely Western configuration of a number of key ethical points; in particular, the declaration has a largely Western view of the nature of the person and, as such, it does not adequately guide investigators to show respect for persons in non-Western settings" (Christakis & Levine, 1995, p. 1782). Much of the discussion that follows in the article rehearses the oft-repeated arguments about how different cultures have different concepts of what constitutes a person, with implications for informed consent to research. Not only the *Declaration of Helsinki* (World Medical Association, 2008), but every other document that addresses research with human beings requires that individuals provide their informed consent to be enrolled as research subjects except in cases where they lack capacity or have diminished autonomy. Cultural norms that might militate against this requirement exist in cultures in which adult women are not permitted to make health-care decisions or participate in research on their own. In some Islamic societies and other traditional groups, women's behavior is controlled by their husbands or other male guardians. If the so-called pluralists come to the defense of cultural mores such as this, they are not only in violation of international ethical standards for research, such as the *Declaration of Helsinki*, but they also transgress the most basic provisions of human rights treaties and covenants.

Human Rights

The most relevant human rights document with respect to cultural practices regarding women is the *Convention on the Elimination of all Forms of Discrimination Against Women* (United Nations, 1979). Article 2 of the Convention says:

States Parties condemn discrimination against women in all its forms, agree to pursue by all appropriate means and without delay a policy of eliminating discrimination against women and, to this end, undertake:... To establish legal protection of the rights of women on an equal basis with men and to ensure through competent national tribunals and other public institutions the effective protection of women against any act of discrimination; [and]... To take all appropriate measures, including legislation, to modify or abolish existing laws, regulations, customs and practices which constitute discrimination against women (United Nations, 1979).

Several articles in the UNESCO *Universal Declaration on Bioethics and Human Rights* (2005) are relevant, as well. Article 5, "Autonomy and individual responsibility," states: "The autonomy of persons to make decisions, while taking responsibility for those decisions and respecting the autonomy of others, is to be respected. For persons who are not capable of exercising autonomy, special measures are to be taken to protect their rights and interests." Article 6, on consent, is even more explicit in both the treatment and research contexts: "Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information"; and "Scientific research should only be carried out with the prior, free, express and informed consent of the person concerned"; and further: "In no case should a collective community agreement or the consent of a community leader or other authority substitute for an individual's informed consent." One can only assume that the defenders of pluralism would say the same things about the UNESCO Universal Declaration that they have said about the *Declaration of Helsinki* – that it reflects a uniquely Western view of what constitutes a person.

It does not require a deep philosophical inquiry to conclude that in the context of medical practice and research, a *person* is the human being whose body may be harmed or benefited by the proposed intervention. The individual whose body may be harmed or benefited is the *person*, and that person should be the only one to decide whether or not to accept the proposed intervention. Of course, nothing in so-called Western medical practice or research precludes a person from consulting with one or more family members about a course of treatment or whether to participate in research. Informed consent documents for research frequently encourage potential participants to do just that. Those cultures that locate the *person* as an interconnected unit within the family or the community are not conflating the individual human being with the larger group. When the individual dies, only that person is mourned and buried – not the whole family or the community. That some non-Western cultures locate the individual human being as more essentially connected to the family or community than is true of European or North American societies does not mean they hold a different concept of "the nature of the person,"

to quote the sloppy formulation of the authors cited above. This conceptual confusion runs through the bioethics literature on ethical and cultural relativism, and it is time that some clarity is introduced to dispel the conceptual errors.

Skepticism about the concept of human rights and its universal application typically invokes the facts of cultural diversity. An anthropologist writing about female genital cutting asked: "Are there universal human rights that can be applied without cultural imposition? How is it to be determined what constitutes a violation of these rights?" (Slack, 1988, p. 473). In support of her contention that these are difficult questions to answer, the anthropologist cited a "Statement on Human Rights" published 40 years earlier in a scholarly journal in her field: "...what is held to be a human right in one society may be regarded as anti-social by another people, or by the same people in a different period of their history" (American Anthropologist, 1947, p. 542). Cultural anthropologists face great difficulty in reconciling the existence of human rights with the dictum in their profession to avoid making value judgments about beliefs and practices of the groups they study. In the case of female genital cutting, the World Health Organization – the United Nations global public health agency – has determined that the practice is a human rights violation.

The biomedical research enterprise today is global in scope. Can a coherent argument be made that because different countries or cultures have varying customs and traditions, different ethical standards based on those customs and traditions can be justified? To argue that different ethical standards are permissible because research in any culture is acceptable so long as it follows the customs and norms of that culture is either to sanction violations of human rights in the countries where those violations occur or else to deny that there are any fundamental human rights. Either view embodies a form of ethical relativism that comes down in the end to the position that "whatever is, is right."

Violence, Culture, and Subordination of Women

If "respect for cultural diversity" requires an acceptance of deeply rooted traditions, it is important to see what some of these cultural traditions allow or even require. It is almost always the case that no culture is monolithic, and almost every country in today's world includes members of different religions, ethnic groups, and subpopulations. It should not come as a surprise that some of the people who are harmed the most and whose human rights are most frequently violated are women. As UN Women (the newly established United Nations organization devoted to women's concerns) points out: "Women throughout the world may be exposed to a wide range of 'harmful practices' across their life cycle, including prenatal sex selection and female infanticide, child marriage, dowry-related violence, female genital mutilation, so-called 'honour' crimes, maltreatment of widows, inciting women to commit suicide, dedication of young girls to temples, restrictions on a second daughter's right to marry, dietary restrictions for pregnant women, forced feeding and nutritional taboos, marriage to a deceased husband's brother, and witch hunts" (UN Women, 2010).

While it is true that many cultural practices are not located within medical practice or research, they may still be relevant to bioethical inquiry. To cite one situation, physicians and other health personnel from North America or Europe provide humanitarian assistance and conduct research in places where harmful traditional practices are prevalent. How should they react when they witness or are called upon to treat victims of these practices? Does respect for cultural diversity require that they remain silent in the face of evident violations of human rights? In the context of research, studies in population health today focus at least as much on social determinants of health as they do on the provision of health care by physicians and other health practitioners. Research on the social determinants of health has mainly centered on disparities in wealth and income both within countries and between industrialized and developing countries. That focus has tended to obscure health inequities between women and men, especially as those inequities exist in developing countries. These latter inequities typically stem from adherence to cultural traditions of one sort or another rather than from differences in wealth or income between women and men.

Although major causes of women's health inequalities compared to men are related to women's inability to access reproductive health services or the availability only of poor quality health services where they do exist, other inequalities are unrelated to health care services. While the circumstances that give rise to these latter inequalities may not be among the most statistically prevalent causes of women's mortality and morbidity, they are nevertheless symptomatic of the enduring widespread subjugation of and discrimination against women. Leading the list is sexual violence against women, due to the prevalence of this factor. Every country in the world experiences civilian rape in varying degrees. However, in South Africa, one in four men admitted to having committed rape, and many confessed to attacking more than one victim (Jewkes, Sikweyiya, Morrell, & Dunkle, 2010). This astounding statistic is hard to believe and leads to speculation that perhaps men in the study who reported this result were exaggerating their exploits. But if that is true, it would hardly be comforting. If men find it appropriate to boast about their violent behavior toward women, it indicates the value they place on domination and subjugation of women.

Physical violence against women occurs everywhere. A WHO study covering 15 countries reported that between 20 % and 64 % percent of women experienced violence by men. Some of the women admitted that before being interviewed for the study, they thought being beaten by their husband was "natural" (World Health Organization, 2005).

As is true of poor women in industrialized countries who suffer from intimate partner violence, abused women in developing countries remain with their husbands because they have no other source of income. But in most developing countries, police and other authorities do not intervene in domestic disputes, no shelters exist for battered women, and courts do not issue orders of protection. Another difference lies in the training of medical professionals in democratic countries committed to gender equality. Where intimate partner violence is openly criticized and condemned, medical associations make recognition of such episodes

part of the training of physicians. Where husbands may beat their wives with impunity, physicians look the other way. Would European or North American physicians working in such places fail to respect cultural diversity if they questioned women patients whom they suspected had been beaten?

Culturally sanctioned violence is an undeniable source of harm to women in many parts of the world (Niaz, 2003). It is beyond doubt that some customs and traditions are not only harmful to women, but violate their human rights as well as existing laws. Consider the following examples. In India, the dowry system continues to give rise to bride burning by husbands or members of the husband's family if the bride's family provides too little dowry money. India passed the Dowry Prohibition Act back in 1961, making dowry a punishable offense. Yet, the practice has continued five decades later despite the law. When such cases are reported to the authorities, the husband or his family claims that the stove exploded and that is why the woman was burned. Corrupt officials and loopholes in the law have mostly favored offenders (Vindhya, 2000). This is a clear example of an existing law that is not enforced.

A different custom that remains surprisingly frequent in some cultures is honor killings. Women are killed by male family members for reasons including their refusal to enter into an arranged marriage, seeking a divorce – even from an abusive husband and allegedly committing adultery (the allegation is made but is typically not followed by an evidence-based inquiry). Perhaps, most egregious is the practice of family members killing a woman after she has been the victim of a sexual assault. The cultural value of maintaining honor and avoiding shame to the family extends to situations in which a female member of the family has engaged in sex outside of marriage, even if the sexual act was coerced.

The United Nations Commission on Human Rights reports that honor killings have occurred in Bangladesh, Great Britain, Brazil, Ecuador, Egypt, India, Israel, Italy, Jordan, Pakistan, Morocco, Sweden, Turkey, and Uganda (Mayell, 2010). In the developed countries, the killings take place in immigrant communities. India has seen a rise in the past several years of honor killings of young people who seek to marry outside their caste (Yardley, 2010). Such killings have included men as well as women, since both members of the couple are viewed as transgressors. Although many people in India claim to have abandoned the caste system, and the government has required that the legislature include members from the "lower" castes, adherence to traditional attitudes and practices remains, mostly in the northern states of the country. An uncle of a slain couple justified the killing, saying: "What is wrong in it? Murder is wrong, but this is socially the best thing that has been done." Five sets of couples were killed in 1 week in India in June 2010 (Yardley, 2010). Here again, the situation reveals the strength of the cultural value of family honor. Parents feel they have to act against their own children – most often daughters – to save the family's reputation. A spate of honor killings in 2010 resulted in the Indian government convening a cabinet-level meeting to discuss imposing a harsher punishment than now exists. It remains an open question whether this could be a successful deterrent, especially in a country that has failed to enforce its laws against dowry.

Still another practice harmful to women is early marriage. In traditional societies where marriages are arranged by families, the age at which girls are married can be as low as 13 or even younger. Being a child or even a young teen is a condition of vulnerability because of physical and emotional immaturity and limited worldly experience. Furthermore, children and teens are not granted decision-making autonomy in most societies, especially in traditional cultures. In almost all such cases, they cannot refuse to enter the marital arrangement. More often than not, in family-arranged marriages, the young girl is wed to an older man, who will exercise power and authority over her decisions and actions.

Being thrust into marriage at a young age places adolescents at physical risk. When girls have reached puberty but their bodies are not fully mature, pregnancy and childbirth can be hazardous. A frequent consequence of pregnancy in very young women is obstructed labor, an actual physical harm. In resource-poor settings and most rural areas where performing a cesarean section is not possible, the result is sometimes the death of the woman; more often, the woman survives but with an obstetrical fistula – an opening between the vagina and the bladder, which results in constant leaking of urine. The women become foul-smelling, are ejected from their marriage by their husbands, and even their own families will not take them back. Unless medical repair of the fistula is available and a woman has access to it, her condition will continue to render her an outcast for her lifetime. According to the World Health Organization, "It is estimated that more than two million young women live with untreated obstetric fistula in Asia and sub-Saharan Africa. Obstetric fistula is preventable; it can largely be avoided by delaying the age of first pregnancy, the cessation of harmful traditional practices, and timely access to obstetric care" (World Health Organization, 2011a). Although some medical practitioners in countries where obstetrical fistula exists are capable of making repairs, many more women remain untreated. Since obstetrical fistula is virtually unknown in industrialized countries, physicians from those parts of the world lack the knowledge and skills to provide medical assistance.

Early marriage, along with the cultural tradition of arranged marriages, violates human rights related to reproductive health. According to the World Health Organization, men and women have the right "to be informed of and to have access to safe, effective, affordable and acceptable methods of fertility regulation of their choice, and the right of access to appropriate health care services that will enable women to go safely through pregnancy and childbirth and provide couples with the best chance of having a healthy infant" (World Health Organization, 2011b). This reproductive right has its basis in several articles of the United Nations Women's Convention (United Nations, 1979). All countries that have signed and ratified the women's convention are therefore obligated to abide by its human rights precepts. Those countries include many in which forced early marriage continues to place adolescent girls at risk of obstructed labor, obstetrical fistula, and even death. The relevant article in the UNESCO Universal Declaration is Article 8: respect for human vulnerability and personal integrity. That article states: "In applying and advancing scientific knowledge, medical practice and associated technologies, human vulnerability should be taken into account. Individuals and groups of special

vulnerability should be protected and the personal integrity of such individuals respected." Although the article refers explicitly to scientific knowledge and medical practice, it also can apply more broadly to those contexts in which obligations of public health are the responsibilities of governments.

Son preference, still very common in China and India, is based on customs and traditions in these countries and persists despite economic development and modernization in other aspects of society. The preference for male children has harmful physical consequences, as well as social consequences for girls and for women who do not bear sons. In poor families, girls may be malnourished as boys are fed first, and girls may be denied medical care as well as education, resulting in fewer opportunities open to them in the future. The single most important cause of the excess mortality rate among females in these Asian countries is thought to be systematic neglect of the health and nutrition needs of girls and women, especially among girls from birth to 4 years of age (Cohen, 2000, p. 1369). The imbalance in the sex ratio in India is attributable to female infanticide, better food and health care for boys, maternal death at childbirth, as well as prenatal sex determination and the abortion of female fetuses in the past 20 years. Selective abortion of female fetuses is believed to result in about half a million "missing" female births each year (Jha et al., 2006). Despite the passage of laws in India that prohibit prenatal sex determination, both the value and the practice of son preference have shown no sign of abating.

The cultural traditions and practices just described are clear violations of the UNESCO Universal Declaration's Article 11: non-discrimination and non-stigmatization. The Article says: "No individual or group should be discriminated against or stigmatized on any grounds, in violation of human dignity, human rights and fundamental freedoms." It would belabor the point to specify the details of the discrimination, stigmatization, violations of human dignity, human rights, and fundamental freedoms embedded in these cultural traditions and practices. Improving public health interventions alone can do nothing to prevent the types of violence against women stemming from custom, culture, and tradition. All governments that have ratified the International Covenant on Civil and Political Rights have an obligation to respect, protect, and fulfill the human rights of the many women in their countries who are killed, maimed, raped, disfigured, or rendered disabled. Injustice in women's health inequalities can be remedied only by gaining control of the social factors that are causally responsible. It can be done, but it requires courage and political will in those countries in which women suffer the greatest health inequalities.

Globalization and Transformations of Values

Cultures are not static. Although harmful traditional practices remain prominent in some societies, in others, they have begun to change or even been altogether eliminated. Numerous examples exist in which harmful traditional practices are condemned by members of societies in which they are practiced. For example,

a transformation has been occurring in Senegal, in which a movement against the practice of female genital mutilation (FGM) has been gaining ground. Not only have individual women – older as well as from the younger generation – abandoned the practice for their daughters, but also, some religious figures have begun spreading the word that FGM is not a religious requirement in Islam (Dugger, 2011). Why the practice of FGM has begun to be abandoned in Senegal but not in Somalia or Sudan, among other places, requires further study.

Governments are accountable for some harmful traditional practices by failing either to enact laws or to enforce existing ones. As noted earlier, India is a case in point with regard to violence against women in the form of bride burning and dowry deaths. One example where the rule of law to honor killings is applied is Kurdistan. The prime minister of the Kurdistan Regional Government (KRG) in Iraq took the initiative in a campaign to eliminate the practice. One step was to establish a Commission on Violence Against Women in 2007. The initiative included calls for open debate, reforms in the law, education and training, and greater support. In this situation, as in many others, the first steps were taken by women's nongovernmental organizations (NGOs), which start their campaigns by raising awareness. Kurdistan saw a rise in honor killings in the past two decades. How much real progress has been made, however, is open to question. In response to a query about why some perpetrators of honor killings received only short prison sentences in spite of an amended law in 2002, a women's rights activist replied: "Reform takes time. The judicial systems, even in progressive countries like the UK, are based on patriarchy and often fail to protect women. . .. Honour killing is deeply rooted in a traditional mentality and requires changes to the law, strict implementation of the law and awareness-raising programmes for the judiciary and the police, and for the public through the education and cultural systems, as well as the media" (KRG.org, 2008). It is hard to say whether good news about reform of the laws here, as elsewhere, will give rise to even better news that these laws will be successfully implemented and will yield judicial reform. The more difficult challenge is to change the cultural views of a public that adheres to traditional norms and beliefs.

As noted above, a preference for sons remains strong in India and China, with serious health consequences for female infants and children. However, what has occurred in South Korea signals that change is possible. After decades of widening increase in the sex ratio in South Korea, a country with the same basic cultural and historical traditions as those of China and India, a reversal has now occurred. A report issued in 2007 by the World Bank Development Research Group (Chung & Das Gupta, 2007) documents these changes in South Korea and suggests implications for China and India as well regarding the still robust preference for sons and imbalanced sex ratio in those countries. Unlike China and India, a reversal began in the mid-1990s, with the sex ratio beginning to approximate that of European and North American countries. The authors of the World Bank report argue that this reversal came about as a result of changes at the societal level rather than the individual level. The explanation is that ideational change occurred, based on alterations in the economic and social conditions in the country.

Conclusion

The role that social determinants play in the health of individuals, as well as that of economically disadvantaged groups, women, and children, is undeniable. When poor health of such individuals and groups is a consequence of low economic status, governments have a clear obligation to seek ways of changing social and economic factors to improve the health of the public. When the social determinants of poor health, deliberate injury, and death are cultural factors, governments are often reluctant to act for fear of offending traditional religions or cultures. However, since governments play the predominant role in respecting, protecting, and fulfilling the human rights of all people who reside in their countries, the state above all has a responsibility to act. Respect for cultural diversity, whether within a multicultural society or across national borders, must give way when cultural practices violate the human rights of any segment of the population.

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Solidarity and Cooperation

12

Volnei Garrafa

Introduction

The terms "solidarity" and "cooperation" seem to have a certain closeness and complementariness, so much so that they appear together in Article 13 of UNESCO's Universal Declaration on Bioethics and Human Rights: "Solidarity among human beings and international cooperation towards that end are to be encouraged" (UNESCO, 2005). However, in practice, these two expressions receive a variety of interpretations, which makes it necessary to undertake a more detailed analysis on them, and especially on the concept of solidarity, in order to achieve better comprehension of their real meanings and the possible repercussions from applying them. As well as being the main constituents of this article, these two expressions are present in several other articles of the Declaration, either directly or indirectly crossing through them.

From the outset, in the first item of the Prologue of the Declaration, cooperation between human beings is recognized as a "moral expression of ethics itself," which is also unfailingly a form of solidarity, as will be seen further on. International cooperation in bioethics, in turn, is justified in Article 15, which deals specifically with research on human beings, through the commitment to take into consideration the "specific needs of developing countries, indigenous communities and vulnerable populations." While solidarity appears in Article 13 as the moral value of legitimation for international cooperation practices, Article 15 establishes examples for putting into effect the sharing of benefits from investigations developed within the field of science.

The theme of cooperation and solidarity is also indirectly referred to in Article 21, under the title "Transnational Practices," in which the Declaration holds states, public and private institutions, and the professionals involved in transnational research responsible for fulfillment of the specific needs of host countries and addressing the problems that affect overall health around the world. In turn, Article

V. Garrafa
Unesco Chair of Bioethics/Faculty of Health Sciences, University of Brasília, Brasília, Brazil
e-mail: garrafavolnei@gmail.com; volnei@unb.br

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24 indicates specific obligations of cooperation and solidarity between the states that promoted the Declaration, namely: (a) to promote dissemination of scientific information and stimulate free circulation of knowledge, (b) to stimulate cultural and scientific cooperation established through bilateral and multilateral agreements that aim to strengthen the research capacity of developing countries, and (c) to promote solidarity between states, individuals, families, groups, and communities, especially those that have become vulnerable through any individual, social, or environmental condition, and individuals with more limited resources.

However, there is no doubt that there are very many situations and examples, in which actions of solidarity are seen to be actions of goodwill, based solely on compassion or even just on a pious intention of replacing the state in which, at the same time as proving some help to improve people's lives, they also contribute toward maintaining deep social differences.

This chapter has the purpose of serving as support for countries, organizations, institutions, or groups of people who intend to develop some kind of reflection or study relating to the duo of solidarity and cooperation, conducted critically and constructively toward diminishing the acute socioeconomic disparities that are evident in today's world.

Origin and Brief History of Solidarity

In analyzing the origin of the word "solidarity," two terms derived from Latin are found: *solidum* (totality, security, or total) and *solidus* (solid, massive, or entire). Among other interpretations relating to solidarity that have been recorded, the following can be cited, which may serve as a matter for discussion in the present study: a state or condition of two or more people who equally share the responsibilities for an action, company, or business, and are answerable all for one and one for all; a mutual tie or bond between two or more things among which one depends on the others; a commitment in which people are each placed under an obligation by the others and each of them has an obligation toward all of them; a group condition resulting from communion of attitudes and sentiments such that a solid group unit capable of resisting external forces, and even becoming more resolute when faced with opposition from outside, is constituted (Weiszflog, 2004); mutual dependence between people; a feeling that leads people to mutually assist each other; a mutual relationship between dependent things; and a commitment through which people put obligations on each other (Ferreira, 1999).

All these expressions of solidarity are thus presented through mutual actions that take place solely among people who are within the same environment and have shared interests, in a kind of "social corporatism" in which all those involved have a relationship of interdependence. These interpretations probably derive from the words of Aristotle, *apud* Avelino (2005), who placed the foundations of solidarity (although he would have used other terms at that time) in a position that is

antagonistic to individualism. In this, a position of solidarity refers to the assemblage that makes group life better, while individualism is a position in which individuals place esteem on themselves, while regarding society with different eyes:

> Domestic societies and individuals are not more than integral parts of the *polis*: all subordinated to the whole body, all with distinct powers and functions and all rendered useless when disjointed, like hands and feet, which once separated from the body, only maintain their names and appearance, but without reality, as if made of stone. The same occurs with the members of the *polis*: none of them can be enough on their own. A person who does not need other men or cannot become settled with them is either a god or a brute. Thus, natural inclination leads men to this kind of society (Avelino, 2005, p. 228).

Within this context, no matter how much humans seek autonomy and respect for diversity, there would always be a need to form part of the universe known as society, albeit fragmented into family, work, nation, and so on, in which one component depends on another for protection, survival, and preservation of the species. Living in this society envisaged by Aristotle therefore signifies respecting others and accepting that the group is stronger than the individual. This makes it necessary to have rules for living together so that a satisfactory balance can be achieved, because without such rules, collective life would not exist.

With a variety of focuses, solidarity has been receiving attention and reports of different nature since ancient times (Hudson, 1999). In Egypt, there were moral codes based on social justice, through which individuals were stimulated to help others without demanding anything in return. The process was named "voluntary work." One example that makes it easier to comprehend this type of activity is that individuals who owned boats were expected to transport poor people to the other side of the river if they needed this. From the earliest times onward, there have also been reports of members of families who became responsible for caring for a sick, orphaned, widowed, handicapped, or elderly member of the family, in situations in which such individuals were found for some reason to be alone and/or destitute. Although this specific example could be described with other words or expressions, it is common to find such situations correlated with solidarity in the literature, as will be seen further on.

It is well known that with the historical development of cities over time and the resultant rural exodus, individuals started to become separated from their families and needed to become closer to each other living collectively in large megacities, helping each other with the aim of making it possible to better live together within society and thereby avoid isolation. A new form of living together socially termed "social assistance" thus gradually emerged. The Christian churches in particular helped poor, sick, and destitute individuals through support funds maintained by means of donations made by their members. These people also helped others by means of donations and voluntary work or service; philanthropic hospitals (named *santa casa* in Portuguese, i.e., "holy house") were created and maintained through donations for the sake of commiseration and charity, terms that are usually confounded with solidarity. Continuing today, voluntary service is interpreted as a non-remunerated activity provided by an individual to a public entity of any nature,

or to a private not-for-profit institution, which has civic, cultural, educational, scientific, recreational, or social assistance aims, including mutuality (Brasil, 1998).

In 1893, Durkheim (1967) analyzed society following the process of urbanization and industrialization, and expressed uneasiness regarding the transformation of individuals into autonomous and individualistic beings. He thus questioned how, within this context, so-called social cohesion could be maintained. He took this society to be a model in which norms ensuring interactions between individuals would be incorporated, thereby making it easier for people to live together, in an attempt to minimize social risks such that people would not suppress others or deny others' rights of citizenship, cultural diversity would be respected, and collective solidarity would be motivated. This response came through differentiation with other factors (economic, cultural, juridical, scientific, religious, and so on), from which the division of labor made individuals become interdependent, thereby further solidifying social cohesion through creation of social ties.

Through this analysis, Durkheim differentiated two types of solidarity. The first, mechanical solidarity, comes from traditional society that provides similar lifestyles for people (physical, social, and cultural) and thus provides the motive for people to unite toward the objective of maintaining equality and preserving and perpetuating the group. The second, organic solidarity, is based on modern society, which has become increasingly differentiated and interdependent because of the division of labor, thus requiring greater interrelation and cooperation between individuals, and causing the collective conscience to be placed above the individual conscience. However, Durkheim stated in his work that organic solidarity may be responsible for problems and pathological conditions consequent to the division of labor, when there is no coordination and fairness in labor relations does not prevail, which may even lead to revolt and breakage of the social ties that had previously been constructed.

However, in today's reality, even though relationships within society have developed basically along the lines of reflection indicated so far, and have a certain historical interface with the concept of solidarity, this is not the type of solidarity that occurs and that is of interest in the present study. On the contrary, the solidarity expressed in UNESCO's Bioethics Declaration requires a different view (bilateral and, at the same time, horizontal) between individuals, groups, or sectors that are in different historical and social situations, in which some of them become capacitated to support others in a disinterested manner, without concern regarding any material return or any of other nature. When this solidarity occurs between different countries, in which a stronger and better organized country supports another one without interest other than providing real help in the light of a situation of temporary or continuing weakness, this is a state of true, real cooperation. Nevertheless, unfortunately, reports have constantly been made both in ancient and in modern history, in which humanitarian actions undertaken in solidarity by certain nations have only given rise to different forms of exploitation and derived advantage over the long term, thereby further weakening these people in need whom such nations had supposedly been willing to "aid."

Expressions Confounded with Solidarity

There are several terms that are often confounded with solidarity, which makes it pertinent to comprehend them adequately in order to avoid misinterpretation and confusion. In the following, a brief conceptual and critical presentation is made on some of these – charity, compassion, fraternity, and philanthropy – to make it easier for readers to differentiate them from each other, and especially from solidarity.

Charity

Charity originates from the Latin word *caritas*, which means love toward one's neighbors. Charity is generally regarded within society as a noble, honorable, and welcoming virtue that strengthens the group's actions of solidarity. With the passage of time, this word gradually acquired a certain religious connotation, in the strict sense of material aid for other people who are in greater need. The Catholic Church and its followers base the practice of charity on the idea of brotherly love, with provision of immediate assistance to the poor and needy, and concerned only with serving one's fellow men without interest in material recompense (Kisnerman, 1983). According to the Catholic Church's Decree on Missionary Activity (Vaticano, 1966), published in 1966 as a result of the Second Vatican Council, charity should be understood as an act of love for one's neighbors. The document said that the presence of Christians in human groupings is heartened by the charity through which God loves us, and through which He wishes that we should also love each other. And therefore affirm just as God loves us with freely bestowed love, so too the faithful, though their charity, will be sought by men, and will love them with the same zeal with which God came to seek the faithful.

Charity, according to Christianity, is not limited to alms, but encompasses all the relationships with one's fellows, whether these are hierarchically lower than the person making the act, or equal, or even higher. Through charity, Christianity guides its followers to be lenient, and forbids humiliation of those who have suffered misfortune, contrary to what often happens in the real world.

However, many people with religious concerns end up doing charitable acts that primarily have the function of "relieving the weight of their own consciences," i.e., acting generously only with the aim of trying to make amends for a bad act committed in the past and imagining that through this compensatory act done during their lifetimes, they will achieve "divine forgiveness and eternal salvation." Bruckner (1996) goes further in his criticism in affirming that:

> The ontological scandal of charity (and of philanthropy) is the inequality between the donor and the beneficiary, who through incapacity to save himself by himself, can only receive and thank, without responding. Loving this person solely for this reason signifies placing on him not the nobleness of our souls but, rather, our desire for power. (Bruckner, p. 261)

Nevertheless, the concept of charity is central to the social behavior of pious people who follow Kardecist spiritism, summarized in the word "generosity,"

which represents constant growth or evolution of the being in seeking to live well, without becoming worn down through feelings of egoism, unhappiness, and hate (Kardek, 2009). In this context, generosity becomes the result from the charity-giver's spiritual maturation, thereby acquiring a meaning of love that is not inert and does not have imposed rules, but which acquires a connotation of experience, acceptance, and comprehension. In other words, this is an act of psychological balance and comprehension of the external world from inside each person. For Spiritists, charity does not have a label, i.e., it is universal (Gomes, 2012).

Charity is also sometimes confounded with "social work," which is not necessarily linked to religious meaning, but to reparation of social injustice that is generally perpetrated within the collective environment and which unfailingly has a sociopolitical basis.

However, there are authors like Nietzsche who have demolished the notion of charity arguing that the ethics of charity, and also of compassion, is no more than a strategy for power that, in promising aid and assistance, concomitantly multiplies the mechanisms of coercion and submission. According to Nietzsche (1981), people who make donations are thinking much more about themselves than about the people that they want to help.

Compassion

The word compassion comes from the Latin *compassio*, which means comprehension of the emotional state of the other person or desire to alleviate the other person's distress. Having compassion does not mean feeling pity for the other person; it means putting oneself at someone's side without judgment, with the intention of only providing relief from the situation of turbulence and distress that the other person is experiencing. In relation to compassion, Hume (2009) stated in his work "Treatise of human nature" that no one is so insensitive that they cannot perceive another person's happiness or unhappiness. Nevertheless, there are some who think that while solidarity makes it plain that some wrong exists, since it signifies that accepting or tolerating actions that belittle or violate people cannot be accepted, compassion runs the risk of trivializing such actions, since it is restricted only to stimulating tolerance up to the limit of what is intolerable (Caponi, 2000). This critical vision of the compassion is very diffuse in some countries of Latin America, especially in Brazil.

In turn, the Dalai Lama has conceptualized compassion as concern for other people, because all human beings have the right to be happy. In his view, the sentiment of compassion is attained by starting from this understanding, thus differing from the feeling of pity, which becomes a barrier against understanding the full essence of other people. Compassion cannot just be among relatives and fields, since this would be affection, rather than compassion. True compassion occurs in situations of thinking about voluntarily alleviating other people's problems. Pious people also say that practicing compassion brings benefits to physical and spiritual health, and that people who are compassionate are healthier than egoists. According to the Dalai Lama, while modern societies show concern for

educating their children in order to attain better intellectual and economic development, they forget to guide their children toward compassionate gestures and leave this responsibility to religions, which all encourage compassion (Dalai-Lama, 1989).

However, pious but immoral personal attitudes can be seen in day-to-day life, in responses to the force of compassion that produce highly illegitimate, albeit legalized coercion over individuals who have suffered misfortune. In this author's view, such attitudes legitimize situations such as internment and isolation of mentally ill individuals in places that should never be called "recovery centers," or removal of homeless people living on the streets, against their will, to put them in public shelters that are often dangerous and unhealthy (Caponi, 2000). This author's full reflections are, however, based on the hypothesis that there is no absolute rupture between care policies based on compassion ethics and those proposed by classical utilitarianism but, rather, continuity, solidarity, and complementariness. According to this idea, it is essential to rethink care policies from a perspective differing both from diffuse utilitarianism and from pious compassion that sustains and perpetuates charity.

In a general manner, compassion is very close to commiseration, another word that is sometimes confounded with solidarity. However, because of the etymological roots of the word commiseration, it always has a direct relationship with misery, which is not necessarily seen in relation to compassion, which may also be directed toward people who have other types of needs, such as physical or emotional needs.

Fraternity

The word fraternity derives from the Latin *fraternitas* (brotherhood, set of brothers, or affection between brothers). In speaking of fraternity, there is an idea of close family, consanguineous ties of kinship with the same genealogy. Over time, this expression has become used to describe relationships with people who have the same convictions, which could be religious, political, economic, or cultural, or even with people performing similar functions. Aristotle stated that citizens join together in groups, to create political communities, an act that he named "political friendship." In "Nicomachean Ethics," he stated that friendship is above justice, since "where friendship exists, justice is present." In his view, equity between people is only consolidated when mutual trust exists, i.e., when one depends on the other, which makes them equal (Aristóteles, 2009).

During the French Revolution, the three-word motto "Liberty, Equality, Fraternity" was adopted. These words are rooted in masonry and Christianity, and they seek a brotherly dimension, i.e., community life without prejudice, under similar conditions, thereby establishing a kind of citizenship between men who would be able to live in a free and dignified manner (Silva, 2006).

In the preamble of the Universal Declaration of Human Rights of 1948, it is recognized that all men are members of the same family: the human family (ONU, 1948). This context of the human family forms the focus for the present reflection on the word fraternity. It is configured from the observed relationship between

people and the dissemination of the concept of equality among human beings, taking all of them to have equal rights. Thus, this interpretation diverges from the concept proposed by Aristotle. According to Aquino (2008):

> Fraternity originates a kind of behavior: a relationship that should be established with other human beings, with action "by some in relation to others", which also implies a dimension of reciprocity. In this sense, fraternity is more than another principle standing alongside liberty and equality: it seems to be the one that is capable of making these principles effective (p. 137).

Based on these ideas, fraternity starts from the principle that all human beings have certain duties in relation to their fellow men, thus maintaining a sentiment of reciprocity, i.e., having a sense of solidarity between themselves. In this manner, fraternity would be the basis for attaining equality and liberty among men, thus closing the triangle proposed by the French revolutionaries.

However, differing from the above interpretations, another author stated that fraternity can only be attained through dialogue, which they considered to be a tool for bringing men together, because in this way, some are forced to hear the others (Simões, 2008).

Philanthropy

The word philanthropy has a Greek origin and means "love of humanity." In its broader meaning, it is understood in the context of present-day society as humanitarian organizations of communities, companies, public bodies, private bodies, or even groups of individuals with the objective of helping other people through donations, without profit-making aims. Organizations with the specific purpose of helping human beings and other living beings to improve their lives are taken to be philanthropic institutions.

Philanthropy is action related to support or donations of financial or other nature, for the benefit of institutions or individuals who develop activities that are considered meritorious and that produce social stimulus. It is understood by many people to be a private form of support for development of activities that might generate transformations in the structure of life of needy groups, without resorting to state intervention. In many countries, philanthropy is now considered to be a significant source of funding, particularly for humanitarian and cultural issues. In some countries, philanthropic actions even take on an important role in supporting scientific research and funding universities and academic institutions.

Although philanthropic activities have also been criticized, in the same way as charity and compassion, its original meaning has a historical sense, through reports of individuals and/or families with a solid financial situation who decide to make part of their resources available for supporting entities or causes that have the capacity to improve the social structure or people's lives, to stimulate the arts and improve libraries, or even to support scientific research in universities, among other initiatives.

Undertaking philanthropy has also been pointed out to be a stimulus for development of so-called social responsibility, developed especially by private

companies. This concept has been gaining greater visibility over recent years. The difference between philanthropy itself and social responsibility is that the former is always motivated by humanitarian reasons and by social actions, even if managed by private companies, while although the latter is also a social action, it is defined from a sporadic or regular active commitment by the company that already forms part of a formal predefined strategic plan.

In all forms of philanthropy, just like the other expressions analyzed in this chapter, there cannot be any confusion with solidarity, since philanthropy does not in practice express the dialectical and dynamic actions that are proposed for the indispensable interchanges, bilaterality, or exchanges of benefits and experiences. Gomberg (2002) went so far as to state that philanthropic actions promote a type of "political silence," which conceals the institutional causes of poverty (especially capitalism) from attention. Such actions would therefore divert the responsibility of institutions that promote them, away from seeking radical alternatives for solving such problems. Other authors have stated that philanthropy "undermines true political change" (Singer, 2010, p. 34).

Contemporary Forms of Solidarity

The theoretical interpretations relating to solidarity vary between different authors. In any event, it is especially important to differentiate it from the terms dealt with above: charity, compassion, fraternity, and philanthropy. Some authors have been more accommodating, interpreting solidarity as an action that is always viscerally linked to virtuous action or even to the so-called ethics of virtues. However, others have taken a sharper view and have deepened the concept by politicizing it and providing it with a more concrete shape, with transformational visibility. The Latin American Dictionary of Bioethics states that solidarity is a social value created from the conscience of a community of interests and is therefore humanitarian in itself. Consequently, it incorporates the moral need to help, assist, and support other people, as part of personal responsibility (Vergés, 2008). In the following, three contemporary ways of interpreting solidarity are explored, thereby seeking to provide a broader and more dialectical view of this topic: voluntary-action solidarity, critical solidarity, and radical solidarity.

Voluntary-Action Solidarity

Voluntary-action solidarity is the most traditional skewing of the concept of solidarity. This type of action in solidarity, for which Brazilian critics have coined the term *assistencialismo*, meaning "handout culture," is based on the volunteer or donor and not on the other person who, in addition to requiring help, needs a way out from his current situation. The antithesis of a handout culture is a commitment toward the other person (Garrafa, 1987).

The handout-culture model therefore consists of action that only maintains the status quo, without contributing toward effective transformational changes in its beneficiaries' lives. Instead of being subjects of an assistance process, such individuals merely become passive spectators of the act of solidarity. This action may even resolve a transitory situation of inequity or necessity, but it does not effectively take these individuals out of the situation that was encountered previously. Instead, it just contributes toward maintaining and perpetuating the situation, because there is no new and transformative element that might alter the structure of the existing relationship between the provider of the help and the person helped (Garrafa, 1989).

Thus, voluntary-action solidarity may have several connotations. One of the best known can be seen through the passive unilateral handout-culture voluntary actions that are provided, for example, by so-called service clubs. These are often organized in peripheral countries based on background reference points that are somewhat unclear, and are established from the so-called central countries, through associations like the Lions' Club or others of similar origin. These groups, generally with the support from private companies interested in a certain line of business, promote special days of help for groups of needy people, usually with certain pathological conditions, thereby seeking visibility and public recognition. This naturally results in dividends of political and other natures for the donor group and its partners.

In this context, it is common to create false expectations in the communities that receive such assistance, given that the activities proposed are implemented episodically, starting from some urgent specific need detected, or even from artificially defined calendars, which are governed by temporality and discontinuity of scheduling (Garrafa, 1987, 1989).

The word "assistencialismo" (handout culture) is erroneously considered to be a synonym for assistance, thus causing aversion among people who are in favor of true and genuine assistance of disinterested nature and free from secondary intentions. Assistance as a social and rights policy is of great importance when carried out responsibly on an emergency basis in situations of natural catastrophe, for example. However, this differs from handout cultures implemented by some populist governments as a way of manipulating their citizens, thereby impeding individuals' emancipation and leading them to depend on public actions for their subsistence (Marx & Engels, 1977).

Some countries have already defined in their constitutional charters that the state has a commitment to provide certain basic rights for its citizens, such as: housing, healthcare, special programs to promote access to school for children and family subsistence programs, among others. On the one hand, these programs may bring real benefits over the medium and long terms, when there is a commitment toward true social change. On the other hand, depending on how they are proposed and implemented, they may create a continual process of submission among the presumed beneficiaries. Handout cultures are no more than concealed paternalism with the aim of achieving social control, implemented in such a way as to maintain a false equilibrium between those who are vulnerable and the elite (Vieira, 1995).

As stated by Alayón (1995), violence and criminality are at best lessened through public and private handout cultures.

In Durkheim's view (1967), societies are only constructed through social cohesion, i.e., from socialization of individuals, through acceptance of norms and social values, and also through creation of awareness that individual actions should reflect actions that have been defined collectively. For this reason, Durkheim defined solidarity as a consensus among the individuals of a given group, thereby defining the existence of two types of solidarity (mechanical and organic), as presented earlier. Today, organic solidarity predominates, at least in most developed countries, since its pillars are based on social reference points that are determined from norms established through rights.

Critical Solidarity

Critical solidarity is taken to be the agent's capacity for discernment, i.e., possession of criteria that are capable of helping him to discriminate among the social and political dimensions that are inseparably present in relationships of solidarity. In this manner, solidarity does not become exhausted as a typical relationship of civil society. On the contrary, it has a political element that has the state as its reference point (Selli & Garrafa, 2011). A capacity to understand this expanded dimension, relating to citizenship and the possibility of intervening actively in defining public policies, also characterizes this critical dimension of solidarity (Bobbio, Pasquino, & Mateutti, 1995).

The identity of critical solidarity is centered on commitment toward the subject, in actions and interventions that fundamentally favor respect for moral pluralism and construction of inclusive social transformations. It is centered on a dialectical commitment toward the subject, in organic actions and interventions that aim to provide the other person with attainment of autonomy, free from paternalism or any other form of handout culture and authoritarianism. Its historical expression is given concrete shape through wielding individual liberty, as set forth in the Universal Declaration of Human Rights. This epistemological proposition also proposes to replace the word autonomy with the words "empowerment" and "liberation," terms that give greater strength to the idea of subjects who are free from any bindings and able to make their own decisions (Nascimento & Garrafa, 2011). In this sense, facing up to social problems presumes that a linkage exists between government disposition and social initiatives, between institutional resources and community dynamics, between technical competence and human skills. The proposition that solidarity can be a value-guiding association in voluntary practices comprises this aggregating factor of civil, political, and social forces (Selli & Garrafa, 2005).

Studies on critical solidarity are based on people's democratic participation in society, without concern for their own benefit or simply for "helping one's fellow men," but with a concern for providing other people with concrete tools to enable them to effectively find a way out from their situation of vulnerability. This would

place such people, in traditional interpretations of solidarity, as the passive and unilateral receptors and beneficiaries of an act of solidarity (Selli & Garrafa, 2005). In other words, critical solidarity suggests voluntary actions that are related mainly to public policies directed toward social organization, with the aim of minimizing social inequalities. The participative process between society and state is constructed cooperatively and may help in scientific and educational training within society, thereby enabling discovery and strengthening of moral and ethical values. This type of cooperation promotes social and economic development, since it stimulates the participants' self-confidence, brings dignity to the people involved, and mobilizes social groups. In essence, in the concept of critical solidarity, the word donation is replaced by cooperation.

The solidarity that is sought to comprehend and propose as the central motivation for voluntary action by organizations within civil society is a value linked to the way in which modern society is itself organized. This manner of organization, by definition, does not derive from political or religious doctrines, which by their nature are partial. However, this is a central value and it serves as a motivator for voluntary associations that have the main objective of providing real benefits for people in need (Selli & Garrafa, 2006). In its ethical dimension, it designates a value that is immanent to the human condition, which results from the fact that human beings live in communities and therefore in interdependent relationships.

Interest in the proposal of critical solidarity as a value for guiding organic voluntary service is motivated by social realities and other reference points based on personal experiences, among other justifications. Use of the adjective "critical" refers to the agent's capacity to note the social dimensions (which are also political dimensions) of the relationship of solidarity. The capacity to understand this dimension, which relates to citizenship and the possibility of intervening actively in defining public policies, also characterizes this critical dimension. In turn, the correlated concept at the foundations of critical solidarity, named organic voluntary action, was constructed as an analogy to the concept of organic intellectual action that was developed by Gramsci (1979). It can be understood as active participation of individuals who develop voluntary activity to construct the conditions needs for effective democratization of the state, in all its dimensions.

Exercising of the proposed critical solidarity, when done democratically and bilaterally, promotes citizenship. It thus differs from handout-culture solidarity, which suffocates autonomy, thereby causing dependence and low self-esteem. On the contrary, its interventions minimize social inequalities through organic voluntary action, with politicized and committed participation by society, with expansion of the individual and collective rights that have already been achieved.

Radical Solidarity

To develop the topic of radical solidarity, studies by the Australian philosopher Peter Singer will be used as reference points. Although this author has frequently used the word "radical," he has not mentioned the expression "solidarity," but has

preferred to use expressions such as "humanitarian help," "donation," or even "charity." Nonetheless, the concept of solidarity formulated in the present chapter, in the critical sense of exercising responsible solidarity, is consonant with some of Singer's ideas. His reflections led the subject studied here preferentially toward the field of personal and individual obligations, dealing rigorously and directly with the topic and placing responsibility for the poverty that exists around the world on all people who have an excess of resources for maintaining their lives, yet are unwilling to help those in need (Singer, 1998).

According to Singer, "helping is not, as is commonly thought, a worthy act of charity to perform, but from which it would not be wrong to be exempted; it is something that should be done by everyone" (Singer, 1998, pp. 241–2). In his view, the wealth of the inhabitants of rich countries makes it possible for them to have income that they could relinquish without this depriving them of the basic necessities of life, and which could be used to diminish absolute poverty in the world: "The amount that we feel obliged to give is going to depend on what we judge to be of moral importance, in comparison with the poverty that we could avoid: expensive clothes and dinners, a second car, vacations abroad. . ." (Singer, 1998, p. 243).

Singer also advocates that because a person is close to us, this does not imply that one should have greater concern for this person than for other people who, by chance, are distant from our eyes and lives. In his view, moral duty should be impartial. In this sense, he advocated that if one agrees with the principles of universality, equality, or impartiality, one cannot disparage someone just because he is not close by. He considered that one of the problems of modern societies is that one always feels less guilty if one is able to point to other people who, in the same situation, would also do nothing. In such contexts, one is influenced by what people around them do and expect that one does.

In reading Singer's work, it can be seen that his affirmations do not relate to the public responsibility of governments, but particularly to each individual who has the economic possibility of doing something to improve the situation of poverty that is observed around the world, yet does not do anything. In such cases, despite the vertical individuality of the proposal, its radicalism is stunning: "If letting someone die is not intrinsically different from killing someone, the impression that remains is that we are all murderers" (Singer, 1998, p. 234). In his view, the lack of an identifiable victim does not have moral importance, even though this may have an important role in explaining our attitudes: "The idea that we are directly responsible for those who we kill, but not for those who we fail to help, results from a very questionable notion of responsibility. . ." (Singer, 1998, p. 239).

Singer stated that if it is within one's reach to stop something bad happening, without having to sacrifice anything of comparable moral importance in so doing, then this is what one should do. Within a context that he called "indisputable principles," he went as far as to propose a "radical" version (as he himself termed it), to impede bad events. This radical version requires that people should stop bad things from happening, unless something of comparable moral significance is being sacrificed in so doing, thereby reducing such action to a level that he called "marginal usefulness" (Singer, 2002). He confessed that he ended up

advocating a more moderate version that recommended preventing bad events unless one had to sacrifice something that was morally significant in so doing, but he finished by stating: "... the radical version seems to me to be more correct" (Singer, 2002, p. 150). He also emphasized that although the idea of charity is thought of as part of people's individual responses, a broader idea of justice seems to be more appropriate, because charity does not simply encompass what individuals do in relation to each other, but also includes the structures and general relationships that exist, or ought to exist, in a society.

Cooperation

The word cooperation comes from the Latin *co* + *operare*, which can be interpreted as "working together" or "working in collaboration." This last word also originates from Latin, *co* + *labore*, and likewise refers to the notion of shared work (Ferreira, 1999).

In different fields of knowledge, understanding of the significance of cooperation presupposes that there are benefits or mutual advantages in interactions between countries, institutions, organizations, groups, or individuals. In studying environmental ethics, for example, cooperation consists of a harmonic, interspecific, and facultative relationship in which individuals obtain mutual benefits without any vital dependence between them. This differs from mutualism, in which a harmonic interspecific relationship is generally mandatory (Instituto Brasileiro De Geografia E Estatística [IBGE], 2004).

As a political and economic doctrine, cooperation was initially formulated within so-called cooperative socialism (Singer, 2001), a proposal that emerged in the nineteenth century as an alternative to the polarization that was then seen between capitalism and communism. One of the authors of this doctrine, John Stuart Mill, advocated that social problems relating to inequality and exploitation of labor would be overcome through cooperative processes involving free associations between workers and other workers and between workers and capitalists. Mill believed that gradual replacement of capitalist companies with cooperatives would result in fairer distribution of the wealth produced by society (Mill, 2001). In diplomatic practice, cooperation signifies political dialogue and assistance between friendly countries, both bilaterally and multilaterally, in opposition to the idea of confrontation (Ceolin, 2011).

Whether as a moral principle of ethics, a natural biological fact, a concept of political science, or even a diplomatic practice, cooperation did not appear as a concept within the discourse of bioethics until the publication of the UNESCO Declaration in 2005. Likewise, there are no indications of specific references to the term "cooperation" in any of the editions of the Encyclopedia of Bioethics (Reich, 1978, 1995; Post, 2004), in the single edition of the Latin American Dictionary of Bioethics (Tealdi, 2008), or even in a systematic search of the literature that was conducted using the BIREME platform of PAHO/WHO in 2008 (Santana & Garrafa, 2012). It can therefore be argued that the Universal Declaration on

Bioethics and Human Rights was the first document that officially incorporated the principle of cooperation in the lexicon of bioethics, with the topic of solidarity alongside it.

Discussing the Relationship Between Solidarity and Cooperation

Until the last decades of the twentieth century, solidarity was still regarded as a markedly individual or group activity, and only rarely as a public initiative by governments. However, the establishment of its relationship with the topic of cooperation came to provide the possibility of new, expanded, and bilateral focuses, with greater social commitment. These focuses came to serve as a conceptual tool with the capacity to contribute toward diminishing the acute inequalities that are observed among individuals and peoples in the contemporary world.

Today, solidarity is a theme that is increasingly born in mind by international organizations, the media, and even governments. Many countries have already gone so far as to include it in their constitutional charters, taking the view that it is a social principle relating to construction of freer and fairer societies. Some constitutional texts, like the Brazilian one, suggest that social change can come through participation with a sense of solidarity, with the state working in conjunction with society toward the objective of creating new values aimed at citizens themselves and citizenship (Rocha, 2011).

In this context, a social group acting through a sense of solidarity comes to be seen as part of a sociopolitical-cultural organization that respects and stimulates equality and social justice. The relationship between state and society comes to be configured with equal values, thus characterizing a relationship of effective cooperation, and no longer one of inequality. Decisions are constructed based on justice, thus creating greater social cohesion. This model may generate good results because it contributes toward diminishing the poverty, violence, and injustice rates, thereby creating greater credibility and security, as well as ensuring better quality of life. This is solidarity delineated from equal rights, with responsibilities that are also shared.

The construction of an ethics of solidarity may start from different motivations, with special emphasis in the present study on so-called critical solidarity, for preferentially public initiative and also individual and private initiatives that have the real intension of diminishing the differences and improving the quality of life among different social segments. In this case, for an appropriate interpretation to be made, it is essential to have a critical differential view between compassion and utilitarianism as distinct forms of social behavior that, at the same time, are complementary. These strengthen the struggle for emancipation of vulnerable classes through charitable or philanthropic actions, but they may equally determine domination by the most favored individuals with the same form of solidarity as the strategy (Caponi, 2000).

According to Freire (2002), exercising solidarity requires a minimum degree of authenticity among its agents, which necessarily includes attainment of democracy

and respect for plurality of ideas and cultures. This author took the view that, more than an isolated act or action, solidarity is an inalienable commitment by each individual, each human being, and states themselves toward people in greater need, with the aim that they should find a way out of their current situation of exclusion and marginality.

Conclusion

As can be seen from the above, there are clear differences between the three angles of solidarity presented here. While voluntary-action solidarity, through unilateral actions centered on promoters of assistance, does not have any continual commitment to the people who are assisted, radical solidarity represents an advance in the sense that real and concrete humanitarian aid is provided to individuals and communities that are in need. Nevertheless, although the latter attains evocation of the principle of justice, rather than individual assistance, it does not go so far as to provide needy and marginal individuals and groups with effective empowerment and liberation mechanisms for them to be able to make future decisions regarding their lives that are truly free and unpressured. Meanwhile, critical solidarity signifies more than a donation, act of help, or act of charity: It is an organic and collective planned act that is carried out starting from bilateral sociopolitical commitment among the players in the donation and reception process. Differing from the other two types of solidarity, it proposes actions to transform the status quo of the people who are on the more fragile side of the equation, which could contribute in a concrete manner toward improving these people's lives and help them to effectively become free from the bonds that keep them marginalized from the worldwide development of society.

Taking the present reflection into the field of the solidarity and cooperation agreements that are often signed between different countries, for these to be considered ethical, it is essential for the activities to consist of real cooperative practices, and not exploitative practices, in which more powerful nations end up being the beneficiaries. This reasoning may be perfectly applicable to research on human beings, in which it is common to conduct multicenter clinical studies on new medications in peripheral nations in which the disease studied has minimal epidemiological impact, such that the study unilaterally serves the interests of the sponsoring company, which has its headquarters in a developed nation.

Article 15 of the Universal Declaration on Bioethics and Human Rights may be highlighted as a normative reference point for conducting cooperative studies, with a sense of solidarity, that result in fair sharing of the benefits, thereby avoiding exploitation. This article postulates that the benefits derived from research should be shared with the entire international community, and especially with poorer countries, even if the development of the assets has taken place only in richer countries. To consolidate an international system of cooperative nonexploitative research done with a sense of solidarity, it has been suggested that an international funding source destined for supporting and applying research and public policies in

poorer countries and communities should be created (Garrafa, Solbakk, Vidal, & Lorenzo, 2010): in other words, a proposal drawn up on a truly horizontal basis, involving solidarity and cooperation.

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Social Responsibility and Health

13

Stefano Semplici

Introduction

The expression "social responsibility" has become widespread only recently, boosted first and foremost by the growing success of the so-called "business ethics" and as one of its flagships. In a very broad sense, the term is meant to imply a change or at least an enlargement of perspective in the strategies and aims of companies and institutions. This enlargement entails two main aspects. First, the concept of the obligation that economic actors should be responsible for is reshaped and integrated. Of course, they are supposed to comply with all the requirements and constraints that are legally binding and establish the rules for any profit-oriented strategy. They are at the same time, however, called upon to meet other and more encompassing duties stemming from a commitment to improve the welfare of the societies they are rooted in and prevent them from suffering the consequences of negative "externalities" resulting from their activity, such as pollution, urban crowding, etc. Many of these "social" responsibilities correspond to *moral* rather than legal obligations, because of the lack of justiciability (people who do not comply with them can be blamed, but not put on trial). Yet, it could never be said that the values involved are something "private" or less important. Thus, we come to the second essential feature. W. Evan and E. Freeman published in 1988 the article entitled *A Stakeholder Theory of the Modern Corporation*: *Kantian Capitalism*. This was the starting point of the new stakeholder approach that looks at the management's responsibility toward not only the property and the perfectly legitimate interest in profit for the stockholders but also the many individuals and organizations that are in many ways targeted by and/or involved in the activity of a corporation or an institution. In other words, the idea of social responsibility widens the scope of the subjects that ought to be involved in the process of decision-making (not only the stockholders and managers) as well as that of the aims (not only profit). It also goes without saying that the idea of social responsibility applies to both private and public sectors, inasmuch as the latter

S. Semplici
Department of Business, Government Philosophy, University of Rome 'Tor Vergata', Rome, Italy
e-mail: semplici@lettere.uniroma2.it

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shares the same scope of activities and produces analogous effects. What is at stake, following a comprehensive and telling definition by R.E. Freeman, is a new need "for theories and strategies for dealing with particular groups and issues, and the need for processes for integration across issues and groups." This new need was triggered by "shifts in traditional relationships with external groups such as suppliers, customers, owners and employees, as well as the emergence and renewed importance of government, foreign competition, environmentalists, consumer advocates, special interests groups, media and others" (Freeman 2010, p. 27).

Responsibility Toward Stakeholders, Responsibility for Health

Social responsibility implies what has been defined as a holistic perspective. An illustrative example is provided by ISO 26000 that has been worked out by the International Standard Organization with the purpose of giving guidance on this new approach. Seven "core subjects" are identified: organizational governance, human rights, labor practices, the environment, fair operating practices, consumer issues, and community involvement and development. It is neither about the idea of immediately widening the reach of legal constraints nor about setting a strict management system standard. On the website of the organization, it is explicitly asserted that ISO 26000 aims solely at boosting "voluntary guidance" and is therefore "not intended or appropriate for certification purposes or regulatory or contractual use." The goal is rather to boost a *shared* commitment, and the addressees are therefore "organizations of all types, in both public and private sectors, in developed and developing countries, as well as in economies in transition." A wide range of goals to pursue and initiatives and tools to improve is underpinned, because of the fact that the decisions, procedures, and deeds of whoever acts within the market of producing and trading commodities and services impinge upon the life of individuals and societies in manifold ways. Sometimes even at the global level, as it unquestionably happens in the case of multinational companies or other institutions whose decisions affect millions of people at one time.

One of the main topics that social responsibility refers to is undoubtedly the protection and promotion of health. In ISO 26000 itself, health is explicitly mentioned as one of the main issues directly related to the core subjects of labor practices, consumer issues, and community involvement and development, but its relevance for the others as well is also quite obvious. This observation corresponds with the awareness that everyone's health depends very much on the conditions in which people are born, live, work, and age. The World Health Organization established in 2005 a Commission on Social Determinants of Health that produced its final report in 2008. The importance of various social, economic, and environmental factors was stressed, together with individual genetic characteristics and behaviors. This is where the concrete opportunity to enjoy "the highest attainable standard of health" that had already been recognized in 1946 in the WHO Constitution as "one of the fundamental rights of every human being without distinction of race, religion, political belief, economic, or social condition" is at stake.

This is where we have to acknowledge the existence of huge, growing inequalities. It is vis-à-vis these inequalities that WHO calls on us to share an ambitious commitment to "closing the gap in a generation" and complying with three overarching recommendations: (a) improve daily living conditions; (b) tackle the inequitable distribution of power, money, and resources; (c) measure and understand the problem and assess the impact of action (WHO 2008, p. 10).

Article 14 of the *Universal Declaration on Bioethics and Human Rights*, adopted by UNESCO in 2005, offers a telling summary both of the social determinants that need addressing and of the "sharing" of responsibility that is required to perform the task effectively. A list of the main targets of this commitment is clearly bulleted in the second paragraph: access to quality health care, access to adequate nutrition and water, improvement of living conditions and the environment, elimination of marginalization and exclusion on any grounds, reduction of poverty and illiteracy. The premise is the traditional underlining of the enjoyment of the highest attainable standard of health as one of the fundamental rights of every human being. It is in the concise wording of the first paragraph, however, that the two pillars of the conceptual link between social responsibility and health are unmistakably stated: "The promotion of health and social development for their people is a central purpose of governments that all sectors of society share." On the one hand, this statement implies the awareness that no actual promotion of health for people is possible without making development of the whole society a pivotal issue. On the other hand, "all sectors" of the latter are called upon to share this responsibility that is unquestionably and in the first place a responsibility of governments, but can in no way be considered a responsibility *just* of governments, lest the goal of promoting health be missed.

The standard of health and health care that is actually available not only for the wealthiest part of the population, as indicated by the figure of life expectancy at birth, is one of the variables that build up the Human Development Index, together with educational attainments and income. The *Annual Report*, an independent publication commissioned by the United Nations Development Programme, offers strong evidence of the impossibility of leading the ranking concerning health while remaining at the bottom of the list as regards the other factors. If we look at the 2011 report, we are still confronted with the brutal fact of a world where the people of some countries enjoy a life expectancy beyond 80 years and many others cannot expect to live beyond 50. The interdependence of the variables is hardly deniable. Only 3 among the 20 countries with the lowest general index are able to offer their citizens a life expectancy of more than 60 years, whereas only 3 among the first 20 countries ranked fall below 80 years. The "inequality adjusted" Index underlines the figures of this deep fault even *within* and not just *between* the different States. Poor people living in less developed countries appear to "share" a doubly burdened life expectancy: greater inequalities in terms of the opportunity to have access to quality health care and greater inequalities in terms of education and income. Better health and a longer life rely on greater and comprehensive human development.

Other benchmarks of development are easy to add. *Health in all policies*, the *Adelaide Statement* adopted in 2010 by the participants at a meeting promoted by the government of South Australia together with WHO, points to many examples of

joined-up government action to promote health across all sectors of government and at the same time engage the health sector in contributing to others: economy and employment; security and justice; education and early life; agriculture and food; infrastructure, planning, and transport; environment and sustainability; housing and community services; land and culture. Once again, it is easy to see how tightly interwoven all these issues are, although education (culture) and income (wealth) directly or indirectly affect most of them and contribute in the most important way to shaping general living and working conditions and thereby the conditions of health. In any case, this is the point explicitly made in Article 14 of the UNESCO *Declaration* of 2005; this unavoidable political challenge turns into a matter of *social* responsibility as soon as we acknowledge that efficiency and effectiveness in the action of governments is not enough, even if supported by a great amount of resources.

Looking at economic actors, whose social responsibility is first underscored, it goes without saying that their role is and will remain crucial, starting with the manufacturing sector. Industry – together with health care, research, and education – is one of the "special areas of focus" identified in the Report of the International Bioethics Committee of UNESCO on Article 14, published in 2010: "Work conditions can be harmful for people. Pollution can damage the environment and jeopardize the well-being of the population. Marketing strategies are often used to boost unhealthy behavior related to food and lifestyles. Research itself may serve profit-oriented activities more than interests and needs of individuals and society" (UNESCO 2010, § 64). Two specific aspects need addressing, however, in comparison with the more general commitment to include goals other than profit, constraints other than law, and respondents other than stockholders in the definition of a corporation's strategy. Health, that is, a fundamental human right, is what we are talking about. Therefore, at least in this context, it is difficult to make a sharp distinction between the term "stakeholder" and the term "citizen." We are all legitimate stakeholders with regard to the responsibility for health. The other specification refers to the concept and context of sharing. The idea of a threshold of sharing, for example, in the sense of the protection of intellectual property, is in principle consistent with an effective, sincere commitment to social responsibility. Can this be the case with the right to enjoy the benefits of scientific development when life itself is at stake? Not surprisingly, in the *Universal Declaration on Bioethics and Human Rights*, the article devoted to the principle of benefit sharing comes immediately after that on social responsibility, repeating almost verbatim the same list of core subjects.

Why Social Responsibility Is Required

There may be many and very different reasons for a profit-oriented company to improve its reputation as a socially responsible one. A producer of detergent could devolve part of the price paid by purchasers to promoting a campaign for the vaccination of newborns in a developing country: not under the table, but as

the pivotal message of an advertising strategy. A bank could donate part of the commission paid by its account holders to a charity which helps to provide health care, medicines, and housing for the poorest in times of financial crisis: a poster in full view at the entrance of every single branch could illustrate all the details of the operation. An industry could pledge to establish a zero-emission plant just outside a town: it is perfectly aware of the steady determination of the inhabitants to protest against the project otherwise. The list can easily be extended. The unavoidable conclusion seems to be that in many circumstances, the protection and promotion of health are the means to obtain something else (approval, trust, readiness to buy, and loyalty in doing that) much more than a goal as such. All the same, even the most instrumental application of the practices stemming from the principle of social responsibility – in terms of "cause-related" marketing or "strategic philanthropy" – is not a justification to dismiss the principle. On the contrary, it underlines its importance and the potential pervasiveness of its effects.

The commitment to improve everyone's standard of health seems to come up against the traditional *weakness argument* applied to all *social* rights. When we look, for example, at the *International Covenant on Economic, Social, and Cultural Rights* that was adopted by the General Assembly of the United Nations on December 16, 1966, in one and the same resolution with the *Covenant on Civil and Political Rights*, the insurmountable difference between the "civil and political rights" on the one hand and the "economic, social, and cultural rights" on the other is conspicuous. Article 1 reads the same in both documents: it is about the right of every individual and people to self-determination and to freely dispose of their natural wealth and resources, according to the principle of mutual benefit and international law. The instruments suggested in Article 2 to respect, protect, and fulfill the rights that the two covenants referred to are quite divergent, however. In the case of civil and political rights, each State is called upon to adopt "such laws or other measures" as may be necessary to ensure "that any person whose rights or freedoms as herein recognized are violated shall have an effective remedy" and that such a remedy is to be guaranteed by "competent judicial, administrative, or legislative authorities." In the case of economic, social, and cultural rights – including, according to the standard definition, the right to "the enjoyment of the highest attainable standard of physical and mental health" (Art. 12) – we cannot always and immediately rely on the force of public coercion. Each State party's commitment can but be to take steps "to the maximum of its available resources." Legislative measures are just part of a broader strategy, aiming "to achieving progressively the full realization of the rights." Needless to say, a progressive achievement can be easily criticized as simply a way to put off the concrete realization of a less unjust society and cannot, in any case, be as effective as a judicial remedy. This is exactly the point at which social responsibility steps in, however, before, beyond, around the law.

A social right is a *positive* right. The word means that it is not enough in order to realize the right, to refrain from doing something, for example, from doing harm to someone else, and to have laws that ensure that every violation is prosecuted and punished. It is necessary to do something actively, as it happens every time that

a new treatment against a disease is made available or a new school is built. Resources are therefore needed, especially when the right to enjoy such benefits as those related to health care and education is recognized independently of any differences in economic condition. Knowledge is also a limit: by enlarging it, we steadily widen the scope of what it is actually possible to achieve. In other words, a positive right is necessarily confronted with the issue of *attainability* and is to be considered, at least to some extent, as a context-related right. There is no reason, however, to understand this observation solely in terms of the difference between what is legally mandatory and what remains an imperfect duty (see below), not only because of the observation that legislative measures may contribute decisively to the progressive realization of social rights. In acknowledging this difference, by the same token, we are looking at the unavoidable and possibly fruitful permeability of the two spheres, besides addressing the specific complexity of the obligation entailed in every social right. Social responsibility boosts this dynamic, thus helping to move forward the limit of what remains – so far and, it is to be hoped, only so far – unattainable.

This statement can be explained by the well-known distinction proposed by Immanuel Kant in the *Metaphysics of Morals*. Kant distinguished, among the duties of virtue, the duty to respect from the duty to love. The former implies an obligation to refrain from intruding on one another's freedom as well as from doing harm to someone else and from treating other human beings as mere instruments. In this sense, the duty to respect sets a distance between individuals, each of them remaining free to pursue their own goals. The duty to love, on the other hand, brings the same individuals closer to one another, looks for the good of one's neighbor, and implies a commitment to doing something actively. It is the duty to enhance everyone's capabilities, as well as to help them in their needs in order to promote their happiness. Only the duty to respect is a strict one, however, and is therefore likely to become a legal duty, secured by the coercive force of the law, and we can consequently call it a *perfect* duty. The duty to love remains a wide, and thus *imperfect*, duty, in relation to both its content and its context. By assuming something as a purpose of social responsibility, we can say that we avoid the temptation to reduce the content to just a matter of private deeds and the context to that described merely in terms of a two-subject game: the State and its law on the one side and the individuals on the other. Kant himself paves the way for such an interpretation by assuming an ethical community besides the juridical one.

A very telling example of this overlap of perspectives has been offered by Amartya Sen in his book *The Idea of Justice*. Taking his cue from a very old distinction in Sanskrit literature, he describes a difference between two roots of this idea: we can speak of justice either in terms of *niti*, that is, in terms of "organizational property and behavioral correctness" related to "the institutions or rules we happen to have," or in terms of *nyaya* that "stands for a comprehensive concept of realized justice." In the real world – this is the very heart of the argument – we cannot be satisfied with performing the task of a sort of perfectionistic, transcendental institutionalism. In the first place, because there may be circumstances where the decision to abide strictly by the law could imply the risk of intolerable

consequences, owing to the overlap of very complex chains of determinants and effects: it is the Weberian call for an ethics of responsibility against the inflexible application of the principle that justice always has to be done, even though the world might perish. Second – and this is for us the most relevant clarification – because good institutions are insufficient in any case to achieve many meaningful human goals and especially to fully realize a social human right. This is also the answer to the "institutionalization critique," that relies on the belief that "real rights must involve an exact correspondence with precisely formulated correlate duties" and – simply because of the inevitable lack of strict juridification – social rights would therefore necessarily fall prey to rhetorical declamations. Reliance on institutions for the realization of "welfare rights" is out of the question. Yet, it is precisely the ethical significance of these rights that widens the scope: "helping to generate greater awareness of the seriousness of the problem" and pressing for changes in "social attitudes" may be as important as serious commitment to producing changes in institutions (Sen 2010, pp. 20–21 and 382–383).

Social responsibility for health works along the edge that separates and at the same time links *niti* and *nyaya*. The commitment to making it possible for every human being to enjoy the highest attainable standard of health is to be conceived as a universal obligation independent of any specific condition and capacity. What is at stake is the first and most important of all *basic* goods. Therefore, albeit we have to acknowledge that there are limits that no institutional framework can overcome, we cannot be satisfied with reshaping just our good will. John Rawls, who possibly produced the most influential example of a political-institutional and yet flexible theory of justice, has no doubt that basic health care for all citizens is one of the principles that all liberal conceptions ought to share, if the goal is to offer to all citizens the essential means to make effective use of their freedom. In meeting the challenge, however, social attitudes are equally important. To assess whether or not the right to X is realized, Thomas Pogge suggests to evaluate not only the fundamental legal texts and the functioning of the judicial system but also any social institution whose action (or inaction) impinges upon the enjoyment of that right. In the end, the pervasiveness of social attitudes may result in a change of the legal system itself. What happens, for example, when a patient dies, in a country where a free public health-care system is not provided, from a disease that required an expensive medical treatment that she/he could not afford? The lack of a strict legal obligation does not justify dismissing the right or even the *duty* to indignation: "a valid complaint against our social institution can be presented by all those whose physical integrity is not sufficiently secure, not by all those who happen to suffer an assault." Good and inclusive nonlegal practices, "such as a culture of solidarity among friends, relatives, neighbors, compatriots," may anticipate or implement what is legally binding (Pogge 2008, p. 53), in the sense of a social responsibility before, beyond, around the law. Even in the case of philanthropy for the sake of profit, it is only because certain behaviors and procedures are appreciated by the public that they may happen to be included in a self-interested strategy.

The difference between legal and social responsibility requires and at the same time strengthens the bonding role of *solidarity*. We find here three main

conceptions, once we accept the principle that it is the standard of health of every human being that ought to be maximized. Solidarity has often been interpreted as a group concept, based on a shared experience of life and events, on a shared narrative identity. In this case, the bond and the obligation we feel and recognize as stronger are toward only some people with the exclusion of others and the coherent conclusion had already been drawn by Adam Smith in the sixth part of his *Theory of Moral Sentiments*: "the state or sovereignty in which we have been born and educated, and under the protection of which we continue to live, is, in ordinary cases, the greatest society upon whose happiness or misery, our good or bad conduct can have much influence," whereas the administration of the great system of the universe and the care for universal happiness are to be considered as "the business of God and not of man" (Smith 1759, VI.II 27 and VI.II.49). According to a second conception, respectful of the comprehensive framework set by the modern tradition of universal human rights and proposed by Michael Sandel in the ninth chapter of his book *Justice*, published in 2009, we should distinguish three different categories of responsibility: (a) natural duties that we owe to human beings as such; (b) voluntary obligations, such as contracts; (c) obligations of solidarity that involve responsibilities we owe to those with whom we share and *feel* we share a particular history or identity. Justice, in the case of a fundamental right such as that to health care, should not be predicated on solidarity, inasmuch as the latter produces asymmetries of commitment: equality is supposed to be the benchmark. It is easy to see, however, that these asymmetries are the standard not only of most practices but also of most normative statements at the international level: the States' first and primary obligation is to their own people, and, although the principle of some kind of responsibility for other, poorer, countries is by now widely accepted, this duty is a very loose one and the States in the end retain their freedom to choose what to do. This is why, for example, the *Report of the International Bioethics Committee on social responsibility and health*, published in 2010, looks at an idea of solidarity that "requires more than that, thus involving an idea of justice." We can call it cosmopolitan solidarity that boosts the awareness of a "shared life or destiny" not only within each person's group but also in the direction of a "profound and active acceptance of our interconnectedness," that turns social responsibility into "a principle that defines and celebrates our common humanity." In this perspective, it is solidarity itself that underpins the conviction that the limits of attainability, the constraints of a progressive and only progressive realization, and the lack of legally binding instruments in the transnational context do not allow us to dismiss the principle that "the maximum of equality remains the ultimate goal when everyone's right to life is at stake" (UNESCO 2010, §§ 41, 101 and 40).

Frameworks for Action

Governments are obviously the first addressees of a call for responsibility for health. They do indeed have at their disposal the most powerful means – taxation and legislation – to collect the resources that are needed and to set the rules

concerning both the access to health care and the protection of their people from the consequences of unhealthy or even hazardous living conditions. Most international documents now distinguish these two clusters of care/assistance and prevention/protection obligations. The *European Social Charter*, revised in 1996, provides – among others – an illustrative example. On the one hand, the States undertake to ensure that any person who is without adequate resources is granted adequate assistance and, in case of sickness, the care necessitated by his or her condition. On the other hand, the States undertake (a) to remove as far as possible the causes of ill-health, (b) to provide advisory and educational facilities for the promotion of health and the encouragement of individual responsibility in matters of health, (c) to prevent as far as possible epidemic, endemic, or other diseases, as well as accidents. The provision to ensure the "care necessitated" has unavoidably to face – as I have already underscored – not only the limits of attainability that applies to all human beings because of the limits of knowledge itself but also the limit of attainability that is the consequence of a lack of resources. Owing to the former, more and more appropriate and effective means to fight diseases are made available only progressively. Owing to the latter, what is readily available for some peoples or some individuals remains unaffordable for others. Nonetheless, it is up to the States to avoid new faults of inequality worsening the situation *within* the countries they are responsible for. This is why we still have to speak here of a responsibility that is, at least in the first place, *political* rather than social.

Of course, a determined and comprehensive action by governments and States is also decisive in addressing the broad social determinants of health, thus improving its standard together with the other figures of human development. Working conditions largely depend on legislation, as well as the control of production and trade of hazardous substances. Food and drugs safety is manifestly crucial for health, and in order to guarantee it, the regulation of a long chain of activities is required. The necessity of such a regulation has long since been accepted with regard to research on new medicines, especially when it involves human subjects, but there is increasing awareness that healthy food is as much a goal, starting with sustainable agricultural practices and ending with clear, exhaustive information for the consumer. Urban and infrastructure planning are also a competence that governments can never dismiss. Think of the impact of the lack of an adequate transport network and of devastating nonrenewable resources on daily life and the environment. Housing may be considered another private matter of public interest: enforceable laws are probably the best instrument to prevent people from building houses in dangerous places or not respecting the security standard required to withstand natural disasters like earthquakes. The whole span of the competences entrusted to public institutions is involved: regulation and standard setting, enforcement and coercion, financing. This, however, is a responsibility that must be shared with other public and private organizations and associations as well as individuals. The best-designed system of disease surveillance, for example, relies on people reporting disease even if they are afraid it could be a very contagious one. There are some thresholds respecting privacy that it may be inappropriate or difficult to cross: everyone should be fully informed about the huge risks of smoking,

and many States have now adopted legislation to prohibit it in every public space, but turning it into a crime still appears to be overzealous. Calling for social responsibility for health entails the commitment to be loyal to the law, at the same time increasing the effectiveness of the principles that cannot be realized only by means of existing law and efficiency in the action of governments and administrative machinery. In this perspective, some contexts of shared responsibility seem to be particularly worth focusing on.

Education and Lifestyle

Illiteracy, together with poverty, is a factor that undermines individuals' capacity to cope with the natural vulnerability to diseases that humankind is heir to, making it at the same time more difficult for them to protect themselves from the risks spread in their living and working environment. By establishing quality educational infrastructure and especially by encouraging scientific learning and education, governments may strongly contribute to improving the health of their people. Health literacy refers to the degree to which individuals are able to obtain, understand, and make use of at least basic information about what can directly or indirectly impinge upon their health. This may be essential if we are not to miss the symptoms of disease at a very early stage, thus missing the opportunity to treat it in the best possible way, as much as to detect the presence of risks, such as those related to hazardous chemicals, that are not immediately perceivable. Health literacy is also the irreplaceable premise of the capacity to make decisions according to the principle of free, informed consent. Indeed, the beneficial effects of higher levels of education go far beyond it. They help to enlarge the number of professionals and the application of the most advanced results of scientific research. They foster the awareness that the standard of health that people enjoy is not a matter of destiny, but of fundamental rights and corresponding obligations, thus boosting the will to claim those rights and to criticize lack of respect of those obligations. The overlap of poor educational systems, weak and often corrupt institutions, deep social inequalities, and poor health is not a chance circumstance.

At the same time, individuals cannot call themselves outside their own responsibility. It is up to them, once they have sound information about the likely causes of many diseases, like lung cancer or cardiovascular problems owed to binge eating, to steer their lifestyle accordingly: appropriate behaviors and commitment to sharing them are nowadays one of the most powerful means of prevention. This is all the more reason for not behaving in such a way that others could suffer harm: sexually transmissible diseases need to be coped with through full awareness of one's personal condition and of the means to check it, together with the decision not to conceal the risk to one's partner; the most severe laws are not sufficient to prevent people from dying and being killed in accidents, as long as too many drivers do not take their responsibility for other people's lives, as well as their own, seriously enough.

Media and Information

The media play a decisive role in knowledge dissemination. They have become one of the most important – for many people, the only – source of information. Therefore, professionals in this sector can help a lot to improve people's sensitivity to health-related issues, trigger serious debate about the most relevant challenges, and give to experts and scientific institutions a wider opportunity to explain to citizens the main outcomes of research that may have an impact upon their daily life or offer concrete hope against disease. This role is crucial when there are valid reasons to fear that an epidemic could break out or some other widespread threat against public health is to be thwarted. The media, however, can fall easy prey to an audience-oriented approach, which is analogous to the profit-oriented strategy of an entrepreneur who is therefore not considered socially responsible. This is the case when they run after scoops and sensationalism by all means, either announcing prematurely revolutionary findings that are not validated by the scientific community or, conversely, raising unjustified alarm that causes confusion and increases pressure upon the authorities to take expensive and perhaps unnecessary measures.

The transparency and reliability of information are the indispensable premise and guarantee for decision-making procedures that are contended with trade-offs more and more difficult to cope with. The costs of making available to the largest number of people what science has made possible are growing: health care needs resources, and resources are limited, even in the richest countries. We therefore need reasonable criteria for their *fair* allocation and priority setting, together with an open-minded willingness to revise and update decisions in the light of new elements of knowledge and discussion among stakeholders. This role of the media, besides the internet and all kinds of social networks, is even more important when civil society and political institutions face the challenge of developing laws on very controversial matters, as often happens in the context of health-related issues.

Professionals and Research

Health-related business is a legitimate economic activity. Notwithstanding, it deals with the very first of all human rights and is therefore exposed not just to the risk of a conflict of interests but to the risk of jeopardizing life itself. Focus on the care and well-being of patients is the crucial calling of all physicians according to their conduct codes, if not the law. It means therefore that medicine is to be considered as a very special kind of profession, where a practice is exerted whose possible commoditization should always be thought of as a means to improve protection of health, without predicating protection on the capacity to pay. This awareness affects many aspects of the activity of all professionals involved in the health-care sector: how they participate in decision-making procedures on priority setting, their relationships with profit-oriented bodies such as pharmaceutical industries and medical equipment firms, and the promotion of their own expertise, which cannot be subject to commercial advertising. No trade activity should in principle stimulate

wanton consumption of goods, but in the case of medicine, this limit ought to be seen as imperative: the target is the actual needs of people, without profiting from the insurmountable asymmetry of competence and in the most cost-effective way.

Research aiming at new treatments and drugs shares this responsibility. There are two main aspects to be considered here, and both are related to the observation that nowadays a substantial amount of applied research is carried out by the private sector. The first one is the possibility that scientific development is driven by the interest in potential financial reward more than potential social benefits. This is a fault of inequality that is not likely to be overcome by any legal instrument. The telling example is that of research on ailments, such as tropical diseases, that affect the poor much more than the rich and entail both high costs and small or even no profit and thus remain largely neglected. The second, crucial, issue is that of sharing of benefits and intellectual property, whose impact cannot be overestimated, especially at the global level. The *Doha Declaration on the TRIPS Agreement and Public Health* of 2001 explicitly acknowledged that "flexibility" is unavoidable, given "the gravity of the public health problems afflicting many developing and least-developed countries." Social responsibility draws on this flexibility and widens its reach and content, neither with the aim of simply dismissing the system of patents that retains in many circumstances its valuable function nor eluding the challenge of financing and rewarding research. Some promising initiatives are already being carried out: a number of charities and nongovernmental and international organizations are addressing specific health problems related to poverty and exacerbated by it. Of course, the results would be significantly improved if the governments of the wealthiest countries agreed to share this approach. At the same time, the agenda of priorities should be reshaped by involving all stakeholders who are relevant, besides empowering people to set it by themselves.

Global Market

The concept of social responsibility was first introduced to strengthen the accountability of economic actors. The premise is the impossibility of thinking of the economy as a monadic and thus exclusively self-oriented activity. Companies themselves – according to Joseph Stiglitz – are communities of people working together with a common purpose and "as they work together, they care about each other, the communities in which they work, and the broader community, the world, in which we all live." For sure, this concept has helped to develop a more careful awareness of the full consequences of what happens in the market. It has also brought about, in many countries, some change "in the mind-set of many corporations and of the individuals who work for them." As "in a world of ruthless competition incentives often work against even those with the best of intentions," however, corporate social responsibility is often compelled eventually to turn itself into a claim for legislation, lest complying with it would depend only on the payoff of good reputation against bad (possibly hidden) behavior. Stronger, legal regulations protect those who are really serious about higher standards "from those who

do not adhere to the same standards. Regulations will help prevent a race to the bottom" (Stiglitz 2006, pp. 198–199). This is not to dismiss the importance of corporate social responsibility but to underline its role as the cultural background of a complex society determined not to elude its obligations in terms of justice and fairness and, at the same time, fully aware of the constraints of efficiency and competition in a globalized market of workers, goods, and financial resources.

Therefore, it is no surprise that in the final report of the WHO Commission on Social Determinants of Health, the responsibilities of the private sector and those of governments largely overlap. The former is trusted, among others, to ensure fair employment and working conditions for men and women, reduce and eradicate child labor, and ensure compliance with health and safety standards. It is up to the governments to implement *regulatory* mechanisms to promote and enforce fair employment and decent work standards for all workers. The risk of a clash of obligations stemming from the duty to aim at the highest standard without accepting any compromise when the most fundamental human right is at stake against the constraints of a pitiless, iron-hearted competition is manifestly much higher when legislation makes the difference. This is why the global market is the arena where the tasks of social responsibility are at the same time the most important to proclaim and, very often, the most difficult to perform. Economic actors are called upon not to profit from double standard opportunities, that is, from the chance not to abide by the same rules in different contexts and with different people when a significant harm or risk to health is likely to result, first and foremost considering working conditions and the protection of the environment. The golden standard set by the most advanced legislations, the best practices, and the most demanding international codes and agreements, even if not legally binding, should be applied.

International Cooperation

The cosmopolitan version of the concept of solidarity, rooted in the experience of living in one and the same world, is presupposed by the principle of sharing the benefits of scientific development as expressed in Article 15 of the *Universal Declaration on Bioethics and Human Rights*, even though this assumption does not and cannot claim that all differences and inequalities can be tackled overnight. The range of the benefits we are looking at is indeed very broad: access to quality health care, provision of new diagnostic and therapeutic modalities, support for health services, access to scientific and technological knowledge, and capacity-building facilities for research purposes. Science, together with market and some cultural mainstreams, is a powerful determinant of globalization. The challenge of a *global* social responsibility for health, however, entails much more than the refusal to predicate the right to share the life-saving benefits of scientific research on participation in research itself, as I have already underscored.

To take seriously the universality of the principles of economic justice implies the willingness to improve the sharing of resources, standards of education,

and policies oriented to ameliorating the poorer statistics of social determinants of health. Sharing of resources does not refer exclusively to income. It entails, for example, the capacity to reverse the brain drain of highly skilled professionals from low-income countries to the richest ones. Sharing of education is made possible by establishing networks organized on the principle of open access and taking advantage of new technologies to connect people from all around the world, thus minimizing the costs of globalization of knowledge. Sharing of policies requires strong determination to support those international institutions whose mission is to assess and reshape the rules of the game that many people reject because all too often, they are set according to the one and only principle that might be right.

This is equally true when there are risks rather than benefits to share. Pollution is probably the most telling example of a potential harm to health that cannot be effectively tackled only by single States or groups of States, both because the one polluter who would still act as a free rider could gain decisive competitive advantage and because the consequences of pollution will inevitably spread worldwide. At the same time, we are today increasingly confronted with new responsibilities that arise in almost every area of medicine and life sciences and could determine a growing delocalization of dangerous practices. Genetics and bioengineering, nanotechnologies and neurosciences, may easily produce unprecedented situations of discrimination, special vulnerability, and multiple standards of respect and protection that cannot be addressed without an agreement on new rules and priorities at the international level, as well as the capacity to foster the feeling that we are all stakeholders in terms of the decisive challenges to the future of humankind.

Conclusion

The right to enjoy the highest attainable standard of health is a social right. Consequently, its realization relies not only on appropriate legislation but also on willingness to strengthen the pillars of education and civil society that contribute to ensure that this right be effectively acknowledged as something that is worth active effort and investment in terms of both individual and collective behaviors. Laws concerning social human rights can but be formulated in a program-type manner, even when they entail some binding obligation and/or prohibition. To let the program become reality, to the furthest extent of what is actually attainable, all individuals and sectors of society, together with governments, ought to do their best to improve the different factors that are requisite for the flourishing of human life: on the one hand, minimizing discrimination on any ground as well as the consequences of inequality of resources, environmental risks, and unhealthy personal behaviors, on the other hand, promoting concrete solidarity, sharing of knowledge, and capacity-building. The right to health is not just about the conditions of access to quality health care that obviously remains the cornerstone of political responsibility for health. It is about boosting awareness of the right and consequently the availability and affordability of the means to prevent diseases and suffering and to deal with them better.

The looser the legal coercion, the more important is the role of social responsibility, not as a weak substitute, but as a front-runner of the effort to dismiss every double standard of human dignity. Global bioethics is at the crossroads of many crucial issues stemming thereof. The idea of a worldwide-shared commitment to provide every human being with the best opportunity to live long and be free to pursue their goals gives perhaps the best unquestionable evidence of the solidity and reasons of the vocabulary of human rights.

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Sharing of Benefits

14

Doris Schroeder

Introduction

Benefit sharing is a legal term used in the context of access to and utilization of biological resources. The term describes an exchange between those who grant access to a particular resource and those who provide compensation or rewards for its utilization. For instance, in 2000, a US-based biotech corporation (Diversa) signed an agreement with a South African research institute (CSIR) to obtain access to South African microorganisms. In return for such access, Diversa supports the CSIR's bioprospecting activities and pays royalties on any successfully developed products. The above exchange is typical for a benefit-sharing agreement as governed by the UN Convention on Biological Diversity (CBD, 1992).

On a broader understanding of benefit sharing, results from scientific research should be shared with society as a whole and not only with those who provide access to resources. This more aspirational meaning of benefit sharing is expressed, for instance, in the UNESCO's Universal Declaration on Bioethics and Human Rights (2005). The main governance instruments for benefit sharing are listed in Table 14.1. The Declaration of Helsinki, the Convention on Biological Diversity, and the UNESCO Universal Declaration on Bioethics and Human Rights will be discussed in more detail in this chapter.

This chapter examines both aspects of benefit sharing and aligns them with different conceptions of justice. The access and benefit-sharing requirements of the CBD – which covers plants, animals, microorganisms, and traditional knowledge – will be described as a justice-in-exchange mechanism. The same applies to the benefit-sharing provisions for human biological resources through post-study access to successfully tested medical interventions or alternative benefits. The distributive justice and human rights aspects of benefit sharing will be examined using the above mentioned UNESCO declaration. Four case studies are added to illustrate the challenges occurring in all areas of benefit sharing.

D. Schroeder
Centre for Professional Ethics, University of Central Lancashire, Preston, UK
e-mail: dschroeder@uclan.ac.uk

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Three Benefit-Sharing Instruments

The Convention on Biological Diversity

In 1992, a UN conference of unprecedented size and scope was held in Rio de Janeiro. What became known as the "Earth Summit" provided a platform for discussing the ongoing destruction of global biodiversity. Almost 10,000 on-site journalists covered the summit, and its main output was the Convention on Biological Diversity (CBD). The CBD recognized that the conservation of biodiversity is a "common concern of humankind."

The legally binding convention has 193 Parties (the world minus the United States of America (USA) and Andorra). It has three major objectives:
The conservation of biological diversity
The sustainable use of its components and
The fair and equitable sharing of benefits from the use of genetic resources

The first objective relates to the common interest of humankind, namely, to deal with the serious loss of biodiversity and its potential implications for ecological functions as well as future technoscientific uses. The twentieth and twenty-first century witnessed the disappearance of species at 50–100 times the natural rate. The figure had risen to 100–1,000 times the natural rate in 2010 and may accelerate to 1,000 or 10,000 times by 2020. The second objective relates to user requirements for the long-term availability of resources, for instance, in scientific or commercial endeavors or to support human livelihoods. The third objective summarizes the demands made by developing countries since the 1970s, namely, to require users to share benefits with resource providers in order to avert exploitation. The Convention on Biological Diversity covers plants, animals, microorganisms, and related traditional knowledge.

To understand the established legal meaning of benefit sharing, it is important to consider why resource use can be exploitative (see Box 14.1 for a definition of exploitation).

Box 14.1: Exploitation
Exploitation is a failure to benefit others as some norm of fairness requires leading to wrongful gain on the one hand and undeserved loss on the other (Mayer, 2007). Three forms of exploitation can be distinguished:

In type 1 exploitation, exploiters fail to benefit other parties *at all* even though they ought to. For instance, public transport users who "dodge" fares are exploiters type 1 or free-riders.

In type 2 exploitation, exploiters do not benefit others *sufficiently*. In this case of exploitation, an exchange takes place, but it does not benefit both parties fairly. One party gains disproportionately, while the other loses out. For instance, a landlord might exploit a recent immigrant's ignorance of local rents and overcharge her.

In type 3 exploitation, exploiters do not benefit others *authentically*. Exploiters might give others what they want and at a fair price, but the exchange does not genuinely benefit them. For instance, the purchase of heroin might be what buyers want and it might be sold at a competitive market price, but they would nevertheless be harmed by the exchange when judged from a neutral standpoint.

Why should a European researcher who uses an African plant in product development be hampered by access and benefit-sharing requirements of a legally binding international convention? Why not assume that the resulting product, for instance, a new medical drug, will benefit humanity as a whole and leave scientists unencumbered by costly bureaucracy?

Indeed, prior to the adoption of the CBD, nonhuman biological resources and traditional knowledge were frequently regarded as the common heritage of humankind. Bioprospectors were able to take resources out of their natural habitat or make use of traditional knowledge to develop commercial products without sharing benefits with states or local communities. This approach was justified on the premise that the planet's biodiversity ought to be shared among humankind rather than being fenced in by individual states.

The idea of the common heritage of humankind entered the canon of international law in the 1970s and 1980s with the conclusion of two UN brokered international treaties: the Agreement Governing the Activities of States on the Moon and Other Celestial Bodies (1979) and the Convention on the Law of the Sea (1982). These treaties declared that the seabed, the ocean floor, its subsoil, as well as the surface and subsurface of the moon should not become the property of any state, organization, or individual. Instead, they were regarded as the common heritage of humankind. But what does the common heritage principle mean? There are two conflicting interpretations exemplified respectively in the initial text (1982) and subsequent revision (1994) of the Convention on the Law of the Sea. One interpretation is that the common human heritage must be used and enjoyed on terms that benefit all. The other is that the common heritage is available to be used and exploited at will on a first-come, first-served basis.

In preparatory negotiations for the CBD in the late 1980s, academics, activists, and politicians from around the world started to point out that the latter interpretation of the common heritage was predominant in cross-border research activities involving biodiversity. This was not surprising given the uneven playing field in science and innovation (see Diagram 14.1 on the technological divide and Table 14.2 mapping biodiversity against poverty).

As can be seen from Table 14.2, the burden of serious poverty and the availability of mega-biodiversity align in most cases, with only a few exceptions. Given in-country lack of resources for investment in science and technology, it is clear that most scientists who access mega-diversity are from the north. If this is

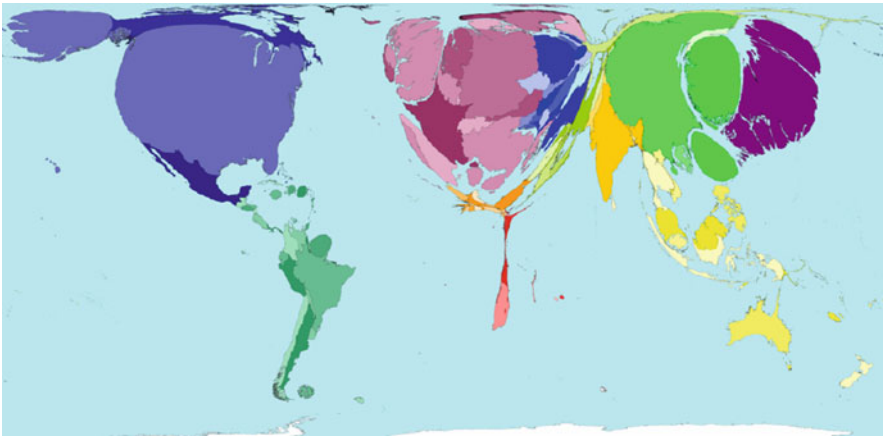

Diagram 14.1 Research and development expenditure in 2002, WorldMapper (© Copyright SASI Group (University of Sheffield) and Mark Newman (University of Michigan))

Table 14.1 Main governance instruments for benefit sharing

Benefit sharing (established sense)	Benefit sharing (aspirational sense)
Convention on Biological Diversity (1992) including national laws: e.g., Biodiversity Bill India 2002, Biodiversity Act South Africa 2004 and including Nagoya Protocol, 2010	The Universal Declaration of Human Rights, 1948, Article 27(1)
	International Covenant on Economic, Social and Cultural Rights, 1966, Article 15(b)
CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects, 2002, Guidelines 5, 10 and 21.	Council of Europe's Convention on Human Rights and Biomedicine, 1997, Preamble
Declaration of Helsinki, 2008 including national laws: e.g. Brazilian National Health Council resolutions 1996, 1997, 1999, 2000	Human Genome Project's Ethics Committee Statement on Benefit Sharing (2000)
	UNESCO Universal Declaration on Bioethics and Human Rights (2005)

combined with a prior history of colonial exploitation and its consequences to this day, it can be argued that an unfair first-come, first-served system to resource use was being practiced rather than the more benign version of the common heritage of humankind principle (Shiva, 1991). In short, resource use was being exploitative (type 2 exploitation from Box 14.1).

Worldmapper uses a technique to resize territories with regard to some subject of interest. Diagram 14.1 is a world map resized according to research and development expenditures in 2002. Africa hardly appears on the map, while the industrialized north appears particularly bloated.

In July 2000, the World Conservation Monitoring Centre named 17 countries as mega-diverse countries: Australia, Brazil, China, Colombia, Democratic Republic

Table 14.2 Poverty and mega-diversity

Country	% <2$/day
Madagascar	89.6
Congo (DRC)	79.5
India	75.6
Papua New Guinea	57.4
Indonesia	46.0
Philippines	45.0
South Africa	42.9
China	36.3
Colombia	27.9
Peru	18.5
Ecuador	12.8
Brazil	12.7
Venezuela	10.2
Malaysia	7.8
Mexico	4.8
Australia	..
United States	..

of the Congo, Ecuador, India, Indonesia, Madagascar, Malaysia, Mexico, Papua New Guinea, Peru, the Philippines, South Africa, the United States of America, and Venezuela. Combined, these 17 countries host more than 70 % of the earth's species. The above table matches these mega-diverse countries with 2009 data of percentage of population living on or under the US$2 a day poverty line.

To address the common concern of humanity, namely, the depletion of biodiversity, developing countries demanded an end to one-sided resource use by foreign parties. Given that most repositories for biological resources were situated in the south (see Table 14.2), these were used to negotiate for concessions from developed countries. In the end, these concessions were:

- Sovereignty over genetic resources to be lodged with national governments, and no longer considered the common heritage of humankind
- A legal framework for dealing with biotechnology, in particular, those aspects that pose a threat to safety (leading to the Cartagena Protocol on Biosafety in 2000)
- Recognition of indigenous communities as the guardians of biodiversity and related traditional knowledge
- The requirement to share benefits with the providers of genetic resources, with their prior informed consent (PIC) and on mutually agreed terms (MATs)

The latter was the birth of benefit sharing as enshrined in the CBD's third principle, "the fair and equitable sharing of benefits from the use of genetic resources." To return to the question at the outset: why should a European scientist be hampered by bureaucracy when developing new products based on nonhuman

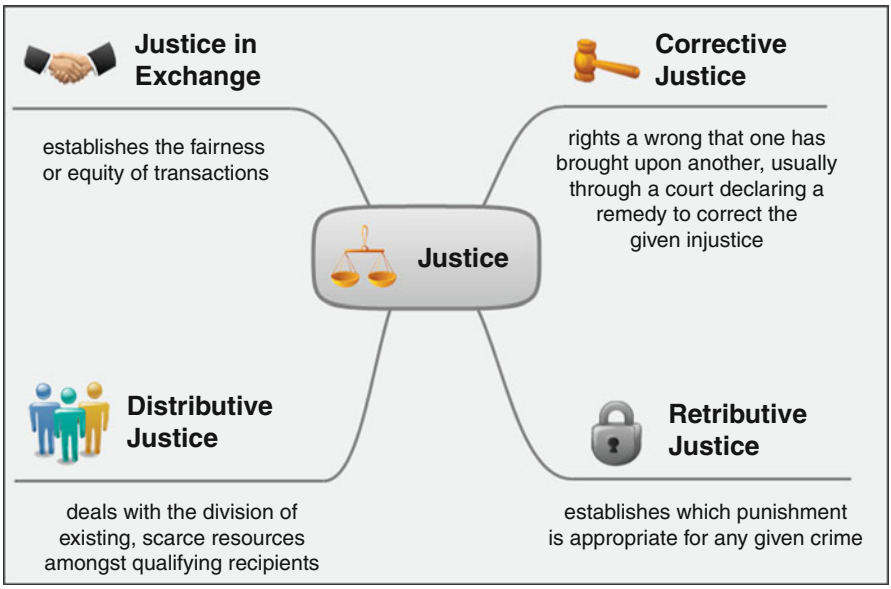

Diagram 14.2 Principles of justice

biological resources and associated traditional knowledge? Two answers are important.

The first answer is that 193 states, in other words, the world without the USA and Andorra, agreed that while the progress of science can be beneficial to humankind as a whole, it should not be based on yet another instance of wrongful expropriation of resources given the long history of colonialism.

The second answer must make reference to justice. Philosophers usually distinguish four types of justice principles, as illustrated in Diagram 14.2. The relevant principle in the context of access to resources is justice-in-exchange (Schroeder and Pogge, 2009).

Justice-in-exchange establishes the fairness or equity of transactions. It regulates the justice of giving one thing and receiving what is due in return. An interaction is considered just if all parties in the exchange receive an appropriate return for their contribution. A hidden, implicit element of justice-in-exchange is that the parties must agree voluntarily to the exchange. If something is taken from one party against their wishes, it does not make the transaction ethical simply to compensate them appropriately. Hence, what is termed prior informed consent in the context of the CBD is part of a just approach. It is an essential first step, a process requirement to achieve a just outcome.

For Aristotle, the fairness of a transaction could be judged by an outsider. The intrinsic worth of something, say a set of books, a supply of antiretrovirals, or South African microorganisms, had to be matched by a return, either in kind or in

monetary terms. Certain prices would have been deemed disproportionate by Aristotle, whether they were paid voluntarily or not. Hence, the fairness of a transaction relied on a judgment that the items exchanged were what Aristotle referred to as proportionate requitals.

Today, an understanding of justice-in-exchange based on Roman law is more common. This only requires that two competent adults (or parties) have agreed on the transaction. If somebody is willing to pay a thousand dollars for a set of books, so be it. The interaction would be considered just if the seller and the buyer had agreed on it without coercion or deceit.

What then is the second answer to the question of why a European scientist should be hampered by bureaucracy when developing new products based on nonhuman biological resources? The answer is to establish fairness in exchange. When it comes to biological resources, be they plants or microorganisms, the ideal scenario would let them be freely accessible to be used for the benefit of humankind without any inherent exploitation. In this scenario, the fair return would be access to a new product, a much needed drug for instance. Those who access resources would share the resulting benefits equitably with others. Bureaucratic barriers to the use of resources (other than for reasons of achieving sustainability) and requirements of benefit sharing would be counterproductive in a benign context where all human beings would have access to the fruits of innovation through the market. Free access to biological resources would facilitate innovation enjoyed by all, much in the spirit of the common heritage idea. But we do not live in a world thus organized. In fact, in the context of a severely unjust international economic order, which disrespects human rights (Pogge, 2008), one needs to – at the very least – avoid the most blatant exploitation, namely, that a person or a group provides access to a resource without *any* return whatsoever. Where appropriation by some (on a first-come, first-served basis) will lead to innovations unavailable to the poor, it makes sense – ethically – to fence in resources with bureaucratic procedures to aim for justice-in-exchange.

To put it simply: *those who contribute to scientific research and innovation ought to share in the resulting benefits*. If benefit sharing with the contributors of biological resources and related knowledge does not take place, scientific advancement is exploitative. For short descriptions of two cases, see Boxes 14.2 and 14.3 (for a short film on the Hoodia case, download here: http://extras.springer.com/2009/978-90-481-3122-8/).

While it is clearer now what benefit sharing according to the CBD means, it may not be clear what counts as a benefit. However, a long list of examples was given with the Nagoya Protocol. The adoption of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization was a most promising development on benefit sharing. The protocol was adopted on 30 October 2010 at the tenth meeting of the Conference of the Parties to the CBD. Adoption was achieved through a consensus decision among the 193 parties, following some 6 years of intense negotiations – which frequently pitted developed countries against developing countries, and providers of genetic resources against users of those resources.

Box 14.2: Hoodia and Skeletium Cases

One of the best known benefit-sharing cases is that of the San Hoodia (Wynberg & Chennells, 2009). The San peoples, also known as Bushmen of the Kalahari, are the oldest human inhabitants of Southern Africa. For thousands of years, they lived as the sole occupants of an area stretching from the Congo-Zambezi watershed to what is now Cape Town. After centuries of genocide and marginalization imposed by colonialists, they now number approximately 100,000 people in Botswana, Namibia, South Africa, and Angola.

Their lives today are characterized by abject poverty. Yet they still possess traditional knowledge covering the biodiversity of southern Africa. This includes knowledge about the appetite-suppressant properties of the *Hoodia* succulent – a plant used in the past as a substitute for food and water when hunting.

In 1963, a South African research institute, the Council for Industrial and Scientific Research (CSIR), developed an interest in the plant. But they were unable to analyze its molecular structure until the mid-1980s when they acquired high-field nuclear magnetic resonance spectroscopy equipment. In 1995, after successfully isolating the appetite-suppressant properties, the CSIR filed for a patent. In the same year, South Africa became a party to the Convention on Biological Diversity. This meant that those using the traditional knowledge needed to obtain consent from the holders of such knowledge and negotiate a benefit-sharing agreement with them.

The CSIR never made contact with the San. Instead, the institute sublicensed its discovery to firms in Europe and the USA. A vigilant local NGO informed San leaders that their traditional knowledge had been used in a patent application and that they could either challenge the patent or demand a benefit-sharing agreement. They chose the latter.

In March 2003, the San and the CSIR signed a historic agreement which will give the San 6 % of all CSIR royalties received from license holders and 8 % of all milestone payments. Payments of around 100,000 US$ have already been received into a benefit sharing Trust. However, Pfizer and Unilever, two high-profile sublicensees, have both dropped their Hoodia product development, and in the late 2012, the future of this high-profile benefit-sharing agreement is uncertain. However, members of the San community have benefitted from capacity building, especially in matters of law and negotiation. More positively though, further benefit-sharing agreements have been negotiated.

In 2008, another agreement was concluded between the San peoples and HGH Pharmaceuticals (Pty) Ltd. The agreement covered the antidepressant properties of the *Skeletium* plant and has to date led to an income of around 80,000 US$. The company has developed the product and has completed all required efficacy and safety compliance tests required for the US market. A resulting product will be released in the second quarter of 2012.

Box 14.3: Nicosan (Formerly Niprisan) Case

Sickle cell disease is a genetic disorder which is endemic in Sub-Saharan Africa. Each year, around 300,000 babies are born with the potentially life-threatening disease or a variant. Those who survive will suffer from recurrent painful crises, which will disrupt their lives continuously. Until recently, only palliative measures were available for affected patients. However, a Nigerian traditional health practitioner (the late Rev. Ogunyale) had developed an herbal medicine recipe, which was promising.

In 1992, a memorandum of understanding (MOU) was signed between Rev. Ogunyale and the Nigerian National Institute for Pharmaceutical Research and Development (NIPRD) under the guidance of Prof. Charles Wambebe. Research commenced and led to patents granted in Nigeria, the USA, England, India, and 42 other countries in Europe, Africa, the West Indies, and the Americas between 1998 and 2000.

In 2002, a license was granted to USA company Xechem for global manufacture. A ceremony was opened by the Nigerian President to celebrate the fact that a medicine (then called Niprisan) was fully developed in Africa by African scientists to be marketed globally. The first limited production of the drug was undertaken by Xechem in 2006 while a manufacturing plant was commissioned to be built in Abuja. In 2008, the company filed for bankruptcy and the plant was closed.

The Nigerian government withdrew the license from Xechem and charged NIPRD with further production. However, in 2010, existing supplies ran out and the drug became unavailable. The research and development of Nicosan (the drug's new name) ceased at the NIPRD in the same year.

While starting out as one of the most promising cases of using traditional knowledge to develop a medicine for a hitherto neglected disease, the results were highly depressing. While the MOU signed between Rev. Ogunyale and the NIPRD was adopted as an example of best practice by the World Health Organization (WHO) and the World Intellectual Property Organization (WIPO), no benefit sharing with the reverend or his community ever took place. The clinical trial participants who were involved to bring the drug to market have no access to the drug, not only because it is no longer manufactured, but also because it was too expensive for the poor during the short duration of being available for sale. Most frustratingly, though, a drug which addresses a serious disease that poses a major public health burden in Africa exists without being manufactured. A sufferer of the disease, Tosin Ola, expresses her severe disappointment in an interview with SciDevNet:

"Before Nicosan, I was in and out of the hospital on a monthly basis, having to have regular blood transfusions, countless IV [intravenous] sticks and daily pain. But, once Nicosan started working for me, the daily pain ceased and I have not been admitted into the hospital since 2008. The sad part is that people are dying every day and suffering needlessly in pain, while the treatment . . . is nowhere to be found" (Abutu, 2010).

1. Monetary benefits may include, but not be limited to:
   (a) Access fees/fee per sample collected or otherwise acquired
   (b) Up-front payments
   (c) Milestone payments
   (d) Payment of royalties
   (e) License fees in case of commercialization
   (f) Special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity
   (g) Salaries and preferential terms where mutually agreed
   (h) Research funding
   (i) Joint ventures
   (j) Joint ownership of relevant intellectual property rights
2. Nonmonetary benefits may include, but not be limited to:
   (a) Sharing of research and development results
   (b) Collaboration, cooperation, and contribution in scientific research and development programs, particularly biotechnological research activities, where possible in the party providing genetic resources
   (c) Participation in product development
   (d) Collaboration, cooperation and contribution in education and training
   (e) Admittance to ex situ facilities of genetic resources and to databases
   (f) Transfer to the provider of the genetic resources of knowledge and technology under fair and most favorable terms, including on concessional and preferential terms where agreed, in particular, knowledge and technology that make use of genetic resources, including biotechnology, or that are relevant to the conservation and sustainable utilization of biological diversity
   (g) Strengthening capacities for technology transfer
   (h) Institutional capacity-building
   (i) Human and material resources to strengthen the capacities for the administration and enforcement of access regulations
   (j) Training related to genetic resources with the full participation of countries providing genetic resources, and where possible, in such countries
   (k) Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies
   (l) Contributions to the local economy
   (m) Research directed toward priority needs, such as health and food security, taking into account domestic uses of genetic resources in the Party providing genetic resources
   (n) Institutional and professional relationships that can arise from an access and benefit-sharing agreement and subsequent collaborative activities
   (o) Food and livelihood security benefits
   (p) Social recognition
   (q) Joint ownership of relevant intellectual property rights

Not all of these benefits would be appropriate for benefit sharing in scientific research involving human participants, but the list gives a good idea of the diverse

Table 14.3 Main challenges for benefit sharing: Convention on Biological Diversity

Type of benefit sharing	Main challenges
Benefit sharing as justice-in-exchange 	Benefit sharing as justice-in-exchange could possibly be used by governments to neglect their duties to secure basic human welfare rights. However, benefit sharing cannot resolve distributive justice issues
	The emphasis in access and benefit sharing, as required by the CBD, must not move away from access. To obtain prior informed consent (PIC) before using nonhuman biological and associated traditional knowledge is essential
	The identification of traditional knowledge holders and their legitimate representatives remains a major challenge to achieving the goals of the CBD
	As CBD-style benefit sharing requires negotiations between users and providers of resources, unequal education, knowledge and skill levels are an impediment to just outcomes
	Managing the expectations of benefit sharing is a difficult task given that very few products ever achieve the commercial viability to lead to significant benefit flows
	Once a benefit-sharing agreement has been concluded, the expectations (as laid down in CBD-compliant national law) of Western-style governance can lead to significant tensions between users and providers of resources as well as auditors
	Resources do not respect national boundaries and benefit sharing involving several countries that can make claims to traditional knowledge, or biodiversity are difficult to handle legally
	Progressive international and national laws are not enough if poor, marginalized communities are not supported in claiming them
	The issue of benefit sharing for traditional knowledge should be promoted at the same time as the issue of land rights. However, only the UN Declaration on the Rights of Indigenous Peoples addresses both
	While the Nagoya Protocol has provided new impetus in resolving the lack of compliance with the CBD internationally, it is yet to be seen whether compliance can be achieved
	Last but not least, the fact that the USA is not a party to the CBD while being a major user of foreign biological resources poses significant ethical issues

possibilities for the sharing of benefits, far beyond profit-sharing. Before moving to benefit sharing as relevant to human resources, Table 14.3 summarizes the main challenges for realizing the spirit of the CBD.

The Declaration of Helsinki

The prevailing approach to benefit sharing for providers of human biological resources such as DNA or blood samples is the prescription of post-study obligations. Essentially, these obligations (previously known as post-trial obligations) describe a duty to provide human research participants with access to a proven beneficial health-care intervention after a study has been concluded. This means that in return for contributing to medical research, the research participants are meant to obtain access to any resulting products or interventions as a form of benefit sharing. One can see that the benefit-sharing spirit of the CBD is being maintained here too. Those who contribute to science ought to share in its benefits, to guarantee justice-in-exchange. However, it must also be noted that those who contribute to research outside the medical field, say cosmetics, are not necessarily guaranteed benefit sharing as the Declaration of Helsinki is unlikely to apply.

Post-study obligations within medical research were first introduced in the Declaration of Helsinki in 2000, when the WMA General Assembly in Edinburgh adopted paragraph 30:

> At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study.

This early formulation of post-study obligations was restricted to patients and, by implication, to trials involving volunteers in need of treatment. As a result, healthy volunteers enrolled in trials, as well as donors of biological materials, were excluded from benefit sharing. This focus on access to resulting products led to problems of equity. For instance, if post-study access to a drug is the only way to avoid the exploitation of research participants, those who take part in studies that do not lead to the marketing of a drug are excluded from benefits. Given that only a very small percentage of medical research eventually leads to products in pharmacies, this was a serious concern.

In 2004, the WMA's General Assembly in Tokyo added a note of clarification on paragraph 30, which opened the way for other benefits in addition to or instead of post-study access to successfully tested interventions (emphasis added):

> The WMA hereby reaffirms its position that it is necessary during the study planning process to identify post-trial access by study participants to prophylactic, diagnostic and therapeutic procedures identified as beneficial in the study or *access to other appropriate care*.

To reduce the rigidity of post-study access to successfully tested drugs, the phrase "access to other appropriate care" was added. At the same time, the term "patients" was changed to "study participants," to allow for the inclusion of healthy volunteers. However, the term "trial" was retained, thus limiting benefit sharing to those taking part in clinical trials. This changed in the 2008 declaration, adopted in Seoul. Articles 14, 17, and 33 relate to benefit sharing. Article 14 deals directly with the issue of broadening the scope of beneficiaries from clinical trial participants to study subjects. It says (emphasis added):

> The protocol should describe arrangements for post-study access by *study subject*s to interventions identified as beneficial in the study or access to other appropriate care or benefits.

It follows, then, that all medical research involving human subjects which needs approval from an ethics review body should describe, in its study protocol, post-study access to successfully tested interventions or other benefits. This implies that donors of biological samples must be included among the possible beneficiaries, as the scope is not limited to "trials."

However, such a formulation gives rise to a practical concern, namely, that compliance with it could mean that any arrangement for post-study access would suffice, as long as it was detailed in the study protocol. Even the sentence "There are no arrangements for post-study access," could arguably be regarded as compliance in that, as long as study participants and ethics review bodies know that there is no provision for post-study access, sufficient compliance with paragraph 14 would have been achieved. Hence, this obligation could be called informational rather than substantial, in which case, it does not satisfy the wider demand for benefit sharing. At first sight, this concern seems to be mitigated through paragraph 33 of the declaration, which reads:

> At the conclusion of the study, patients entered into the study are entitled to . . . share any benefits that result from it, for example, access to interventions identified as beneficial in the study or to other appropriate care or benefits.

This paragraph implies that post-study obligations are a substantial rather than an informational demand for all medical research involving existing patients. However, that still seems to leave healthy volunteers and donors of human biological samples potentially excluded from any post-study benefits, as benefit sharing is only envisaged with patients rather than all participants in medical research. This would seem contrary to the spirit of benefit sharing as understood through the CBD, which aims to reward "resource providers" in particular in order to avoid concerns about exploitation.

Here, one needs to remind oneself of the purpose of benefit sharing for human genetic resources. Formal benefit-sharing frameworks such as the CBD or the Declaration of Helsinki are only required where participants contribute to research but derive no benefits at all. In developed countries, the situation is different. Human sample donors contribute to research and in return have access to increased medical interventions, tailored to local health needs, to achieve and maintain their health. Where this is not the case as in developing countries, other solutions have to be found. In this regard, one could argue that such solutions are only required for vulnerable populations – and this is the approach taken by the Declaration of Helsinki through paragraph 17:

> Medical research involving a disadvantaged or vulnerable population or community is only justified if . . . there is a reasonable likelihood that this population or community stands to benefit from the results of the research.

This means that when ethics review bodies are presented with proposed studies on vulnerable groups which do not fall under the category of "patients," they still need to ensure that the research population or the wider community stand to benefit from the research. Hence, a study protocol which notes that there is no provision for post-study access or alternative benefits would be unethical, according to paragraph 17 (rather than paragraph 14), if it involved vulnerable populations, whether they take part in clinical trials or donate DNA. It is evident that the latest version of the declaration is therefore comprehensive in its benefit-sharing clauses, in providing somewhat intricate frameworks on which arguments in favor of benefit sharing with donors of biological samples can be based. Example cases are described in Boxes 14.4 and 14.5.

Finally, it is important to note that the 2008 Declaration of Helsinki added a benefit to the list of benefits to be shared, which was not hitherto included, namely, feedback. Article 33 requires that:

> At the conclusion of the study, patients entered into the study are entitled to be informed about the outcome of the study.

Before moving onto the next section, it is worth noting that the USA has effectively opted out of the benefit-sharing sections of the Declaration of Helsinki (Kimmelman, Weijer, & Meslin, 2009) by not recognizing the right of vulnerable populations to post-study access to successfully developed interventions or alternative benefits. Table 14.4 summarizes the main challenges in realizing benefit sharing through the Declaration of Helsinki.

The above concludes the section on the established legal sense of benefit sharing as governed through the CBD and the Declaration of Helsinki.

UNESCO Universal Declaration on Bioethics and Human Rights

The UNESCO's Universal Declaration on Bioethics and Human Rights (2005) supports a more ambitious or aspirational approach to benefit sharing, which goes beyond sharing benefits with the contributors to research. The declaration is built on earlier human rights frameworks, of which, the following two are the most important. The Universal Declaration of Human Rights (1948) Article 27(1) notes that (emphasis added)

> [e]veryone has the right freely to participate in the cultural life of the community, to enjoy the arts and *to share in scientific advancement and its benefits*.

Hence, every human being whether they contribute to science, research, and innovation, or not has the *human right* to share in the benefits of scientific advancement. While the Universal Declaration of Human Rights is a nonbinding instrument, the legally binding International Covenant on Economic, Social and Cultural Rights (1966) includes a similar human right. Article 15(b) reads:

> 1. The States Parties to the present Covenant recognize the right of everyone:
> (b) To enjoy the benefits of scientific progress and its applications.

Box 14.4: Nairobi Sex Workers

In 1982, a clinic to investigate the natural history of sexually transmitted diseases was established in Majengo, a slum in Nairobi, Kenya. In 1986, studies focusing on HIV/Aids commenced with particular emphasis on potential resistance to the virus. It appeared that about 5 % of the then 2,000 sex workers did not contract the virus, despite frequent, unprotected sex with HIV-positive men. Since 1998, the main aspiration of the clinic's studies has been the development of an HIV vaccine.

The only way to access the clinic and its health services is by enrolling in its research programs. The Majengo sex workers often have no other income or support, live in small tin shacks, work well into middle-age, and have dozens of clients every day, as payment from each is very low. They belong to an extremely socio-economically disadvantaged group, who would be unable to access health care in any other way. In return for biological samples, the clinic provides health monitoring and health education as well as treatments for all health conditions, irrespective of whether they are sex work-related or not. This includes, since 2005, access to antiretrovirals.

To date, the research has not yielded a vaccine or other treatments. However, considerable progress has been made to understand the immunological protection mechanisms at play. According to the Declaration of Helsinki, the sex workers or their community must benefit from the results of the research. Alternative benefits such as health care can be appropriate. Given that the research began in 1986, this case shows why access to developed drugs is too rigid a mechanism for benefit sharing without the proviso that other benefits might be acceptable.

As in the case of the CBD, the USA is one of the very few countries not to have ratified or acceded to the International Covenant on Economic, Social and Cultural Rights. The only other countries which are not a party to the covenant, except for tiny island states, are Cuba and South Africa. Ratification or accession requires parties to ensure that any provisions from the covenant can be enforced through the domestic legal system.

Before outlining the provisions of the UNESCO's Universal Declaration on Bioethics and Human Rights, it is important to ask the following two questions: What is the relevant justice framework for this type of benefit sharing? And why can this human rights-based approach to benefit sharing be called more ambitious or aspirational than the approach taken by the CBD or the Declaration of Helsinki?

Today, 2.7 billion people live on less than US$2/day. Of these, almost 1 billion are chronically undernourished, 1.1 billion do not have access to safe drinking water, 2.6 billion lack adequate sanitation, and nearly 2 billion have no access to life-saving drugs. People who suffer such massive deprivations are more likely to be susceptible to health risks and enter a vicious cycle of ill health, unemployment, and severe poverty. The above deprivations have little to do with science and

Box 14.5: Indonesian Virus Samples

The World Health Organization (WHO) collects virus samples for distribution to affiliated laboratories in an effort to monitor and assess the risk posed by flu and other infectious diseases, to detect mutations and develop vaccines targeted to specific strains.

In 2006, the Indonesian government decided to withhold avian flu samples from the WHO and its associated vaccine-development laboratories. The argument was that even though Indonesian samples were crucial to the development of vaccines, the results of vaccine research would be unaffordable to its citizens. Indonesia maintained that – in the spirit of the Convention on Biological Diversity – human genetic resources fall under the sovereignty of the nation state and that no global public health measures can enforce access. At this time, Indonesia was the country with the most fatal cases of avian flu.

Appealing to all members of the WHO in 2007, the WHO Director-General Margaret Chan said that cooperation is crucial to combat pandemics and that international public health security is a mutual responsibility. However, she also convened a working group to develop fairer ways for virus sharing.

After several years of negotiations, the WHO working group reached agreement on an alternative framework for virus sharing in April 2011 (WHO Pandemic Influenza Preparedness (or PIP) Framework). This framework is meant to be responsive to the concerns raised by the Indonesian government. The framework was ratified by the WHO at the May 2011 World Health Assembly (WHA) meeting and includes the requirement for two Standardized Material Transfer Agreements (SMTAs). The first SMTA contains terms and conditions which prohibit laboratories that are part of the WHO from making intellectual property claims in relation to the samples shared with them. The second SMTA, among other things, requires those outside of the WHO to commit to at least two conditions, selected from a list of options that includes giving developing countries 10 % of the resulting vaccines and/or antivirals, selling 10 % of these at an affordable price, or granting manufacturing companies within developing countries licenses to produce vaccines/antivirals at affordable royalties or royalty free.

While the PIP Framework addresses some of the concerns with regard to virus sharing, other human biological resources such as DNA and blood are not yet covered by an equivalent, legally binding framework.

innovation. While nanotechnology, for instance, might provide new techniques for water purification, all the necessary means to provide food, water, shelter, and health care to humans around the world are available today. As Amartya Sen pointed out in “Poverty and Famines” (1983), the earth’s resources are sufficient

Table 14.4 Main challenges for benefit sharing: Declaration of Helsinki

Type of benefit sharing	Main challenges
Benefit sharing as justice-in-exchange 	There are almost no examples of good practice for the compliance with post-study obligations in the medical field (except for those cases where comprehensive health care is provided, see Box 4 on Nairobi sex workers)
	Benefit sharing and avoiding undue inducement are ethical obligations that can be difficult to align. However, fear of the latter must not lead to neglecting justice-in-exchange requirements
	The pandemic influenza preparedness (or PIP) framework is to be welcomed, but only covers virus sharing. Similar frameworks need to be established to govern the exchange of other biological specimens of human origin
	Currently, no difference is made between commercial research, basic research, or publicly funded research when it comes to post-study obligations. This topic needs further attention
	The fact that the USA has opted out of the benefit-sharing requirements of the Declaration of Helsinki poses significant ethical issues given the prominence of US researchers conducting clinical trials and other medical studies in developing countries

to feed the world population (as one example of basic human need satisfaction). The main reason for famines is not a shortage of food or the lack of new scientific solutions, but rather the lack of power, sense of entitlement, and resources of the poor. It is thus a matter of distributive justice, the justice that deals with the division of scarce resources among qualifying recipients (see Diagram 14.2) that is at stake. There are enough resources to feed the world, according to Sen, including those in "famine" areas, but some are not regarded as qualifying recipients for such resources.

The main question in distributive justice, namely: *who* deserves *what* from *whom*, has been answered by the human rights framework. Those who live legitimately within a state (*who*) qualify for the receipt of income support at subsistence level plus other services to cover their basic needs (*what*) from the state (*from whom*). The International Covenant on Economic, Social and Cultural Rights from 1966 specifies individual welfare rights, and parties are committed to make these rights claimable through domestic legislation. However, not all states are in a position to respect, protect, and fulfill human rights, as this requires significant resources. It is here that cosmopolitan ethics (Pogge, 2008) as well as international legislation intervenes by adding a demand for international assistance. Hence, the justice framework for sharing the benefits of science, which the Universal Declaration of Human Rights and the International Covenant on Economic, Social and Cultural Rights requires is a distributive justice framework. Resources have to be moved from the affluent or powerful to the poor and vulnerable to secure

everybody's human rights. And it is the UNESCO's Universal Declaration on Bioethics and Human Rights which emphasizes the need for international assistance to do so.

Having clarified the justice framework involved in the more aspirational approach to benefit sharing (international distributive justice), it is also clear why it is more ambitious to demand a sharing of the benefits of science as a *universal human right* rather than a contributor right. To provide equitable access to the results of science to people who are dying because they cannot even get the most basic foods or off-patent drugs will require a mammoth effort, extraordinarily more than achieving compliance with the CBD, which in itself is a difficult task.

The advantage of the UNESCO's Universal Declaration on Bioethics and Human Rights is that it has agreed and described this mammoth commitment as detailed as is possible in a declaration. In the Preamble, it is emphasized that scientific progress can promote the welfare of human beings and that the target is *all of* humanity.

> Recognizing that, based on the freedom of science and research, scientific and technological developments have been, and can be, of great benefit to humankind in increasing, inter alia, life expectancy and improving the quality of life, and emphasizing that such developments should always seek to promote the welfare of individuals, families, groups or communities and humankind as a whole in the recognition of the dignity of the human person and universal respect for, and observance of, human rights and fundamental freedoms.

Thus, a belief in scientific progress is combined with the demand to make benefits available to all. In Article 2(f), the importance of international assistance for developing countries is emphasized. The aim is

> to promote equitable access to medical, scientific and technological developments as well as the greatest possible flow and the rapid sharing of knowledge concerning those developments and the sharing of benefits, with particular attention to the needs of developing countries

While this is more than previous instruments have included on benefit sharing, the declaration goes further by giving good practice examples through Article 15:

> 1. Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries. In giving effect to this principle, benefits may take any of the following forms:
> (a) special and sustainable assistance to, and acknowledgement of, the persons and groups that have taken part in the research;
> (b) access to quality health care;
> (c) provision of new diagnostic and therapeutic modalities or products stemming from research;
> (d) support for health services;
> (e) access to scientific and technological knowledge;
> (f) capacity-building facilities for research purposes;
> (g) other forms of benefit consistent with the principles set out in this Declaration.

Example 15(1)a could be aligned with benefit sharing as practiced under guidance from the CBD or the Declaration of Helsinki. To give special assistance to those who contribute to research recognizes that their efforts need to be rewarded to

Table 14.5 Main challenges for benefit sharing: UNESCO Universal Declaration on Bioethics and Human Rights

Type of benefit sharing	Main challenges
Benefit sharing as distributive justice 	While people are dying from lack of access to the most basic foods or medicines, the human right to sharing the benefits of science is unlikely to be a human right priority among policy-makers. For instance, none of the millennium development goals mentions science and innovation (except indirectly in an appeal to the pharmaceutical industry to provide affordable drugs; Goal 8E)
	While the UNESCO Declaration expands on the International Covenant on Economic, Social and Cultural Rights, it lacks the covenant's legal bite as it is a nonbinding guideline
	Other human rights, such as the right to food, are more easily specified and interpreted. What does it mean to have a human right to share in the benefits of science? The benefits of science range from interactive video war games to tuberculosis drugs
	How will the required international assistance to realize the human right to benefit sharing be mobilized, in particular in a time of financial instability?

avoid exploitation. It is therefore based on justice-in-exchange. Procedural considerations based on a contribution to science are also included in the declaration through recommendations on transnational practices. Article 21(4) requires that when "negotiating a research agreement, terms for collaboration and agreement on the benefits of research should be established with equal participation by those party to the negotiation." Hence, those who are contributing to science need not only be rewarded for their contribution but should also have a say in the direction, conduct, and dissemination of the research. One might want to term such collaboration as an equitable partnership.

The remaining benefits from Article 15 must be read as human rights, given the spirit of the declaration, and are goals of universal coverage. All human beings should be given access to the benefits as outlined from (b) to (g). Likewise, Article 24 on international cooperation covers universal human rights independent of contribution.

> Within the framework of international cooperation, States should promote cultural and scientific cooperation and enter into bilateral and multilateral agreements enabling developing countries to build up their capacity to participate in generating and sharing scientific knowledge, the related know-how and the benefits thereof.

At the time of writing, the USA has also withdrawn its financial support from the UNESCO, thereby potentially remaining outside of all leading binding and nonbinding legal instruments involving benefit sharing. The above Table 14.5 summarizes the main challenges in realizing the human right to sharing the benefits of science.

Table 14.6 Tensions between types of benefit sharing

Compensation rights	<- Tensions ->	Human rights
Benefit sharing as justice-in-exchange 	Open access and open source movements can violate compensation rights while furthering human rights	Benefit sharing as distributive justice 
	Patent applications can provide a compliance opportunity for compensation rights, but hinder the protection of human rights	
	Patents can provide financial means to comply with compensation rights, but hinder the protection of human rights	
	Significant bureaucracy necessary to facilitate benefit sharing as compensation could be used to facilitate benefit sharing as a human right	

Conclusion

Two types of benefit sharing can be distinguished. Benefit sharing as governed by the Convention on Biological Diversity and the Declaration of Helsinki aims to reward those who *contribute* to scientific progress, be it by providing resources such as plants or traditional knowledge or by taking part in medical studies. This approach avoids the most blatant exploitation, where somebody's blood sample or traditional knowledge leads to commercial products for the sole benefit of distant others. The aim of this type of benefit sharing is to achieve justice-in-exchange.

The second type of benefit sharing emphasizes that all human beings have a right to access to the benefits of science. The UNESCO's Universal Declaration on Bioethics and Human Rights is the clearest document to promote benefit sharing as a human right given that it does not shy away from the implications for affluent states. "Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries."

Neither type of benefit sharing is easily achieved, and to complicate matters, the two types can come into serious conflict, as outlined in conclusion in Table 14.6.

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Protection of the Environment, the Biosphere and Biodiversity

15

Johan Hattingh

Introduction

For decades, scientists, educators, philosophers, ethicists, and concerned citizens have articulated strong warnings from different vantage points with a steadily growing measure of intensity that humankind is being confronted with a multilayered crisis entailing environmental degradation, biodiversity loss, climate change, and the detrimental effects this have on poor communities who depend directly on the environment and biodiversity for their livelihoods. All of these crises combine and reinforce one another through intricate internal feedback loops to form what Edgar Morin (1999) has called a polycrisis that not only places the quality of human life under threat but the very survival of life on earth.

In 1962, Rachel Carson published a book entitled *Silent Spring* (see Carson, 2002) to warn against the overuse of pesticides in agriculture, conjuring up the apocalyptic image of a world waking up one spring morning without the sounds of any bird singing. In 1968, biologist Garrett Hardin published an article on "The tragedy of the commons" pointing out that freedom in the commons, that is, open-access resources with no regulation on their use, leads to ruin for all (Hardin, 1968), while in 1972 the Club of Rome published the Meadows Report (Meadows, Meadows, Randers, & Behrens, 1972) with the self-explanatory title of *Limits to growth*. Focusing on accelerating industrialization, rapid population growth, widespread malnutrition, depletion of nonrenewable resources, and a deteriorating environment, this report warned that if present growth trends in the world continued unchanged, the world would reach physical limits to growth within 100 years. However, it also pointed out that these growth trends can be changed to establish a world that is ecologically and economically stable so that it is sustainable into the future. Similarly, *The Ecologist* also published in 1972 *A blueprint for survival* outlining "the overwhelming necessity for change towards a stable and sustainable society" (The Ecologist, 1972).

J. Hattingh
Department of Philosophy, Stellenbosch University, Stellenbosch, South Africa
e-mail: jph2@sun.ac.za

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Around the same time, environmental ethics emerged as a separate academic discipline with the publication of two seminal articles. In Australia, Richard Routley (later Sylvan) (1973) published a paper with the telling title: "Is there a need for a new, an environmental ethic?" in which he called for a new, non-anthropocentric ethics based on the idea of the intrinsic value of the environment, while Arne Naess, a Norwegian philosopher, published an article in 1973 with the title "The shallow and long range, deep-ecological movement." In this article, Naess challenged the self-interested concerns of business and the middle class about pollution that may threaten a consumerist lifestyle, arguing that the solution to environmental problems should be sought on a much deeper level, that of radically questioning the identities assumed by consumers, driven as they are by a narrow egotistical and materialist notion of self. Instead, he argues for the realization of an expanded, mature self through identifying with the plight and interests of wider circles of being, based on the premise that every self is constituted by the wider circles of being in which its existence is embedded (Næss, 1973).

In parallel with this growing sense of crisis and of radical questioning, science, business, and international politics have responded with various initiatives that have recorded different measures of success over the years. The United Nations Conference on the Environment and Development (http://www.un.org/geninfo/bp/enviro.html) that was held in 1992 in Rio de Janeiro brought many of these initiatives together in a number of documents and conventions that were adopted. Among them were *Agenda 21* (http://www.un.org/esa/dsd/agenda21/) that is a comprehensive plan of action for sustainable development in the twenty-first century, the United Nations Framework Convention on Climate Change (UNFCCC) (http://unfccc.int/2860.php), and the United Nations Convention on Biological Diversity (http://www.cbd.int/). Today, however, 20 years later, serious questions are being asked about the efficacy of these initiatives in preventing or minimizing the combined crisis of unsustainable development, environmental destruction, biodiversity loss, climate change, and its disruptive impact on marginalized communities.

The urgency of responding to these crises and their primary drivers, however, has not disappeared. While population growth has become a politically loaded topic to address, and the same applies to the problem of overconsumption of about one billion of the affluent part of the world's population (Swilling & Annecke, 2012), population growth is still regarded as one of the biggest drivers behind these crises (TEEB, 2010; The Royal Society, 2012). Others (Turner, 2008) argue that the world's population still has not learned how to overcome unsustainable use of resources in industrial production and private consumption. From a biological point of view, E.O. Wilson (1992) has pointed out in 1992 already that the biodiversity crisis entails one of the biggest extinction periods that the history of life on earth has experienced in the last 65 million years, while Stephen Gardiner has argued recently (2011) that climate change confronts the world with a perfect moral storm that challenges the most basic assumptions underlying ethics and moral responsibility, paralyzing humankind into believing that nothing can or should be done about climate change.

In a strange turn of events, it seems as if these crises have been eclipsed to some extent by the financial crisis of 2008 and 2009 that has hit the world's economy and financial systems, and from which quite a number of national economies have not yet recovered from at the time of writing this chapter. Strict austerity measures, financial discipline, and smart investments will be required to overcome this financial crisis, but this has already raised the concern that little, if any, additional resources will be available to also address the challenges of environmental degradation, biodiversity loss, climate change, and the social disruption that they bring. In recent discussions of this polycrisis, it is recognized that measures to address the financial crisis will not be successful if environmental degradation, biodiversity loss, climate change, and their social impacts are not also addressed with the same measure of intensity (Stern, 2010).

With this as broader context, the focus in this chapter will fall on the challenge of protecting the environment, the biosphere, and biodiversity. In particular, an overview will be given of the conceptual, philosophical, and ethical challenges related to defining exactly what should be protected regarding the environment, the biosphere, and biodiversity and what the arguments are to justify why this should be done. The crux of this discussion will be devoted to different kinds of values that have been used to justify protection, as well as the different implications these values have for conservation management, not only in setting its goals but also in determining its tools and methods. Some of the discussion will also focus on the drivers behind biodiversity loss, destruction of the biosphere, and the environmental crisis and what if anything could be done about them. This chapter will begin with a discussion of definitions and conceptual issues and will conclude with an outlook on the future of the environment, the biosphere, and biodiversity.

Definitions

While there is substantive overlap in the meanings of *environment*, *biosphere*, and *biodiversity*, and while these concepts are sometimes used interchangeably, it is important to note that there are also subtle but important differences between them. As concepts, they do not fully coincide with one another. In its most widely accepted definition, biological diversity, or biodiversity in its abbreviated form, refers to "the variability among living organisms from all sources including, *inter alia*, terrestrial, marine and other aquatic ecosystems, and the ecological complexes of which they are part: this include diversity within species, between species and of ecosystems" (Article 2 of the United Nations Convention on Biological Diversity, 1992).

In this definition, there is reference, albeit indirectly, to both the *elements* of biodiversity such as genes, species, and ecosystems, as well as the *processes* of which they form part. The latter is captured in this definition with the reference to "ecological complexes" which entail complex and dynamic processes of interaction between "elements" over time. As such, this definition represents a movement away from a "bits-and-pieces" or "itemizing" approach to the protection of biodiversity,

to one where living and evolving wholes, and the processes making the existence of these wholes and their evolution possible are studied (O'Neill, Holland, & Light, 2008).

The biosphere is generally defined as "that part of the land, sea and atmosphere in which organisms are able to live. The biosphere is an irregularly shaped, relatively thin zone in which life is concentrated on or near the Earth's surface and throughout its waters" (*The American Heritage Science Dictionary*). According to a more general definition from the same source, the biosphere entails "all the Earth's ecosystems considered as a single self-sustaining unit." Here also the notion of life as an all-encompassing whole emerges but also the wider notion that this whole encapsulates all of the conditions that make life possible.

How incredibly fragile and also precious this biosphere is was first graphically illustrated with the photographs (http://www.nasa.gov/vision/earth/features/bm_gallery_4.html) that were taken from outer space by NASA astronauts aboard Apollo 8 on Christmas eve of 1968 of the earth rising over the moon. Statements by subsequent astronauts, for instance Loren W. Acton (http://www.solarviews.com/eng/earthsp.htm), as well as similar photographs (http://planetary.org/explore/space-topics/earth/pics-of-earth-by-planetary-spacecraft.html) from other space missions reinforced this image of the biosphere, an image of the whole earth that lies in the hands of humankind (http://farm3.staticflickr.com/2063/5769488751_83de7508b4_m.jpg) to be protected and cherished but at the same time is something that can be broken (http://www.freakingnews.com/pictures/63000/Cracked-Earth-Egg-63050.jpg) beyond repair, if not handled with care. Making the earth thus visible as a single, fragile whole inspired the notion of the biosphere as a living system *with limits* (Swilling & Annecke, 2012).

In the *Merriam-Webster Dictionary*, a distinction is made between a generalized meaning of *environment* and a more biological meaning. In a general sense, environment refers to the "circumstances, objects or conditions by which one is surrounded." In its biological sense, environment refers to "the complex of physical, chemical and biotic factors (as climate, soil and living things) that act upon an organism or an ecological community and ultimately determines its form and survival." In this comprehensive biological sense, the meaning of *environment* and *biosphere* virtually coincides, but there is also an overlap with *biodiversity*, in that the elements "making up" the environment, for example, individual living entities, species, communities of life, biomes, biological "hotspots," or ecosystems, can be emphasized, or the whole of the environment together with the natural processes of life unfolding in it. In a third meaning, environment refers in human terms to "the aggregate of social and cultural conditions that influence the life of an individual or community."

These definitions already illustrate the complex relationship between that which is taken as the environment, the biosphere, and biodiversity, and that they contain elements, entail processes, and display characteristics that are mutually dependent upon one another, and mutually influence one another in intricate feedback loops. It can thus be argued that these three terms refer to different aspects of the same unified system spanning the earth, namely, life in all of its different forms: *environment* serves as a framework concept, encapsulating the comprehensive

preconditions of life in general (e.g., the water cycle, photosynthesis, and the absorption of heat); *biodiversity* is used to refer to the many differences in and between individual living organisms, species, and ecosystems, while *biosphere* is more of a geographical term that refers to the thin "layer" of life that spans more or less the surface of the earth.

Accordingly, it is not easy to distinguish between threats to biodiversity and the biosphere that are not at the same time threats to the environment as well, and vice versa. Similarly, it is not easy to think of environmental protection that is not at the same time protecting the biosphere or biodiversity. To illustrate the point, if the protection of biodiversity is set as a goal for conservation policies, such protection will at the same time entail protection of the environment and of the biosphere. To acknowledge the overlap between these three concepts but also to prevent confusion that may emerge from using these three terms interchangeably, the term "earth system" will be used in this chapter to refer to the environment, the biosphere, and biodiversity taken together as a whole, functioning as a complex living system with its own history and evolutionary path, possibilities, and boundaries. In the discussion below, however, references to the environment, the biosphere, and biodiversity in their own right will be made when required by the context.

Before proceeding to an overview of the arguments that are used to underline the importance of protecting the earth system, it is important to first consider a few conceptual issues, as well as the drivers leading to damage of the earth system. The discussion of conceptual issues will already illustrate some of the philosophical and ethical challenges involved in efforts to identify what exactly it is that should be protected and why it is important to do so. The discussion of the drivers will facilitate an understanding of the magnitude and extent of the problem facing humankind.

Conceptual Issues

In this section, an overview will be given of philosophical and ethical issues related firstly to the *vagueness* that is often encountered around the concepts of the environment, the biosphere, and biodiversity; secondly to the impossibility of giving *scientifically objective* definitions to these three concepts; and thirdly to approaching these three concepts from an *element* or a holistic, *processes* perspective.

The first conceptual issue emerges from the vast number of definitions that exist with regards to both *biodiversity* and *environment*. Gaston (1996) and Faith (2008, p. 1, 2) discuss the different variations that exist of *biodiversity* defined as "the variety of all forms of life, from genes to species, through to the broad scale of ecosystems," while Reaka-Kudla, Wilson and Wilson (1997) give an overview of the rapid rise of the term biodiversity, and trace aspects of the term back to the ancient Greek philosopher, Aristotle. Johnson et al. (1997) in turn focus on terms and expressions related to the environment and make a very valuable contribution toward standardizing the use of the ten most commonly used environmental terms.

O'Neill et al. (2008), however, point out that there is no such thing as *the* environment. If environment refers to the "surroundings *of* some person, being or community," there is always "a variety of places, processes and objects" that make up a vast variety of environments.

This highlights the problem that *biodiversity* and *environment* are concepts that can easily be taken to mean "everything" (Faith, 2008, p. 2) so that all concerns about the environment and biodiversity are lumped together in one big whole. *Biodiversity*, for instance, has sometimes been used to mean "life" or "wilderness" or "ecosystems" or "ecosystem processes" (Faith, p. 2), while the concept of the *natural environment* is commonly used to refer to "water," "oceans," "rivers," "lakes," "the atmosphere," "climate," "the weather," "life," "ecosystems," "biomes," "biogeochemical cycles," "wilderness," "vegetation," "soil," "rocks," and "natural phenomena" (see Wikipedia entry on *Natural environment* [http://en.wikipedia.org/wiki/Natural_environment]). This vagueness should be avoided and can be avoided by not only giving more precise conceptualizations of environment and biodiversity, respectively, but also defining much more precisely what exactly should be protected with regard to the environment, the biosphere, and biodiversity and why it should be done.

In the second place, it is important to note that many scholars, including prominent philosophers and conservation biologists, have pointed out that it is impossible to formulate a definition of biodiversity that is "scientifically objective." Instead, they accept that the kind and the level of biodiversity that is set as a target to protect, to maintain, or to restore is based on certain value assumptions that characterize the identity of a certain society, and that these values should be made explicit for critical scrutiny in ongoing societal debates. The same applies to the nature and extent of environmental protection that is accepted or set as a target by a certain society. As such, this constitutes what Faith (2008, p. 2) refers to as the problem of "biodiversity plurality": the existence of a wide spectrum of biodiversity targets or models that can be pursued, bringing about the question on what grounds a decision-maker should choose between them. Similarly, there exists the problem of "environmental plurality" and the concomitant challenge for someone like an environmental manager to find appropriate and sufficient grounds to choose between different targets or models of environmental protection (see Norton, 2003; O'Neill et al., 2008).

In the next section, the discussion will focus on the typical arguments that are used to justify choosing between different environmental/biodiversity targets for protection. At this point, it is important, though, to note that the problem of environmental/biodiversity plurality and responding to it by making explicit the values on the basis of which the choice between models/targets is made constitutes a "post-positivist" approach to conservation. As Faith (2008, p. 3) has pointed out: "there is no one, correct measure of biodiversity to be discovered but many, each having different values."

In this regard, the argument goes that all facts pertaining to conservation, whether they are related to the environment in general or to biodiversity more specifically, even if they are produced by scientific studies, are value-laden. This, however, does not make conservation or conservation science a totally arbitrary and

fully subjective exercise (see Davis, 2009 for an insightful overview of this debate). On the contrary, this insight rather calls upon conservation scientists to make the values explicit that inform their work so that they can become part of the ongoing self-conscious and critical conversation taking place in societies about the sources of these values, as they are related to histories and social identities, that is, notions of who people are, how they wish to realize themselves in the present and in the future, and what role they deem conservation should play in all of this.

A third important conceptual issue to take into account is raised by biologists E.O. Wilson (1988) and David Ehrenfeld (1988). Summarized by Faith (2008, p. 3), Wilson sees the rise of the term *biodiversity* as a dramatic shift away from a "bits and pieces" to a much more holistic approach to biology. Where the protection of biodiversity was first aimed at endangered species, the emphasis shifted to the protection of ecosystems (Rolston, 2001). Wilson correctly identifies that the rapid emergence of the term *biodiversity* since the 1980s represents a growing concern about biological variety as a general phenomenon, that this variety is rapidly disappearing, and that "unlike other threatened things, is irreversible." Ehrenfeld also elaborated on this idea of a "biodiversity crisis" by emphasizing the "idea of the value of diversity in the aggregate. He argues that diversity previously was never regarded in itself to be in danger, but that biodiversity now is recognized as endangered in its own right" (Faith, 2008, p. 3).

In a slightly different formulation, Norton (2003, p. 501) also draws attention to the biodiversity as a whole when he argues that biodiversity is not merely a resource among other resources, "but a generator – a source – of biological resources." Norton argues that biodiversity is a necessary condition for the creation of biological resources. Such a holistic approach is also evident in literature about the environment and the biosphere, emphasizing that it is not only their compositional elements that are important but also the functional processes that constitute the environment and the biosphere as resilient, adaptive living wholes that should be considered as such in decision-making (Callicott, 1999).

The concepts of the environment, the biosphere, and biodiversity are brought closer to one another by placing the emphasis on the *earth system* as a functioning whole supporting all life on earth, as it was pointed out above. Accordingly, this conceptual shift from parts to the whole resonates with a significant expansion of conservation from a focus on the individual elements of the earth system, for example, species or specific species populations, even ecological "hotspots," toward a focus more on ecosystem processes, and the manner in which, for example, a population unit of a species, characterized by a certain size and geographic distribution, in interaction with other population units of other species, together contribute to the functioning, resilience, and evolution of an ecosystem or ecosystems (Luck, Daily, & Ehrlich, 2003).

Such a systems approach thus introduces *ecological effectiveness* as the primary conservation goal, in which the protection of ecologically effective population sizes and critical ecological interactions rather than maintaining minimum viable populations stands central (Soulé, Estes, Berger, & Del Rio, 2003). This is at the same time a strong argument for *ecosystem recovery* as a conservation goal for

damaged or degraded ecosystems, following explicitly formulated operational targets. The difficulty in pursuing these systemic goals, however, is uncertainty about future ecological dynamics, exacerbated by rapid environmental change: "... we cannot know exactly which interactions and which species will be most critical for the maintenance of biodiversity in the future" (Soulé et al., 2003).

In spite of such cognitive constraints, strong arguments can be formulated to explain why it is important to protect the earth system – based on the knowledge already available about its functioning and its value. Important background to these arguments is an understanding of the nature and extent of the damage that is currently done to the earth system and what the drivers behind this damage are.

Human Impact on the Earth System

According to paleontologist Niles Eldredge (http://www.actionbioscience.org/newfrontiers/eldredge2.html), Curator-in-Chief of the Hall of Biodiversity (http://www.amnh.org/exhibitions/permanent/biodiversity/) of the American Museum of Natural History in New York, human impact on the earth's ecosystems started about 100,000 years ago with the dispersion of humans around the earth and has been associated with the onset of the first phase of the Sixth Extinction period (http://extinct.petermaas.nl/). In this first phase, the biggest impact was on large game species like mammoths, mastodons, buffaloes, and big birds through overhunting. Phase 2 commenced with the onset of the Holocene epoch about 10,000 years ago when humans turned to agriculture, and the biggest impact of this phase occurred through the transformation of land to produce crops, changing on the one hand the habitats of natural species but on the other hand freeing humans from their dependence on natural ecosystems for survival, and through that, making it possible for humans to overpopulate.

Current concerns about the earth system stem from the impact of vast numbers of humans, empowered by mechanized tools, science, and technology that intensify and accelerate the impact. What makes the Sixth Extinction period different from the previous "Big Five" is that the sixth period is anthropogenic, that is, caused by humans, while all of the previous ones have been caused by natural events such as the eruption of volcanoes, the impact of a meteorite hitting the earth, or climate change. Formulated in broad terms, it is recognized that the drivers behind the current extinction period include population growth, the destruction or transformation of habitats (because of reasons that include the encroachment of agriculture), using biological resources faster than their natural rate of regeneration, clear-cutting of forests, water diversion, water extraction from rivers, pollution, alien invasive species, and climate change. The general consensus is also that these drivers are currently putting all of life on earth in the balance, unless the whole of humankind turn to and adopt a sustainable mode of living.

Factual data that are regularly updated about the current impact of human activities on the earth system, and that are based on literally thousands of scientific studies, can be found on various websites. The Convention on Biological Diversity

(http://www.cbd.int/convention/) regularly publishes a *Global Biodiversity Outlook* (http://www.cbd.int/gbo/), of which the third edition (http://www.cbd.int/doc/publications/gbo/gbo3-final-en.pdf) appeared in 2010. Other United Nations agencies also provide regularly updated data and indicators, for instance, the United Nations Environmental Programme (UNEP [http://www.unep.org/]), the United Nations Development Programme (UNDP [http://www.undp.org/content/undp/en/home.html]), and the World Bank (http://www.worldbank.org/). Private sector initiatives and nongovernmental organizations also publish regular reports on the state of the environment and biodiversity, the most important of which are the World Resources Institute (http://www.wri.org/) that published the Millennium Ecosystem Assessment (http://www.maweb.org/en/index.aspx), The Club of Rome (http://www.clubofrome.org/), the Worldwide Fund for Nature (WWF [http://wwf.panda.org/]), the International Union for Conservation of Nature (IUCN [http://www.iucn.org/]), Greenpeace (http://www.greenpeace.org/international/en/), and the Heinrich Böll Foundation (http://www.boell.org/web/137.html).

The assessment reports of the Intergovernmental Panel on Climate Change (IPCC [http://www.ipcc.ch/]) also provides very valuable information about the extent of climate change in different parts of the world and what climate change could entail under different scenarios in the future. The extent of the impacts of climate change on sustainable development and biodiversity is also discussed in these reports, as well as measures that could be taken in the area of conservation, sustainable development, and caring for biodiversity to adapt to climate change. The *Fourth Assessment Report* (AR 4 [http://www.ipcc.ch/publications_and_data/publications_ipcc_fourth_assessment_report_synthesis_report.htm]) of the IPCC appeared in 2007, and the four volumes of the *Fifth Assessment Report* are to be published during the course of 2013 and 2014.

In these reports, a bleak picture of life on earth under severe threat is sketched. In the 2010 *Global Biodiversity Outlook 3* (http://www.cbd.int/doc/publications/gbo/gbo3-final-en.pdf) of the United Nations Convention on Biological Diversity the following is stated: "The target agreed by the world's Governments in 2002, 'to achieve by 2010 a significant reduction of the current rate of biodiversity loss at the global, regional and national level as a contribution to poverty alleviation and to the benefit of all life on Earth', has not been met. There are multiple indications of continuing decline in biodiversity in all three of its main components – genes, species and ecosystems . . ."

This is confirmed by the *Millennium Ecosystem Assessment* of 2005 in which it is stated that "Over the past 50 years, humans have changed ecosystems more rapidly and extensively than in any comparable period of time in human history, largely to meet rapidly growing demands for food, fresh water, timber, fiber, and fuel. This has resulted in a substantial and largely irreversible loss in the diversity of life on Earth" (General *Synthesis* of its report on *Ecosystems and Human Well-Being*, p. 1 [http://www.maweb.org/documents/document.356.aspx.pdf]). While it is difficult to put figures on biodiversity loss, biologist E.O. Wilson has calculated in 1992 that human-induced extinctions have reached crisis proportions in that between 20,000 and 30,000 species are lost annually from a total number of

between 10 and 30 million extant species (Wilson, 1992). Using different assumptions, Pimm, Russell, Gittleman and Brooks (1995) calculated that about 140,000 species are lost per year – while the background rate of natural extinctions is calculated to be about 10 species per year (Raup, 1991). In addition, the WWF in its *Living Planet Report* of 2012 (http://wwf.panda.org/about_our_earth/all_publications/living_planet_report/) indicated a decline of almost 30 % in the Living Planet Index in the period from 1992 to 2008 (p. 18), while UNEP pointed out in 2011 (http://unep.org/geo/pdfs/Keeping_Track.pdf) that every year, 52 vertebrate species move one Red List (http://www.iucnredlist.org/) category closer to extinction.

Others have studied habitat loss and the destruction of ecosystems, and while it is equally difficult to quantify this, Primack (2006) mentions that, for instance, only 15 % of land in Europe remains unmodified by human activities, while only 9 million square kilometers of tropical rain forests remain today from an original 16 million square kilometers. Laurance (1999) estimates that the current rate of deforestation is 160,000 km^2 per year, while it is pointed out in the *Millennium Ecosystem Assessment* (2005) that 20 % of coral reefs have been destroyed and another 20 % have been severely damaged by overfishing, while 35 % of mangrove forest systems have been destroyed.

While it is important to note that this pressure on the earth system will increase in future as the demand for food rises with a growing world population, it is equally important to note the social and health impacts of environmental degradation. As it is pointed out in the *Millennium Ecosystem Assessment* (2005), habitat destruction not only impacts negatively on biodiversity but also on the livelihoods and health status of already marginalized people, that is, those most vulnerable to changes in the environment. Habitat destruction, for instance, impacts directly on water quality, and poor water quality can be a significant disease vector in poor communities.

From this, it follows that protection of the earth system is not only a "green" or conservation issue in the narrow sense of nature conservation. It also has to do with the protection of livelihoods, of human health, and the survival of people and that policies designed to address environmental degradation, threats to the biosphere, and loss of biodiversity unavoidably also have a people's agenda intertwined with them. To formulate it differently, conservation policies, measures to protect biodiversity, and strategies to safeguard the biosphere against threats such as pollution or climate change can play a significant role in the empowerment and development of marginalized communities and at the same time help to address the issue of world poverty.

Arguments for Protection of the Earth System

Why is it of the utmost importance to protect the environment, the biosphere, and biodiversity? Why are threats to the earth system such a big danger that they require urgent attention? There are typically two sets of reasons used to answer these questions: reasons based on *instrumental value* and reasons based on *intrinsic value* (Afeissa, 2009). In the first, most widely accepted set of reasons, the use value of the earth system in maintaining human well-being in the widest possible

sense of the word, is emphasized – acknowledging that there is a wide spectrum of human interests that are or can be satisfied in many different ways by the earth system. The earth system, however, is more than just a resource for human use alone. The earth system taken as a whole, as well as its component parts, have value in and of themselves, it is often claimed, regardless of any use value that humans can derive from them. In this context, the flourishing, abundance, and diversity of life in general, as well as its component parts, are seen as having intrinsic value that need to be protected for nothing but their own sake.

While both types of value provide strong arguments to protect the earth system, the ethical basis of instrumental value is often questioned for its anthropocentrism: it argues that the earth system should be protected because it is in the interest of humans to do so. Duties to the earth system are then only indirect duties; ultimately the only concern is to satisfy human interests, and this more often than not leads to exploitation or even destruction of the earth system or parts of it, including the complex processes that sustain life and its ongoing evolution. On the other hand, intrinsic value emphasizes that humans have direct duties to the earth system as a whole, its parts, and its processes, and thus claim to offer deeper or stronger reasons for their protection (Rolston, 2001). In this latter context, the challenge is to determine these duties in such a manner that they do not lead to the trap of the opposite extreme of an absolute reverence for the earth system that makes human life on earth impossible in that the earth system cannot be used to satisfy any human interests. Furthermore, critics argue that intrinsic value cannot inspire and move people to protect the earth system if the notion of intrinsic value is not combined with values that humans can strongly identify with (O'Neill et al., 2008).

Below different kinds of instrumental value will be discussed, showing how *direct use value, indirect use value, amenity value*, *option value*, and *existence value* can all be used to provide strong reasons to protect the earth system. Some discussion will also be devoted to intrinsic value and how a certain interpretation of it can provide equally strong reasons to protect the earth system.

Direct and Indirect Use Value as Basis for Protection

Resource economists, consumers, and ethicists alike emphasize that the direct use value of natural phenomena derives from transforming them into something that is useful to humans. Accordingly, a patch of land has to be cleared and plowed and watered to plant crops on it that can be harvested for the market and sold for human consumption. A river has to be dammed in places to make use of its water for agriculture and industry. Trees in a forest have to be cut to provide timber for building and furniture or pulp for paper. Animals have to be slaughtered to feed people. This transformation or primary resource extraction forms the basis of a value chain that spreads throughout society and makes a variety of other human activities possible, besides primary consumption for the sake of subsistence and survival. As such, this transformation has an economic value, and as such, it forms the material basis of human well-being.

Under the assumption that the earth is an infinite repository of raw material and energy, the direct use value of the earth system has been horribly exploited to satisfy short-term human interests, creating the problems of environmental damage, biospheric deterioration, and biodiversity loss. However, many have come to realize on rational, utilitarian grounds that this unrestrained development and expansionism (see Fox, 1995) cannot be sustained. Under the conviction that the well-being of humankind should be ensured over the long run, it was realized that the goal for resource management should be shifted from maximum benefit to maximum *sustainable* benefit, that is, benefit that can be maintained over time. This new goal was first known as *wise use*, or *conservation* of resources, and later from the 1980s as *sustainability*. As Holland (2001, p. 390) states, sustainability entails at least the hope "that we might provide for human needs with decreasing impact on the natural environment, and even reverse some of the degradation that has already occurred." Of late, sustainability has also been interpreted to include equitable sharing of the benefits and burdens of resource use (Swilling & Annecke, 2012).

One of the strong arguments often used to justify protection of the earth system is thus maintaining its direct use value over time, since it forms the material basis of all economic activity, human well-being in the present, as well as the ability of future generations to meet their needs – as the well-known definition of sustainable development of the Brundtland Report suggests: "Sustainable development is development that meets the need of present generations, without compromising the ability of future generations to meet their needs" (WCED, 1987, p. 43). There are a number of problems with this argument, though, if it is articulated purely in economic language based on the narrow assumptions of neoclassic economic theory. Economic efficiency and optimality then becomes the dominant values, leading to a weak interpretation of sustainability that has no concept of limitations and thus cannot protect the earth system from unrestrained exploitation.

In the first place, if interpreted in narrow financial terms, the espoused management goal of sustainability will not lead to the protection of the earth system as a whole. It will rather lead to a protection of only those components of the earth system that has clear economic value – reinforcing a "bits-and-pieces" approach to protection of biodiversity and the environment. If a holistic approach is followed, though, the economic argument will similarly only be able to justify protection of those processes and systems that have economic value derived from direct use. Other components of natural phenomena, or natural processes and systems that have little or no obvious economic value, will thus be left to their own devices with not special protection for them available.

In addition, those components, processes, and systems of the earth system that indeed have economic value clearly will only be protected as long as they have economic value and only up to the point where it is economically viable to do so. Bluntly formulated, this will entail the principle: *If it pays, it stays*. However, this principle cannot guarantee protection in the long run. Instead, the principle of diminishing marginal utility applies, which states that humans

will protect the earth system or its components only up to that point where they start to feel that they can spend their money better to satisfy other interests.

In the second place, a narrow financial approach to protection based on the values of efficiency and optimality entails a weak interpretation of sustainability. Formulated in economic terms, *weak sustainability* sets the management goal of maintaining the total value of capital over time (Solow, 1993). According to this view, there are different kinds of capital besides natural capital, for instance, human-made capital such as infrastructure (roads and buildings and power stations), human capital such as education, and financial capital such as funds available in a bank for utilization. Under the meaning of maintaining total capital over time, sustainability implies an infinite intersubstitutability of capital (Norton, 2003). As long as total capital is maintained, the argument goes, sustainability is achieved.

There is a problem with the notion of infinite intersubstitutability of forms of capital, however, since it implies that a natural resource, for instance a forest, can be totally "used up" over a short period of time, as long as its capital value has been transformed in other forms of capital – for instance, used for education or the building of roads, schools, and hospitals. The total and irreversible loss of a forest and all of the biodiversity and ecosystem functions it entailed, would therefore, under this interpretation of weak sustainability, still be acceptable as an instance of sustainability. Besides the problem of seeing the earth system and its functioning as merely another form of capital that can be "traded in" for another form of capital, it clearly also entertain no conception of systemic limits that should be taken into account when decisions about resource use and development paths are taken (Norton, 2003; Swilling & Annecke, 2012).

Some critics of weak sustainability therefore introduced a strong interpretation of sustainability as a corrective (Costanza, 1991). Formulated in economic terms, *strong sustainability* would entail maintaining *natural* capital over time. This introduces the notion of certain limits to the use of natural capital below which humans should not go. The notion of strong sustainability also acknowledges that "the environment provides humankind with 'benefits' which no human-made capital can replicate: both particular functions (such as climate regulation and genetic diversity) and non-eliminable inputs (such as raw materials, land, and waste assimilation capacities)" (Jacobs, 1995, p. 59).

From this point of view, there is not only recognition of the direct use value of the earth system and some of its components but also of a number of very real nondirect "services" that humans depend on for survival and well-being, for instance, the provisioning of a tolerable climate, the processing of waste, the provisioning of clean air and water, as well as the raw material required for subsistence, shelter, agriculture, etc. Strong sustainability as a management goal thus calls for much more than maintaining the commodity (direct use) value of the earth system and its components; it argues for the maintenance of the *functioning* of the earth system that provide those commodities in the first place, as well as a wide spectrum of other, indirect, and nonconsumptive use values on the basis of which protection of the earth system can also be based.

While much is already known about the functioning of the earth system, what keeps it together and going as it were, there are also many gaps in this knowledge on these topics. A certain species, for instance, or a certain process, can play a key role in the functioning of a particular ecosystem, and a fair amount of scientific or localized knowledge may be available about it, but there may be many other key components or processes of ecosystems that very little or nothing is known about. Formulated in terms of a metaphor, there may be a number of known "rivets" that keep the ecological support system intact, but there may be a number of other important "rivets" that are not known, that may be discarded or destroyed in ignorance at the peril of humankind (Rolston, 2001). Accordingly, it is often recommended that a cautious approach should be followed in human actions that may have an irreversible impact on the functioning of an ecosystem (Norton, 2003) – because humans may never know when they may destroy something that is crucial to the very functioning of the earth system they depend on for their existence and their well-being.

Amenity Value as Basis of Protection

Besides direct and indirect use value, some nonconsumptive values are also often used to justify protection of the earth system. *Amenity value*, one of these nonconsumptive values, is derived from the mere existence of natural phenomena. While the direct use value of natural phenomena is derived from transforming them, using them up as it were in consumption, amenity value is largely based on keeping the earth system relatively intact, allowing it and its components to be what they naturally are, or letting its processes and systems function and unfold as they naturally do, with the least possible human interference.

A wide range of amenity values can be distinguished that justify protection of the earth system, if not as a whole, then parts of it, in a condition as pristine, free, or wild as possible. In one of his earlier works, without actually using the term amenity value, Warwick Fox (1995) provides an insightful list of the amenity values of what he refers to as untouched nature:

- *Information value*. Scientific studies of untouched nature and the impact of human activities on it can serve as an early warning system that things are starting to go wrong with the health of ecosystems, making it possible to take early remedial measures to minimize the problem. Studying untouched nature can also yield a treasure house of information about the functioning of healthy ecosystems and what could be done to keep them functioning in a healthy state. It can also help to understand evolutionary processes and how humans are not only dependent on it, but also part of it – it helps to understand how humans have arrived at the evolutionary place they currently occupy, how the evolution of culture and nature are codependent upon one another, and how humans are currently influencing that evolutionary process. On the latter point Rolston (2001, p. 404) observes that destroying a species "is like tearing pages out of an unread book, written in a language humans hardly know how to read, about

the place where we live." It denies insight into the history of evolution in which humans are embedded, precluding "insight into the full text of natural history."

- *Recreational value*. The mere existence of natural phenomena also provides a wide range of opportunities for humans to relax from their daily activities. These opportunities can range from taking a walk in a well-preserved forest or along a pristine beach, taking a swim in a clear lake, or testing one's agility and strength by scaling a high cliff in a mountain.
- *Aesthetic value*. Fox argues that nature can also function as an "art gallery" when its components, systems, or processes are contemplated and appreciated for their beauty.
- *Religious value*. Nature, as a whole, or some natural places can also function as sources of religious experience, generating respect for creative processes and creation that surpasses that of humans.
- *Symbolic instruction value*. Fox argues that untouched nature or untouched parts of it can also serve as "monuments," reminding humans of, for instance, symbiotic relationships in nature, or hierarchical relationships in nature, or efficiency in nature in that nothing in nature is wasted.
- *Refuge value*. This is closely related to recreational value, but Fox gives it a special mention to focus on the function that untouched nature can have in the psychological rejuvenation and development of humans. With its contrast to heavily managed places, untouched nature can serve as a necessary counterpoint, helping humans to achieve a psychological balance in their lives but also prompting them to acknowledge that everything on earth need not and cannot be fully managed and that some natural things and systems and processes can just be left alone to be what they are. (As such, this interpretation of amenity value comes very close to the notion of intrinsic value that will be discussed below, but there are some important differences in the arguments for protection of the earth system that are based on amenity values and intrinsic value.)

Taken together, and in interaction with one another, the nonconsumptive amenity values listed above play a large role in the formation of *human character and identity* – of individuals as well as communities. Wild nature, for instance, extremely cold temperatures in winter, or habitats populated by large alpha-predators, can be a survival challenge to humans, but by learning to overcome these challenges with certain behavioral patterns, the character and the identities of humans and communities are formed. These challenges and responding to them become part of the "lived stories they as humans are."

While others have drawn up similar lists, giving slightly different nuances to the notion of amenity value, all of these lists emphasize the value that humans can derive from a nonconsumptive interaction with the components, systems, and processes of the earth system, keeping them as untouched and pristine as possible. Wilderness preservation and wildlife sanctuaries are clear examples of management contexts where these nonconsumptive values are foregrounded. However, these amenity values can also be enjoyed where natural phenomena are kept intact, or restored in urban or industrial spaces to enhance, for example, their

aesthetic appeal, or to break down "the hard edges" of life in manufactured environments. Parks in the centers of cities, or landscaped and beautified industrial areas, simulating natural landscapes are examples of this – serving as reminders that human well-being entails more than merely satisfying material needs.

Apart from the factual question whether the preservation of wilderness areas and wildlife sanctuaries or manufactured landscapes simulating nature are really adequate to stem the tide of biodiversity loss, habitat destruction, ecosystem damage, and destruction of the environment and the biosphere, the biggest conceptual and practical difficulty around amenity values occur when they are for all practical purposes separated from the consumptive, use value of the earth system. Such a separation occurred during the early years of industrialization in the Romantic movement, leading to an isolation of the spiritual and aesthetic dimension of human existence in the experience of nature, which represented the ideal of a rekindling of the human spirit, but also a flight to nature away from the industrialized world that is left to its own devices.

The trap of such a dichotomous world where the sphere of direct use value, dominated by efficiency and optimality, clashes with other dimensions of human existence that are equally essential for human well-being – recreation, aesthetic enjoyment, spirituality, and psychological rejuvenation – is still evident in the environmental debate today. The challenge, therefore, seems to be in finding a sufficient integration of direct use value and amenity value, and this could perhaps help to appreciate the manner in which humans are dependent for both survival and well-being on the existence of a well-functioning earth system. In the discussion below of *ecosystem services*, an effort is made visible to think direct use value and amenity value together right from the start.

Option Value as Basis of Protection

Protection of the earth system is also often justified on the basis of *option value*, an important nonconsumptive value that can be distinguished from amenity value. While direct and indirect use value as well as amenity value are derived from the known present value of components, systems, and processes of the earth system, option value is derived from the *unknown future value* that humans may derive from a well-functioning and healthy earth system. Option value entails the potential value that humans may derive from the components, systems, and processes of the earth system – whether it is direct use value or nonconsumptive amenity value. An as yet undiscovered species, for example, may in future yield the cure for AIDS; as an already discovered species that is currently regarded as of little medicinal value may prove to be highly valuable in the fight against a tropical disease that may develop in, say, 50 years' time from now. However, if these species are not in existence in the future, either to be discovered or to be used in a new application, humankind has lost its ability to exercise certain options.

But option value is not only dependent on the protection of the components of the earth system, for example, biodiversity on all of its levels (genetic, species, ecosystems). Option value is also and predominantly dependent on the systems and processes that generate, for example, ecosystems and biodiversity in the first place – and thus it is these processes that should be protected for the sake of future generations, the argument goes. In almost lyrical terms, Wilson (1988) points to *biodiversity* as a "frontier of the future" (see Faith, 2008, pp. 3–4). From an evolutionary point of view, Wilson (1988) argues that biodiversity presents "a dazzling prospect of largely unknown variety, with unanticipated uses" (Faith, p. 3). But even more importantly, from an evolutionary point of view, option value represents and recognizes the possibility of new forms of life and of forms of existence and interaction that are not existent yet but can emerge if the earth system is protected to function well and without irreversible damage.

Option value, however, is extremely difficult to translate into conservation policies and actions – mainly for two reasons. In the first place, humans are subject to cognitive constraints: they do not know exactly what the preferences of future generations will be and also do not have complete knowledge at present of all of the component parts and all of the systems and processes that maintain a healthy and robust earth system. Faith (2008, p. 3) refers to this as the problem of "unknown variety and unknown value." In the second place, humans may not be able to save all of the components of the earth system and all of its evolutionary systems and processes that will ensure its maintenance and evolution. The costs involved to do so may be prohibitive.

Norton (2003) acknowledges this uncertainty about the exact preferences of future generations, but based on general human experience, he argues that those living now may be pretty sure that future generations may not want to inherit a world that is poorer in options than the one this generation has inherited from its ancestors. Those living now may also be sure that future generations will not want to inherit a world that is full of unpleasant surprises, such as toxic waste or ecological time bombs that were passed on to them. Accordingly, Norton argues (2003, p. 301) that those living now should do their utmost best to adopt policies that ensure the healthy functioning of the creative processes of nature that will maintain complexity, biodiversity, and evolution and at the same time make it possible to learn more about the components of life, the systems, and the evolutionary processes in which they are embedded.

When it comes to the question of how much should be invested in this, Norton (2003) is hesitant to argue for protection at all costs. However, from the point of view of his environmental pragmatism in which he opts for the coexistence of a plurality of values that should inform conservation efforts, he argues that conservative safe minimum standards should be set for activities whose effects are reversible at a reasonable cost in the short or medium term. He also argues that a precautionary approach should be followed (where costs are put in the background) when human action start to have irreversible effects – for instance, pushing a species toward the brink of extinction.

Existence Value

Existence value is usually reserved for elements of the earth system, such as dramatic landscapes or magnificent animals such as lions, wolves, ice bears, whales, dolphins, elephants, and rhinoceros, but it can also be extended to the earth system as a whole, either in its component parts such as biodiversity, biomes, and ecological "hotspots" where a number of biomes intersect to bring about an unusual concentration of diversity, ecosystems, or communities of life, or conceptualized in terms of the processes at work in these systems. This value represents *the satisfaction humans experience* from the knowledge of the mere existence of phenomena such as these, over and above any of the use values mentioned above. Encountering a pride of lions in a conservation area, for instance, may be the high point of a visit to Africa, while spotting an ice bear may have the same value for those on a visit to Siberia (see Rolston, 2001): the mere existence of these animals and the species they belong to are regarded as highly valuable, and therefore, the argument goes, these animals and their species should be protected. Existence value thus move very close to the argument that the earth system, its component parts, and its processes should be protected for their own sake (see O'Neill et al., 2008), but in so far as this argument is still based on instrumental value, albeit a subtle and nonconsumptive version of it, it cannot be equated to intrinsic value, as will be shown below (see Afeissa (2009) for an insightful discussion of the difference between instrumental and intrinsic value in environmental ethics).

Ecosystem Services as Basis for Protection

While a number of different kinds of use value can serve as basis to protect the earth system, it is clear from the discussion above that these kinds of values can be separated from one another and even played off against each other if they are not put into some kind of systematic relationship right from the outset. Direct use value, for instance, always seems to be the most obvious basis for protection, but this value, if not strongly qualified by indirect use values, amenity, option, and existence values, can serve as basis to justify the complete opposite of protection, namely, the overexploitation or even destruction of the earth system.

In response to this need, the notion of *ecosystem services* has emerged in an effort to conceptualize different kinds of use values in relationship with one another, mapping how they are mutually dependent upon one another, and how they all, in combination with one another, through direct, indirect, and nonconsumptive use value, contribute not only to the physical survival of human beings but also to their identity, general well-being, and quality of life. Usually, four main categories of ecosystem services are distinguished, three of which represent direct services (namely, provisioning, regulating, and cultural services), while the fourth represents a cluster of indirect services in the sense of supporting the other direct services (Millennium Ecosystem Assessment, 2005). As such, these categories of ecosystem services cut across the distinction of the direct and indirect use values, amenity, option, and existence values that can be derived from the earth system.

Provisioning ecosystem services include things such as food, fresh water, wood, fiber, and fuel that can be directly provided by natural entities, systems, and processes. But these basic goods can also be provided by way of artificial systems such as farms, water purification plants, plantations, and refineries. The point, however, is that all of these secondary provisioning services are dependent in some way or another on direct provisioning coming from natural entities, systems, and processes.

Regulating ecosystem services include climate regulation, flood regulation, disease regulation, and purification of water. Cultural ecosystem services, in turn, include the aesthetic or spiritual experience of natural entities, systems, and processes, or using them as a source of education or a space for recreation and rejuvenation. Supporting ecosystem services form the foundation of the other services that have already been mentioned and include nutrient cycling, soil formation, and primary production of which photosynthesis is an example.

While the components of human well-being and quality of life are fields of study for the different disciplines of the social and human sciences, there is agreement among most social scientists that security, access to the basic material for a good life, health, good social relations, and freedom of choice and action form the basic components of human well-being. Security includes personal safety, secure access to resources, and protection from disasters, while the material for a good life includes adequate livelihoods, sufficient nutritious food, shelter, and access to goods. Health, in turn, requires strength, feeling well, and access to clean air and water, while freedom of choice and action entail the opportunity to be able to achieve what an individual values doing and being (Millennium Ecosystem Assessment 2005, *Synthesis*, p. vi).

What must be emphasized as the core of this approach, but is often overlooked, is that the ecosystem services that support human well-being are all based on *biodiversity*, as it is understood in the *Millennium Ecosystem Assessment* as life on earth in general. In this meaning, "biodiversity" approximates the meaning of "earth system" as it has been used in this chapter. Something of this insight is captured in the United Nations Convention on Biological Diversity (1992) where it is stated that biodiversity should be protected because it provides the foundation of the "social, economic, scientific, educational, cultural, recreational and aesthetic values" that contribute to human well-being. However, as such, biodiversity, understood as life on earth, is not only a value among other values in a human calculus of what contributes or not to human well-being. Biodiversity rather forms the basis of such a value calculus. As Norton (2003, p. 501) has argued, "biodiversity ... is not a resource among others, but a generator – a source – of biological resources." Thus, biodiversity, understood as life on earth in general (i.e., including the environment and biosphere), is a necessary condition of the use values that can be derived directly or indirectly, consumptively or nonconsumptively, from the earth system, while biodiversity as life on earth, as this necessary condition of resource values, is not a resource itself.

With this insight, a notion of value is revealed that actually falls outside the ambit of ecosystem services, or direct, indirect, and nonconsumptive use values that

can be played off against one another in a calculus of what does and what does not promote human interests. It is the notion of value that makes the ecosystem services and use values of the environment, the biosphere, and biological resources possible – and as such, this value approximates the notion of the intrinsic value of the environment, the biosphere, and biodiversity, but is perhaps not exactly coinciding with it (see Afeissa, 2009), as will be shown in the next section.

Intrinsic Value

Intrinsic value features very prominently in arguments for protection of the earth system from an ethical point of view. Since the inception of environmental ethics in the middle 1970s, different aspects of the earth system have been singled out to have intrinsic value, ranging from certain individual animals (Tom Regan), any living entity (Paul Taylor), land (Aldo Leopold), species and ecosystems (Baird Callicott and Holmes Rolston), the community of life (Aldo Leopold), the evolutionary process (Rolston), the abundance and diversity of life and its flourishing (Arne Naess), and so the list can go on. The one element common to all of these arguments is the recognition that the whole of the earth system, or its component parts and constitutive processes, have value in and of themselves, regardless of any human use that can be derived from them. On the basis of intrinsic value, it is then further argued that these elements or the whole of the earth system should be morally considered or respected in their own right and not for their instrumental value for humans. Differently formulated, intrinsic value means that humans have direct moral duties to the earth system and its component parts and processes.

While there are debates between supporters of the intrinsic value approach, with some arguing for intrinsic value as objectively located within nature (Holmes Rolston) and others maintaining that intrinsic value is subjectively attributed by humans to nature (Baird Callicott), intrinsic value in this context, in whichever way it is deemed to be constituted, can be equated to a respectful reverence for all life in its variety and abundance, for individual entities as well as for the systems and processes making this variety and abundance possible. From this perspective, any loss of abundance and variety through, for instance, human-caused extinctions, represents a loss from the rich and complex tapestry that life itself is, consisting of a continuing process of complex interaction and biological creativity that unfolds through evolution.

In the words of Holmes Rolston (2001), the loss of a species is the loss of genetic possibilities – it is the death of a type and thus the loss of a form of life itself. In so far as a species represents an adaptive fit with a particular habitat that has evolved over millennia, a human-caused extinction represents a shutdown in a very long evolutionary story, and it leaves no further possibilities of regeneration, speciation, and the creation of further biological variety. Rolston argues that artificial extinctions in distinction from natural ones impoverish the earth system and close down the spontaneous evolution that otherwise would have taken place. For Rolston, the difference between a natural extinction and an artificial extinction can in moral terms be likened to the difference between death by natural causes and murder.

Accordingly, Rolston argues (2001) that humans have no direct moral duty to preserve species from natural extinction, although they do have a direct moral duty to avoid artificial extinctions. But Rolston goes even further by claiming humans also have direct moral duties to the habitats, biomes, and evolutionary processes that generate species in their abundance and variety in the first place. It is not only important that *species* are protected but that species are protected *within the system* that they survive and evolve. In this perspective, the appropriate level of moral concern is not the individual – either persons or sentient beings – as conventional Western ethics will maintain, but rather the appropriate survival unit that leads to the existence of individuals, like species, habitats, biomes, and evolutionary processes.

The central concern of Rolston's environmental ethics is thus not so much the loss of resources that humans may experience in the destruction of the environment, the biosphere, and biodiversity but rather the killing of and insensitivity to forms of life that stands within an evolutionary history. Accordingly, Rolston argues, the core of environmental ethics should be much more than prudence; it should entail a principled responsibility with the primary duty to consider every form of life as valuable in itself and to care for and about it – except for pest and disease species. With reference to the human species as a late arrival in evolutionary history, and the tendency of this species to act in mere self-interest, Rolston states (2001, p. 414): "On the naturalistic account, the host of species has a claim to care in its own right. There is something Newtonian, not yet Einsteinian, besides something morally naïve, about living in a reference frame where one species takes itself as absolute and values everything else relative to its utility."

Like option and existence value, the intrinsic value of the earth system is extremely difficult to translate into policy terms or into action – mainly because intrinsic value is so vastly different in nature from instrumental or use value. In fact, intrinsic value is mostly evoked in arguments to oppose the overemphasis of use value that often leads to an overexploitation of the earth system and sometimes even to its destruction (see O'Neill et al., 2008). The argument then usually goes that a natural resource cannot be treated in this manner because it has intrinsic value – it is alive – and forms a part of a rich web of life that has value independent from human use value and stands to be damaged or destroyed by human activity.

Under one extreme interpretation of this approach, the appeal to intrinsic value can be seen as an argument for the total protection of nature/the earth system (see Norton, 2003, p. 125), saving all of it at all costs. However, many will reject this as a legitimate management goal because, they would claim, it cannot be implemented without severe negative impacts on human well-being. A total "hands-off" approach to the earth system, they would argue, would bring agriculture, science, and medicine to a total halt, making it impossible for humankind to survive, let alone to thrive.

There is, however, a less extreme interpretation of intrinsic value possible that still opposes the reduction of nature and life to a commodity and rather sees the intrinsic value of the earth system and of life as point of departure for a caring and careful interaction with the earth system and the life it supports, in which its

richness and diversity are embraced as valuable in itself – and is protected, cared for, nourished, and celebrated for nothing else than it being the wonder it is (Rolston, 2001). The general thrust of recognizing intrinsic value from this perspective is not in the first place to protect the earth system and life from harm but rather to enhance the earth system and the life it sustains so that it can flourish – for its own sake, in its own way (see Swilling & Annecke, 2012). The flourishing of life is thus the point of departure; it is not relegated to an afterthought after human use value has taken precedence.

From this point of view, intrinsic value does not entail a total abolishment of the human use of the earth system but rather opens up space for a modest use of it, inspired by the premise of the wonder of life as something extremely precious and fragile, something that requires respect and care – not only for the individual elements of life but also for life in general as a whole, together with all the conditions that make life possible in the first place. Under this interpretation, arguments for protecting the earth system based on the notion of intrinsic value do not stand far apart from arguments for protection based on option and existence values. The internal logic of intrinsic value, however, differs from the instrumental logic within which option and existence values are embedded. Intrinsic value arguments entail an approach of principled responsibility to be careful and take care of all life as valuable in itself, while instrumental value arguments entail a prudential approach to resource preservation in which human interests stand central.

Integrating the Value Arguments

From the discussion above, it can again be stated that protection of the earth system is more than just a green issue – in the narrow sense of focusing only on nature conservation. The different instrumental values derived from the earth system emphasize that its protection is ultimately done to ensure the well-being, and satisfy the interests of humans. In the words of Rolston (2001, p. 403), protection of the earth system justified from this perspective "is ultimately for the purpose of its enlightened exploitation." The emphasis on ecosystem services forming the foundation of the well-being of humans underscores this point. Instrumental value arguments for the protection of the earth system, however, presuppose a sort of separation between humankind on the one hand and the earth system on the other hand: The earth system is seen as something removed that stands at a distance from humans, and the mode of interaction with it is that of an object of management (often at arm's length) to make it and its component parts and processes available to "serve" humans in a variety of ways to satisfy their interests. In order for it to be available for human use, the earth system (comprising of the environment, the biosphere, and biodiversity) is simplified and reduced to become something less than what it fully is.

From an intrinsic value point of view, this separation and reductionism are challenged. Instead, the fundamental unity of humankind with the earth system is emphasized, arguing that human life, together with all other forms of life, emerged

from a long history of evolution that has value in and of itself. From this perspective, protection of the earth system, that is, ensuring that the earth system is functioning well and continuing with its process of spontaneous evolution, is done for its own sake, regardless of any use value it may have for humans. Stated in positive terms, and under a modest interpretation of intrinsic value, the earth system is protected to enhance the richness, abundance, and flourishing of life – for the sake of life itself. In practical terms, this implies that humans, while dependent for their survival and well-being on well-functioning ecosystem services, should always see the earth system, in its component parts and processes, as well as the whole that it forms, as something much more than just a commodity or an amenity or an option that are or could be of use to humans. From an intrinsic value point of view, the earth system should rather be acknowledged as the very basis of the wonder of life itself, and therefore, it should be respected, treated, cared for, and celebrated as such.

From both angles then, strong arguments can be made for protecting the earth system. From a use value point of view, it is argued that the preconditions for human well-being can be lost if the ecosystem services provided by the environment, the biosphere, and biodiversity are not protected. From an intrinsic value point of view, it is argued that life itself will be diminished if the earth system is not protected and cared for. While the internal logic of instrumental and intrinsic value approaches differ vastly from one another, a survey of the environmental attitudes of the general public in the USA (Kempton, Boster, & Hartley, 1995) has found that the earth system/the environment is appreciated both instrumentally and intrinsically.

This is an important finding, although it calls for further studies in other countries. It means that there is a lot of common ground between the espoused attitudes of environmentalists and resource users, even if the challenge clearly lies in the translation of attitudes into action in a global transition from a development path based on overexploitation and even destruction in some cases of natural resources, to one that is based on justice and respect for all of life on earth.

In rising to this challenge, it is clear that humankind will have to figure out how to combine instrumental and intrinsic value with one another in an intelligent and productive manner in the very concrete management, and life choices that will have to be made in everyday contexts. Formulated in general terms, this will require that some limits are placed on consumptive use that leads to overexploitation, damage, and destruction of the earth system, but also that realism is brought to human action in response to the runaway idealism that sometimes characterizes ideas about the nonconsumptive value of the earth system, or its intrinsic value.

Conclusion: An Outlook for the Future of the Environment, the Biosphere, and Biodiversity

At the time of writing, 40 years after the Club of Rome has published its report on the limits to growth in 1972, the outlook for the future of the earth system looks bleak. In the second finding of the *Biodiversity Synthesis* of its report on *Ecosystems*

and Human Well-Being (http://www.maweb.org/documents/document.354.aspx.pdf), the *Millennium Ecosystem Assessment* stated that "The drivers of loss of biodiversity and the drivers of changes in ecosystem services are either steady, show no evidence of declining over time, or are increasing in intensity" (p. 8). The same conclusion is reached in the *Global Biodiversity Outlook 3* that was published in 2010 by the United Nations Environmental Programme (UNEP), placing the loss of biodiversity and ecosystem services within the framework of a collective, global failure that will require extraordinary measures to turn around.

Having considered the state of biodiversity in 2010, the *Global Biodiversity Outlook 3* found that the "five principal pressures directly driving biodiversity loss (habitat change, overexploitation, pollution, invasive alien species and climate change) are either constant or increasing in intensity," and that the "ecological footprint of humanity exceeds the biological capacity of the Earth by a wider margin than at the time the 2010 target was agreed" (p. 9).

With this continuing and intensifying loss of biodiversity and ecosystem services due to human activities, the general consensus among scientists from a wide range of disciplines is that humankind is at risk to push the earth system beyond certain thresholds or tipping points "that could lead to large, rapid and potentially irreversible changes" (p. 71). As defined in the *Global Biodiversity Outlook 3*, a tipping point is a situation in which an ecosystem experiences an abrupt shift to a new state, "with significant changes to biodiversity and the services to people it underpins, at a regional or global scale," which will first and foremost affect the poor populations of the world since they are mostly directly dependent on the ecosystem services of the natural environment (p. 71, 72).

This outlook becomes bleaker if it is taken into account that the world population is expected to grow to nine billion in 2050, an increase of two billion people over the seven billion that the world population is in 2012. With higher demands placed on the agricultural sector to provide food for nine billion people, it can be expected that more and more pressure will be exerted on the earth system. At the same time, this will put more pressure on those societies that are already marginalized and are directly dependent on the maintenance of well-functioning ecosystems for their survival. For the future, this will require an intensification of an ethics of limits, justice, and sharing, in which efforts should be significantly increased to restore those ecosystems and ecosystem services that have already been damaged, to prevent further damage to those ecosystems and ecosystem services that are still intact, and to work toward a transition in which the conditions that sustain the flourishing of life on earth – all life on earth – are really cared for and enhanced.

In such an ethic of restoration, care, and transition, people and justice will have to play a central part, since life cannot be respected and celebrated without everyone enjoying their fair share of its richness and abundance (see Swilling & Annecke, 2012). While numerous examples exist of groups, organizations, and societies experimenting with the practical implementation of such an ethics in efforts to learn again how to live sustainably in a particular place, humankind is unfortunately a far way off from a position where mainstream decision-makers,

governments, and business organizations make the transition to this ethic. It is possible, though, for individuals, consumers, landowners, NGOs, and any custodian of the smallest part of the earth system to influence these mainstream role-players and to start living this ethics of becoming sustainable in a place – even if this may entail overcoming prejudice and ideological resistance.

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Section III

Cultural Perspectives

African Perspectives

16

Jude M. Mathooko and Julius K. Kipkemboi

Introduction

Africa is a continent of complexities, with a wide diversity in terms of climate, topography, culture, peoples, and languages. This diversity characterizes the people's relationship with the environment and with each other. It, therefore, implies that any attempt to unify any aspect of life would be a daunting task and would require some ingenuity to do so. With pockets of diversity scattered all over the continent, a broad understanding of the African diverse landscape is of paramount importance if the African perspective in bioethics is to be fully addressed. It appears, therefore, that bioethics, which is the study of ethics in the fields of life sciences, medicine, and the related technologies, is enshrined in the lives of Africans and defines their existence and their connectivity with each other and with the environment in which they live. This environment has dictated the type of bioethics that has emerged over the years since an African draws, consciously or subconsciously, his or her bioethical practices and reflections from it. Intuitively, bioethics reflections are guided by the available resources in the familiar environment and how they are utilized while cautiously adapting to the forces of externalities.

African perspectives of bioethics revolve around harmonious coexistence with the cosmos and the promotion, defense, and protection of life, including maintaining the integrity of the human species, protecting the dignity of the person, and protecting nature and diversity. These tenets are well enshrined in the Universal Declaration on Bioethics and Human Rights (UDBHR) and it is useful to relate the African perspectives on bioethics to it. However, while most of the normative instruments for bioethics are generic and universal, they cannot be implemented

J.M. Mathooko (✉)
School of Management and Leadership, The Management University of Africa, Nairobi, Kenya
e-mail: mathookoj@yahoo.com

J.K. Kipkemboi
UNESCO Regional Documentation and Research Centre on Bioethics, Egerton University, Njoro, Egerton, Nakuru, Kenya
e-mail: j_kkipkemboi@yahoo.co.uk

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in totality before being domesticated and interpreted in concurrence with the African way of thinking and acting. Further, van Bogaert (2007) stated that the diverse cultures, ethnic groups, ways of life, and world views of Africa share a common underlying concept of bioethics that is centered around the traditional ideal of kinship and personhood. This idea emphasizes the ties of kinship in which the concept of a person is tied to the community, where persons become persons only after incorporation into the community.

During the 14th Ordinary Session of the International Bioethics Committee (IBC) held in Nairobi in 2007, African perspectives were discussed and organized around the following themes: what is special about bioethics in Africa? an overview; challenges and institutional constraints on bioethics development in Africa; legislative and administrative measures for the implementation of the Universal Declaration on Bioethics and Human Rights in Africa; and moral sensibilities and emerging technologies: implications for Africa. The speakers attempted and did their best to go round these themes despite limited time. Despite their in-depth contributions, African bioethics still has glaring gaps that this chapter attempts to fill, especially the status of bioethics education in Africa. The agenda for the Nairobi IBC meeting, therefore, provides the backbone of this contribution bearing in mind the complexities attached to this issue.

Characteristics

Bioethics: New or an Old Concept in Africa?

It has been argued in several forums that bioethics is a new concept in Africa. In this chapter, a two-pronged view is given – in practice, no; as a study, yes. African communities, like other communities all over the world, have been employing bioethical approaches in tackling their life challenges since time immemorial. Bioethics is part of life and is practiced, subconsciously or unconsciously, by humans as they tackle challenges of life, transformations from one practice to the other, and during intergenerational transitions. What makes it appear as new is when it is considered as an evolving study, with its jargon and terminologies to describe it, raising the question: which comes first – the practice or the evolution of definitive terms of study? Generally, ethical activities come first and terminologies are coined to describe the actions and practices. Therefore, African bioethics, defined in terms of practices and reflections, is not new but has been in existence from antiquity to the present. It should be remembered that bioethics is not about use of terminologies and evolution of words but about actions in relation to human life *vis-à-vis* its relation with the environment.

Is There an African Bioethics?

Africa is a complex multicultural society and is believed to be the cradle of humankind, which could provide insights into medieval bioethics practices and

thinking. Lamentably, African bioethics, in its present form, has been transformed into hybrid bioethics through infusion and domination by foreign concepts developed in the Western world, some of which are not relevant to the practices in Africa. Perhaps, this could be one of the reasons why bioethics has experienced a slow development in Africa. Cultures cannot exist in isolation and are not impervious to the influence by other cultures, and the African culture is not an exception. However, it is important to realize that bioethical practices and reflections of a community or race cannot be decimated in totality by any culture without encountering some form of resistance. If bioethics is to be popularized globally, it is imperative that the best practices and reflections in each culture be harnessed and promoted without infringing on the rights of the individuals and the communities or races. This is perhaps why UNESCO member states focused on generality and universality in the UDBHR to accommodate the wishes of the different races of the world. It is time to assess how far the western bioethical ideologies have intruded into the African bioethics as a response to the scientific and technological transfer and advancement in the Western world, coupled with the rapid globalization.

In Africa, different bioethical reflections do exist, but there are also certain ethical principles that transcend both culture and geographical boundaries. Therefore, a globalized bioethics approach cannot apply to the diverse bioethical reflections in Africa and elsewhere. A truly global ethics, if there is any, should take into account bioethical pluralism, including the coexistence of alternative and competing ethical frameworks. It is therefore within this diversity of ethical reflections where the differentiation of African bioethics converges and diverges from the other ethical reflections. An effort should be made to harmonize the cultural, religious, and secular approaches to bioethics, a task that could be daunting in Africa. One wonders how many approaches and schools of thought there are on African bioethics and how much of this bioethics is migrated to the Western world. Complaints abound on the export and import of bioethical concepts into the different cultures. However, bioethics as it is today is trapped in Western categories of thought and relies heavily on Western analytical philosophy without decimating completely the African philosophical thought. Mbugua (2009) notes that the question of whether or not African bioethics exists cannot be addressed without due cognizance of the answer to the question of whether or not an African philosophy exists. He further expounds in a philosophical manner that since bioethics is one branch of ethics, to assert the existence of an African philosophy is to assert the existence of an African bioethics, which in turn, is one of the traditional branches of philosophy. However, other schools of thought postulate that to speak of African philosophy is to make a huge generalization because Africa as a continent is very heterogeneous, with numerous ethnic groups, each with a unique identity. There is a fast influence of technological transfer into the region and concomitant bioethical ideologies. While these concepts are useful as precautionary approaches, there is a need to contextualize them. Meanwhile, it could rightly be postulated that African bioethics has evolved over time and is now a hybrid between the African and Western bioethics.

Individualism Versus Communitarianism in the African Bioethical Approaches

The African cultures are tightly held by communities and each community has its own way of operation; they also think and act collectively as a community and in most cases the autonomy of an individual is eroded by decisions made by a well-structured clique of elders whose decisions are revered and final. Going against such decisions is going against the whole community and could lead to being banished from the community or a severe punishment could be meted upon you. The happiness of the community therefore supersedes that of the individual. Due to the problems of underdevelopment, poverty, preventable communicable diseases, poor healthcare infrastructure, and differences in belief systems, bioethics emerges consciously or subconsciously over time and responses to these emergencies dictate the bioethical practices and reflections. From this also emanates the African philosophy that is seen as an item of communal property rather than an activity of an individual. However, African bioethics can be approached, not only ethno-philosophically but also as professional philosophy approach. This dichotomy is extremely important if the so-called African bioethics is understood.

From the foregoing, it is clear that in reflecting on bioethics in the past traditional Africa, one has to look at the context of traditional Africa in which the social fabric was embedded in diverse cultures based on informed decision on human dignity and human rights. During this era, cultures shaped morality and consequently values that guided personal and communal life. In this regard, a person was attached to the community and this emphasizes the uniqueness of bioethics approaches in the African context (van Bogaert, 2007). The core traditional values have, however, been influenced by globalization. Individualism has taken over communitarianism and this is perhaps why Africa is grappling with the issue of informed consent in research, development, and practice of modern medicine.

Africa: ignore Bioethics at Your Own Peril: Selected Issues of Bioethical Concern

As stated earlier, African bioethics is very complex if it ever exists. To attempt to understand it requires teasing the discussion into a few aspects that could address more vividly bioethics in the African perspectives. These are not, in any way, exhaustive but will help to shed some light on the current status of the African bioethics.

Traditional Medicine

Traditional medicine in Africa is as old as human civilization. Africa has comparative advantages in indigenous medical knowledge, biodiversity, and diagnostics development. Traditional medicine is sometimes misused and is currently not regulated. Research should therefore be undertaken to identify the appropriate evidence-based tools, standards, policies, safeguards, codes of ethics, and codes

of practice for assessing and enhancing traditional medicine. Furthermore, there are several aspects of bioethics that concern and conflict with other general practices as viewed by Western bioethicists who mistakenly discern it as witchcraft or magic. This is further complicated by the fact that there is always a thin line between the spiritual aspect of healing with traditional medicine practice. This blends well with conventional medicine-religion synergy whereby the medics treat and healing is through faith.

In Africa and even beyond, traditional medicine is still respected as a cure to most diseases, with the advantage that the raw materials for such are extracted from resources available in the immediate environment, and many of the medicines are dispensed in raw form unlike the Western medicines. What the traditional medicine lacks are the bioethical guidelines and regulations. Disease ethics is treated as per traditional beliefs in some communities and some are viewed as curse and no need to seek for further medication if the traditional medication fails. Other beliefs and religions even bar a sick person to be taken to hospital, thus violating human rights pertaining to treatment. In other contexts, especially where religion has penetrated and influenced the way of thinking of the communities, both Western and traditional medicine could be used. Western medicine and traditional medicine should be viewed as two different co-existing systems that should complement each other through use of accurate knowledge acquired through dialogue.

One challenge that arises when dealing with African traditional medicine is when it is benchmarked, evaluated, and equated to that of modern medicine. Arguably, the main ethical issues in African traditional medicine are informed consent, paternalism, and lack of confidentiality. Another challenge is the fact that traditional medicine practitioners often take all the powers of decision from the patient. Van Boegart (2007), on the other hand, argues that one has to go beyond the routine conventional methods of drug development and perhaps look at the context and conditions in which the African traditional medicine is applied. Nevertheless, it is estimated that about 80 % of the population in Africa still relies on traditional medicine. The high percentage using traditional medicine is perhaps a good testimony that modern medicine has lost its efficacy against the new emerging diseases and therefore most ailing persons have lost hope in modern medicine. This is also exacerbated by the poor economies of most of the African countries, which cannot cater fully to the health of their citizens. There is still a dearth of information on how bioethical concepts can be applied to the traditional medicine. One of the missing links is research on African traditional medicine as it was largely acquired through apprenticeships in the past. There are, however, efforts being made to create synergy and complementarity of the African traditional medicine and contemporary medicine. The other challenge is dealing with quacks, whose sole interest is not the patient but money.

Legislation in Bioethics

The bioethical practices and reflections are not guided by any known legislation but by controls within the wide spectrum of communities. Communities have their own rules and regulations when dealing with bioethical practices and they slavishly

adhere to them. However, with the high diversity of communities, African bioethics lacks universality and this makes legislation on its application very complicated. Some governments have attempted to develop legislation that addresses issues related to bioethics, especially those related to life and human dignity. Issues on abortion and female genital mutilation (FGM) have recently received a lot of debate. Some communities still practice FGM even when governments have outlawed the practice. African governments should, therefore, develop controls and regulations on the application of bioethics through a universal understanding on which practices are not applicable in the modern world. Perhaps, it is the lack of legislation that has made the domestication and application of the Universal Declaration on Bioethics and Human Rights difficult.

Advancement in Medical Technologies

Issues on how emerging technologies are influencing bioethical practices in Africa are pertinent and need to be critically examined. African bioethics does not and should not dwell on Western technological advances at the expense of locally available technologies that have been used for many generations. Bioethical thinking is constructed through association with the environment in which one lives; it cannot be build on tangible instruments one has not associated with. Use of age-old technology in African health care is not new and some are as old as the early civilizations in Africa. It is proposed that they should be used alongside the modern technologies.

Embracing Bioethics in Research

The strength of bioethics lies in the regulation of research on human and animal subjects. In the past few decades, Africa has received increased funding towards international research, concentrating mainly in agricultural biotechnologies and biomedical research. There has always been debate on how this research benefits poor countries struggling with poverty and how it impacts on the existing biodiversity. On biomedical research, the main issues revolve around Article 14 (social responsibility and health) and Article 15 (sharing of benefits) of the Universal Declaration on Bioethics and Human Rights. As a response to this challenge, African countries have set up frameworks for research ethics and biosafety committees. There exist 21 national bioethics committees in various African countries (WHO, 2011) whose jurisdiction should be separate and distinct from the jurisdiction of other committees and institutional bodies (UNESCO, 2006).

The other area with challenges in research in the African context is the issue of collaborative research and sharing of benefits accruing from research. Often because of weak legal frameworks, there are cases of infringement of intellectual property rights due to an unclear research environment. Research on bioethics in Africa is in its infancy and very few universities and research institutes are engaged in such research. One of the most plausible reasons for the slow uptake is the enormous cost of undertaking research related to bioethics coupled with the high cost of equipment. With Africa being strong in biology (UNESCO, 2010), it would seem easy to embrace bioethics in research and to research on bioethics. However,

Africa needs to adopt the "fifarization concept" (*sensu* UNESCO, 2010) to ameliorate the effects of brain drain witnessed in the recent decades if it is to jumpstart this process.

Medicine has its challenges in Africa. One of the most controversial issues in medicine is clinical trials. These are usually carried out by multinational companies and often pose ethical dilemmas. Often the issues of nonmaleficence, sharing of benefits, and inadequate information and consequently informed consent emerge (Kilama, 2005; 2010). There seem to be gaps in information dissemination in clinical research trials, which has led to negative attitudes towards them. For instance, in some cases, vaccinations have been rejected because of inadequate information (Jegede, 2007). Africans, by their nature, are sensitive and skeptical of any scientific activity conducted without prior information and briefing.

African Bioethics in the Context of the UDBHR

African states have embraced the principles of the Universal Declarations on Bioethics and Human Rights and what remains for many states is the interpretation and domestication of the declaration to permit implementation. Langlois (2007) highlights the development of various instruments in the continent with specific reference to Kenya and South Africa that are in tandem with the UDBHR. She singles out particular articles of the declaration such as community consent (Article 6), vulnerability (Article 8), cultural diversity and pluralism (Article 9), social responsibility (Article 14), benefit sharing (Article 15), transnational practices (Article 21), and bioethics education, training and information (Article 23) as areas where concerted efforts in the implementation of the declaration have been realized. A number of countries in Africa have made efforts to domesticate the declaration through workshops and ethics education. In Kenya, for instance, there was a workshop on the UDBHR in 2009 organized by the UNESCO Regional Centre for Documentation and Research on Bioethics and the Kenya National Commission for UNESCO in which participants were drawn from Kenya, South Africa, and the Democratic Republic of Congo. For the UDBHR to be fully implemented in Africa, UNESCO needs to come up with facilitation strategies and a generic implementation plan that could serve as a guide for member states.

Bioethics Education in Africa

The relevance of bioethics education in Africa is not in doubt, especially with the fast advancement of science, technology, and innovations. This has encouraged the proliferation of contentious and questionable insights that could be perilous to one's own existence. For instance, a report that scientists have succeeded in creating artificial life in a test tube could be used to "play God" with life

(Saturday Nation, 2010). Furthermore, the debate on genetic engineering and genetically modified organisms (GMOs) still continues without any foreseeable conclusion. All these advances raise bioethical issues that need to be addressed before any decisions are made.

With bioethics applications becoming more apparent and its relevance transcending all spheres of life and the existence of the human race and biosphere generally, it is time that bioethics education be made a compulsory course in universities in Africa. Its inclusion in the curriculum will also enhance the understanding of bioethical dilemmas in traditional medicine, HIV/AIDS, female genital mutilation, abortion, and environmental degradation that Africa faces.

Despite the efforts by UNESCO to promote bioethics education in Africa, it is still in its infancy and its development is bedeviled by numerous challenges. Therefore, its extent and current status are unknown and also difficult to ascertain. Like in any other part of the world, bioethics is a bridge to the future. It is against this backdrop that there is need for evaluation and management of risks in health and environment domains (Dikenou, 2007). Furthermore, there is still an inadequate number of experts on bioethics and hence the need for bioethics training in the continent (Adebamowo, 2007). In pursuit of Article 23 of the Universal Declaration on Bioethics and Human Rights, UNESCO has developed a Core Curriculum on Bioethics. The curriculum, however, needs to be adopted by local institutions of higher learning and the teaching cases contextualized. The present situation in Africa is that ethics and bioethics are taught as hidden curricula in medicine and life sciences (Ogundiran, 2004). When teaching bioethics, care has to be taken not to over-emphasize Western ideologies and downplay the core values of the African traditions.

Whither and Thither Is Bioethics Education in Africa? The Case of Kenya

In Africa, transmission of bioethical information is selective and limited to those groups that are supposed to know. But because ethical issues transcend all groups, it is important that a free flow of information is ensured. Bioethical issues are relevant not only to bioethicists but also to all other spheres of life and professions. Indeed, they are relevant to individuals and societies as a whole (Cheek, 1992). Consequently, any form of information and strategy communicating bioethical issues in education must be selected and dispatched in a form that should be understandable at all levels of the society. Therefore, the goal of bioethics education should be to provide a guide that gives the correct judgment and direction for problems that people are confronted with in their daily lives (Shoji, 2004). Towards this end, it is pertinent that production of teaching materials and delivery of content for different education levels in Africa should cascade and reflect the thinking, traditions, and culture of the people. This is important, especially when tackling bioethical dilemmas, mostly in the field of medicine, both modern and traditional medicine. Most African practitioners in traditional medicine have

no background in taught medicine; they require some education on the application and use of this type of medicine. Further, textbooks and guidelines on ethical applications and approaches are needed; perhaps UNESCO could facilitate the process so that the exercise receives wider acceptability and a global view.

The extent of bioethics education in Africa is unknown and its future status is also difficult to ascertain. This could be as a result of difficulties in conceptualizing what it is and also the lack of emphasis on bioethics in the educational system. This led to the question: "*Whither and thither is bioethics education in Africa?*" In order to answer this question, Kenya will be used as a case study representing most of the African countries as far as bioethics education is concerned.

Promotion of Bioethics in Kenya by UNESCO

Over the years, UNESCO has produced several documents that are useful as reference materials for preparing curricula and teaching of bioethics. Some of these materials include, *inter alia*, the Core Curriculum on Bioethics, the 1997 Universal Declaration on the Human Genome and Human Rights: From Theory to Practice, the 2003 International Declaration on Human Genetic Data, and the 2005 Universal Declaration on Bioethics and Human Rights. Another important source of content is the UNESCO Global Ethics Observatory website. In its endeavor to advance bioethics in the universities world-wide, UNESCO also initiated the UNITWIN Programme in 1992, in which UNESCO Chairs are established within its areas of competence. The program focuses on capacity building through exchange of knowledge and sharing in the spirit of solidarity, that is, the chairs promote globally the ideals of UNESCO and complement its work (Mathooko, 2008). Through this program and with the help of UNESCO, a Chair on Bioethics was established in Kenya in 1998 and it has since been popularizing bioethics through pedagogy, workshops, and conferences. The establishment of the UNESCO Regional Centre for Documentation and Research on Bioethics in 2007 at Egerton University is a further milestone in UNESCO's efforts to promote bioethics in Kenya. The Centre is mandated to promote research and documentation; develop database and share information; collaborate and network; contribute to education and capacity building through training; and to initiate, guide and contribute to public debate on bioethical issues.

In order to support bioethics implementation in institutions, UNESCO conducts the Ethics Teacher Training Course, from which Kenya has so far benefited. This course provides training to bioethics teachers with the purpose of enhancing their skills and abilities. It further aims particularly at training a younger generation of teachers so that ethics teaching programs in the near future can expand and improve in all member states of UNESCO, Kenya being one of them. In this regard, Kenyan universities could also take the lead in bioethics education development in the region.

UNESCO has also supported meetings, conferences, and workshops in order to enhance bioethical reflections within institutions of higher learning in Kenya. Kenya has been at the forefront in the domestication of the Universal Declaration on Bioethics and Human Rights in the East African region. Already, one international conference on "*Bioethical Perspectives and Practices in Research, Medicine*,

Life Sciences and Related Technologies in sub-Saharan Africa" was organized by the UNESCO Regional Centre for Documentation and Research on Bioethics in 2008. Furthermore, a workshop on "*Sub-regional capacity building on the interpretation and domestication of the Universal Declaration on Bioethics and Human Rights*" was held in Nairobi in 2009. These efforts by UNESCO underscore and demonstrate the importance of bioethics in the modern world.

Bioethics Status in Kenyan Public Universities

Although bioethics is desperately needed in the medical fraternity, most medical training curricula are not explicit on inclusion of bioethics and very few books are available for its teaching. Kenya has in recent years played key roles in the development of bioethics instruments, but bioethics training still lags behind in the Kenyan universities despite the existence of the affirmations of the Dakar Declaration on Ethics and Bioethics in 2003 and in particular that of the necessity to put in place programs of training and teaching on bioethics. With this slow pace in the development of bioethics education, the question that remains is: *Is there a place for Bioethics teaching in universities in Kenya*? The answer is "*Yes*," although the uptake of bioethics teaching is not commensurate with the efforts by UNESCO to promote bioethics education in Kenya.

The Need for Bioethics Courses in Universities

Advances in medicine, life sciences, and their related technologies are threatening the natural being of the biosphere. These threats could come from, *inter alia*, the introduction of GMOs without adequate debate on their benefits, and the risks and impacts of the introductions of new combinations of genes that may irreversibly be part of future evolution and affect the environment and biodiversity (Kinyamario, 2009). Issues on HIV/AIDS, abortion, and others (Box 16.1) affecting the wellbeing abound in public debate and in literature. Unfortunately, universities have not confronted these societal challenges using bioethical perspectives and rarely contribute to public debate on these issues. With the rapid development of science, technology, and innovation, universities should take the lead in bioethics teaching and contribute to bioethics policy and debates.

Box 16.1
Some key bioethics topics commonly included in public universities' curricula in Kenya (Mathooko, 2007).

Abortion; euthanasia; confidentiality; death and right to die; bioengineering and experimentation; mental health; informed consent; termination of pregnancy; patient-doctor relationships; national and international codes and relevant Acts of Parliament; Clinical Officers Act; Public Health Act; Hippocratic Oath; the role of research and ethics committees; organ transplantation; in vitro fertilization; embryo transfer; science and conscience in the moral evaluation of recombinant DNA technology; policy governing use

or release of artificially-produced DNA in the ecosystem; legal and ethical issues in HIV/AIDS.

Mathooko (2008) conducted a survey on the teaching and inclusion of bioethics in the curriculum of three public universities in Kenya. The data were obtained from the universities' current catalogues, interpersonal contacts, and consultations. It was found that none of these universities had an undergraduate and/or a postgraduate degree program in bioethics. Further, no university had a department of bioethics in its structure. However, there were fragmented elements of bioethics teaching distributed within semester units or courses that were available to a very small number of students. At the end of the survey, the following observations were made about the status of bioethics courses in Kenyan universities. That:

1. There is limited inclusion and coverage of bioethics content in Kenyan public university curricula, especially in science, medicine, biotechnology, biochemistry, and biomedical science and technology where bioethics is highly needed
2. The semester distribution of the bioethics courses in the universities lacks any definite pattern. This is exemplified by the fact that the majority of the courses with ethical/bioethical dimensions were either taught in the second, third, or fourth years
3. There was limited awareness of bioethics content and aspects of focus since it does not feature prominently in the national education system and
4. Nearly all bioethics courses were theoretical with minimal reference to practical bioethical cases

Challenges Faced by Universities in Teaching Bioethics

Kenya is strategically placed as a focal point for championing efforts in networking, fostering, and integrating bioethics teaching at national and regional levels of education through capacity building, establishment of national committees, and enhancement of the implementation of the UNESCO Ethics Teacher Training Programme. This focused coordination approach could help to minimize some of the challenges faced in bioethics education. Generally, bioethics is a complex field and therefore it is pertinent that criteria for measuring the success of bioethics education should be developed before any program is implemented. Incidentally, the content surrounding bioethical issues is complex because it is made up of personal, social, and emotive aspects as well as specific biological information (Conner, 2004). Coupled with this complexity is the question of who is qualified to teach and the blurred approaches of teaching bioethics. The assessment becomes even more challenging and untenable when analyzing dilemmas and divergent views are taken into consideration. Because of the associated uncertainties, bioethical teaching requires more holistic teaching approaches that take into account feelings, aesthetics, affective dimensions, the diversity of peoples, and the environment in its totality.

Cascading bioethics content to lower levels of the education system is a daunting challenge that calls for ingenuous approaches and strategies. Involving the lower levels of the education system is appropriate because they hold a large number of students, implying that transferred content reaches a large number of students resulting to a multiplier effect for the wider community. Therefore, bioethics should be taught at all levels, but it should be imparted in a manner that a child can understand (Macer, 2004). Furthermore, bioethics education requires small groups for it to be taught effectively, but the numbers of students in all Kenyan levels of education are high. This could also create another challenge in the teaching of bioethics in Kenya. Other challenges faced by universities include the following:

1. *Human capacity to teach bioethics*: In the Kenyan universities, very few lecturers and curriculum developers have been trained in bioethics. Therefore, for bioethics education to be developed, training of lecturers in the field of bioethics is imperative.
2. *Awareness of bioethics' existence as a discipline*: Bioethics' existence as a discipline is not apparent to many lecturers since it does not feature prominently in the education system in Kenya. There is need to create awareness among the lecturers in public and private universities.
3. *Availability of teaching resources*: Since this discipline is not manifested in the education system, teaching materials have not been developed. Bioethics education teaching will require tailor-made books, e-library facilities, and even videos for it to be properly taught.
4. *Socio-cultural diversity based on many ethnic groups and languages*: This could be a major challenge, especially in the analysis of ethical dilemmas. Kenya has a diverse population with different cultural backgrounds and languages. This also reflects the manner of thinking and the way they relate with the environment. Therefore, analysis of dilemmas will require careful and skilful handling by both the teacher and the students.

Strategies for Promoting Bioethics Education in Kenya

Several appropriate strategies are proposed for promoting bioethics education in public and private universities in Kenya. These strategies either require the involvement and participation of the individual, the university and/or external entities like UNESCO for them to be implemented.

1. *Networking strategy*: Kenya is strategically placed as a focal point to boost efforts in networking, fostering and integrating the UNESCO ideals in the field of bioethics at national and regional levels through capacity building, establishment of national committees, and enhancement of the implementation of the UNESCO Ethics Teacher Training Programme. The UNESCO Chair on Bioethics at Egerton University is eager to establish networks with other Bioethics Chairs in the world. This will enhance exchange of ideas and cross-cultural understanding in the field of bioethics especially in bioethics education.
2. *Human resource capacity building strategy*: Teachers in Kenyan universities need exposure to bioethics in general and in bioethics education in particular.

They require training in bioethics teaching methods, curriculum development, and measurements and evaluation. This is extremely relevant, especially for the junior teachers. Furthermore, teachers should be trained in ethical dilemma analysis and development of teaching materials. Training on the delivery of content in a manner that makes the learners comprehend the complexities of bioethics demands that teachers should be well trained in pedagogical skills. Training approaches could be two-pronged: training on pedagogical skills and training on content.

3. *Mentoring strategy*: Cultures of mentoring are needed to bring junior and senior bioethics teachers together and to encourage intergenerational learning. Junior teachers should gain bioethics teaching experience at the early stages of their teaching careers in order to be productive in terms of not only teaching but also in research in bioethics. With this strategy, it is expected that delivery of the subject matter will be improved.
4. *Internet connectivity strategy*: Information access and flow is important in teaching and is usually a challenge in most African universities, where the Internet is lacking or, in most cases, out of order. The Internet service is unreliable and the cost of access is still a challenge to teachers. Bioethics teachers should be availed reliable Internet connectivity to facilitate the acquisition of current information for teaching.
5. *Program expansion and diversification strategy*: PhD-qualified staff are essential for bioethics teaching due to its complexity, and individuals must therefore be developed through training, study, and research involvement. Therefore, the expansion and diversification of degree programs to include bioethics education is necessary to build a critical mass for ethics teachers. UNESCO, through its institutes, should mount and sponsor a degree course in bioethics education. This would provide junior teachers with opportunities to obtain scholarships for masters, PhDs, or postdoctoral studies, or to work alongside senior teachers. This could further strengthen and sharpen their skills for teaching bioethics.
6. *Bioethics resources sharing and development strategy*: African countries appear to lag behind in their bioethical reflections and in resources development. Sharing of bioethics education materials and new pedagogical approaches should be encouraged. This way, there will be cross-fertilization of ideas in teaching of bioethics. Enjoined to this strategy is the "*Exchange visit strategy*." The UNESCO Chairs on Bioethics should initiate exchange visits to learn from each other and to exchange ideas; in addition, exchange programs should be initiated for bioethics teachers to meet and share their experiences in teaching and examining bioethics.
7. *Facilitation strategy*: There are so many activities and conferences on bioethics taking place over the world. Facilitation of teachers to attend them is vital as this will enhance the mastery of the subject matter and supplement the limited reference sources. In order to promote bioethics education and research, facilitated publication and dissemination is appropriate, especially where the teachers are facilitated to attend workshops/symposia and conferences in order

to present their bioethics research findings. UNESCO could play a leading role in supporting conference bioethics proceedings and any other materials that could enhance bioethics education.

8. *Infrastructural development strategy*: Bioethics resource centers and libraries should be established to facilitate preparation of teaching materials and research. Libraries will afford teachers and students accessibility to secondary information for teaching and research and they ought to be equipped through planned and sustained channeling of resources to the libraries.
9. *Bottom-up strategy*: In developing any curriculum and teaching materials on bioethics education, the bottom-up strategy would be appropriate where students, lecturers, and curriculum developers are all involved. This helps in deepening the understanding of the subject, creates ownership of the content and better delivery. Using a bottom-up strategy, teachers can fine-tune their teaching approaches and identify the most appropriate ways to communicate the content.
10. *Combination strategy*: This strategy takes on board all the above strategies and could be the most appropriate strategy to arrive at a workable common ground. In the event that all of them cannot be accommodated, selection of a few of the most appropriate strategies will suffice rather than choosing a single strategy.

Recommendations

It is evident that bioethics teaching in Kenya is not developed despite its societal relevance. It is required in medicine, life sciences, and in the related technologies. Its growth is hampered by several challenges that include lack of well-trained teachers to teach bioethics coupled with limited teaching materials. This chapter recommends that the relevant government ministry should declare bioethics a common core course in public universities and that universities should adopt, domesticate, and implement the UNESCO Core Course on Bioethics that has been prepared by experts from all over the world. The relevant ministry should work closely with UNESCO to oversee course implementation in the universities and, further, to cascade it to secondary and primary schools. To hasten creation of a critical mass of bioethics teachers, UNESCO should also facilitate a model International Postgraduate Bioethics (IPGB) Certificate Programme in the universities.

Conclusion

African bioethics has been hybridized through infusion and domination by foreign practices, culminating from globalization. With fast-growing developments in science and technology and emerging chronic and terminal diseases, bioethics, hybrid or otherwise, has a prominent place in Africa. The question is no longer whether Africa needs to embrace bioethics. Indeed, it can ignore it at its own peril. What needs to be put in place is education, legal framework, and contextualization

of international normative instruments such as the Universal Declaration on Bioethics and Human Rights among others. It is evident that bioethics education in Africa has not developed and requires immense resources for it to advance. Its growth is hampered by several challenges which include lack of well trained teachers to teach bioethics coupled with the absence of teaching materials. This chapter has highlighted some of the strategies that could be used to promote bioethics and some of the possible approaches of teaching bioethics education. The "*whither*" of bioethics education in Kenya and Africa can be summarized thus: *no significant progress has been made in bioethics education*" and the "*thither*" by the statement that "*the future of bioethics education is bleak unless the strategies and recommendations herein are taken into consideration by schools, universities and governments.*"

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Arab Perspectives

17

Bahaa Darwish

Introduction

Bioethics in the Arab world is addressed from an Islamic perspective. The dominant institutions in the Arab world and prominent researchers writing on Arab bioethics address bioethical issues from an Islamic perspective. Though there is no old or contemporary Arab or Islamic theory of bioethics that delineates the *necessary and sufficient* principles by appeal to which bioethical issues can be justified, in addressing bioethical issues, nevertheless Arab bioethicists, most of whom are religious scholars and physicians, appeal to Qur'anic verse(s), *Hadith* (Prophet sayings and deeds), and/or jurisprudence rule(s). Therefore, in explaining the Arab perspective(s) of the global principles of bioethics, the Islamic perspective will have to be further elucidated.

The trend that gained popularity since the last decade calling for global bioethics was fostered by connecting ethics to human rights. Because ethical problems were seen to be violations of human rights, ethical principles, at least some of them, can be seen as global principles that can be acceptable across national and cultural boundaries. Though this trend has had many advocates, it does not go without challenges. Tristram Engelhardt can here be cited as one prominent challenger of the possibility of global ethics (Engelhardt, 1998). However, the overarching principles of the UNESCO Bioethics Declaration, which will be regarded in this handbook as the basis of global bioethics, are acknowledged in Islam. However, they have different weights and justifications shaped by culture and religion, and are examined by Arab bioethicists in addressing the bioethical issues. These principles can be expressed from an Islamic perspective as follows.

Humans are the vicegerent of Allah, therefore they have *dignity* that should be preserved. To preserve it, humans should avoid *harm* and seek *benefit*. To respect human dignity is to respect a human's *privacy* and *autonomy* in taking decisions limited by their *responsibility* for such decisions. People's autonomy is reflected in their right to *consent*. To preserve their dignity, *persons unable to give consent*

B. Darwish
Department of Philosophy, College of Arts, Minia University, Minia, Egypt
e-mail: elsayed.baha@mu.edu.eg

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should be given due care, and their *vulnerability* should be respected. As humans are the vicegerent of Allah, no one has superiority over the other, so the principles of *justice*, *equity and equality*, *non-discrimination* and *non-stigmatization* are invoked. This applies to current as well as *future generations*. The *environment with all its components* also has intrinsic value as Allah's creation, so it should be *protected* for the intrinsic value it has, not only for the future generations.

Therefore, the Islamic perspective of each principle needs to be understood as to how it is applied or regarded in addressing the bioethical issues from an Islamic perspective. Application of these principles will add to the explanation of the principles' connotations seen from the Islamic perspective.

Human Dignity

Human dignity is a principle that is universally acknowledged though for different reasons in different cultures. Some, especially in the West, see that humans possess dignity because they are "persons with autonomous desires, beliefs, and intentions" (Glannon, 2005, p. 92). Such qualifications are "what make a person worthy of self-respect and respect from others" (Glannon, 2005). Therefore, autonomy has a sort of priority over other principles (Aramesh, 2008).

In Islam, all sorts of life are precious and have intrinsic value because life is created by God Who creates it with His divine quality: Among God's attributes and names in the Islamic scriptures is "the Living" (*al-Hayy*) (Shomali, 2008, p. 1). However, among all forms of life in the world, human life is the most precious. In *Qur'an*, which is for Muslims the agreed-upon first source of jurisprudence, Allah says, "We have indeed honored the children of Adam, and provided for them means of transportation in land and sea, and given them wholesome food and exalted them high above the greater part of Our creation" (Qur'an17: 70). Such privileged status is conferred on humans because humans are God's vicegerents on earth (Qur'an2:30). whom Allah has endowed with reason and freewill and therefore are responsible for what they do (Shomali, 2008, p. 3; Daar & Al-Khitami, 2001, p. 60). Thus, human dignity is grounded on such sanctity of life, applied to people in life and death, and explains why humans are worthy of self-preservation, self-respect, mutual preservation, and mutual respect.

Such sense of human dignity justifies the positions of Arab ethicists towards a variety of bioethical issues. Human dignity is the concept that explains the dispute among Arab bioethicists concerning the permissibility of abortion. Most Arab ethicists see that because human life has intrinsic value, it should be respected in all stages of development beginning as an embryo, and therefore the embryo should not be attacked by aborting it or by any other way unless there is a medical necessity. The necessity about which there is nearly a consensus among most ethicists is when pregnancy threatens the mother's life. In this case, abortion is considered a necessity to save her life. Aborting a late-stage fetus (after 120 days) resulting from rape or because it is physically or mentally deformed is not considered for most ethicists as necessary.

And because human life has such privileged status and therefore should be respected, human cloning, whether reproductive or therapeutic, is considered an affront to human dignity. The first type aims at creating a full-fledged human being, while the other aims at creating embryos from which to mine embryonic stem cells to be used for therapeutic purposes. The moral objection is that the mere fact that an embryo is created violates the sanctity of human life that should be respected from the time of conception.

For the same reason, embryonic stem cell research, where embryos are created specifically for research purposes, is considered an affront to human dignity. A common theme of the Arab regional provisions is a prohibition of commercial exploitation of IVF patients and others to provide surplus embryos for research. However, on the basis of influential religious rulings, the Islamic Organization for Medical Sciences (IOMS) Seminar of November 2007 agreed that use of surplus IVF embryos within 14 days after fertilization for the purposes of treatment and scientific research, excluding introduction of human embryonic or pluripotent stem cells into non-human blastocysts, is better than wasting them (UNESCO, WHO, & ISESCO, 2008).

Donation of organs is considered an act of charity, benevolence, and altruism through which many lives can be saved. The *Qur'an* says that "whoso helps one to live, it shall be as if he had given life to all mankind" (Qur'an5:32). "Human organs are not a commodity nor a chattel, and hence should only be given for the love of fellowmen. Commercialism, entrepreneuring and organ trafficking is an affront to human dignity and hence deplored and proscribed" (AlBar, 1996). This is quite well expressed in nearly all the legal codes of the Arab countries.

Respect for human dignity is extended in Islam to the dead body, whether it is a body of a Muslim or non-Muslim. The dead body of a Muslim should be prepared after death for burial, by being washed, dressed, prayed on, then buried in a respectful place as soon as possible to avoid putrefaction, which occurs rapidly in hot climates (AlBar, 1996). It is not allowed to dig the graves or unveil the buried body. However, autopsy is allowed only if necessary, for instance, when there is the suspicion of murder (Shomali, 2008, p. 3).

As evidence for the respect of the non-Muslim human corpse, there is the story when Prophet Mohammed stood in veneration for a funeral of a Jew passing by, at the time when Jews were his bitter enemies. One of the companions exclaimed; "It is only a funeral of a Jew!" The Prophet answered "Is it not a human?" (AlBar, 1996).

Benefit and Harm

Because human life is precious and has intrinsic value, it should be protected from all kinds of harm. Therefore, avoiding, or protecting people from harm is teleological. It is to preserve the human life that has dignity.

Maximizing benefits and minimizing harm are two correlative concepts that are expressed in the following two Islamic rules: the universal rule "harm is to be

removed," and its derivative: "preventing harm has the priority over obtaining benefits." The wording of the latter rule explains why the former is universal and the latter derivative, and also explains the order of importance of "removing harm" and "obtaining benefit." Accordingly, the former rule is considered one of the universal rules of Islamic jurisprudence that Muslims are required to regard and follow in all aspects of practical life. This rule is one of the most important rules of Islamic jurisprudence because the domain of its application is wide. It can be nearly applied in all aspects of Muslim life. This rule is originated in the Prophet's *hadith*: "no harm or harming." One of the basic goals of *Shari'a* is to remove all kinds of harm of individuals and groups. IbnAtheer explained the Prophet's hadith by saying that "no harm..." means that you ought not start by harming others, and "no harming.." means do not return one's or others' harm by harming them, so there is a prohibition either to harm or to return others' harm by harm (Kassem, 1983, p. 217).

From this rule, the following rules are derived:

(a) Necessities override prohibitions: for instance, killing an attacker to defend oneself is justified: it is a necessity (self-defense) that overrides a prohibition (the act of killing); the government is justified in taking money from a person without consent if she refused to pay her debt: there is a necessity (paying her debt) that overrides a prohibition (taking one's property without her consent).
(b) Harm should not be removed by another harm: for instance, one is not allowed to save one's agricultural land by drowning another's, or to save one's money by destroying another's.
(c) In case of two harms, the lesser harm should be done: for instance, if a Muslim cannot wash before praying (which is a prerequisite for praying and a precondition for the soundness of praying), he ought to pray as he is; and a husband will be imprisoned if he refuses to pay for his wife's living costs.
(d) Preventing harm has priority over receiving benefits: for instance, the money owner is to be prevented from using his money if it is proved that he harms others by such usage (Kassem, 1983, p. 218; Khallaf, 1947, pp. 238, 239).

This universal rule and its derivatives are very well equally applied in bioethical issues. Abortion to save a mother's life is justified by the rule: "necessities override prohibitions"; aborting a deformed fetus, or a pregnancy that resulted from rape, is justified by its proponents as "harm (that) ought to be removed"; and that "the lesser harm should be selected." In the same way, those who disagree regarding aborting a deformed fetus or a pregnancy that resulted from rape appeal to the same rules in justifying their position. They see that abortion ought to be impermissible as "the lesser harm should be selected," which for them means that the future suffering of the deformed embryo or that from rape and their families is lesser than that from depriving it of the right to live. It ought also be impermissible as "harm should not be removed by another harm," which for them means that the future suffering is admittedly "harm" but should not be removed by aborting it, which is "another harm," thus using the same rules to justify their position.

Though organ donation is accepted and encouraged in Islam, donating an organ that may lead to the death of the donor is impermissible because "harm should

not be removed by another harm," and because "preventing harm has the priority over getting benefits."

Since ethics of science is the endeavor to harness scientists' non-stop curiosity and making sure that their scientific and technological products are directed towards the good of mankind, the preservation of the human values and the human rights' principles long fought for, "ethics of science and technology" can generally be justified by the Islamic rule "preventing harm has the priority over getting benefits."

Autonomy and Individual Responsibility

A form of respecting people's dignity is to respect their autonomy. As ethical principles, autonomy and individual responsibility are two correlative principles. Responsibility reveals autonomy: there is no sense in calling an agent a responsible agent if he or she is not autonomous. Autonomy without responsibility turns one into an egoist who does not take into consideration the interests of others. Such sense of the correlative principles: the autonomy of persons to make decisions, while taking responsibility for those decisions, is an important Islamic concept that is expressed in the *Qur'an* repeatedly: "No bearer of a burden can bear the burden of another" (Qur'an6:164), (Qur'an17: 15), (Qur'an35: 18), (Qur'an39: 7), (Qur'an53:38). Prophet Mohammed said, "All of you are guardians, and all of you are responsible for whom you guard." In Islam you cannot be held accountable for others' deeds and when you are praised or punished, you are praised or punished for the deed for which you are praised or punished not for another.

This responsible autonomy explains why Muslims are held responsible for their deeds in this life and why there will be "Hell & paradise" in the hereafter. If persons in Islam were not held autonomous, it would be unfair to hold them responsible for their deeds.

It is to be noted that what is confirmed here is "autonomy" not "individuality." Individuality invokes indifference and a focus on one's own interest, which is surely against the focus on cooperation and solidarity for which Islam gives much weight, as we shall see.

This concept of autonomy is reflected in the Muslim bioethicists' opinions in the domain of health and research. There is a consensus among Arab ethicists that the patients have the right to choose to be cured or not. Such right is materialized in the patients' right to give informed consent before being cured or operated on. The concept also explains their right to be told the available types of cure and to select the one they like. And it explains their right to participate as research subjects and to withdraw the consent anytime.

Autonomy has limits, however. Persons who are incurably sick do not have the right to end their lives by themselves or with the help of a physician. By so doing, they would surpass the limits of their autonomy. The act would be considered suicide, and the physician a killer. Euthanasia is prohibited based on

the rules "harm should not be removed by another harm," and "the lesser harm should be done." In Islam, killing is not only a harm, but the greatest sin a Muslim can commit.

Consent

In Islam, consent is one of the basic rights of humans as people who have dignity that ought to be respected. It is based on the jurisprudence rules: "A person's right is not to be revoked without her permission," and "Man's right is not to be used without his permission" (IOMS Islamic Organization of Medical Sciences [IOMS] (2005, p. 191). Applying such rules in the field of health care, the Islamic *Fiqh* Council ruled that "it is impermissible to recruit any person to participate in any research involving human subjects without a clear informed consent of that person. Participation in research must not involve any coercion or financial inducement or any risk other than the risks expected during the normal investigation" (rule 67/5/7) (IOMS, 2005, p. 192). Such consent ought to be provided after the agent's full knowledge of the nature of the therapy or the research and its potential consequences. This is based on the jurisprudence rule: "agreement is not achieved with ignorance." Based on the principle of justice, it is permissible to financially compensate subjects for being absent from work or/and travel cost resulting from their participation. If the intention behind money paid is to tempt the subject to give consent, then it is impermissible (IOMS, 2005, p. 211). In line with the principle of personal autonomy, no one has the right to give consent for persons who do not have the ability to consent except in exceptional cases. Such cases will be discussed later (IOMS, 2005, p. 198).

However, there is always a limit to a person's autonomy and consequently to their right to consent. It is not the subject's sole right for instance to consent to removing her uterus when she is a wife. In exercising her right, she transgresses her husband's right. Also, if a pregnant woman who has decided to participate in a clinical research knows that the research may involve certain risks to the embryo, the husband's consent becomes a condition to the research conduct because the husband also has a right to the embryo (IOMS, 2005, p. 271). Also, a person does not have the right to choose to be cured or not if his or her disease is infectious. The principle "necessities override prohibitions" is invoked here.

Persons Without the Capacity to Consent

Islam calls for giving due care to persons who are unable to give consent. These people include children, prisoners, refugees, educationally or economically disadvantaged persons, and individuals with diminished mental capacity. It is impermissible to coerce, press on, or exploit their hard financial, psychological, or mental situations to get them participate in research when they are unable to give their consent. This in Islam is considered unjust. To get persons from such

categories participate in research, three conditions must be met: the research should be intended to improve the medical interventions for such category; research subjects, as well as other people of the same category, are guaranteed access to treatments or practices developed by the research; and risks resulting from participating are not more than minimal (IOMS, 2005, p. 250).

Of these categories, children are given special care. There are few cases when it is permissible to give consent on their behalf. Such cases encompass the case when it is in the child's interest that the research be conducted. In that case, it should be left to the ethics review committees to decide whether the research be conducted or not after taking the parents' or guardians' consent. If a review committee confirms that the research is in the child's interest, then the research should be conducted even if the child objects, in order to prevent the child from missing a good chance of finding a cure or to protect the child from harming itself by such objection. The other case occurs when the research is about pediatrics and drugs used specifically for children. Here, it is permissible that the research be conducted if the risks involved are not more than minimal risk encountered during the normal investigation. This in Islam is justified by the jurisprudence rule "necessities override prohibitions" (IOMS, 2005, pp. 256, 257).

Respect for Human Vulnerability and Personal Integrity

The above paragraph explains the respect Islam gives to groups characterized as vulnerable. Respect for the body, whether dead or alive, is based on the principles of sanctity (*hurma*) and dignity (*karama*), and it serves to "acknowledge the superior status of the human being." Cremation or mutilation of the body is completely prohibited, and Prophet Mohammed is reported to have said that "breaking the bone of one who is dead is like breaking it while he is living" (Haque, 2008, p. 14).

Personal integrity is invoked also by the Arab ethicists in their objection to female genital mutilation (FGM), a tradition that is still practiced in some Arab countries, attributed wrongly to religious teachings. Ragab argues that female circumcision is unethical and that the evidence that the Prophet Mohammed recommended it is unreliable (Ragab, 2008). Elsayed et al. argue that "FGM obviously violates the fundamental ethical principles of bodily integrity, autonomy and self-determination, and is practiced without the full informed consent of the victim" (Elsayed et al. 2011, p. 67). Most religious scholars who have their saying in the bioethical discourse in the Arab world occasionally declare the disconnection between religion and FGM. To give just a few examples, a conference held in 2006 on preventing the mutilation of women's bodies was organized by *Dar al-Ifta'* in Egypt (the governmental body responsible for issuing *fatwas* (religious opinions) on Muslims' issues in life), attended by important religious experts like the former Shaykh of al-AzharTantawi, the former Minister of Awqaf, (religious endowments) Mahmud HamdiZaqzuq, the Mufti of Egypt Ali Gum'a, and the head of the World Union of Muslim Scholars, Yusifal-Qaradawi. The recommendations in the end

were: "female circumcision (FGM) is an old custom that appeared in some human societies and that some Muslims practiced in some countries without any basis in Qur'anic versus or in *hadith sahih*" (Tolino, 2011, p. 215). And then:

"The circumcision which is practiced today harms women physically and psychologically. Therefore, it should be avoided to comply with one of the highest values of Islam that is to avoid harm to the human being, as the Prophet said: '*la dararwa la darar fi- l- islam*'" (no harm or harming) (Tolino, 2011). During the session of 28 June 2007, all members of the Islamic Research Council of al-Azhar agreed that there is no basis in Shari'a for female circumcision, and that it "is a harmful custom that spread and grew steadily in a small number of Islamic communities" (Tolino, 2011, p. 215). This opinion has been shared by *Dar al-Ifta'*, which issued a *fatwa* in July 2007 where it stated that "female circumcision belongs to the category of traditions and not of religious obligations" (Tolino, 2011). Al-anba Musa, the bishop of Youth of the Coptic Church in Egypt, says, in his book *khitan al –inath : ilamata* (FGM till when), published in 2005, that "when God created man, he did it in the best form and every part of his body has a function and a role." He also declares that chastity has nothing to do with a harmful practice, because "chastity does not come from the body, but from will and spirit" and it is built "through good family, educational and religious upbringing" (Tolino, 2011, p. 217).

This does not mean that all religious scholars agree with this. Some religious scholars, such as Muhammed al-Musayyar, still think that FGM is a religious duty or at least permissible (Tolino, 2011, p. 213): a confusion that they must settle.

Privacy and Confidentiality

Privacy issues came under the spotlight as a result of the contemporary technological devices able to store and give other parties access to people's private and sensitive information, such as mining datasets (Islam and Brankovic, 2004). Confidentiality of one's information is a resultant right along with and assurance of one's right to privacy. People's privacy entails keeping all information about them confidential. People's privacy is also an entailment of their autonomy: being autonomous entails my right to the privacy of my information and my right against undue invasion of my privacy.

While privacy is a reaction to the modern technological inventions that invoked such principle, in Islam, privacy is part of a complete vision about how a human's dignity, as the vicegerent of Allah, should be protected and respected.

This principle is stressed in the Qur'an in various verses such as: "Spy not, nor backbite one another" (Qur'an49:12), "O ye who believe, enter not houses other than your own until you have obtained leave and have saluted the inmates thereof" (Qur'an24:27). However, privacy in Islam, as in every other culture, has certain boundaries.

A clear application of the principle of confidentiality in bioethics is the Islamic *Fiqh* Council decision no. 79 (10/8), which ruled in term 3 of the decision that

initially breaching confidentiality is religiously impermissible. The decision continues with terms 4, 5, and 6: Term 4 states that confidentiality is a necessity, specifically in jobs where breaching confidentiality negatively impacts the job itself, such as the medical professions, because patients depend to a large extent on professionals working in the domain of medicine for advice and consultations about issues, sometimes sensitive, related to their health. Breaching confidentiality creates distrust between the patients and medical professionals that consequently destroys the profession itself (IOMS, 2005: 277). Term 5 declares that, based on the jurisprudence rule that in case of two harms the lesser should be chosen, revealing a person's secret is not a breaching of confidentiality when the benefit of such revealing for either the person or the community outweighs the harms of its remaining confidential, or when such revealing protects the person or the community from harm (IOMS, 2005). Term 6 says that all exceptional cases in which breaching confidentiality is required or recommended must be exclusively mentioned in the medical codes with details of the methods of revealing and the parties to whom the secrets are to be revealed (IOMS, 2005, p. 278).

Equality, Justice and Equity

Justice has been a philosophical subject since Plato. However, in the twentieth century, especially in the West, the concept of distributive justice, that concerns the allocation of resources in a certain community, has moved to the core. In the West, two main theories are central to the discussion: egalitarianism and libertarianism. Most recently, an articulation of the difference between micro- and macro-level obligations of justice has gained some interest.

In Islam, justice is one of the human values that Muslims have to achieve, because it is the reason behind Allah's sending all messengers to humans throughout all ages. Allah said "we have sent Our Messengers with manifest Signs and have sent down with them the Book and the Balance, that people may act with justice" (Qur'an57:25). Justice in Islam is based on the concept of equality, and both are based on the concept of dignity of all descendants of Adam previously referred to. It should be applied to all human beings, Muslim and non-Muslim, regardless of gender, race, or social status. Allah said: "When you judge between the people, you do it with justice" (Qur'an4:58). Justice should be observed in giving witness: Allah said, "O ye who believe, be strict in observing justice and bear witness only for the sake of Allah, even if it be against your own selves, or against parents or kindred" (Qur'an4:135). He also said, "And that when you speak, hold the scales even though the person concerned be a kinsman" (Qur'an6: 152). It should also be observed in settling disputes between groups of people. Allah said, "If two parties of believers should fall out with each other and start fighting, make peace between them. If one of them should transgress against the other, fight the one that transgresses until it submits to the command of Allah. Then, if it should so submit, make peace between them with equity, and act justly. Verily, Allah loves the just" (Qur'an49: 9). Justice should also be observed in dealing with enemies:

Allah said, "let not the enmity of a people. . . incite you to transgress" (Qur'an5:2). He also said, "O ye who believe, be steadfast in the cause of Allah, bearing witness in equity. Let not a people's enmity towards you incite you to act contrary to justice; be always just" (Qur'an5:8).

Therefore, in applying the Islamic concept of justice in the healthcare domain, the egalitarian concept is the nearest concept of justice to the Islamic perspective. All healthcare professionals have the responsibility to provide all people with the highest possible attainable standard of health without any discrimination of religion, race, gender, or social status, as shall be explained later.

Non-discrimination and Non-stigmatization

If people are equal and should be treated justly, then it is easy to expect that Islam forbids non-discrimination and non-stigmatization. Allah says: "O mankind, We have created you from male and female; and We have divided you into tribes and sub-tribes for greater facility of intercourse. Verily, the most honored among you in the sight of Allah is he who is the most righteous among you" (Qur'an: 49:13).The verse clearly means that because we share one humanity, then no one is to be favored over another based on race, ethnicity, color, or gender. Allah has made us diverse as a way to help differentiate between people and come to know one another (Wafi, 1979, p. 9). In what has become known as his "farewell speech," Prophet Mohammed affirmed the same message when he said, "O people, your God is one and your father is one. All of you are the descendants of Adam and Adam is created from sand. An Arab is not to be favored over a Non-Arab except for devoutness" (Wafi, 1979, p. 10).

In the Arab states, however, at least two groups, women and the disabled, suffer from discrimination that carries a stigma, though not specifically in the domain of health care. However, the kinds of discrimination that these groups suffer from in other respects have implications for their health.

Discrimination against women still exists within some Arab families but not as a governmental attitude. This discrimination is the outcome of misconceptions among such families about the duties, rights, and relevance of certain jobs and positions in the society of each gender. It starts in these families by taking the form of favoring male over female children, and thinking that a boy's education is more important than a girl's. Evidence of such existing views is that two-thirds of those deprived of education are female. In 2005, an estimated 40% of Arab women could not read or write. The implication of illiteracy on their health is that these women will most probably be effectively blinded from the fundamental principles of health, hygiene, nutrition, and diet that can keep them and their families healthy. Illiteracy can also perpetuate customs and traditions that are harmful to women's health, such as early marriage and its ensuing early child bearing and FGM (UNDP, 2009, p. 155). Low levels of education among the females and in families in general contribute in finding compliance among the girls to such harmful habits.

In addition to the low average literacy rates among women, there is also the belief in some families of the irrelevance of the women's practicing certain jobs and/or political and economic activities, such misconceptions extend to deprive the Arab woman of practicing all her personal rights and enjoying a complete social life.

Despite the fact that we are living now the *Arab Decade on Disability* (*2004–2013*), it is estimated that about three to four million people are disabled in the Arab world (Nauk, 2011:3). Types of disability include hearing, visual, speaking, mental, learning difficulties, mobility, and lack of self-care.

During the period 2008–2009, most Arab states signed and ratified the International Convention on the Rights of Persons with Disabilities: the first legally binding instrument with full protection of the rights of persons with disabilities. Actually, they supported the importance of rehabilitating persons with disabilities and integrating them in the labor force since the League of Arab States adopted resolution 17/1993 on the Arab Agreement on the Rehabilitation and Employment of the Disabled (Nauk, 2011: 8). Nearly all Arab states now have laws that commit public and private sectors to incorporate the disabled in the labor force. However, actionable commitment to remove the obstacles that hinder the integration of persons with disabilities and to end all forms of discrimination against them remains elusive in the majority of countries. In terms of progress made in the area of rehabilitation and employment of persons with disabilities, several countries have introduced quota systems to allocate a percentage of jobs for persons with disabilities in both the public and private sectors, providing incentives and enforcement measures that range from weak to strong in different states, to private employers to hire persons with disabilities. However, in many countries, discriminatory attitudes, lack of proper rehabilitation programs, and the mismatch between vocational training and labor market demands block the prospects of those who want to improve the disabled situation (Nauk, 2011:9). Overall, "social stigma and tacit discrimination against persons with disabilities remains a significant barrier for realizing their rights and potential as catalysts of development" (Nauk, 2011:8).

In the domain of bioethics, it is argued that advances in medical technology have the potential to create disproportionate disadvantages for some social groups by encouraging the adoption of social policies that discriminate unfairly against them with significant individual and social consequences (UNESCO, 2008, p. 48). Some Arab and Muslim scholars accept sex selection by the use of pre-implantation genetic diagnosis. This may be considered a form of gender discrimination, specifically when the sex chosen is the male sex, which may imply stigmatization of the female sex (UNESCO, 2008, p. 52). However, it is important to note that Arab scholars accept sex selection only at the personal level, not at a nation level. Here, it is to be noted that in accepting sex selection, as long as it is a way of achieving a personal wish to enjoy the fruits of science to have a child with a certain sex, not to marginalize or treat the children of the other sex unjustly, by depriving them of equal chances of education or health care, selecting a certain sex is not infringement of any other fundamental principle.

As proof of the above-mentioned argument and consistent with it, the IOMS recommended, at the end of a symposium in 1998 on genetic engineering, human genome, and gene therapy from an Islamic perspective, that premarital genetic testing was highly recommendable for the couple, but that the resulting information should be kept confidential because of the sensitivity of such data and their cultural significance for some groups. Premarital genetic testing is now obligatory in some Arab countries such as in Jordan and Qatar. In an attempt to protect people against discrimination and stigmatization, the Qatari panel code 11/2004, article 331, for instance, holds legally liable anyone who discloses information pertaining to another's private life (Al-Zamman & Al-Khanji, 2008, p. 159). Accordingly, in case of divulging the genetic data resulting from the premarital genetic testing, the panel code would apply. Thus, both recommendations and the law are in harmony with the international instruments that limit cultural specificities to the protection of human rights represented in article 4, paragraph iv of the *International Declaration on Human Genetic Data* that stipulates giving due consideration to the sensitivity of human genetic data and establishing an appropriate level of protection for these data and biological samples (UNESCO, 2008, p. 52).

Respect for Cultural Diversity and Pluralism

Some writers (e.g., Engelhardt, 1998) argue that religion in general and Christianity in particular are incompatible with pluralism. Equally, there is no consensus on whether or not Islam encourages diversity and pluralism (Yitik, 2004). However, Islam supports pluralism, whether it involves the acceptance of divergences among Muslims (for example, about all aspects of Muslim life), or its tolerance of people of other religions. Therefore, upholding pluralism in Islam means respect for diversity within the Muslim community as well as between Muslims and non-Muslims.

If we start with the second meaning, we can find in *Qur'an* many verses that can be interpreted as a clear assertion of pluralism of faiths. The verse that is often cited by those who see that Islam encourages pluralism is the verse where Allah says, "there shall be no compulsion in religion" (Qur'an2: 256), a verse that clearly shows that no one is compelled to adopt Islam. Another is, "For each of you We have prepared, according to the capacity of each, a path or a highway, to enable you to approach the fountain of revealed guidance. Had Allah so willed, He would have made you all one people, but He wishes to try you by that which He has given you" (Qur'an5: 48).

From the history of Islam, the covenant of Medina (called *Mithaq-ilMedina*) is also given as evidence that Islamic tenets do not disapprove pluralism (as a way of life). When the Prophet migrated from Mecca to Medina owing to persecution in Mecca at the hands of Meccan tribal leaders, he found Medina a pluralistic society where Jews, pagans, and Muslims co-lived. Jews and pagans were divided into several tribes, each tribe having its own customs and traditions. The Prophet drew up a covenant with these tribes, guaranteeing them full freedom of their faith and also

creating a common community in the city of Medina with an obligation to defend it, if attacked from outside (Ahmad, 2009, p. 95). In this way, he gave a good example of how a Muslim pluralistic community with multiple faiths can be established.

Such example was followed throughout Islamic history. After Prophet Mohammed, the caliphs and Muslims in general followed the same way: When Jerusalem came under the rule of Islam, Omar, the second caliph, signed a pact with the inhabitants of Jerusalem, which granted security for them and their property. It recognized rights of the Jews and Christians of Jerusalem freely to practice their religion; their churches and synagogues were respected and left intact (Yitik, 2004, p. 4).

Such understanding of a pluralistic community was what allowed various Muslim rulers to encourage non-Muslims to participate in and contribute to the intellectual and political life of the community under Islamic rules. The Christians and Jews were welcomed to hold posts in public offices. Some of them became ministers, especially in the periods of the Abbasids, Mamluks, and Ottomans. Religious tolerance was well observed by the Muslim rulers of Christian Spain. At that time, in Spanish cities like Cordova, Seville, and Toledo, Christians, Jews, and Muslims lived in peaceful co-existence and many distinguished scholars and philosophers played a crucial role for exchanging cultures, the most famous of whom was Moses Maimonides (Yitik, 2004).

The Islamic civilization that flourished in the Middle Ages was based on translating the intellectual works of those who lived in the empires that existed before Islam or were contemporary with the Islamic State in the Middle Ages. Caliph Al-Mansour encouraged a large number of scientists to translate the Greek books on medicine. Caliph Al-Rasheed encouraged translating the old books of physics, astronomy, and mathematics. This translation movement culminated in the establishment of *Dar Al-Hekma* (a translation center), in the era of Al-Ma'moun, in whose time nearly all old philosophy books were translated into Arabic: a clear admittance by those caliphs of not only the possibility of living in harmony with others but also of the possibility of learning from them.

Regarding the first meaning where Islam allows divergence of opinions, much historic evidence can be found starting from the time of Prophet Mohammed. The principle of *Shura*, which Prophet Mohammed established among his followers, occasionally consulting them about various issues, is one piece of evidence that Islam is and should be based on pluralism of opinions. The different ways via which Abu Bakr, the first caliph, and Omar, the second caliph were chosen show that there is no one specific way to choose the Muslim's ruler. The story with which *fiqh* is said to have started is another piece of evidence. When the Islamic state began to expand beyond *Mecca* and *Medina*, Prophet Mohammed had to send envoys to these newly Islamic estates. He decided to send Mu'adIbnJabal to Yemen to hold the position of a judge. The Prophet asked him how he would judge the cases; IbnJabal replied that he would judge in accordance with *Qur'an*. "And what if you do not find guidance in *Qur'an*" the Prophet asked. He answered that he would seek the answer in the *Sunna*. "And if the *Sunna* does not help?" the Prophet asked. He answered that he would try to form an opinion *(ijtihad)*. The Prophet

tapped on him and thanked Allah who helped his messenger to find what pleases Allah and His messenger. Lastly, the four Islamic *fiqh* denominations, and not only one, that give different religious opinions that regulate all aspects of the Muslims' life is another clear piece of pluralism within Islam understood as a religion that regulates all Muslims' aspects of life.

In the domain of bioethics, such a principle of pluralism may raise questions about discrimination and autonomy. However, as explained above, the recommendations given by Arab bioethicists about premarital genetic testing show that cultural diversity is accepted in Islam as long as it does not infringe upon human dignity. It was also shown how their opinion and the law limit cultural specificities to the protection of human rights.

Solidarity and Cooperation

Solidarity as a moral value is not the reciprocal solidarity where individuals cooperate out of self-interest expecting mutual gain; it is the humanitarian solidarity whose motivation is the help of others – the needy – without expecting any return (UNESCO, 2008, p. 54). Such sense of solidarity is one of the life-governing principles for Muslims. Muslims should be responsive, helpful, caring, and cooperative, not indifferent or care only for their own interest. Therefore, solidarity is assured in Islam at all levels. The following Qur'anic verse is clear in expressing the concept of solidarity: "O ye who believe [. . .] assist one another in piety and rectitude, and assist not one another in sin and transgression" (Qur'an5: 2).

Prophet Mohammed confirmed this meaning by saying, "In their mutual intimacy, mercy and kindness, the believers in Allah are like one body in that if any part of the body is not well, the whole body will respond with insomnia and fever"(Hadith 6586 in Sahih Moslem: 1130). He also said, "A Muslim is a brother of another Muslim [. . .] Whoever fulfils the needs of his brother, Allah will fulfil his needs; whoever relieves his (Moslem) brother of a discomfort, Allah will relieve him of one of his discomforts in the Day of Judgment" (Hadith 6578 in Sahih Moslem: 1129).

The above-mentioned verses and Hadith show that solidarity is not restricted only to material solidarity.

In showing how to turn material solidarity into action, Islam imposes *Zakat* on all Muslims as a tool to apply such principle. Zakat is a sum of money imposed on the rich to be given to the poor. In the Qur'an, Allah addresses Prophet Mohammed telling him about the rich to "take a portion of their wealth as alms, that thou mayest purify them thereby and provide for their uplift and welfare" (Qur'an9: 103). The Qur'anic specifies that alms should be given to "the poor and the needy, [. . .] and for those burdened with debt" (Qur'an9: 60).

In this sense, it is easy to see how solidarity should be applicable in the context of the healthcare system. States and rich people have the responsibility of providing the needy with the necessary health care that can protect their human dignity, as shall be explained.

Social Responsibility and Health

Humans are defined by Spinoza as social animals, a living being who is "scarcely able to lead a solitary life" (Spinoza, 2005, p. 197). Humans in our time live in a social context ranging from the family, the national community to the global human community. The social context a human lives in and his or her status confers on him or her certain duties and responsibilities towards those he or she lives among. However, some argue that the word responsibility is rather modern in the sense of its being "a virtue that we demand of both people and organizations – speaking of socially responsible corporations, managerial responsibility, individual responsibility and so forth", and "for which we praise some people and organisations, while we criticise others for its lack" (Williams, 2008, p. 457).

However, responsibility in this sense has always been a virtue of the true Muslim. As Allah's vicegerent on earth who is endowed with reason and free will, the Muslim has responsibility towards Allah and simultaneous responsibility towards the whole creation, where creation means nature and the environment, other human beings and society as a whole (Zinken, 2007, p. 208): responsibility about which to be praised or blamed.

However, as this principle seems to be devoted to the social responsibility towards promoting health and human development, this section will be confined to such role of social responsibility showing how it has always been a part of the duties and responsibilities of the Muslim, though it is not fully achieved in the Arab world.

It has recently been recognized that the social and economic contexts people live in determine their health not less than their genetic inheritance and their personal choices and way of life. According to WHO (WHO Commission on Social Determinants of Health, 2008), income and social status; education; physical environment; employment and working conditions; social support networks; customs and traditions, and the beliefs of the family and community; genetics; health services; and gender all contribute in determining health (UNESCO, 2010:13).

In Islam, there is a much evidence to show the importance of human health grounded on the principle of sanctity of life. The responsibility for improving all determinants of health is explicitly directed towards individuals and states, and implicitly to other corporations.

In the Qur'anic injunction, "Let not your own hands push you into destruction" lies the command to save oneself from the occurrence of diseases or inflicting harm on oneself. The importance of human health is reflected in many verses and Hadiths: "Children of Adam . . . eat and drink but be not immoderate" (Qur'an7: 32). Prophet Mohammed is related to have said that, "no barrel that a human fills is more evil than a full stomach" (Hadith3349 in SonanIbnMaja: 2679). If interpreted either way, these references will show the importance of health: they will either mean that overeating and drinking may render one unhealthy, and thus being in a healthy condition is itself a duty, or that it is important to stay healthy to be able to colonize the earth, which is in modern terms to participate in the development of your community.

And because health is important, treatment, education, and sports are all religious demands.

In Islam, humans should seek remedy. "The Prophet Mohammed said, "O Servants of Allah: seek remedy. Allah who caused ailment, also brought cure and redemption." He also declared that there is a cure for every illness, though we may not know at the time. Muslims are encouraged to search for new modalities of treatment and should apply them if proved successful" (Albar, 1996). Acknowledging that treatment is basically the physician's role, in 1981, the "Islamic Code of Medical Ethics" ICME was endorsed during the First International Conference on Islamic Medicine held in Kuwait organized by IOMS, coding the physician's duties and responsibilities towards himself or herself, patients, and society. Medicine, according to the code, is a specialized knowledge, "lawful only to persons suitably educated, trained and qualified, fulfilling the criteria spelt out in the Law. A clear guidance is the Prophet's tradition: "Who-so-ever treats people without knowledge of medicine, becomes liable"" (ICME, 1981: 7). However, it is a holy mission, bringing God's mercy unto His subjects, and as mercy is as accessible to all people including good and evil, virtuous and vicious as are the rays of His sun and the coolness of His water, the medical profession should operate along that single track: God's mercy (ICME, 1981, p. 1, 2). Therefore, "It shall never yield to social pressures motivated by enmity or feud be it personal, political or military" (ICME, 1981, p. 2). In order for physicians to perform such task in the best way, they should be cheering not dispiriting, smiling and not frowning, loving and not hateful, tolerant and not edgy, tranquil as never to be rash even when he is right, neat and trim, conducive of trust and inspiring of respect, well-mannered in his dealings with the poor or rich, modest or great, in perfect control of his composure and never compromising his dignity, however modest and forbearing. They should also be truthful whenever they speak, write or give testimony, invincible to the dictates of creed, greed, friendship or authority pressurizing him to make a false statement or testimony (ICME, 1981, p. 3). They should offer good example by caring for their own health responding to the Qur'anic injunction that they ought not to make their own hands throw them into destruction," to the Prophet's advice that their bodies have rights on them, and finally to the known dictum "no harm or harming in Islam" (ICME, 1981). It is also clearly stated in the code that the physician should always be at the service of the patient, describing the patient as the physician's master for whose welfare and comfort the physician should give top priority over other considerations (ICME, 1981, p. 5). The physician should also protect the patient's secrets and keep confidential all information about him or her. The Prophet described the three signs of the hypocrite as follows: "He lies when he speaks, he breaks his promise and he betrays when confided in" (ICME, 1981, p. 6). The physician is linked to the larger moral tradition, that is: should never help one another in sin or rancor or give false legal testimony (ICME, 1981, p. 4). The physician's duties extend beyond treating patients to help in combating health-destructive habits such as smoking, uncleanliness, and so on. Physicians also have the responsibility of pressurizing the judiciary to issue the necessary legislation that can help improve health (ICME, 1981, p. 9). They should

also engage in scientific research as long as such research does "not entail the commission of sin prohibited by Islam" (ICME, 1981, p. 10).

In addition to such responsibilities of the physician to prevent and cure diseases and help in improving health, it is the responsibility of the governments to provide their people with all necessary health services responding to health needs, as well as the responsibility of the rich towards the poor at the personal as well as at the national levels to provide them with all possible means that can lead to healthy life.

Education is one important determinant of health. Knowledge in Islam is given high rank. In showing such rank, Prophet Mohammed is reputed to have said that knowledge seekers will be rewarded with paradise and that angels in the heavens bow with their wings expressing satisfaction and respect for knowledge seekers (Hadith 3641 in SonanAbiDawoud: 1493). As an indication of how important it is to educate people, there is a story that soon after *GazwatBadr* (the Battle of Badr, 624 AD), Prophet Mohammed agreed to free some of the Muslims' prisoners if every prisoner taught 10 children of Muslims reading and writing (Abu Zahra, 1986, p. 772). So, it is a heavenly duty of everyone, individuals, parents, and governments, to make knowledge accessible to all.

Sports in Islam are also acknowledged as a health determinant. Prophet Mohammed recommends Muslims to "teach (y)our children archery, swimming and horse riding" – the sports available in his time – to care for their own and their guardians' health.

Acknowledging social status' role in improving health, Caliph Omar asked rulers of other Islamic provinces to financially help youth get married from *Zakat-lmal* paid by the rich. However, the current situation in the Arab world is far from that ideal for different reasons.

At the personal and family levels, many people are neither aware of the social determinants of health, nor regard them, nor do they have the right understanding of religion regarding such issues. The result of which is the perpetuating of poor health habits and customs that negatively influence health attributing some of them wrongly to religion. Discrimination against females in the domain of education, as explained before, is one example. Traditional harmful customs adversely affecting women's health, such as early marriage and the ensuing early child bearing and FGM, is another. Lack of awareness of the importance of practicing sports for health that may cause diseases such as diabetics is a third.

At the governmental level, some states are too poor to provide all their citizens with a good standard of health and education due to the non-affordability of having strong health systems and qualitatively good education systems. In providing citizens with the necessary components of the sound physical environment that affect health, such as clean water, safe roads, health centers, hospitals, and educational institutions, some governments do not allocate to the rural areas the same care the urban areas receive, either for financial reasons or because of the absence or weakness of accountability systems or weak political will.

Sharing of Benefits

Though mostly intended at the global level, benefit-sharing from an Islamic perspective can be more considered as an application of the principles of justice and non-discrimination rather than an independent principle. Since, in Islam, justice or non-discrimination applies at the local, the regional, or the international level, the principle of sharing of benefits cannot imply something additional other than that the principles of justice and non-discrimination should be implemented. That the benefits of scientific knowledge and research should be justly distributed among countries, regions, and social groups, and between the sexes; and that research subjects should be given equitable options to benefit from their free participation in health research; and that research and ethical review capacity should be strengthened in the low-income countries in return to allow externally funded research to be conducted are all suggested models of benefit-sharing agreements (UNESCO, 2008, pp. 61–62). However, from the Islamic perspective, all these models are accepted but for different reasons: the benefits of scientific knowledge and research should be justly distributed because all humans are equal: they are the worshippers of Allah and the children of Adam. Claims of justice require that they all benefit from the results of scientific knowledge and research. Therefore, the benefit from the health research that might include access to treatments or practices developed by the research should not only be given equitably to research subjects but extended to all those who need it without compromising the right of researchers, the funding agents, or the sponsor governments. Equally, if committing organizations from high-income countries to improving research capacity in the host countries where research is conducted is meant to help international clinical research fill the inequality gaps that are left by non-existent or underperforming state actors in host countries that are unable to regulate nor can afford to fund and conduct research on local health needs (Pratt & Loff, 2011, p. 76), such entities, from an Islamic perspective, have the moral commitment to reduce health disparities between countries regardless of the benefit they will get from research conducted in such poor countries.

Protecting Future Generations

The concept of protecting future generations has emerged as a result of the booming economic growth based on the overexploitation of the natural resources and the ensuing environmental pollution and degradation. Such concept was extended to other examples of technological and scientific progress in the domain of health care that were found to have serious impact on future generations such as germ line gene therapy and xenotransplantation.

It is argued, for instance, that germ line gene therapy and xenotransplantation may have serious impact on the future generations because of the risks involved in both. The problem with germ line gene therapy lies in that the procedure is irreversible, and whether manipulations resulted from intervention adversely affect

future generations is impossible to predict in advance or to correct after being propagated to future generations (Nielsen, 1997). As for xenotransplantation, infections through viruses restricted to a nonhuman host species may be transmitted from the source animal to the human recipients to other people after being adapted to humans as a host species (Daar and Chapman, 2006, p. 107).

The Islamic opinion on gene therapy is mentioned within the broader topic of genetic engineering. Al-Qurradaghi expresses the Islamic opinion on gene therapy as follows: gene therapy is permissible if it does not lead to any harm (Al-Qurradaghi and Al-Mohammady:324). Islam encourages somatic cell gene therapy as it is like any other kind of therapy. Germ line gene therapy is prohibited for the uncertainty involved in its outcome. The extent of harm to the descendants is not clear. If it becomes certain in the future that such kind of therapy will lead to no harm, then it is permissible as long as it aims at curing diseases. Enhancement genetic engineering, through manipulating hereditary traits such as intelligence, stature or beauty, is impermissible as it may imbalance human life (Serour, 2000, p. 12).

As for the Islamic opinion of xenotransplantation, though the conclusion of the majority seems to be that using pigs for transplantation would not be a barrier to xenotransplantation, based on the Shari'a's principle that "necessities override prohibitions" – and that, in any case, the prohibition is only from eating pig tissue (Daar and Chapman, 2006, p. 115), xenotransplantation is prohibited for the risks involved.

The Islamic perspective of protecting future generations, applied in the case of germ line gene therapy, is that it is injustice to expose future generations, being equal to us, to potential harm that could have been avoided. As for xenotransplantation, it is equally unjust to expose the public to harm even if they may "benefit indirectly from successful widespread xenotransplantation due to a decrease in the societal burdens of health-care costs and years of productive lives lost due to chronic diseases" (Daar and Chapman, 2006, p. 110). The principle of "avoiding harm has the priority over getting benefits" applies to current as well as future generations.

Protection of the Environment, the Biosphere, and Biodiversity

It is widely acknowledged that Islam, like Christianity, advocates anthropomorphism: Islamic Shari'a not only places humans on top of all creation, but Allah has also "constrained the sun and the moon to serve" them (Qur'an13:2). "He has created cattle for your benefit; they are a source of warmth for you and you have other uses for them and you also eat of their flesh; and they are a credit for you when you drive them forth to pasture in the morning and when you bring them home in the evening. They carry your loads to places which you could not reach without great hardship to yourselves. Surely, your Lord is Compassionate, Ever Merciful. He has created horses, mules and donkeys that you may ride them, and also as adornment; and He will create for that purpose other means which you do not know" (Qur'an16: 5–8). "He it is Who sends down water for you from the clouds, from it you drink and with it grow trees on which you pasture your cattle.

Therewith, He grows for you corn, and the olive and the date-palm and the grape, and all kinds of fruits . . . He has constrained to your service the night and the day and the sun and the moon; and the stars too have been constrained to your service by His command . . . He it is Who has constrained the sea to your service that you may eat fresh sea-food therefrom and may take out therefrom articles that you wear as ornaments. Thou seest the vessels ploughing through it that you may voyage across the oceans seeking His bounty and that you may be grateful. He has set in the earth firm mountains lest it roll beneath you, and has made rivers and tracks that you may find your way; and He has set up other marks. By these and by stars they set their course" (Qur'an16: 10–16).

However, it does not mean that Islam gives people the right to use the environment and its components lavishly. As Allah's vicegerents, endowed with reason and provided with what have in themselves intrinsic values: the environment and the biosphere, that are also creations of Allah, humans are supposed to use them wisely. Unwise usage is a misuse of reason that Allah has endowed man and a degradation of what Allah has conferred intrinsic value on, and a violation of the responsibility given to man to protect and develop them.

Therefore, as it is clearly observed and mentioned in the economics and environment literature, protection of the environment is frequently considered in the *Qur'an* and *Sunna* to the extent that some writers see the Qur'an "greener" than the Bible which shares with the *Qur'an* common views of the natural world (Smith, 2002, p. 26).

In the early history of *Medina*, Prophet Mohammed established the first natural protectorate in Islam: a green belt of 12 miles around the city, where he prohibited people from cutting, removing trees or plants or hunting activity. He also prohibited them from polluting portable and bathing water, which by analogy Muslim jurists prohibited the throwing of garbage, harmful animals or industrial filth into waterways or under trees, in forests, or in the middle of roads that people use (Zinken, 2007, p. 216; Yousri, 2005, p. 27).

Prophet Mohammed also encouraged the practice of cultivation which he then, and still is, considered as a sort of worshipping, because according to him, any vegetation that a Muslim plants, or a crop that he sows so that human beings or animals eat, becomes an act of charity (*sadaqah*) (Yousri, 2005, p. 27). Charity should not only, then, be directed towards humans but to all creatures: "For charity shown to each creature with a wet heart, there is a reward," Prophet Mohammed declared (Smith, 2002, p. 26).

He also encouraged the revival of barren land by granting land to Muslims who are ready to reclaim it: "anyone in possession of a barren land granted to him, does not have the right to keep it after 3 years, if he does not revive it". This is due to the fear that the land will remain unutilized: a clear encouragement for not letting a beneficial natural resource remain idle (Yousri, 2005, p. 27).

Regarding the protection of living creatures, kindness to animals in Islam is an article of faith for Muslims. Prophet Mohamed ordered his followers to treat animals with gentleness and kindness (Smith, 2002, p. 26). The Prophet proscribed the killing of animals unless they prove to be dangerous for humans such as rats and poisonous snakes. "He who kills a sparrow in vain, this sparrow will cry

complaining to Allah on the day of judgment saying: O Lord, so and so killed me in vain and not for any benefit" (Yousri, 2005, p. 28). There is a tale that the Prophet related to his followers of a woman who was tortured by Allah by being put in Hell because during her life she once locked a cat up till it died of hunger Hadith 5852 in Sahih Moslem: 1076).

Though Muslims have the duty to protect the environment, the biosphere, and the biodiversity, the motivation is different from that of the conventional secular thinking. The latter's motivation to call for protection of the environment is to stop the accelerating consumption for fear of "degradation of natural resources and the increasing probability of their insufficiency to meet future material human needs" (Yousri, 2005, p. 29). The Islamic perspective is that protection, preservation, and development of the environment is a duty of the Muslim, as Allah's vicegerent who was held what is on the earth as a trust, to preserve what has been created with an intrinsic value and use it wisely, not just for any utilitarian reason whether it is the wellbeing of the current generation or the future generation. It is an understanding that the Muslim jurists arrived at in the Middle Ages before the modern understanding that stemmed out of the fear of the depletion of the natural resources (Yousri, 2005, p. 28). Muslims do not have the fear that the earth will run out of its natural resources. But on the other side as was explained, this does not mean a call for a lavish use of the natural resources. Allah expresses clearly that "He loves not the extravagant" (Qur'an6: 142).

Conclusion

In the Arab world, the concept of bioethics, understood as the discipline that encompasses the ethical issues resulting from the development of biological sciences and technology, is relatively new. Solutions given so far in the modern Arab world to such issues are mainly Islamic, reflecting the specific adoption and interpretations of the underlying principles. Bioethics is a dynamic discipline, whose issues expand as a result of the accelerating development of science and technology. It is important that the solutions given in the modern Arab world to various bioethical issues, and the interpretations given to underlying principles, continuously respond to the ethical needs of a contemporary open Arab society, that is, a society that encompasses non-Muslims and interacts with other societies. Thus, Arab bioethicists need ongoing discussions between Muslim and non-Muslim Arab bioethicists as well as between themselves and bioethicists of non-Arab cultures, specifically those from scientifically and technologically more developed countries, since it is there where most bioethical issues arise first.

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European Perspectives

18

Jacob Dahl Rendtorff

Introduction

The choice of "autonomy," "dignity," "integrity," and "vulnerability" as the four basic principles in European bioethics and biolaw illustrates the intention to give a solid foundation of the protection of human beings in relation to the fast developments in biomedicine and biotechnology. These principles can be said to express a European Ethical and Legal Culture (Häberle, 1997) of the recognition of the autonomy, dignity, and integrity of the human being. The principles must be seen in the framework of human rights law and the law of the human person. Persons are "liberty holders" and right-claim holders (Rendtorff & Kemp, 2000). The principles manifest the concern to protect the person and to value the development of the individual human being, which is a strong spirit of community in the European societies. The principles imply basic human rights: the right to self-determination of the individual but also legal protection of the life, privacy, and bodily integrity of the human person. Against this background, this presentation of bioethics and biolaw in Europe proposes to interpret the basic principles as being at the same time an ethical horizon of the actual bioethical and biolegal developments and as being important for the formulation of guidelines for future European politics on bioethics and biolaw.

Among the four principles autonomy is the most widely mentioned in the debate about bioethics and biolaw. It has also been widely discussed in the Anglo-American bioethical debate where the principalist philosophies of Tom Beauchamp and James Childress in their influential book *Principles of Biomedical Ethics* has become the foundation of much research in bioethics (Beauchamp & Childress, 1979). This book proposes the principle of respect for autonomy, the principle of non-malfeasance, the principle of beneficence, and the principle of justice as the foundation of biomedical ethics. This account of patient autonomy in relation to the three other principles has been widely accepted in the USA and to some extent in European countries. At the same time, it has a tendency to consider autonomy as the

J.D. Rendtorff
Department of Communication, Business and Information Technologies, Roskilde University, Roskilde, Denmark
e-mail: jacrendt@ruc.dk

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only guiding principle concerning the protection of the human person and therefore forgets other dimensions of the protection of human beings that are particularly important in bioethics and biolaw.

Therefore, other supplementary principles must be taken into account when dealing with bioethical principles and the protection of human beings in bioethics and biolaw (Rendtorff & Kemp, 2000).

In particular, the principles of respect for human dignity, integrity, and vulnerability are important principles that can be proposed as principles that protect the human person, life, and bodily integrity. In this way, they are presented as more fundamental than the utilitarian account of quality of life that plays an enormous role in biomedical decision making. This approach is sometimes very instrumental and needs to be supplemented with ethical principles for protection of the human person and body. At the same time, the principles are founded as important expressions of the human culture and life world in Europe. It is presupposed that the basic principles are implicit in the public debate and the every-day understanding of the ethics of human existence. The principles must be interpreted as expression of the ethical understanding of the human person in daily ethical life.

In this way, the four principles must also be seen as an expression of the European humanistic tradition of giving a high value to individual or singular human beings and their development in society. The principles can be interpreted in the perspective of the European personalistic and existentialist philosophy from the point of view of Emmanuel Mounier's philosophy as the foundation of a European Humanistic bioethics and biolaw (Rendtorff & Kemp, 2000). As such the principles draw especially from the humanistic conception of the person and the corporeal well-being of the person that plays an extensive role in the humanism of French and Italian philosophy. But also the traditions of valuing the freedom of the individual in northern European countries are of basic importance for the understanding of the cultural foundations of the basic principles. In modern legal system, it is very important to protect the psychical and physical being of the human person as the subject of law. The basic ethical principles provide a framework for such care for body and person. The concept of a just legal order is closely linked to the protection of the life and well-being of the participants of society.

The principles can be seen as the foundation for the protection of human rights in biomedicine. The formulation of the definitions and contents of the basic principles in the different biomedical subfields contributes at the same time to formulate the protection of the human person in biomedicine. The promotion and interpretation of the autonomy, dignity, integrity, and vulnerability of the human person contributes to give stronger foundations for human rights, in particular the contribution to claim human dignity and protect the human person. In this way, the investigation of the basic principles implies their legal realization in the different legal orders in the European societies. Human rights and biorights can be seen as the concrete realization of the necessary protection of the personal sphere of human beings that is demanded by the technological development in biomedicine (Rendtorff, 2002).

There are a number of proposals for determining the metaphysical foundation of the basic principles. Without entering deeply into this discussion, the investigation

considers the principles as factually present in the debate about protection of the human person. The analysis focuses on the cultural signification of the basic principles in the public debate, the legal regulation, and the legislation processes on biomedical issues. In this context, society experiences a closer connection between ethics and law, where the basic principles are interpreted both as ethical and legal principles and they are also closely related to legal and political rights. We can say that protection of the basic ethical principles is a question of "political morality" and rights can be seen as trumps to realize the protection of the human person (Dworkin, 1977).

The relation between principles and concrete cases shall be understood as a dynamical hermeneutical relation, i.e., a case of constructive interpretations between particular cases and theoretical justifications where cases and principles mutually determine the development of bioethics and biolaw. Principles cannot only be abstractly determined but must also be seen in the light of the situation of application. At the same time interpretation of the ethical principles in these situations cannot be understood without general rules and principles. What is needed is a theory of reflective judgments to determine the relation between principles and cases. Reflective judgment according to theory of interpretation is the ability to relate principles to cases and cases to principles (Ricœur, 1995). Reflective judgment searches to find the right application of principles to new situations of decision making. In this way, there is no real contradiction between casuistry and principalism.

Also the principles should not be interpreted in a hierarchical way. They express different dimensions of the same concern for the protection of human beings. They are descriptions of different aspects of the same concern for protection of the human person. This means that the hermeneutical analysis of the signification of the principles in different ethical and legal orders and cultures leads to different interpretations and points of views about how the principles should function in the European societies and their future in the European Union. In this way, the principles can be seen as a "communitarian" expression of the ideal of a common European legal morality.

The Definitions of the Concepts of the Ethical Principles

In order to propose the basic ethical principles as essential for European bioethics, we need to say something more about their conceptual content and the foundation of their use for bioethics and biolaw in Europe. The following definitions of the concepts of the principles were based on hermeneutic analysis of the possible uses of the ethical principles combined with a critical analysis of their philosophical content. The ethical principles may be justified within a phenomenology of moral values in human intersubjective relations. The definitions were also based on empirical analysis of uses of the principles in different European countries.

Accordingly, autonomy is not only to be defined in the liberal sense as "permission" (Rendtorff & Kemp, 2000). Rather, five important meanings of autonomy can

be put forward: (1) autonomy as capacity of creation of ideas and goals for life, (2) autonomy as capacity of moral insight, "self-legislation," and privacy, (3) autonomy as capacity of decision and action with lack of outer constraint, (4) autonomy as capacity of political involvement and personal responsibility, and finally (5) autonomy as capacity of informed consent (Rendtorff & Kemp, 2000). Autonomy should be considered as a principle of the self-legislation of rational human beings taking part in the same human life world where they as human beings share as much of a form of life that they are able to understand each other. This does not exclude the recognition of pluralism as a political fact of modern society. But it is necessary to work with a more comprehensive idea of autonomy, recognizing the tensions between different conceptions of the good. The republican sense of autonomy is based on the vision of "the good life for and with the other in just institutions" (Ricœur, 1990, 202). This vision is put forward as the basis for privacy, confidentiality, and informed consent.

Autonomy is not considered as the only fundamental concept in bioethics and biolaw. Autonomy remains merely an ideal because of its structural limitations, i.e., human dependence on outer factors, lack of information, reduced capacity of reasoning, etc. This limitation of the concept of autonomy is also due to tension between the human existence as an "unencumbered self" and the embodied, embedded, character of human experience which means that the self is never really fully master over its life and situation. It must be recognized that the human person should be considered as a situated subject. In any case, autonomy is not a sufficient normative concept to ensure ethical and legal protection in relation to a number of subjects: minors, coma patients, the mentally ill, etc.

Dignity cannot be reduced to autonomy. Rather, dignity is defined both as an intrinsic value and as a matter for constructive morality in human relationships (Rendtorff & Kemp, 2000). It expresses the outstanding position of human beings in the universe. It refers to the inviolability of individual human life. It further expresses the moral responsibility of the human person. This idea of dignity must be respected in the intersubjective relations of the kingdom of ends-in-themselves. On this basis, it is possible to argue that human dignity has the following meanings as an intersubjective concept: (1) It expresses the intrinsic value of the human being in a community or society. (2) It includes respect for the moral agency of the human subject. (3) It means that every human being must be considered as being without a price and unable to be commercialized. (4) This includes that human dignity refers to the indeterminacy of the position of human beings in the universe – as they are able to create their own destiny. (5) Emotions of self-esteem, to be proud, feel shame, or having feeling of inferiority and degradation are essentially matters of human dignity that are expressed in the intersubjective relations between individuals. (6) Dignity can establish restrictions on interventions in human beings in taboo-situations, because of the necessity of human civilized behavior. (7) Finally, dignity relates to metaphysical experiences of human beings in existential limit situations where they face degrading treatment. But the relation between rights and dignity is also essential. In that context, human dignity expresses the intrinsic worth and fundamental equality of all human beings.

The principle of integrity may be said to refer to the totality of life saying that it should not be destroyed (Rendtorff & Kemp, 2000). Integrity is a coherence that in a certain sense must not be touched. This coherence, or rather "Lebenzusammenhang," is the narrative coherence of a person's life (the life story) or the narrative (historical) unity of human culture. On this basis, integrity has four meanings. (1) Integrity as a narrative totality, wholeness, completeness. (2) Integrity as a personal sphere of self-determination. (3) Integrity as a virtue of uncorrupted character, expressing uprightness, honesty, and good character. (4) Integrity as a legal notion, where it expresses the moral coherence of the legal or medical system. In bioethics and biolaw, the idea of integrity as an untouchable core, the personal sphere, which should not be subject to external intervention, is the most important. The personal body must be considered in a phenomenological perspective of the self-mastery of the body. In this perspective, the body is an expression of human subjectivity through the experience of the self in the body. Integrity expresses bodily completeness in a private sphere. In medicine, it is indispensable for trust between physician and patient. There is a close link between respect for identity and respect for integrity where a personal narrative expresses the life context of the individual. In this way, respect for integrity is recognition of the right to privacy and constitutes the virtues of the legal and medical systems.

Vulnerability of mental and corporeal life is closely linked to integrity. But it expresses more characteristics of the human condition (Rendtorff & Kemp, 2000). Protection of vulnerability is considered as the bridging factor between moral strangers in a pluralistic society, and therefore respect for vulnerability is essential to policy making in the modern welfare state. Vulnerability should be considered as a universal expression of the human condition (Lévinas, 1961). Moreover, it appeals to protection of both animals and the teleological auto-organization of the world where human beings take part of the ecosystem that also searches to preserve its integrity in evolution. However, vulnerability has been largely misunderstood in modern society, which has been guided by a so-called vulnerability reducing agenda, which aims to eliminate all vulnerability, i.e., suffering, abnormality, deafness, and disability, in order to create perfect human beings (Rendtorff & Kemp, 2000; Rendtorff, 2002). Respect for vulnerability must find the right balance between this logic of the struggle for immortality and the finitude of the earthly presence of human suffering. As an expression of the destiny of finitude, the moral receptivity of vulnerability, i.e., the respect for the vulnerability of the other, is the foundation of ethics in this time.

With these definitions of the main concepts in the principles, it is possible to describe and analyze the basic ethical principles (see below).

The Principle of Autonomy

The term "autonomy" consists of "auto" and "nomos." This means self-government in Greek language and in Ancient Greece, a city state was said to be autonomous when it was self-governing (Dworkin, 1988). In the Western tradition, autonomy

has been linked with the freedom of the individual and the possibility of the harmonious development of the human person according to personal choices, desires, and wishes for his and her future life. For Immanuel Kant, the person has moral freedom and is autonomous because it is an end in itself. Here persons are their own legislators. For John Stuart Mill, autonomy is said to be the freedom of coercion and the possibility of making one's own actions and decisions. The intimate connection between autonomy, moral independence, and personal self-development is also stressed in the European personalist and existential philosophies (Sartre, Mounier) that emphasize the personal freedom, engagement, and moral responsibility of the human individual. In the existentialist perspective, autonomy also implies a process of reflection and active presence of the individual. Existential freedom is a condition for personal identity and self-development. Autonomy is a second-order capacity of individuals to reflect on their first-order preferences and desires (Dworkin, 1988). It is important to stress that a theory of autonomy must imply positive liberty and active choices of the individual.

As the political origins of the term "auto-nomos" suggests, there is also a close connection between individual autonomy and the political organization of society. Modern political philosophies, such as those of John Rawls, Ronald Dworkin, and Jürgen Habermas, all value individual autonomy very high as the foundation of the political structure of society (Dworkin, 1977; Habermas, 1992; Rawls, 1992). In modern society, the principles of justice presuppose that human individuals are free and equal. Society is developed in a procedure of construction where autonomous agents are supposed to agree rationally on some common principles of justice (Rawls, 1992). In this context, autonomy often implies other basic characteristics, e.g., rationality, individuality, independence, and moral responsibility of the human person. It is central to the idea of liberal democracy that the individual has the possibility of self-realization and of self-development. Legitimate government has to be built on the self-determination by autonomous individuals. Therefore, protection of individual autonomy is a basic principle in all European constitutions. It is important to stress that a society built on responsible, autonomous decision making is not necessarily a society without communitarian engagements and common values. This is implicit in Habermas' notion of *Verfassungspatriotismus*, Rawls' concept of a liberal political community and Dworkin's ideas of "law as integrity" and law as an expression of "political morality." Indeed, the choice of such values should be motivated by individual decision making rather than collective coercion.

However, there is a broader and more serious communitarian critique of the concept of autonomy. It states that the concept of autonomy presupposes an institutional and cultural background. Autonomy must be recognized as a basic value if it has to have any real impact on decision making. Only a free and democratic society can make autonomy possible. At the same time, autonomy should not rule out social obligations to help others. An account of autonomy cannot be totally libertarian but must recognize the situated subject in a large number of social practices, commitments, compassions, and relations to other people (Reich, 1978). An exclusive focus on autonomy also forgets the fragile and vulnerable components of the human condition requiring care and respect for the human person.

The problem is whether autonomy implies a total substantial and procedural independency or whether it is possible to be autonomous and at the same time rely on communitarian values, the legal system, moral or religious authorities. The question is if it is possible to act autonomously in situations with little room for personal decision making because of determination of action outside the self. And in which way are autonomous decisions allowed to rely on the opinions of other persons. In this context, it should be evident that moral autonomy is related to free and autonomous choice but that this does not imply total independence from outer factors. Autonomy implies the capacity to make one's own decisions about one's own life. These decisions can, however, also be taken in collaboration with other human beings and according to other values. To be morally autonomous is related to sincere choice and personal decision making rather than to the invention of genuine personal values. Autonomy does not always have to imply one's own invention of the moral law (Sartre) but can equally imply the personal insight in moral reason and categorical imperative (Kant). Moral autonomy is a question of free moral choice according to a set of values that the individual finds right and just (Dworkin, 1988).

The central importance of autonomy for development of the human person (personal agency), political democracy, and one's conceptions of moral decision making is the background for the basic significance that is attributed to autonomy as a fundamental right that is used to justify protection of privacy, confidentiality, refusal of treatment, and informed consent. The notion of "informed consent" has been introduced after the Nuremberg Declaration and the Helsinki declarations as a basic requirement in the legislation on healthcare and biomedical practice in most of the European Countries. Every medical intervention must be legitimated by informed consent. The patient must have the right to make his own decisions about treatment and refusal of treatment. The concept of informed consent is introduced to secure a thoroughgoing self-determination of patients in medical treatment. The patient has the right to make the decisions about his own body in the context of medical treatment. We can mention some basic requirements of the doctrine of informed consent which are necessary for the functioning of the concept in practical medicine (Beauchamp & Childress, 1979). It implies that the patient has a meaningful choice and freedom in relation to the process of medical treatment. Therefore, the patient has to engage intentionally and with understanding and knowledge in the process of treatment. It has to be free and capable decisions without violence and coercion. An autonomous action implies: (1) freedom, (2) authenticity, (3) deliberation, and (4) moral reflection (Reich, 1978). The decisions made are compatible with an existing moral tradition in the hospital as long as they are made with a substantially free and independent decision with respect for the principle of autonomy. Informed consent should be considered as an event, as a process of communication and action between physician and patient that eventually leads to the decision and the undertaking of treatment. In this context, essential elements in informed consent are according to Beauchamp and Childress: (1) disclosure, (2) understanding, (3) voluntariness, (4) competence, and (5) consent (Reich, 1978; Beauchamp & Childress, 1979).

Although it has an enormous importance in biomedicine to secure the right treatment of individuals, autonomy and informed consent are concepts, which imply several problems. Thus, they cannot be the only concepts to express the humanistic concept of biomedicine and the protection of human beings in the biomedical field. It is possible briefly to mention a certain number of difficulties that necessitate complementing autonomy with other fundamental principles in bioethics and biolaw. First of all, the concept of autonomy abstracts from the vulnerable and fragile human condition and the existence of the person as a "situated subject." However, in the real world, it is not sure that the patient is able to judge the treatment process or fully understand the situation of treatment. Further, there is the problem of the correct disclosure of information and the eventual paternalist intervention of the doctor. And what about the therapeutic privilege of the doctor in a situation where the information would be of doubtful benefit for the patient? It is also possible to mention religious and moral traditions and conceptions within the hospital that are in conflict with the personal conceptions of the patients. So there may be many obstacles for respecting autonomy, and therefore, autonomy is limited as a guiding principle for biomedical treatment.

Apart from these internal difficulties in using the principle of autonomy, there are situations in bioethics and biolaw where the principle of autonomy simply does not apply (Rendtorff & Kemp, 2000). In cases concerning the unborn life, embryos, fetuses, the human body and its body parts, the body after death, organs, etc., the principle of autonomy is of little significance because one cannot say that the body before birth and after death or the different body parts have moral autonomy. This is the same for incompetent patients, e.g., minors, coma patients, or mentally diseased persons who are not able to make their own decisions. However, there is a reluctance to contribute moral value and concern to these people and living objects. Therefore, the concept of autonomy is very limited as a basic concept of bioethics and the adequate protection of the human person must take into account the other dimensions of protection: the principles of dignity, integrity, and vulnerability.

The Principle of Human Dignity

There is a close link between autonomy and dignity. Sometimes dignity is even equated with autonomy, and is seen as a part of being a human person. Human dignity has been a very influential concept in the Western tradition (Rendtorff & Kemp, 2000; Lebech, 2009). The principle of human dignity signifies that the human beings have a special position in the universe that places it over the natural and biological place of other beings in nature. As a moral being and because of its status as a human being with dignity, the human person has intrinsic value and possesses a unique place in the world. In the European cultural history, the idea of human dignity indicated the outstanding position of the human beings in the universe. The Stoics pointed to "dignitas humana" as an essential part of human existence. As moral beings with freedom, autonomy, capacity of moral reasoning

and responsibility, human beings are contributed dignity (Dignitas) that determine their value and position in the world. This idea of the intrinsic value of human life and dignity was developed in Christianity where the individual human person was regarded as intrinsically valuable. Augustine said that the human being was created in the image of God and therefore, the individual life would be inviolable. The concept of dignity as a characteristic of the human beings, who have to choose between good and evil and secure their own and the dignity of other people, was further developed in renaissance thinking, especially by Pico della Mirandola in the *Oration on Human Dignity*. Here dignity means that human beings are free to choose if they want to fall down to the lower levels that characterized animal life or ascent to the higher divine levels. In antiquity, Christianity, and the renaissance, the concept of human dignity expressed the moral superiority and responsibility of human beings in relation to themselves, animals, nature, and the whole universe (Rendtorff & Kemp, 2000).

These aspects of human dignity found a new synthesis in Immanuel Kant's philosophy about the human being as an end in itself and the idea of the categorical imperative. The Kantian idea is to treat every human being as an end in itself because of the relation between human autonomy and self-government. He states that every human being is possessing dignity and sovereignty because of its will and inner intrinsic value. In Kant's philosophy, human dignity is a basic moral principle that expresses the intrinsic dignity of Man. Although dignity is an intrinsic element of humanity that cannot be lost, human beings can be degraded and their dignity can be violated. Because of this potential degradation and violation of dignity, the protection of dignity becomes a great moral requirement that is closely linked to the concept of personal autonomy (Rendtorff & Kemp, 2000).

The close connection between dignity and autonomy is also very important in existentialist philosophy of the twentieth century. This philosophy can be seen as a contemporary way of interpreting the concept of human dignity. The underlying argument in Jean-Paul Sartre's defense of existentialism as a humanistic philosophy is the connection between human dignity, freedom, and autonomy (Rendtorff & Kemp, 2000). Because of the intrinsic capacity of choosing the meaning and significance of their own lives, human beings have intrinsic value that can be lost or destroyed. Human dignity applies to the intrinsic human capacities of engaged existence in passion and action in the world. This idea of human dignity is also present in Gabriel Marcel's catholic existentialism, in Simone de Beauvoir's argument for the equal dignity between man and woman, as well as in the antiracist argument for the extension of the concept of human dignity to the whole of mankind so that human rights are universal and inalienable (Rendtorff & Kemp, 2000). What is essential in this humanism is the protection of what is human dignity in present and future society in particular with regard to protection of human rights and dignity in sustainable development (Rendtorff, 2009).

The concept of human dignity is essential as the foundation of the development of human rights as legal instruments for the protection of the human person. This is especially present in the extension of the concept of human rights to the so-called biorights. In this context, the specifically human that is implied in the concept of

human dignity is seen as unity of body and soul. This implies that the human body and body parts as parts of the human person are expressions of human dignity and of what is specifically human (Rendtorff, 2002). Therefore, to respect the human body and body parts is a question about the respect for human dignity. The understanding of the person as bodily incarnated is the primary task in the legal regulation of the biomedical sciences. From the point of view of European bioethics, the aim of bioethics and biolaw is to protect what is specifically human, and can be understood as the human dignity in the technological development (Rendtorff & Kemp, 2000; Rendtorff, 2002). It is the task of human rights law to promote the humanistic ideals in the Western European Culture and take care of the idea of the intrinsic dignity of human beings as the foundation of autonomy and personal freedom. In this way, human dignity is more important than autonomy and self-determination, because human beings who decide for themselves can do actions that degrade and violate their dignity. Accordingly, autonomy may be limited in order to protect dignity. The respect for human dignity as an expression of what is specifically human expresses a fundamental principle of justice that goes beyond self-determination and distribution of goods in society. Accordingly, human rights express human dignity and are dependent on a view of the human person that goes beyond the sole protection of the conscious agent. The right to life, fairness, equal treatment, and other basic rights express the European constitutional culture, where the constitutional state can be seen as the "cultural gene of humanity" (Häberle, 1997).

The Principle of Integrity

Integrity is a philosophical concept that is closely connected with autonomy and dignity. It concerns the integrity of the human person and personality. The human person has a private sphere which can be described as the sphere of integrity. This sphere of integrity has at the same time a spiritual and a corporeal dimension: psychical and physical integrity. The spiritual dimension can be expressed by the concept of the zone of the "untouchable" developed by the Danish philosopher Knud Erik Løgstrup. He argues in relation to psychiatry that a permanent focus on motives for actions rather than reasons constitutes an infringement intervention in the integrity zone of the individual (Løgstrup, 1982). The infringement in this zone of the "untouchable" by the psychiatrist may imply violation of the integrity of the person and therefore psychiatry should rather be silent concerning the personal "untouchable" aspects of the human person. This concept can be generalized as a definition of integrity. Integrity in this sense concerns the untouchable core of the personality that must not be subject to unwanted external intervention. In a wider context, this implies the necessity of the protection of the personal integrity of the individual, e.g., in the access to bodily integrity or in relation to protecting individuals in relation to public storing of personal data.

But the notion of integrity also implies certain physical characteristics. The bodily incarnated human subject can be said to constitute a zone of integrity. This is the personal body which belongs to the subject as such. The personal body can in

a phenomenological perspective be said to constitute a zone of what is personal and proper to the individual. This zone of the bodily incarnated personality is proper to the individual and in existential sense singular human person and is therefore "untouchable." This means that the human body and its parts form a sphere of integrity that is supposed to be treated with special care and comprehension (Dübeck, 1997). Here integrity implies the right to life and the right to decide about one's own death.

The concept of integrity can also be seen in a legal perspective. It is an old legal principle that has become new actuality in the present legal situation. In the legal sense, the principle of integrity originates in Roman law, where it originates in the Latin "integritas" and the other notion of Latin origin "intact" as well as "noli me tangere," that signifies what is "untouchable," undisturbed, and "not be touched." In the French legal tradition, this is emphasized by the notion of "L'intangibilité de la personne" (Arnoux, 1994). In addition, the principle of integrity plays an important role in declarations of human rights and the different European constitutions and can therefore as such be said to constitute a necessary presupposition for the development of biolaw. The legal reference to the integrity of the human person sets limits to biomedical interventions in the human body. It is the realization and protection of the private sphere as a personal zone of the "untouchable" where the individual is protected by limits to the permitted intervention in the autonomy and dignity of the human person.

The protection of the physic-psychical integrity of the human person is becoming more and more central in the formulation of legal norms concerning genetic manipulation and the protection of the human genetic structure. The right to inherit a genetic substance that has not been artificially changed is an important aspect of integrity. In this way, integrity is used to protect the personal identity of the human person in connection with manipulation. This does not only concern actual people, but it also applies to what is typical for the human species. Integrity protects the genetic inheritance of future generations and opposes the manipulation of the genetic patrimony and their genetic identity. Manipulations with the human body that substantially changes personal identity can be stopped by reference to the integrity of the human person and the protection of privacy. In this context, there is an intimate connection between integrity and the private sphere of the human person as subject to individual autonomy.

Furthermore, integrity does not only apply to the human body but also concerns a wider sphere of protection of social and economic aspects of the person. Special mention merits the right to protection of information about the person, but also the right to a minimum of economic and social protection of vulnerable and weak social groups. Economical and social integrity refers to the concern for the protection of a minimum of welfare of the citizens in a welfare state.

The different perspectives on integrity manifest the close connection between integrity, personal identity, and character. As early as in Plato's ethical theory, integrity had this meaning of basic moral virtue and human character. The psychical and physical aspects of integrity confirm this comprehensive definition and relate the right to privacy that is revealed by integrity to the concepts of autonomy and dignity (Rendtorff & Kemp, 2000).

Finally, integrity can also be said to apply to the legal system as such. Ronald Dworkin uses the concept of integrity to describe the political morality of a just legal order. In this understanding of integrity, judges and agents in the legal order are said to have integrity when they build their decisions on impartiality and fairness and contribute each person "equal concern and respect." This is seen in *Law's Empire* where Dworkin talks about political morality and the integrity of the judge as well as the whole legal system as such (Dworkin, 1986). This is the objective counterpart to the subjective definition of the integrity of the human person.

The Principle of Vulnerability

The principle of vulnerability is also a very important European principle in bioethics and biolaw. Recently, it has become more and more present in the philosophical discourse. One could argue that a philosophical anthropology of the vulnerable human condition is the foundation of this concept. Vulnerability can be seen as an expression of the human condition and is therefore not only a mere descriptive concept but rather a concept with an explicit, normative content. Vulnerability is also an important notion underlying the juridical regulation of human activity. One can say that law is fundamentally institutionalized in order to protect vulnerable human beings (Rendtorff & Kemp, 2000).

The French philosopher Emmanuel Lévinas has defined the concept of vulnerability as the foundation for understanding of the human condition. He analyzes vulnerability as the foundation of morality. Morality is a compensation for man's vulnerability. The moral imperative is an imperative to take care of the other and an ethical responsibility toward the other. In this way, vulnerability can be said to imply an immanent normativity where the vulnerability is expressed in the corporeal incarnation of the other, e.g., in the face of the other. The existence of the other person expresses vulnerability and demands ethical engagement. Lévinas argues that the imperative "Thou shall not kill" is an essential expression of the need to protect vulnerable existence (Lévinas, 1961). This shows the ethical function of the corporeal finitude of human beings that becomes the foundation of Lévinas' philosophy. In this perspective, the deepest point of morality is presented in the vulnerable situation of human beings in the world. Vulnerability manifests a nonsymmetrical imbalance between the weak and the powerful; it demands the ethical engagement of the powerful to protect the weak. It is a person's vulnerability that makes one receptive for the responsibility emanating from the other as a vulnerable being. This ethical receptivity is the fundamental point of the human condition. The same concern for vulnerability as a fundamental ethical concept can also be shown in Jürgen Habermas' philosophy. His argument for communicative understanding in a domination free dialogue also situates vulnerability in the center of the ethical concern. This is openness toward the vulnerable other being taking part in a dialogue (Rendtorff & Kemp, 2000).

Vulnerability is therefore an extremely important concept as the foundation of ethical notions of care, responsibility, and empathy with the other. Vulnerability motivates ethical concern for the fragility of the human condition. The human

condition is marked by an extreme degree of fragility because of the temporal and finite character of all human life. The bodily incarnated human subject is destined for death, and it is not possible to abstract from mortality and destiny as basic to human life. Instead one has to live with mortality but also to take care of the vulnerable situated subject (Callahan, 1992).

In this context, vulnerability can also be interpreted as an important legal concept and even as the foundation of the legal system. The British philosopher of law and jurisprudence H.L.A. Hart says that the vulnerability of human beings is the background for the regulation of its activities in rules of the social institutions (Hart, 1961). Legal organization, legal principles, and concrete legal rules have the task to protect the vulnerable human being confronted with the possibility of destruction and the interventions from other people and the state. It is the task of the legal regulations of the biomedical problems to protect the weakest and the poorest in society against the discrimination and destruction from other social groups.

Within the Framework of the Welfare State

As such the basic principles constitute a sphere of protection of the human person. It is however necessary to consider the basic principles in a larger framework of the European welfare state. In this context, the concepts of state responsibility and solidarity concerning the protection of the vulnerable human beings are of essential significance.

The principles emphasize the need to protect the bodily incarnated human subject in relation to the development in modern risk society (Beck, 1986). They are also necessary tools to secure the development of the right legal rules to protect the body of the individual. The permanent pressure on the intimate human body in modern society is the background for the necessity to see the principles in the larger context of social responsibility and solidarity.

Here the concept of care is correlative to the dignity, integrity, and vulnerability of the human person. The ethics and law of the human person are closely connected to the concept of care. The humanist Erasmus already saw this concept as the basic attitude of society toward the vulnerable and weak (Rendtorff & Kemp, 2000). In modern biomedicine, the importance of care is especially present, not only between individuals but also between the state and individuals (Rendtorff, 2002). Against this background, the protection and care of vulnerable individuals becomes an integrated part of modern legal systems.

In *The Concept of Responsibility* the German-American philosopher Hans Jonas has given an argument for the thesis that the position of human beings in the modern world and the possibilities of domination and destruction of nature in industrial society have changed the ethical obligations of the human beings (Jonas, 1979). Society must be conscious about the responsibility not to destroy all life on earth. This implies state responsibility to set limits to social intervention in nature, animals, and the human body as well as a limitation of the ongoing destruction of the life-possibilities for future generations. The principle of responsibility is

founded on the intimate connection between the human body and the organic nature placing human beings as a part of the living world.

The duty to protect vulnerable and fragile life is an application of the categorical imperative in bioethics and biolaw. Jonas extends this to future generations. The imperative goes: "Act in such a way that the effects of your action are compatible with the permanence of genuine human life on earth" (Jonas, 1979 [1984], p. 11). This means that the protection of the autonomy, dignity, integrity, and vulnerability of the human person must be directed toward the protection of future generations and the variety of the species in nature to give future human beings the best possible conditions of existence. Therefore, the principle of responsibility functions as the foundation of the formulation of the basic ethical principles as legal principles. State responsibility implies conscious attitude, where decision makers respect autonomy, dignity, integrity, and vulnerability and put limits to a scientific and industrial development that manipulates the private sphere of the human person (Rendtorff & Kemp, 2000).

In a way, this concept of state responsibility is already present in the legal development in modern risk society where social intervention in the intimate sphere of the human person is more and more common. The French philosopher Paul Ricœur emphasizes the paradox that the re-moralization of the notion of responsibility means that one is approaching a society where more and more people as well as the state are responsible without being guilty. But he also shows how responsibility is responsibility toward the vulnerability of the other. He thinks that one has to find the right distance between risk, responsibility, and justice (Ricœur, 1995). While the principle of responsibility earlier indicated a well-defined juridical notion concerning attribution of responsibility for a specific action to a specific person, the intentional agent, it is the consequence of Hans Jonas definition of responsibility that human responsibility for future generations as a moral responsibility that goes beyond intentional legal agency and the following duty to take care of the week and the vulnerable must be seen as a part of responsibility. In other words, one is confronted with an extension of the content of the notion of responsibility, which means that we are also responsible for not doing anything to solve the global ecological and climate problems or the social problems of contributing with the adequate protection of the vulnerable populations. Today, it is possible to be responsible without having committed an error in a strict juridical sense. Juridical responsibility is also social responsibility. In the welfare state, this responsibility implies the duty to take care of the weak, the poor, and the sick people in society. The extension of the notion of responsibility in the modern welfare state implies that the welfare state in legislation and legal practice must continue the protection and care for the individual human body that earlier was a question of private activity or solely left to social institutions like the church and the medical profession (Rendtorff & Kemp, 2000).

The implementation of the basic ethical principles in modern legal practice does not only concern civil law and criminal law but it is also important in work, social and health law as well as in the legal system as such. The actual legal development shows an extended protection of the human person as the driving force in bioethics and biolaw. The French philosopher François Ewald shows in his famous book *L'Etat Providence* about the modern welfare state how risk society compensates for

work accidents, sickness, and social problems by developing an extended system of insurance – work and health insurance, collective systems of care that obligate firms and society to give compensation for social unhappiness even though neither the corporations nor society in a juridical perspective can be held responsible for the destiny of the individual (Ewald, 1984). In this way, many social insurances are created in opposition to the increased intervention in the intimate personality of the individual. At the same time, this means that legislation and juridical practice try to develop an extended protection of the human person by more or less implicitly applying the basic principles of autonomy, dignity, integrity, and vulnerability.

The link between responsibility and the protection of basic ethical principles constitutes the framework of social solidarity in the welfare state with regard to the formulation of norms for protection of the bodily incarnated human person in the welfare state. The project of care in the welfare state realized in social security as state responsibility protects the legal subjectivity of the vulnerable and weak. In most European constitutions, the basic principles are more or less present as indications of basic human rights of the personality. Legal subjectivity does not only imply taking part in a social contract, but is rather included as a subject for the protection of law. The legal subject has become the one who is worse respect and care (Ricœur, 1995). The subject of the law is to protect the autonomy, dignity, integrity, and vulnerability of the human personality.

The relation between basic ethical principles, rights, and protection of person and body must be seen as a consequence of the development of the welfare state and risk societies into a state of care and protection. Legal regulation is no longer built on a contractual relation between legal subjects but develops into a relation of social solidarity and collective responsibility that also concerns the basic principles related to bodily incarnated human person. In this way, law is built on social solidarity between the members of society. The law recognizes the autonomy of the individual but at same time, as the other three principles suggests, society has collective responsibility to put limits to the rights of the individual to its own body. The basic principles in relation to the human body must be considered in a broader perspective. The notions of dignity, integrity, and vulnerability are expressions of the necessary protection of the human body in the actual legal development and motivate a human rights–oriented duty to protection of the personal and corporeal sphere of the individual in the modern welfare state. In the framework of responsibility and solidarity, the basic principles confronted with the threat of powerful technological intervention in the personal sphere of the human person constitute an effort to formulate a humanistic conception of man as foundation of policy and legal regulation in the welfare state.

European Bioethics and the UNESCO's Universal Declaration on Bioethics and Human Rights

In fact, it is possible to see a strong influence of the European principles of bioethics and biolaw on the UNESCO *Universal Declaration on Bioethics and Human Rights* that implicitly can be said to be based on the basic ethical principles of European

bioethics. The concept of human dignity may be said to include the human body, because human beings are considered as a unity of body and soul, where the body has its own rights of protection of autonomy, dignity, integrity, and vulnerability. To respect the human body is therefore to recognize its dignity as manifestation of a human person. This concept of the human being does not only refer to the individual but to the common destiny of humanity as a form of life.

Already the previous UNESCO Declaration in the area of bioethics, the *Universal Declaration on the Human Genome and Human Rights* (1997), says that every human being has the right to respect for its genetic structure. Humanity ought to take care of the plurality and difference of our human genes. Society ought to have solidarity with those human beings who have weak genes and it should not systematically favor people with a specific genetic constitution and therefore, the Declaration characterizes the human genome in its diversity as the "common heritage of mankind." The human genome can be considered as an irreplaceable work of art, that we are required to protect. This concern for human dignity in genetic research is an international obligation, which goes beyond internal affairs of states and signifies that the interests of the individual always should prevail over the utilitarian use of the body in the interest of society.

When using biomedical technology, we have the obligation to respect human rights of autonomy, self-determination, and informed consent and indeed "the right not to know" if an individual does not want to know its own genetic structure. The *Universal Declaration on the Human Genome and Human Rights* connects human dignity with the legal notions of human physical and psychological integrity as an important foundation for regulation of biomedical progress. This does not mean that no intervention in the human genome should be allowed, but when gene technology is used for medical treatment, it should not be allowed to make interventions that have direct eugenic purposes of modifying specific human characteristics. The concern for the human genome as common heritage of mankind therefore includes the protection of valuable aspects of the genetic structure of future human individuals. At the same time, personal information about the genetic structure is considered as a part of the integrity and vulnerability of individuals. There is a close relation between protection of the right to privacy and this integrity that express the human body as a private sphere of self-determination.

We can deduce from the UNESCO *Universal Declaration on Bioethics and Human Rights* that the concepts of human autonomy, dignity, integrity, and vulnerability require concrete significance in bioethics and biolaw because protection of individual human beings prevails over the interests of science and society. Recognition of the significance of technological progress for collective interests, respect for the human body, extension of law to be valid for life before birth and after death and in relation to future generations are important aspects of this protection of human privacy based on protection of the inviolability of the human body. Thus, concern for human dignity precedes self-determination and society has a duty to avoid that human individuals in despair or desperation are forced to violate their own bodies in selling their organs or offering themselves for dubitable genetic experiments. The concept of humanity implied in the international conventions and

declarations can be considered as an expression of the humanism of the philosophy of the basic ethical principles that cares for humanity and wants the persistence of "real" human life on earth in the future.

Conclusion

In this chapter, the basic ethical principles of autonomy, dignity, integrity, and vulnerability in European Bioethics and Biolaw have been presented as essential to European perspectives in bioethics and biolaw. The results of the research project have been published in the BIO-MED research project report *Basic Ethical Principles in European Bioethics and Biolaw* (2000). Moreover, the research has led to the Barcelona-Declaration, proposed by partners in the project (1998), that gives a good indication of the policy implications of European bioethics (Rendtorff & Kemp, 2000; Rendtorff, 2002; Rendtorff & Kemp, 2009). Indeed, we can also see that the basic ethical principles are more or less implicitly or explicitly present in the UNESCO *Universal Declaration on Bioethics and Human Rights*. The principles are important to protect the life and dignity of bodily incarnated human person in biotechnological development, and they are historical and cultural incarnations of European morality and legal systems. They express the essence of a European human rights culture and the focus on the protection of human rights and personhood in European societies.

Indeed, the important European principles in bioethics and biolaw must be considered in the framework of responsibility, solidarity, and justice in the sense that the basic ethical principles concern the protection of human beings not only as isolated persons, but also as members of European societies and nations. In this sense, the basic ethical principles are founded in European democratic political thinking, where concern for the corporeal and psychical well-being of individuals is in the center of considerations of political philosophy in personalism, existentialism, and democratic political thinking. In this context, the basic ethical principles are not only European principles, but they also have a universalist and cosmopolitan possible application, where the concern for protection of human beings in the framework of the basic ethical principles also can be applied globally as an expression of a universal protection of the life and dignity of bodily incarnated human beings in biotechnological development.

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Latin American Perspectives

19

Fernando Lolas

Introduction

The geopolitical region known as Latin America is composed of countries and territories derived mainly from the Spanish and the Portuguese empires. The designation "Latin" stresses the fact that, culturally, the countries belong to the linguistic domain of the Romance languages derived from Latin. It was coined by intellectuals during the nineteenth century in order to differentiate these nations from Europe, the Slavic and Teutonic nations, and the Anglo-Saxon ones. The term seems to have attained currency after it was employed by French politicians and writers as a way of establishing the influence of French culture in an area dominated by the Spanish and Portuguese empires. Most of the countries where Spanish or Portuguese languages are spoken share similar cultural traditions, language, and customs, and became politically independent during the nineteenth and twentieth centuries. The expression Ibero-America is also used for countries derived from Spanish and Portuguese rule. Other designations apply to countries where Spanish is spoken: Spanish America or Hispanic America (hence the term "Hispanos" in common North American parlance). In most of these countries, the official language is Spanish, although other indigenous languages are spoken and sometimes also have official status (Quechua, Guaraní, Aymara, or Mayan). In Puerto Rico, as an independent state affiliated with the US, English is also official.

In such a sensitive area as ethical regulation and research oversight, the issue of language is not a negligible one. As it has become clear throughout the years, many international and national documents regarding bioethical issues either lose their connotations in English or acquire in translation shades of meaning not intended, or absent, in the original language. This is important when considering that the linguistic space of Latin America trying to accommodate intellectual import such as bioethics may not always interpret correctly the cultural underpinnings of

F. Lolas
Center for Interdisciplinary Studies in Bioethics and Department of Psychiatry, Clinical Hospital, University of Chile, Santiago, Chile
e-mail: flolas@uchile.cl

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concepts and uses. This applies to norms, regulations, and expressions translated and used for conditions and situations different from the original ones.

Although some degree of similarity could be expected, Latin American countries exhibit different histories and their public policies, governments, education, and insertion in the world economies make it difficult to generalize, especially in areas like health care or scientific research. The estimated Latin American population in 2010 was about 590 million and, among the countries, great differences in size and population can be observed. The majority of the population professes the Christian faith, mostly Roman Catholic, which was at some point in history the official religion of some nations. The political structure of most countries is that of a republic, although the continent has seen the emergence of dictatorships, *de facto* governments, and even attempts at establishing empires (e.g., Mexico). The poverty index ranges from 3.0 of Uruguay to more than 30 in Haiti, reflecting the disparities existent between nations. The inequities internal to each country are also important, with countries with high (e.g., Chile) and low (e.g., Haiti) human development indexes.

Intellectual Life

Indigenous cultures, prior to the arrival of European conquerors, had sophisticated systems of thought that can be reconstructed from the remnants of their empires. Their contribution to current scholarship is not evident. Academic philosophy can be dated back to the sixteenth century and was stimulated mainly by the Catholic Church, which established the first institutions of higher learning and scholarship in the Spanish colonies. At the beginning of the twentieth century, one of the dominant forms of philosophical reflection was positivism, contested by other streams of thought. Some prominent writers have expanded traditional Marxist and Christian thinking and adapted them to the particular environment of the Spanish-speaking countries. The continent is the birthplace of special forms of theological thinking, in particular the theology of liberation, and some forms of philosophical reflection inspired by European traditions.

In authoritative accounts of Ibero-American bioethics, the topic is usually dealt with on a country-by-country basis (e.g., Pessini, de Barchifontaine, & Lolas, 2010), reflecting the diversity of approaches, insights, and contributions from the nations comprising the continent. Bioethics became known to Latin American scholars during the 1980s, with precursors and pioneers in Argentina, Mexico, Colombia, and Chile (the names of José Alberto Mainetti, in Argentina, Manuel Velasco Suarez, in Mexico, and Alfonso Llano, S.J., in Colombia, are usually mentioned as pioneers in introducing bioethical thinking to the continent). The most common form adopted is the principialism emanating from the Belmont Report in the US and the seminal work of Beauchamp and Childress stating *prima facie* principles that appeared to offer a practical way of posing and solving moral dilemmas in the biological and medical sciences. Since then, the number of institutions bearing the word *bioethics* in their title, courses offered in bioethics,

and people engaged in what could be called bioethical discourse has grown steadily (Lolas, 1998). Currently, diverse forms of bioethics are present, including feminist approaches, personalist bioethics, ecological ethics, and others. In some quarters, a confusion between bioethics as an academic enterprise and bioethics as a political discourse related to human rights and protests against poverty, inequities, and political corruption determines a picture in which it is difficult to evaluate quality of the contributions.

History and Context

Most Ibero-American countries were freed from the imperial tutelage of Spain and Portugal during the first half of the nineteenth century. The period immediately following the Conquest is known as the Colony, and the dominant climate was one of paternalism in the relation between the Metropolis and the colonies. The French invasion of Spain at the beginning of the nineteenth century (1808) and the replacement of the Spanish king by Jose Bonaparte led to a nationalist movement, both in the Iberian Peninsula and in the colonies. It found expression in "*juntas*," governing bodies that produced constitutional documents and initiated a movement toward independence that consolidated after struggles against Ferdinand VII, the reinstated king, when he and his advisors did not understand that many of the juntas had been established in order to preserve, not to alter, the king's sovereignty. Inspired by the French and American Revolutions and the 1776 Constitution of the United States of America in the North, many colonies started to develop their own independentist movements inspired by free thinkers and the freemasonry. The struggle against Spanish rule was different in Brazil, which was ruled by the Royal Family of Portugal, settling there for some years, and initiated by a member of the Royal family.

The ruling classes in the remnants of the Spanish Empire were composed by "*criollos*," mostly of Peninsular and local stock, whose attitude toward the aboriginal inhabitants of the continent (known as "Indians" by the old Columbian notion that these territories were the Indies sought after by colonial powers) was no better than the one held by Spain. In point of fact, in almost all of the newly formed nations or countries, the Indians or aborigines were badly treated and left without the protection accorded them by the Spanish rule. This historical fact is a starting point for discussing part of the inequalities and the inequities that prevail in communities highly stratified by race and ethnic origin, despite declarations to the contrary in most political constitutions. The importance of multiethnicity and multiculturalism has to be considered when analyzing the application and scope of generalizations regarding human rights, ethical attitudes, and academic consolidation of bioethics.

While in some countries the Indian past and origin are greatly appreciated and vindicated, in others the traces of their influence have been diluted or lost. From an anthropological point of view, this might constitute one of the sources of the tension between different identities experienced by inhabitants and elites of the countries.

They sometimes reject completely the influence of Europe or of the new world power constituted by the United States of North America or fail to come to terms with a pervasive influence on their habits and commodities. Much of the militant voices raised against "foreign influence" will not reject enjoying the money and facilities of the imperialist countries while at the same spending time and effort in vitriolic discourses against them. The quest for identity, not always recognized as a source of tension, explains much of the superficial approaches to relevant bioethical issues in many areas of real concern.

Research ethics curricula and bioethical discourse (as an intellectual import) face the challenge of multiethnic and multicultural contexts existent in Latin America, whose indigenous population averages 11 % but varies widely, with 80 % in Bolivia, 60 % in Guatemala, and 40 % in Peru. Even language diversity is a factor hampering research, particularly in the field of social studies and public health. Stigmatization has been found to affect genomics research in populations, and the need for a "culture fair" approach to data gathering and interpretation is as an ethical an imperative as the need to respect dignity or request consent. The notion of "ethical sustainability," essential in continent-wide work, stresses what international documents identify as fundamental in the pursuit of science at the service of development. The UNESCO Universal Declaration on Bioethics and Human Rights, among other documents, underscores the vulnerability of resource-poor populations and the ethical imperative to avoid the typical "safari research": researchers from affluent societies behave as "data hunters" and disregard opportunities for real collaboration. A permanent dialogue between scientists and scholars from Latin America and those from other continents is essential if the "bi-directional" character of all ethical dialogue is to be preserved.

The history of the continent exhibits cases where human dignity was disregarded in the pursuit of scientific goals. Some vulnerable populations in the continent have fallen prey to commercial interests of pharmaceutical companies or research interests of academic institutions from industrialized countries. The ensuing mistrust in the scientific enterprise is a powerful stimulus for developing local forms of ethical oversight in consonance with community interests, cultural traditions, and scientific development. Although vulnerability is part of the human condition, and cannot be simplistically attributed to certain groups of people, it is evident that many illiterate masses in the Latin American continent, ignorant of their rights and without access to the benefits of civilization, are vulnerable to exploitation and discrimination. This may partly explain the curious phenomenon of inferiority complexes that result in aggressive stances against dominant world cultures.

The very notion of bioethics and its attendant methodology as an intellectual enterprise is an import introducing the tenets and fundaments of the culture in which it was born and its standards of scholarship and argument. The idea of a dialogical transdisciplinary discipline and other features are caricaturized in attempts at "re-discovering" the same under new terms or gestures.

The search for new fields of inquiry and problems is a recent feature of Latin American bioethics. Roughly *three periods or stages* can be discerned in the development of bioethics in the continent. A first one is characterized by contact

with publications from the US and reproduction of ideas and topics. A second period marks the sometimes critical reaction to bioethics methods and problems. Finally, a third stage of creative appropriation and original developments is visible only in selected groups or centers. The influence of European thinking has begun to be felt in more recent decades.

As a social *process*, bioethics has arisen out of emotional reaction towards undesirable effects of science and technology, which in the continent has been associated with the effects of imperialism and dominance from the North. As *procedure* for arriving at decisions, the social institution of the committee or the national commission has been adopted as the standard of practice. Finally, as an academic *product*, the Latin American scenario is rich in initiatives, although not all of them of equal merit or value.

In all three forms of conceptualization of bioethics, peculiarities can be worked out. For instance, a national commission for analyzing and deliberating on bioethical issues, modeled after the European model, presupposes a democratic frame of mind and clear organization of the state in order not to produce conflicts with the legal system. Academically, the relation of students to teachers and opinion leaders is influenced by the cultural traditions. In general, it may be stated that the period of assimilation of bioethics, still unfinished, will certainly lead to institutions adequate to the idiosyncrasy and uses of the populations.

Norms, Laws and Regulations

The version of bioethics that achieved early and widespread currency in Latin American countries is the one which places great emphasis on the medical and biological importance of the bioethical tradition and discourse. Of the two original strands discernible by the second half of the twentieth century, one emphasizing ecological concerns and the other insisting upon rehumanizing medicine, the latter is most commonly associated with the word. This is certainly changing as time goes by, but it is evident when considering the impact of bioethical thinking upon norms and regulations. Bioethical principles are frequently invoked in the fields of hospital care and the relation between healthcare professionals and the population. They also find expression in norms, regulations, and laws related to scientific research. In all the countries of the continent, consideration to ethical standards is given to hospital and ambulatory care, with legislations passed on such diverse subjects as patients' rights, access to treatment, and duties of medical professionals toward users of healthcare systems. In the majority of the countries, biomedical research is regulated by technical norms complementing and expanding the ethical principles held by transnational drug companies or scientifically advanced countries (in the continent, the presence of US research is widespread). A useful compilation can be found at the website of the Office of Human Research Protection, updated every year (www.hhs.gov/ohrp/international/index.html).

A National Commission of Bioethics (or a commission at the national level with a similar designation and comparable tasks) is not present in every country as an

active body recognized as essential for democratic dialogue. In some cases, the political orientation of those who proposed it or the compromises of some of their members made consensus difficult. In others, difficulties concerning the scope and character of the national body were voiced. Viewed in perspective, most of these national bodies are related to the health sector and serve as advisors to governments in the areas of scientific research, health policies, and general orientation of the legal system as it relates to health care and research. In only a few cases do these bodies enjoy sufficient financial and administrative autonomy to serve as a critical forum for discussion on policymaking or legislation. One notable example is Mexico, with a funded national commission operating throughout the entire country. The first countries to establish such national commissions were Argentina and Mexico in 1992, followed by Cuba (1996), Dominican Republic (1997), Ecuador (1998), Venezuela (1998), Colombia (2001), Uruguay (2001), Bolivia (2003), Costa Rica (2003), Panama (2003), and El Salvador (2009), among other countries. In some countries, the bioethics body is part of a preexisting institution, like Peru, incorporated into Consejo Nacional de Salud. In Brazil, a national commission devoted to research has operated since 1996. These bodies have different origins, forms of operation, scope of influence, and activities. In Chile, for instance, a law from 2006 rules that the members of the national commission will be appointed by the Senate upon proposal from the president of the republic.

The existence of hospital ethics committees, research ethics committees, and ethics committees of professional associations is already common in all the countries of the Latin American continent. Overall, the quality of their work and performance are difficult to ascertain. Many of them are composed by members not duly qualified to the tasks, and accreditation by international agencies is not a common practice. Perhaps the main weakness is the lack of appropriate legislations and regulations. In addition, the general culture does not consider work in these bodies as equivalent to administrative, clinical, or research activities, and time and effort of members are not compensated financially or in terms of professional promotion.

Teaching and Training

Advanced programs and training opportunities exist in almost every country in the Latin American region, some at the level of doctorate. The progressive inclusion of bioethical topics in undergraduate training has resulted in a wide array of opportunities for professionals in the biological and health sciences. However, many teaching programs replicate what used to be taught as professional deontology, legal aspects of the professions, or miscellaneous topics not included in other areas. A unified set of concepts, methods, and aims of these teaching activities would greatly facilitate the constitution of a disciplinary discourse and would improve accreditation practices. Several initiatives in this direction have come from the work of a group of practitioners under the aegis of UNESCO (RedBioética), or from

institutions offering virtual courses in several languages (e.g., the CITI program promoted by a consortium of institutions, mostly in the US, with a Spanish language version widely used in Latin America).

In the training sphere, the imprint of the ideological orientation of the institutions is evident, with manifestations of doctrinarian character in the position towards issues like abortion, euthanasia, assisted reproduction, and research. The aim of regulatory bodies to have professionals conversant with responsible conduct of research, appropriate policymaking, and respect for human dignity and rights is not always evident in advanced curricula. Despite the interest and enthusiasm on the part of institutions for advanced training, a general picture of confusion emerges. It is a common experience that persons with advanced degrees in bioethics do not find appropriate working opportunities in the field and continue performing duties at institutions that either do not value appropriately this expertise or do not have enough funds to profit from bioethical training (i.e., improving the work of clinical, professional or research ethics committees, accrediting oversight bodies, etc.). This signalizes a potentially limiting factor in the effort to increase the "bioethical alphabetization" of scientific and practice communities and hampers the development of a truly representative form of bioethics in Latin American countries.

During the 1990s, several master's programs were established in leading institutions of the region with the aid of the Complutense University of Madrid. The Bioethics Program of the Pan American Health Organization (PAHO), which existed until 2010, was a joint venture with the University of Chile and the Chilean government. In addition to encouraging training, it helped publish the journal *Acta Bioethica* (ISSN 0717–5906), a trilingual publication (English, Spanish, Portuguese) of the Centro Interdisciplinario de Estudios en Bioética (CIEB) of the University of Chile, indexed in most relevant databases of scientific and medical literature. The CIEB also edits series of books and monographs freely available at the websites www.bioetica.uchile.cl and www.actabioethica.cl. The trend toward establishing advanced degrees in bioethics has accelerated and institutions strive to have masters or doctorate programs as a matter of prestige and influence. The question about the employability and real working opportunities for these graduates is seldom posed. Master's-level programs in accredited institutions are on the rise, with varying degrees of involvement. Useful information can be obtained at the universities involved, and also at the UNESCO website (www.unesco.org).

Not many continent-wide initiatives exist and the ones that do, for instance the work of the Fogarty International Center of the National Institutes of Health, meet with resistance in some quarters for the prejudice indicated before that it might represent a pervasive form of ideological penetration. There are other initiatives stemming from cultural and international foundations and institutions, but efforts to constitute a unified group of practitioners and a set of standards of practice are in the process of consolidation. Mutual recognition of credits and activities between universities and other higher learning institutions presents some difficulties, which can be solved by conjoint efforts.

Institutionalization of Bioethics. Organizations and Societies

The UNESCO GEOBS database lists 68 institutions bearing the name bioethics in the region of Latin America. Some of them are programs or institutes, others are teaching facilities.

There are active users of the bioethical discourse in all countries of the region, with the establishment of hospital, research, and professional ethics committees and a reasonable knowledge of international regulations and practices. The actual situation, as it appears in field studies and through anecdotal evidence, is different from what is claimed by some authors, with inappropriate or inexistent policies for obtaining informed consent, scarce attention to research integrity issues, no specific training on responsible conduct of research, and a discussion climate dominated by political/ideological slogans when not by religious biases. The impact of bioethics on policymaking is more a rhetorical device than an actual practice. In the continent, with its gross inequities in access to health care, it could be said that a large *know-do gap* exists. Much of the knowledge accumulated and of the technologies developed does not reach large segments of the population. This is probably one of the greatest bioethical challenges as it affects public health and well being of populations.

In the course of its development, bioethical discourse has also found expression in the constitution of associations and groupings. FELAIBE (Latin American Federation of Institutions in Bioethics) was initiated by the pioneers Alfonso Llano, Colombia, José Alberto Mainetti, Argentina, and Manuel Velasco-Suárez, México, and has survived a series of avatars. It organizes meetings, identifies prospective contributors to the bioethical movement, and brings together professionals from different backgrounds. FLACEIS, expressly devoted to research ethics committees, has more or less the same aims concentrating on research ethics and its practice in different countries. In many countries, local bioethics societies exist, with membership from active professionals in the fields of medicine, the sciences, and the law. Groupings such as the so-called RedBioética with relation to UNESCO, transient societies organizing meetings, and NGOs also work in the broad area of bioethics. During the existence of the Pan American Health Organization (PAHO) Program on Bioethics, this group also served a continental purpose of bringing together practitioners and scholars from different countries. Other professional societies have either direct connections with the bioethical discourse (like Sociedad Iberoamericana de Derecho Médico, SIDEME) or have constituted "bioethical chapters" within their respective organizations. Many professional associations have also incorporated the term *bioethics* for some of their activities.

Belonging to a national society or academy does not always constitute proof of competence or scholarly background. Membership is subject to waxing and waning, depending on the need to establish good professional contacts or acquire influence. Although the same happens in other parts of the world, the climate in many Latin American countries is signaled by a context in which political and administrative corruption, both actual and perceived, demands an analysis of the level at which certain customs or activities may affect scientific integrity, good

clinical practices, and professional conduct. It is expected that the work of societies devoted to bioethics may have an impact on societal regulation of moral behavior.

Bioethics societies exist currently in all countries of the Latin American region, and their structure, membership, and contributions can be consulted in the chapters devoted to each country.

At universities and other teaching institutions, bioethics (or some of its derivatives) occupy a place in curricula and are represented as institutes, centers, or study groups, with or without third-party support.

A Typology of Perspectives

In many respects, Latin America is a continent in transition. For instance, it finds itself in an epidemiological transition. Old diseases of poverty and underdevelopment, such as infectious diseases, coexist with diseases of civilization, such as chronic ailments. In the bioethical sphere, there is also a transition. The problems inherent in the state of undeveloped independent thinking coexist with sophisticated analyses of individual rights and access to the benefits of civilization. Political thinking influences the uses of bioethical discourse at the macro level in the countries of the Latin American region, as evinced by the conformation of national commissions and advisory bodies. The term *bioethics* has become current in common parlance, at least in professional circles. Everywhere groups are established, courses offered, and journals published with the word *bioethics* in their designation.

Several streams can be discerned in the continent. On the one hand, there is the influence of the Catholic Church and other Christian religions, which try to impose their agenda on the bioethical discourse. On the other hand, a strong secular movement, mostly imposed by the economic and social realities, is evident in policymaking and the establishment of guidelines and regulations for research and clinical practice. The university work is reflected in training programs at the master's level, in the teaching of undergraduates in the sciences, and in the publication of a growing body of literature, not always original but indicative of an interest in the furtherance of bioethical knowledge.

In the overall picture, there are countries with low development of bioethics, countries in the process of acquiring the bioethical discourse, and countries with developments at the institutional and conceptual levels. Among the latter, the examples of Mexico, Brazil, Argentina, Colombia, and Chile can be mentioned. In these countries, several groups have been formed, sometimes in contradiction to each other, but reflecting an enduring interest in bioethics institutions, discourse, and applications. The existence of discrepant views about different topics of social interest is a sign of maturity, provided the canons of tolerant discussion and the acceptance of differences are respected. This is not always the case, with militant groups claiming to have a monopoly on human rights and institutional organization.

The existence of national bodies for bioethics counseling of governments, ministries of health, and society in general is widespread. However, the existence

of these bodies does not always mean that they are consulted or that they make a contribution to the discussion of issues. In many cases, they are nominated on the basis of political proximity to the leading parties, and, in others, they are not provided with sufficient funds for a proper functioning. The case of Mexico can be singled out as a commission endowed with adequate means for serving the needs of a federal country, a reasonable budget, and enough personnel to fulfill its mission.

Publications and Scholarship

There are several periodic publications in different countries. With few exceptions they are not included in international index services. Books bearing the word *bioethics* in the title have been produced in almost all countries in the continent. Originality of contributions, as estimated by current standards of scholarship, is not a strong characteristic. The road to a mature scholarship is hampered in the institutions due to a lack of opportunities for working in the area at academic and learning institutions.

The existence of publications in each country depends on adequate funding and, more critically, on the continuous production of intellectual deliverables. The overall quality of the publications in the periodicals surveyed is acceptable. However, there is a great need for achieving a more original contribution to world bioethics and more rigorous standards for publication. When analyzing medical and scientific publications, the results regarding ethical considerations are mixed.

As an academic community develops, students should be aware of the developments that take place. Like other communities of this type, objectionable practices arise, with plagiarism, fabrication and falsification of data, biased accounts, and ideological orientations of arguments. In many respects, an "ethics of bioethics" is needed in Latin America.

When viewed globally, the contribution of Latin American scholars is still in need of a more critical analysis and deeper compromise with standards of scholarship. The production of written materials and websites has increased ostensibly in the last decades. The listing of periodic publications, their publication policies, and the impact of their contributions is considered in the chapters devoted to each country. The following list, compiled by Dr. E Rodriguez, Santiago, gives an idea of those titles in Spanish or Portuguese that have been present in most libraries (for supplemental information, the reader is referred to the Scielo, Latindex, or Scopus databases).

Journals Related to Bioethics in Latin America

Acta Bioethica. Centro Interdisciplinario de Estudios en Bioética, Universidad de Chile

Ars Bioética. Campo de Estudio Principal Bioética, Universidad Nacional Autónoma de México

Ars Medica. Revista de Estudios Médicos Humanísticos. Universidad Católica, Santiago

Bioethikos. Universidad Sao Camilo, Brazil

Bioética. Revista del Centro Juan Pablo II de Bioética, La Habana, Cuba

Bioética. Revista del Conselho Federal de Medicina de Brazil

Bioética y Bioderecho. Revista del Centro de Investigaciones de Filosofía Jurídica y Filosofía Social. Facultad de Derecho. Universidad Nacional de Rosario. Argentina

Bioética desde América Latina. Universidad Nacional de Rosario

Bioética, Educación y humanidades Médicas. Fundación Internacional Cataldi Amatriaín. Argentina

Bioética un desafío del tercer milenio. Fundación Fraternitas y Universidad Católica de La Plata

BIOPHRONESIS. Revista de Bioética y Socioantropología en Medicina, Revista online. Universidad de Buenos Aires. Facultad de Medicina. Departamento de Humanidades Médicas.

Cuadernos de Bioética. Buenos Aires. Edición impresa y online.

Diálogos de Ética y Bioética. México, Seminario de Ética y Bioética. UNAM.

Medicina y Humanidades. Revista de Bioética, Medicina y Filosofía. Escuela de Medicina Sur de la Universidad de Chile

Medicina y Ética. Revista del Instituto de Humanismo en Ciencias dela Salud, Facultad de Bioética, Universidad Anáhuac, México

Persona y Bioética. Centro de Bioética, Facultad de Medicina de la Universidad de La Sabana, Bogotá.

Perspectivas Bioéticas. Facultad Latinoamericana de Ciencias Sociales (FLACSO) Argentina.

Quirón. Revista de Humanidades Médicas. Fundación Mainetti, Instituto de Bioética y Humanidades Médicas. La Plata, Argentina.

Revista de Bioética Latinoamericana. Facultad de Medicina, Universidad Los Andes, Mérida, Venezuela.

Revista Brasileira de Bioética. Sociedade Brasileira de Bioética. Cátedra UNESCO de Bioética, Universidade de Brasilia.

Revista Colombiana de Bioética. Departamento de Bioética, Universidad El Bosque.

Revista Latinoamericana de Bioética. Universidad Militar de Nueva Granada, Bogotá.

Revista Sociedad de Ética en Medicina. Edición electrónica. Buenos Aires, Argentina.

Selecciones de Bioética. Revista del Instituto de Bioética CENALBE, Universidad Javeriana, Bogotá.

Vida y Ética. Instituto de Bioética. Facultad de Ciencias Médicas, Universidad Católica Argentina, Buenos Aires. Año de inicio: 2000.

Future Prospects. Toward a Biocentric Ethics for Latin America

In a continent characterized by inequities and social disparities, undoubtedly the most pressing need is sound reflection on social issues from a bioethical point of

view and with the capacity to influence political and technical decision-making. To this end, current state of development seems a good starting point but one that does not ensure realization of the expectations of large segments of the population. A resolution of the know-do gap will certainly need to improve education, communication, and professional training. A resolution of the gap between what is available and what problems should be solved needs political elites well aware of their responsibility towards the public and academic elites really believing in dialogue and tolerance for contributing to the developmental effort.

The main decision to be taken is whether to professionalize the work in bioethics or make it an ancillary discipline to the training of health and other professionals. This should be responded to by stating that, aside from alphabetizing the communities, making them aware of their rights and duties, professionals that are capable of original thinking should be trained, who can liberate themselves from self-imposed constraints, such as the rejection of outer influences or the ignorance about the true position of their contributions in a globalized world of knowledge.

As a continent in transition, with disparities and differences, there is the expectation that collaboration between the countries could be achieved. To this end, all forms of expected or alleged supremacy of one over the others should be avoided and a climate of dialogue and collaboration should ensue. Tolerance is a much-needed attribute of the societies, all the more so in places where funding is scarce and opportunities for development rare.

The political and socioeconomic climate greatly influences academic endeavors, and bioethics is no exception. The countries of the Latin American continent rank high in perceived and actual corruption in government and administration. Issues discussed in academic circles, or considerations related to health research and health care should be considered against the background of this societal characteristic. As a continent with great inequities in access to health care, the benefits of scientific progress or the welfare of civilization, the influence of bioethical thinking is undoubtedly more than a luxury and should be considered a necessity of the times.

Fundamental Issues

There are fundamental issues related to psychosocial and biomedical research in Latin America. One is the very notion of research. Standards of scholarship and university training are not uniform throughout the continent. This affects the way in which ethics is considered. Sometimes it is possible to argue that to insist on the ethical oversight of scientific practices is misguided, considering that the idea of what research really is is fuzzy or nonexistent in some contexts. In point of fact, research is frequently confused with other activities, such as surveillance or industry-guided clinical trials, or areas such as social science where the need for ethical evaluation is not considered due to a presumed low risk. These misunderstandings may need some time to disappear and may require an in depth-analysis of cultural practices. An exploration of what research really is in different cultural

settings constitutes an interesting field of inquiry. Some aspects of this cultural difference in conceptualization and of the difficulties in devising appropriate methods to tackle with ethical issues were addressed by the Program on Bioethics of the Pan American Health Organization (PAHO), a collaborative effort of the Chilean Government, the University of Chile through CIEB, and PAHO, which was operative from 1994 through 2010. The history and development of science funding in Latin America is a much-needed enterprise and should be pursued alongside training in ethics and integrity (Lolas, 2006).

The experience gathered throughout the years has demonstrated that an ethical approach to science and technology, in the current state of development of disciplines, by necessity must incorporate specialized knowledge, be based on deliberation and dialogue, and depends on an organic and cohesive community. This community includes researchers, policymakers, politicians, administrators, students, and laypeople. Because research is a cultural process shaped by expectations, hopes, and practices, it cannot be examined isolated from other aspects of social life. In point of fact, ethical oversight of research cannot be treated independently from the general "ethical level" of the community at large. Political and administrative corruption, if present in a country and accepted as normal, cannot be irrelevant for the establishment of sound scientific practices. The notion of *ethical sustainability* suggests that any change in attitudes, goals, and practices must be based on sound argument and endure over time. A sustainable effort depends critically on the establishment and maintenance of communities: epistemic communities (or cultures), practice communities, and moral communities. These communities rarely overlap, although it might be expected that the moral one embraces the others and its foundations include knowledge and its applications. A biocentric ethics is not simply another form of applied ethics. It represents a change in the paradigmatic construction of the moral universe. It goes beyond the classical anthropocentrism in the formulation of moral imperatives. It is knowledge on how to produce, expand, and apply knowledge. It is also an indication that the very foundation of welfare and progress includes a joint consideration of goals and means; goals formulated as culture and civilization, and means legitimated by discursive practices permitting respect of persons, living beings, and environment, tolerance of diversity, and agreement on basic principles of communality. To achieve this long-term goal, adapted to the historical peculiarities of a world region and started from the analysis of biomedical and psychosocial research, one's contribution depends on dialogue and common discourse. The establishment of a network of users of the bioethical discourse has been an important mission of several institutions and will continue to be in the future.

Common Features of Latin American Bioethics

Among the features that seem to be characteristic of Latin American bioethics, one that is frequently mentioned is the communitarian orientation, as opposed to a more individualistic approach (Bulcock, 2010). This assertion is in need of empirical

demonstration, for the fact that extended families participate in decision-making processes in health care or care for their elders is probably valid in some rural areas but it does not seem a universal characteristic of urban populations, particularly in the great megacities of Brazil or Mexico. While it is true that some ethnic groups do in fact show a predominant orientation towards group decisions (relevant in obtaining informed consent and necessarily of importance for conducting medical research), the characterization of bioethical thinking as communitarian, which stresses a potentially important difference with the bioethical discourse from the North, it is not an exclusive character of Latin American bioethics (Lolas, 2009).

Perhaps more interesting to note is the fact that bioethical discourse – or something akin to it – is manifested and applied in the context of sociopolitical interests. While these sometimes overlap or are confused with academic pursuits, the impact it has on the institutionalization is not negligible. Under the name of bioethics, political agendas seeking social justice or opposition to conservative movements are promoted. At the same time, religious orientations manifest other forms of utilization of the bioethical discourse for the benefit of other groups. In no way do these utilitarian uses of the bioethical enterprise serve the cause of developing an academic discipline, as it seems to be the case in other traditions. It is not the content but the manner of implementing the discursive practices that separates Latin American contributions from other traditions and contributes to its identity. As indicated above, the formative stages of Latin American bioethics can be characterized by replication, critical appropriation, and creative contribution. The latter is still a development to come in the form of critical decisions regarding institutionalization. For instance, despite manifest efforts to establish graduate programs and generate specialists in bioethics, it is by no means clear whether the social demand allows for the existence of professional bioethicists, whose role in the scientific or the professional spheres is far from clear, or whether the contribution of academics to pressing needs of the communities will have the effect expected from political and social reform. That bioethics may constitute a weapon for social struggle against imperialism or against political orientations is not a proof that its fate as an academic discipline is obscure or nonexistent. Remembering the admonition of one of the world pioneers of bioethics, the German theologian Fritz Jahr (1895–1953), one of the first and foremost duties of a community of ideas is to use properly the language it employs. The fuzzy boundaries of topics surrounding human rights, social justice, the search for truth, and others make it imperative that the bioethics community in Latin America devotes its best efforts to carefully demarcate fields of interest and inquiry and to not abuse a term that has become polysemic and partly useless because of abuse. The construction of an academic discipline depends on the existence of a critical group of persons respectful of the rights of others to dissent, tolerant of the differences, and devoted to academic pursuits in the first place.

The great inequities observable in access to the benefits of science and civilization are a good stimulus for the development of a local Latin American bioethics. Social injustice and exclusion, discrimination against minorities and disadvantaged populations, and great deficiencies in the provision of social services are among the

challenges faced by Latin American bioethicists in the near future. Some of these challenges are not much different from the ones observable in other regions of the world. The creative solutions and the importance of ethical discourse in posing the right questions and searching for the appropriate answers will depend to a great extent on the work of dedicated practitioners and academics, on intellectual solvency, and on the recognition by society at large of the importance of bioethics for posing dilemmas and choosing adequate responses (Lolas, 2010a, b).

The continent is a natural reservoir of biological diversity, thus bringing the ecological aspect of macrobioethics to the forefront of preoccupation and interest. Ecological ethics, the somewhat forgotten strand of thought at the very beginning of the origin of European bioethics, with Fritz Jahr, and American neo-bioethics, with Aldo Leopold and Van Rensselaer Potter, has an important role to play in developments that should take place in Latin America. Biological diversity is of interest not only from a theoretical point of view. It has a darker side when the exploitation of it by imperialistic powers is considered. The search for gold and riches was one of the great forces behind conquest and colonization. The exploitation of the natural resources without benefiting the populations of the continent is a serious bioethical concern that should have a place in the development of the discipline with a distinct Latin American emphasis (Brena, & Teboul, 2009).

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North American Perspectives

20

Lucie Kalousova and Raymond De Vries

Introduction

Scholars disagree on exactly when bioethics was "born." Was it in the years immediately after Nuremberg? Was it in the 1950s with the move of "pastoral medicine" into the realm of ethical confrontation? Was it in the late 1960s and early 1970s with the founding of the Hastings Center and the Kennedy Institute? While the exact date of the birth of bioethics as a distinct area of inquiry and practice is debatable, it is clear that bioethics is now part of the landscape of the life sciences in the United States and Canada. In both countries, accrediting agencies have declared that hospitals must have a mechanism for considering ethical issues that arise in patient care, all federally funded research that involves human beings or animals must be reviewed by a board constituted to protect the subjects of research, biotechnology corporations regularly appoint "ethics advisory boards," a plethora of seminars offer training in bioethics for those who need – or wish to offer – ethical advice, and bioethics courses have become a regular part of the curriculum at universities, colleges, and medical schools. It would be even fair to say that the bioethics discipline crystallized and emerged from North America (Fox, Swazey, & Watkins, 2008; Roy, Dickens, & Williams, 1993). Given that bioethics is well established in these North American countries, the *Universal Declaration on Bioethics and Human Rights* has the difficult task of finding its way into preexisting frameworks for thinking about matters bioethical. Furthermore, the *Declaration*, with its emphasis on communal good and responsibility for future generations, must contend with an approach to bioethics that has, until recently, given little attention to justice, focusing instead on autonomy and individual benefit.

L. Kalousova (✉)
Department of Sociology, Department of Health Management and Policy, University of Michigan, Ann Arbor, MI, USA
e-mail: luciekal@umich.edu

R. De Vries
Department of Medical Education/Department of Obstetrics and Gynecology, Department of Sociology, Center for Bioethics and Social Sciences in Medicine, University of Michigan, Ann Arbor, MI, USA
e-mail: rdevries@med.umich.edu

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This collision between the history of bioethics in North America and the *Declaration* has kept the impact of the UNESCO document on the practice of, and debates within, bioethics in this region to the minimum. Indeed, the arrival of the *Declaration* was barely noticed in North America. Six years after its enactment, there is little evidence that it has played the role the drafting committee had intended – as a guideline for policy makers and practitioners (Solbakk, 2011). Aside from its mismatch with bioethical ways of seeing in North America, some commentators believe the Declaration has been ineffectual because of its use of vague language and its lack of direct recommendations (Macpherson, 2007; Schuklenk, 2010).

In order to situate the Declaration in the North American context, the chapter begins by recounting the foundational moments and historical trajectory of bioethics in the region and then moves on to examine the meaning of the individual articles in this social and cultural setting. An evaluation of the impact of the Declaration on the bioethics conversation in North America concludes the chapter.

Historical Development of Bioethics in North America

The United States and Canada have well-developed institutional bodies for deliberating on bioethical questions and for developing regulations pertaining to research and clinical ethics. Federal organizations and ad hoc committees offer guidance on ethical issues in the life sciences and medicine; federal research funds are available for exploring the ethical, legal, and social implications of new medical technologies; and several universities have "centers for bioethics" that do research, offer advice to clinicians and researchers, and contribute to the education of health professionals and research scientists. This network of bioethical bodies emerged from the community of North American scholars who began exploring ethical questions in medicine and the life sciences in the 1960s. Their work was a turn from the traditional practitioner-dominated approach to medical ethics to a more inclusive discussion. As Keirns, Fetters, and De Vries (2009) note:

> In the 1960s and 1970s a series of scandals, together with unprecedented technological challenges in medicine, transformed the insider's game of medical ethics to an interdisciplinary project that came to be called 'bioethics'. The ethics of medicine became a topic, not just for medical practitioners, but for scholars from the humanities and social sciences; these 'strangers' to the clinic and the research laboratory began to make judgments about the moral problems of medicine.

Because North American bioethics is informed by a strong awareness of its founding moments and because, as Fox puts it, "[North] American bioethics is an expression and a part of the society and culture from which it has emanated" (1996, pp. 5–7), it is necessary to offer a bit of detail about how bioethics came into being in the United States and Canada in order to understand the reception of the *Declaration* in North America. There exist several accounts of the beginnings of bioethics, a reflection of the fact that the recounting of the genesis of a discipline is inevitably an exercise in aligning one's historical and political imaginations.

While some North American bioethicists prefer a historical narrative that favors strong political leadership of a few outspoken individuals, others place more emphasis on gradual change. Fox et al. (2008) identify several major competing stories of the emergence of bioethics in North America. These stories can be divided into two main accounts. The first contains event-centered "big bang" perspectives that see the emergence of bioethics as a response to new technological developments or hotly debated issues. The second account includes narratives that attribute the rise of bioethics to "a number of converging social, cultural, and political phenomena and events, and medical and scientific developments" (Fox et al., p. 32). It takes into account both the generative power of events and the wider societal influences that helped push bioethics to the forefront of public debates. This accounting places less emphasis on turning points and personas, and more on the timing of the intellectual gestational period.

In both the United States and Canada, bioethics began to germinate in the 1950s, in a decade when medicine made "miraculous" advances. In 1952, the first open-heart surgery was performed and by the mid-1950s, polio vaccines became routinely available. It seemed that the possibilities of modern medicine were boundless, but the medical professionals who were involved in testing and early adoption of new therapies were aware that these advances did not come without human experimentation and disproportionately large risks to the first patients undergoing these procedures (Jonsen, 1998). This discomfort from within medicine was coupled with challenges to medicine from without. Along with other institutions, medicine was increasingly seen as racist, sexist, and oppressive, leading to a call for oversight by nonphysicians. This external oversight began as early as 1958 when the Law-Medicine Research Institute at Boston University began to investigate the "actual" practices of medical professionals within the United States (Fox et al., 2008). Keirns et al. (2009) explain:

> In this cultural climate, old-style medical ethics – granting unilateral authority to physicians to make decisions about certain aspects of life, death and medical care – was deemed insufficient. New technologies such as the ventilator, incubator and artificial feeding tube brought the promise of success in medicine's long struggle with disease and death, but they also increased the risk of prolonged suffering and technological dependence. Doctors were not trusted to respond to the pressing questions created by the new machines of medicine. From the 'God Committees' of 1960s' Seattle... to debates about genetic enhancement, physicians were (and are) no longer trusted to be the sole decision-makers on matters medical.

The social turmoil of the 1960s underlined the need for clearer definitions of patient rights in experimentation. Scientists and medical professionals began to raise their voices above their typical professional boundaries, and reached out to the general public. Notably, Henry K. Beecher, a physician, published an article titled "Ethics and Clinical Research" where he discussed several examples of unethical research on the part of medical researchers. He made a strong argument for the practice of truly informed consent: "The statement that consent has been obtained has little meaning unless the subject or his guardian is capable of understanding what is to be undertaken and unless all hazards are made clear. If these are not

known, this, too, should be stated. In these situations the subject at least knows that he is to be a participant in an experiment" (Beecher, 1966, p. 372). Jonsen terms this period "The Decade of Conferences" (1998), but one might also call this period "The Decade of Patient Rights" or "The Decade of Hesitation." The debates that were emerging regarded issues as diverse as eugenics, food safety, and human experimentation.

The sense of movement during this period is perhaps best characterized by a term used by a German theologian Thielicke in a keynote speech to a panel of scholars and theologians brought together by the Institute for Religion at the Texas Medical Center. The group was assembled in 1967 to deliberate on the first human heart transplant. In his address, Thielicke spoke of the "ambiguity of progress" . . . "the half-light between creation and fall" (Guinn, 2006, p. 32). The uncertain and charged atmosphere, with its call for the empowerment of patients in the medical system, gave rise to a core group of scholars, including medical professionals, who placed increased emphasis on individual patient rights. This focus coincided with the consumer rights movement in the United States, and the bioethics community in North America has retained that individualized focus since then (George J. Annas, 2005, p. 30).

By the end of the 1960s, bioethics centers began appearing in the United States, among them the Hastings Center (1969) and the Kennedy Institute (1971). Canada established their first Center for Bioethics in 1976, affiliated with the Clinical Research Institute in Montreal (Roy et al., 1993). The growth of these centers contributed to wider dissemination of knowledge about bioethical issues. Popular media that were previously captivated by stories of miraculous medical progress began to take interest in the human costs and controversies behind medical discoveries. Gradually, bioethical questions came to the attention of the public and eventually these questions arrived before the US Congress (Fox et al., 2008; Hoffmaster, 2001).

Under the influence of the outrage that followed revelations about the Tuskegee Experiment (Reverby, 2009), the US Congress established a body for addressing the ethics of medical research: the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (Jonsen, 1998). From 1974 to 1978, this body considered the ethical principles that should guide medical research in the United States and ultimately issued the well-known Belmont Report (http://ohsr.od.nih.gov/guidelines/belmont.html). The Belmont Report established a principle-based approach to ethical decisions in research involving human subjects, setting out three essential principles: (1) respect for persons, (2) beneficence, and (3) justice.

Notably the commission did not ground these principles in the idea of "human rights." Instead they found their justification in "our cultural tradition":

> The expression "basic ethical principles" refers to those general judgments that serve as a basic justification for the many particular ethical prescriptions and evaluations of human actions. Three basic principles, "*among those generally accepted in our cultural tradition*," are particularly relevant to the ethics of research involving human subjects: the principles of respect of persons, beneficence and justice. (United States & National Commission for the Protection of Human Subjects of Biomedical & Behavioral Research, 1978)

After the limited term of this first commission expired, it was replaced by The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research and stayed functional from 1980 to 1983 (Jecker, Jonsen, & Pearlman, 2007).

During this decade, bioethics became a part of the official discourse in regulating research and medical practices in North America. The prominent debates no longer focused on *who* has the right and authority to regulate experimentation, but *how* and *how much* it should be regulated. As Jonsen points out, the conversation over the issues at stake assumed a new tone, "the discourse over research could be directed toward resolutions that would be widely accepted in American society" (Jonsen, 1998, p. 158). The strong connection between bioethicists and the political establishment has remained a stable part of the landscape of North American bioethics. Of the past five American presidents, four established a committee or a commission dedicated to providing guidance on matters pertaining to science, medicine, and technology to the President and the Congress (Jecker et al., 2007).

It is worth noting that the bioethics commissions reflected the political orientation of Presidents they served (see: bioethics.gov/cms/history). The National Bioethics Advisory Commission (NBAC) was created by President Clinton to explore the ethical issues associated with cloning and with the use of human subjects. The NBAC had a largely technocratic approach to its work – "thin bioethics" in the words of John Evans (2002) – focusing its energies on developing guidelines to aid researchers in doing their work (http://bioethics.georgetown.edu/nbac/). The President's Council on Bioethics (PCBE), appointed by President G.W. Bush in order to provide advice on stem cell research, took a much broader approach to bioethics. Rather than efforts to create guidelines for the ethical practice of medical research, the PCB spent more time exploring how new medical technologies altered what it means to be a human (http://bioethics.georgetown.edu/pcbe/). President Obama's Presidential Commission for the Study of Bioethical Issues has steered a middle course, reviewing the ethical challenges of new developments in medicine, including synthetic biology and neuroscience (http://bioethics.gov/).

This brief historical account demonstrated that bioethics has a well-established tradition in North America. The *Declaration* is poised to make a difference in countries with no established bioethical infrastructure and in countries that have begun to develop conversations about ethical decision making and guidelines (Have & Jean, 2009). The *Declaration* can certainly help with these tasks, but it should come as no surprise that the *Declaration* may pass unnoticed in North America.

UNESCO Principles in North American Context

The articles of the *Declaration* are fundamentally split between those that secure individual rights and those that promote justice and the welfare of the collectivity. Culturally and historically, the North American bioethical tradition has relied heavily on traditions that focus on individual decision making: Bioethical issues in this region are rarely framed as questions of justice or even human rights. Rather, they have been

understood in the context of individual autonomy, and thus give little attention to collective justice. In the sections below we discuss how the articles of the Declaration fit, or do not fit, within the existing incarnation of bioethics in North America. The articles that have no relevance to this region are not explicitly discussed.

Informed Consent

North American bioethics has focused on respect for individuals, their rights, freedoms, and liberties, as evidenced by the widespread adoption of the informed consent procedures that stand at the heart of articles 5, 6, 7, and 9. The research community in the United States remains conscious of its painful history with medical experiments that were performed without consent or regard for human rights (Katz et al., 2008; King, 1992). Most notorious is the Tuskegee Syphilis experiment that left hundreds of poor African-Americans untreated for the sake of observing the natural progression of the disease even after penicillin became widely available in 1947.

Today, oversight of the ethical integrity of research in North America falls on the shoulders of appointed Institutional Review Boards (IRBs) in the United States and Research Ethics Boards (REBs) in Canada. REBs and IRBs serve largely the same functions. In Canada, their decision making is guided by the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans published by the Canadian Panel on Research Ethics (Canadian Institutes of Health Research, 1998). In the United States, these institutionally affiliated regulatory bodies are approved by the Office for Human Research Protection and are charged with reviewing and monitoring all research that involves human subjects. Institutional Review Boards serve as the guardians of human rights in biomedical research (http://www.hhs.gov/ohrp/). One of their major responsibilities is making sure that every research project has a well-planned informed consent procedure. Those who are unable to give an informed consent, such as minors, are typically given the opportunity to provide an assent.

Informed consent as practiced in the United States has not been unchallenged. Canadian scholar Charles Taylor critiqued informed consent as built on an "atomistic" view of the human actor. He wrote: "The social nature of man is not just that men cannot physically survive alone, but much more that they can only develop their characteristically human capacities in society. The claim is that living in society is a necessary condition of the development of rationality, in some sense of this property, or of becoming a moral agent in the full sense of the term, or of becoming a fully responsible, autonomous being … [O]utside society … our distinctively human capacities could not develop" (Taylor, 1985, pp. 190–191). His understanding of consent stems from his work on relational autonomy, and is closer to the understanding of consent depicted in the *Declaration*.

Although informed consent permeates all domains of academic research in the United States and Canada with human subjects, academics debate the effectiveness of this practice in actually informing patients and research subjects. In her fieldwork in ICU nurseries, for example, Anspach (1993) found that the "assent-model" was frequently used instead of informed consent, especially when the parents were

expected to have a difficult time making a decision. Similarly, in his study of the work of nurses in hospitals, Chambliss (1996) found that the informed consent process was at best a "polite fiction" engaged in by patients and staff. It seems that although the United States and Canada already have codified respect for individuals into their research standards, clinical practices occasionally do not live up to their spirit. Corrigan argued that some of the shortcomings of the current informed consent practices can be accounted for by recognizing that some have treated informed consent as "an ethical panacea" and allowed its existence in an ethical void where it is simply executed without attention to the relevant social and cultural environment (Corrigan, 2003). The study of the informed consent procedures by these and other researchers needs to be taken very seriously because it points to the gap between policy intentions and practice. Unfortunately, the *Declaration* offers no guidance on the best approach in translating policy prescriptions and institutional rituals to effective practice and misses a key opportunity to contribute to the current conversation on the topic.

Justice as a Bioethical Issue

A key point of difference between the North American tradition of bioethics and the framework put forth in the *Declaration* is found in the distinct emphasis on whose benefit comes first. While the *Declaration* champions equity and communality, the committees that typically serve as bodies of bioethical oversight in the United States focus on individual patient empowerment. There is a fundamental distinction between justice for individuals and justice based on the notion of equity. Drawing on the *Nicomachean Ethics* by Aristotle (1962), Gabriel d'Empaire points out – in his chapter on the genesis of Article 10 published in Ten Have and Jean (2009) – there are at least two basic definitions of justice – commutative justice and distributive justice. While commutative justice is concerned with overseeing interpersonal transactions and ensuring that all parties exercise their rights equally, distributive justice focuses on the equal distribution of wealth in society (Aristotle, 1962; d'Empaire, 2009).

The conflict here – a conflict that remains unresolved in the *Declaration* – is between "equal rules" and "equal shares" orientations to justice. Individualistic societies, like the United States, emphasize "equal rules" – fairness is achieved when everyone is constrained by the same rules, and those who succeed (in terms of health and wealth) have properly earned their position in society. In less individualistic societies, the emphasis is on "equal shares" – a notion of fairness that recognizes equal rules affect the wealthy and the poor differently, and thus, there must be an effort to insure equality of result.

Nondiscrimination and Pluralism

Articles 11 and 12 underscore the value of inclusiveness, nondiscrimination, and pluralism. Both cultural and religious pluralism are embedded in the founding

documents of the United States and Canada and have been a central component of national identities in both the countries, in spite of the fact that these ideals have not always been realized. These are values that have a special place in North America's past, present, and future because it has been a place populated by a diverse group of immigrants. Pluralism and diversity are not interchangeable, although it may appear so at times. Plurality implies a more active engagement with each other's values and may not be fully achieved, even when the population is diverse.

Pluralism, when nations take it seriously as a form of governance, implies conflict. It forces interest groups into disagreements about the ethical underpinnings of their values. Societies, whether they are diverse or homogeneous, need to work toward establishing a common ground to find answers to bioethical questions that respect all. Full pluralism requires a person to take into account and fully respect minority ethical views even if they stand in opposition to accepted bioethical standards and "may appear to endanger the universally accepted norms" (Revel, 2009, p. 208). Setting international standards for bioethics and human rights, even standards that call for pluralism, is not an act of pluralism. From that perspective, Articles 11 and 12 force one to consider a question: Is global bioethics possible? Can culturally specific and contextually dependent standards of bioethics be expressed in a pluralistic manner? The *Declaration* tries to remedy the implied conflict by asserting that pluralism must exist within limits and is "not to be invoked to infringe upon human dignity, human rights, and fundamental freedoms, nor upon the principles set out in this Declaration, nor to limit their scope." There is an internal tension here: Is "dignity" realized the same way in all cultures? And if not, how can it be realized across different cultures without imposing the values of one culture upon another?

In the United States, matters pertaining to bioethics are most often administered on the level of local committees. This became the standard practice as a result of the 1983 report of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research that recommended that every health care facility create a multidisciplinary body to deal with bioethical questions (see: http://bioethics.gov/cms/history). The role of each committee would be to "(a) confirm the patient's diagnosis and prognosis; (b) provide a forum for discussing the social and ethical issues that a particular case might raise; (c) educate staff on the identification and resolution of ethical problems; (d) formulate institutional policy and procedural guidelines on decision making; (e) review treatment decisions made for specific patients by doctors and surrogates; and (f) mediate conflict over patient care between health care professionals, patients, family members, and the institution" (Bulger, Bobby, & Fineberg, 1995, p. 541). This local approach allows community standards to inform bioethical decisions, although we do not know the extent to which decisions made in these committees are representative of the community, or if the voices of ordinary community members are heard by committees where health care professionals are in the majority.

The operation of hospital ethics committees (HECs) has not been extensively investigated in the United States or Canada, although the day-to-day work of these committees is a major determinant of their effectiveness in regulating medical

practice and channeling communication between medical professionals and patients. The few studies that have been done have found inequality of access among different types of health care providers and patients (Griener & Storch, 1992; McBurney, 2001). While researching HECs, Canadian scholars Griener and Storch (1992) found that the committees reinforced the existing professional power structures, rather than providing effective mediation. Doctors held a majority of the power within the committees, and the evidence presented by nurses was discarded as less valuable. Their findings are well aligned with the power structure in medical decision making as described by Anspach (1993). Similar conclusions were reached by a more recent research project executed by McBurney (2001). While McBurney recognized the systematic effort for more balanced ethical decision making, she suggests that the obvious imbalance might simply be replaced by more "subtle, cautious paternalism" (McBurney, 2001, p. 196).

Although not always advocated for with great success, Articles 11 and 12 of the *Declaration* are among priorities of the North American bioethical community. Here again there is a need for more guidance on how the articles can be put into practice in an effective manner.

Solidarity and Social Responsibility and Sharing of Benefits

Taken together, these articles are intended to promote distributive justice, encouraging policy makers to promote solidarity and cooperation in access to food, clean water, health care, a healthy environment, and the benefits of medical research. As noted above (see the section on Article 10), these goals, while recognized as noble in North America, often take second place to the culturally more important goals of individual freedom and responsibility. While North American bioethicists argue that health research done by western governments and corporations in low resource countries should be guided by an interest in human development (London, 2005), in practice, these countries are seen as a resource for developing new therapies and medications for western populations. Discussions of the ethical problems of international research center on improving efficiency, streamlining procedures, and on things like "transparency," "quality," and "independent oversight" (Glickman et al., 2009) – all worthy ideas, but none of which require attention to concerns articulated in these articles.

Appropriate Level of Ethical Review of Research in Other Countries

The United States, Canada, and indeed other western countries continue to struggle with the appropriate level of ethical review in other countries. In 2010, the American public learned about the unethical testing of sexually transmitted diseases on Guatemalan mental patients between 1946 and 1948. Disguised as inoculations, patients were injected with disease agents by the US Public Health Service. The administrators of these trials took advantage of less established guidelines for protecting human rights in the community where they were experimenting, and carried out trials that

would have not been approved in the United States at the time (Reverby, 2009). There are also ethical concerns with US government-supported international trials of HIV transmission rates between mothers and infants in African and Asian countries (G. J. Annas & Grodin, 1998). In this trial, some mothers were administered a treatment that was known to prevent transmission, while others were given a placebo. While these trials were ongoing and exploiting ill mothers and children in the developing world, the international community debated their appropriateness (Ballantyne, 2010; Lurie & Wolfe, 1997). This runs sharply against Article 21.

The United States has been working toward establishing (and maintaining) clearer guidelines for medical trials outside of the country, although they often are difficult to enforce. When the US government officially admitted to having supported the unethical medical research in Guatemala, the US president, Barack Obama, ordered the Presidential Commission for the Study of Bioethical Issues (PCSBI) to begin an investigation of whether the "Federal regulations and international standards adequately guard the health and well-being of participants in scientific studies supported by the Federal Government (Presidential Commission for the Study of Bioethical Issues, 2011, p. 1)." The PCSBI did not use the *Declaration* in its deliberations. After a series of meetings, the panel issued a document assessing the current state of bioethics in international research. Their final report underlines lack of unity in rules of ethical research internationally and takes no notice of the UNESCO *Declaration* (Presidential Commission for the Study of Bioethical Issues, 2011).

Their final report highlights that the United States is in a very unique position with respect to taking responsibility for enforcing transparent and just bioethical standards, especially with respect to their involvement in the developing world. Their federal resources fund more clinical trials than any other country can afford. Further, it is arguable that US-based pharmaceutical companies are among the most powerful on the world, and they are able to administer trials on their own (Law, 2006).

Conclusion

The Declaration has had little visible impact on the field of bioethics in North America. This lack of attention is likely the result of the development of a bioethics framework in Canada and the United States that predates the Declaration by more than three decades. Rather than setting the agenda for bioethics, the Declaration must find its way into the existing agendas of clinical and research ethics in North America. This task has not been easy, as it requires both structural and cultural accommodation. The existing *organization* of bioethics, including the centers that proffer bioethical advice, the regulations that govern the monitoring of human research, and the agencies that fund bioethics research, has developed in a *cultural* climate that is focused on individualism, autonomy, and the belief that societal good is best served by individuals seeking their own best interests. The justice-oriented approach of the Declaration is thus at odds with the present structure and culture of North American bioethics.

This is not to say that the Declaration is of no use in North America. Bioethics in this part of the world is beginning to recognize the need to consider justice and solidarity alongside autonomy, making the Declaration more relevant to the ethical questions that emerge here. Recent research (Wilkinson & Pickett, 2010) has shown that the high levels of inequality found in North America and other highly individualistic societies harms the wealthy as well as the poor: High inequality is associated with higher levels of crime, a less-educated work force, shorter life expectancies, and higher infant mortality for the rich as well as the poor. If citizens of North America can be convinced that their individual interests, including their health, are best served by solidarity and sharing, a concern with justice may replace the existing preoccupation with autonomy.

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Section IV

Religious Perspectives

Buddhism

21

Soraj Hongladarom

Introduction

Siddhartha Gautama, a prince from what is now southern Nepal, gave rise to Buddhism some two thousand and five hundred years ago. He attained Enlightenment, the state of total liberation from all causes of suffering, at the age of 29 thus became the Buddha, literally one who has already awoken. The Buddha spend 45 years in north India teaching to his disciples, planting the root of the religion which then spread out across its land of origin to become a world religion. Now, Buddhism has adherents living in areas ranging from Mongolia and some parts of Russia and Sri Lanka and many countries in Southeast Asia, such as Thailand, Myanmar, Laos, Cambodia, and Vietnam. Buddhism is now the world's fourth largest religion, after Christianity, Islam, and Hinduism.

A special characteristic of Buddhism is that it is a nontheistic religion; that is, it does not recognize a God or a Supreme Being who created the world and who is the ultimate source of ethical judgment. On the contrary, the religion recognizes the dharma, or the way things are naturally, as the source of how things come to be as well as how action should be judged ethically. Another Indian religion, Jainism, also shares this characteristic of being nontheistic. The term "nontheistic" is used in this context to contrast with "atheistic," which means no recognition of any ultimate source of meaning or value judgment whatsoever. Instead, Buddhism and Jainism are nontheistic in the sense that they do recognize an ultimate source of meaning and ethical judgment. Such a source, however, is not based on a personal conception of a supreme deity.

The goal of being a Buddhist is to perfect oneself so that eventually one achieves total liberation of oneself from the cycle of births, deaths, and rebirths known as *samsara*. This is a belief shared by Buddhism, Jainism, and also Hinduism. When one does not realize the total liberation, one wanders around from one life to another, depending on what one has done in the previous life. If one does something "unwholesome" (akusala), or negative, one is reborn in a lower realm such as that of

S. Hongladarom
Department of Philosophy, Faculty of Arts, Chulalongkorn University, Bangkok, Thailand
e-mail: hsoraj@chula.ac.th

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animals, hungry ghosts (*preta*), or hell beings. On the contrary, positive or "wholesome" (*kusala*) action results in a rebirth in one of the heavens. However, the time a being spends in any of these realms, higher or lower, is limited. That is, no matter how bad one's action in one life has been, one has to spend only a limited amount of time in hell. After the time is up, one is propelled again to take another birth in one of the realms in samsara, and if the causes and conditions that propel one to wander in samsara are still there, one will wander around this cycle indefinitely. All the major three Indian religions, Buddhism, Jainism, and Hinduism, concur that such wanderings around in samsara are totally unsatisfactory, and the goal of a serious practitioner is to find a way toward releasing oneself from it. Each of the three major religions here offers slightly different ways toward this release. When one reaches the state of total liberation from samsara, so that one will not be reborn there again, it is said that one has achieved the status of the *arahat*, or one who has defeated all defilements which are causes of taking a life in samsara. This is an ultimate goal of being a Buddhist.

In a nutshell, Buddhism offers three stages of practice to achieve the state of total liberation, namely, disciplined conduct (*sila*), meditation (*samadhi*), and wisdom (*prajna*). Disciplined conduct means that one always observes what one is doing both through the physical, verbal, and mental aspects so that one does not commit any action which will result in taking a birth in the lower realms. Disciplined conduct will be very relevant in the discussion of Buddhist ethics and bioethics as we will see later. It is the foundation of the further practices which involve purifying the mind through meditation and achieving total understanding of the way things really are. When one has mastered disciplining one's own physical, verbal, and mental conduct, one goes on to practice meditation to stabilize and purify one's mind. Through this effort in meditation, one gains an insight into the real nature of all things, and it is this wisdom that destroys *avidya*, or fundamental ignorance, that is the direct cause of attaining total liberation, which is known as Nirvana.

These are the basics of the Buddha's teaching. Later, Buddhism branched out into two main groups, namely, the Theravada (or Hinayana) and Mahayana. The differences between the two are more on what is emphasized rather than any differences in the doctrine. Theravada Buddhism is practiced mostly in Sri Lanka, Myanmar, Thailand, Laos, and Cambodia, while Mahayana is practiced in China, Japan, Korea, and Vietnam. In the Tibetan speaking area of China and Bhutan, moreover, a special branch of Mahayana is practiced known as the Vajrayana. Basically speaking, the Theravada emphasizes realizing the eventual release of oneself from samsara, which was the Buddha's apparent goal in his teaching during his lifetime. However, a few centuries after the Buddha's death, a group of monks started to reconfigure the goal of practice. Instead of trying to achieve total liberation from samsara in this lifetime, this group of monks emphasized instead the goal of themselves becoming a Buddha in the future. This is the key aspect of Mahayana Buddhism. According to the Mahayanists, one should instead become a bodhisattva, or one who vow to practice and perfect oneself, not only in order to release oneself from samsar, but also to become a Buddha in the

future so that one has the capacity needed to free all sentient beings from samsara. Thus, in a nutshell the main difference between these two branches of Buddhism is on different emphasis on the goal of practice rather than any doctrinal difference. The main content of the teaching remains the same in both traditions. Furthermore, within Mahayana itself, another branch emerged, that of Vajrayana, which retained the core objective of the Mahayana while introducing their own special kinds of practices. While both Mahayana and Vajrayana subscribe to the bodhisattva ideal where the aim of practice is eventually to become a Buddha, Vajrayana introduces special techniques not found in the other tradition which it claims help the practitioner realize the final aim much faster. It is possible, according to Vajrayana, for the practitioner to realize Buddhahood within this very lifetime, whereas it would take many lifetimes to do so according to purely Mahayana practice.

In this article, the main teaching of the Buddha will be referred to which is shared by both the major traditions of Buddhism. Among the key concepts directly relevant to bioethics are compassion and interdependence. In the next section, these two key Buddhist concepts will be explained in detail. Then, in the section that follows, it will be shown that Buddhist teachings are not in conflict with the global ethical principles stated in the Universal Declaration on Bioethics and Human Rights. Furthermore, Buddhist perspectives on a variety of bioethical issues will be discussed based on these two key concepts. The bioethical issues that will be discussed are those involving beginning of life, end of life, and human vulnerability.

Compassion and Interdependence

The key concepts which are directly relevant to judgment of action are compassion (*karuna*) and interdependence (*pratityasamutpada*). Compassion is the wish to relieve all beings of their suffering. It arises when one feels the sufferings that others are feeling and wish to share in those suffering and to eliminate those sufferings. Compassion is one of the four immeasurables, which are the qualities that one needs to cultivate as an essential part of one's practice to attain Enlightenment and Buddhahood. The four immeasurables (also known as the four brahmaviharas) are so called because one practices these four qualities that emphasize complete lack of boundaries between oneself and others, as well as lack of boundaries between any being whatsoever. The love and joy that are parts of the immeasurables cannot be measured because they are boundless, extending toward all beings in the universe. They consist of loving-kindness, compassion, sympathetic joy, and equanimity. Loving-kindness consists in the wish to impart happiness to all beings without any kind of discrimination. One wishes all beings to be happy and always to meet with causes and conditions of happiness. It does not matter where those beings reside; they could be gods in heaven, or hungry ghosts, animals, or hell beings. In practicing loving-kindness, as well as the other three immeasurables, one does not make any distinction between beings. Instead, one radiates love and the wish of happiness to every being without exception.

The second immeasurable, compassion, is the wish that all beings are relieved from suffering. Again, there is no discrimination. The practitioner shares in the sufferings and pain of all sentient beings and there is a genuine wish to eliminate those sufferings from them. One sees oneself in all beings; as no being wants to experience and endure sufferings, one wishes that no being at all suffers or is in pain. This, together with the other immeasurables, is the basis for concrete action of Buddhas and bodhisattvas to help the beings in samsara. The third immeasurable, sympathetic joy, is the feeling of happiness and joy that spontaneously arises when one realizes that other beings are happy. The joy that arises is as spontaneous as a bell which spontaneously rings itself when another bell nearby is ringing. Sympathetic joy is an antidote of envy and jealousy and is a very important quality for those who wish to practice to become a bodhisattva. The fourth and last immeasurable, equanimity, is the feeling of sameness, equality, and undifferentiatedness toward all beings. In fact, it is a basis of immeasurability because it underlies the feeling that all beings need to be considered equally without any discrimination. In practicing equanimity, one does not distinguish one group of beings from others. Naturally, people would normally differentiate between those which are closer to them, such as the members of their family, members of their villages and community, and those who are strangers and have nothing to do with them. This differentiation gives rise to the separation, for example, of "us" and "them," which leads to competition and conflict. In practicing equanimity, one tries to do away with this feeling of separation. One tries to regard a stranger and a close member of one's own family as deserving the same treatment and the same love and compassion. Buddhist teachers usually say that the practice of equanimity can be said to be accomplished when one does not see and feel any kind of distinction at all between oneself and another; it is the realization that any sentient being deserves the same love and compassion as does one's own self.

It is quite clear how compassion and the other three immeasurables are important in ethical decision-making and judgment. If one can see that there is no distinction between a sentient being and oneself, then anything that one would not do to oneself will not be done toward the other being either. For example, one naturally would not act to harm oneself; thus, the practice of loving-kindness and equanimity would imply that one would not do the same harm to any other being either. This is a basis for not harming other beings. Compassion and the other immeasurables also underscore the realization that every sentient being wants happiness and seeks to avoid suffering and pain. Since we know from our own first-hand experience that we ourselves want happiness and do not want pain, all other beings share the same feeling. Hence, it is thoroughly unwholesome to cause pain and suffering in others.

The other key Buddhist teaching is about interdependence (*pratityasamutpada*) and emptiness (*sunyata*). In fact, the two concepts here always imply each other. Interdependence is the characterization of things when the being of each depends on their relation and dependence on others. A table, for example, is what it is only because it rests on a floor, consists of four legs (in most cases), has a flat top, made of some kind of material (such as wood or plastic), and is used so that things can be

put on its top. All these characteristics of the table depend on other things, and without those things, the table cannot be what it is. Another way of putting it is that a table always has a boundary, a line where the table ceases to be a table and whatever lies outside it begins. This line demarcates the table from its environment. If this line is nonexistent, then the table cannot be a table at all, so its very being depends on its relation to the other, in this case whatever lies outside the table itself. Since all objective entities whatsoever must have this line that demarcates them from their environment, all things are thus interdependent on others.

This way things depend on other things also implies that they are "empty of their inherent character." This typical Buddhist way of describing the way things are means that things are empty of whatever that forever makes them what they are. This idea is closely related to the idea, also central to Buddhism, that things are always changing and in flux. Here, Buddhist philosophy resembles Heraclitus' thought in ancient Greek philosophy who says that things are always changing and one cannot enter the same river twice. As things are always changing, they change from being one thing to another. A table, for example, has not always been a table from a very ancient time. Instead it used to be a tree, and before that, the tree used to be something else, such as carbon molecules in the air. Things change and our designation of what they are changes accordingly. In Buddhist terms, if the table had its own "inherent character," it would mean that the table would remain a table in eternity, for anything that possesses an inherent character would be able to remain what it is without depending on others in any way. Since that is not possible, all things then do not possess inherent character. This is just another way of saying that all things are "empty of their inherent character." Since all things are interdependent, they are empty of their character because the characteristic of being interdependent means that any essential feature that would enable the things always to remain what they are is not there. Furthermore, all things being empty of their inherent character also means that they are interdependent because when they lack their inherent character, any feature that would tell us what they are is ultimately dependent on other things. This is why Nagarjuna, a Buddhist saint in the second century A.D., emphasized that emptiness is just interdependence and the other way round (Nagarjuna, 1995).

What is distinctive about Buddhist thought is that interdependence and emptiness not only apply to material things but also to the self or the ego too. This is perhaps the most important part of Buddhist philosophy and what makes it unique among philosophies and religions in the world. A startling conclusion offered by Buddhism here is that even our own selves, whatever we refer to when we use the first person pronoun " I," is not exempt from being interdependence and empty too. In fact, the self is composed of various mental and physical elements which are exhaustive, and when these elements are analyzed, it is found that no self is there; thus, what is understood to be the self is nothing but a conglomeration of various elements and episodes. It is always changing and interdependent. What one understands to be the subject of one's own thoughts, feelings, and action is ultimately an illusion. Whatever is commonly understood to be the subject behind the changing mental and bodily episodes is analyzed to be nothing over and above those episodes themselves; hence,

what is taken to remain behind as the subject is just another such episode. This doctrine is known as the doctrine of non-self (*anatman*). It is not a doctrine that says that there is absolutely speaking no self, but it says that what we take to be the self behind our own thoughts and action is not exempt from the rule of interdependence and emptiness of all things. Contemplation of this truth, as well as the truth of all things as interdependent and empty, is a key ingredient in one's practice toward attaining total liberation from samsara and attaining Nirvana.

Compassion and interdependence are always linked to each other closely. In fact, Buddhist teachers usually say that compassion and interdependence are like the two wings that a bird needs in order to fly. Just as a bird needs two wings to fly, so too does a practitioner need both compassion and the realization of the wisdom of interdependence in order to attain Nirvana and Buddhahood. In compassion, one sees the ultimate interlinking of all beings with one another; in the same vein, in emptiness and interdependence, one realizes the same interlinking of all beings, which leads to compassion toward all beings as there is absolutely nothing that separates oneself and all other beings.

Foundation of Buddhist Ethics

As a nontheistic religion, the foundation of ethics in Buddhism is not based on the command of God. Instead, it is based on *dharma*, or the nature of things. Another key doctrine in Buddhism and other Indian religions which is relevant here is the *law of karma*, which says roughly that any action will have consequences into the future and an explanation of why things are the way they are at present is because of prior causes and conditions. In this way, action in the present comprises a cause and condition for the way things will be in the future; hence, the law of karma is an expression of the main characteristic of dharma, namely, that things are always determined by causes and conditions. (There are a number of excellent introductions to Buddhism, such as Gethin (1998) and Siderits (2007). An introductory text in Buddhist bioethics is Keown (2001)).

Nevertheless, the law of karma should not be confused with fatalism or complete determinism. That the way things are depends on their causes and conditions does not imply that things must always be the way they are, or that the future will always be predetermined. The future can be fully open depending what kind of action is taken at present. Man is free in taking his own course of action because that is a prerequisite for them to realize the highest goal, which is only achievable through one's own effort. Moreover, this freedom must also be presupposed as a basis for moral responsibility. Within samsara itself, there has to be someone who gets to heaven as a result of someone's doing some kind of deed in the previous life. Without being free to taking one's own course of action, reward and punishment as a kind of encouragement and deterrent of action would not be possible. An action that is ethically valuable must be done out of intention. This is why something done by a zombie or an unconscious robot would never be ethically valuable (neither good nor bad). Since freedom

is already implied in the concepts of intention, then one has to have freedom in order to perform deeds that would result in a change in the course of one's path in samsara and also ultimately a path leading beyond it.

This compatibility between the law of karma and freedom to act points to the important role that motivation or intention (*cetana*) plays in Buddhist ethics. According to Buddhism, the nature of an act itself is not as important as the motivation behind performing the act as the arbiter of the result that will ensue as a consequence of performing the act. For example, there are three types of defilements, namely, greed (*lobha*), anger (*dosa*), and delusion (*moha*). These are "defilements" because they defile the mind, obscuring it and obstructing it toward the real path and the real goal. Action done out of defiled motivation, such as action done by greed or anger, always takes one out of the real path, which is the realization of Nirvana. As such it is an "unwholesome" action (*akusalakarma*), as it leads one outside of the real path and hence is negative. On the contrary, action that is "wholesome" (*kusalakarma*) leads one on the right path and eventually contributes to one realizing the ultimate goal.

In a nutshell, then, Buddhist ethics consists in whether an action is performed under the right intention or motivation or not. An intention is "right" just in case it is free from the three defilements, when it is done out of purely altruistic and compassionate motif under the correct understanding that things are empty and interdependent, and is "wrong" otherwise.

Specific Issues

The teaching of Buddhism is in accord with the general ethical principles outlined in the UNESCO Declaration on Bioethics and Human Rights, a document which is accepted by all member states. For example, Buddhism fully endorses the concept of human dignity and rights, which is stated in Article 3 of the Universal Declaration and is perhaps the most fundamental concept in the general bioethical principles endorsed by the member states. The first clause of Article 3 says "Human dignity, human rights and fundamental freedoms are to be fully respected." The teachings on compassion and interdependence fit with the conception of human dignity in that they promote human welfare and respect. Since all beings, humans included, deserve to be happy and to be relieved of sufferings and since it is not enough for the Buddhist merely to wish these beings to be happy and not to suffer (otherwise they would be contradicting their own wishes), there needs to be concrete mechanisms by which all beings, especially humans, are actively relieved of sufferings. The text of Article 3 is one such mechanism. The concepts of rights and fundamental freedom also follow logically from that of dignity.

Moreover, Clause 2 of Article 3 is very interesting. It says: "The interests and welfare of the individual should have priority over the sole interest of science or society." It is discussed elsewhere in this chapter that Buddhism pays special attention to the concept of solidarity among individuals, which is seen to function as an antidote to the overly individualistic tone of much current ethical thinking that

is focused on the role of the autonomous individual. However, the Buddhist emphasis on solidarity (discussed in the section on Vulnerability below) does not conflict with the language of Clause 2 here, for both are applied in different contexts. Promoting solidarity among individuals is not the same thing as subjugating the interests of the latter to those of the society or community. Individuals can enjoy solidarity among other fellow individuals without having their interests subjugated in this way. In fact, solidarity can even promote the interests of individuals and can well act as a foil by which individuals join forces to resist against the state or society. As for the interest of science, it is clear that the interest of the individuals need to take priority, for the benefits of science will eventually accrue to none other than the individual human beings themselves; hence, it would be self-contradictory to put up the interest of science above that of the individuals.

As for the more specific issues, literature on Buddhist perspectives on these issues in bioethics is voluminous and is growing rapidly. Unlike the monotheistic religions such as Christianity and Islam, which seem to have rather clear-cut views on a number of bioethical issues, Buddhism does not have a united front, so to speak, on these issues. There is no central authority in Buddhism who can issue statements on behalf of the whole religion in the way that the pope can for Roman Catholics. Many Buddhist monks and scholars disagree among themselves as to what the proper Buddhist attitude should be on these issues. This is not surprising given the fact that the Buddha himself specifically did not appoint any one of his disciples to be the leader after his death. Instead, he encouraged each of his students to follow the teaching, taking the teaching itself as their leader when the Buddha himself is no longer in this world. Thus, for Buddhists the most important authority is their own understanding of the teaching, which is recorded in the Scriptures. However, different Buddhist groups such as the Theravadins and Mahayanists do not recognize exactly the same set of Scriptures as authoritative. While the Mahayanists accept the Theravada *Tripitaka*, or the Three Baskets of the Buddha's teachings, as authoritative, they added many more texts which are not accepted by the Theravadins.

All this leads to a basic principle in Buddhist ethics. In deciding what the Buddhist perspective should be on an issue in bioethics, the texts or the Scriptures alone are not enough. One has to add to the content or the meaning of the texts with one's own interpretation. Since bioethical issues are new and obviously did not take place in the Buddha's time, one can certainly not find any direct reference to them in the Scriptures. Thus, one has to interpret, and the lack of central interpretive authority and the emphasis on one's own internal understanding mean that judgments on the Buddhist perspective on any specific bioethical issue can diverge widely.

Nonetheless, this does not mean that anything goes. Even if the emphasis is ultimately one's own internal understanding of the texts and the teaching, there is enough centrality in the teaching itself, such as those on compassion, interdependence, and emptiness discussed above, to enable one to judge whether an interpretation is correctly Buddhist or not. These teachings are central to Buddhism in that all the schools, Theravada, Mahayana, and Vajrayana, accept

them as comprising the core of the teaching self. Hence, in this section, the interpretation offered will follow these key Buddhist concepts and will be divided into the following sections, namely, Beginning of Life, End of Life, distribution of scarce resources, and human vulnerability.

Beginning of Life

Perhaps the most widely discussed issue regarding a Buddhist perspective on the beginning of life centers around human reproductive cloning. The theistic religions tend to regard reproductive cloning in a negative light, as they look at the practice as imitating God's work. What seems to be objectionable according to the perspective of the theistic religions is that human reproductive cloning subverts the natural course of things designed by God where humans reproduce themselves asexually. Furthermore, since a human being is created in God's image, cloning a human being, producing somebody who is just like his or her original in every detail, would be tantamount to challenging God's role in this respect.

On the contrary, Buddhism, being a nontheistic religion, does not have anything particularly negative to say about human or animal reproductive cloning. If the cloning is performed with altruistic intention, such as when an owner suffers from a psychological trauma as a result of a loss of her pet and can only get over it when the pet is cloned and brought back, then the action can be viewed positively. Buddhism does not regard the action in itself as wrong, and in this case, nobody is harmed. That a nonunique creature is now created as a result of the cloning hardly counts as a reason for the action being wrong in Buddhism because Buddhism does not see anything wrong in nonuniqueness. What is wrong is how one performs action that leads to negative karmas.

However, in the case of therapeutic cloning, where stem cells are cultured which are taken from cloned embryos, Buddhism is more ambivalent. Since the embryos would have to be destroyed, Buddhism views it as a destruction of living organisms and thus regards it to be wrong. One of the most important aspects of the *sila*, or disciplined conduct, is that the practitioner should not harm or kill any sentient beings. Doing so will create a chain of negative karmas such as being reborn in the lower realms and so on, which is a great obstacle toward realizing Enlightenment in the future. However, if therapeutic cloning is performed out of altruistic motives, such as when the action is needed to provide tissues for treatment of life-threatening diseases (and where this is the only possible option), then the ambivalence is much more visible. According to Somparn Promta (2004), one has to distinguish between "personal" and "social" morality. Therapeutic cloning involving destruction of cloned embryos may be wrong according to personal morality, as the embryos have to be destroyed, but according to social morality, this action may be right to a certain extent because it creates something good or useful for society. Suppose the only way to treat a life-threatening disease is to culture tissues out of cloned embryos which will have to be destroyed, then Promta (2004) would view this as something positive according to social morality because in this imperfect world,

one has to make a choice, and since therapeutic cloning here would result in many people being cured of this disease, then the choice weighs toward adopting the therapy as a necessary course for society to take, even though it involves destruction of life which clearly is a wrong action. Simply put, then, personal morality is the kind of morality that is centered only within an individual or a person; the question is whether such and such action is right or wrong from the perspective of the person alone. Social morality, on the other hand, takes a wider view toward the society or community as a whole and regards the value of action as whether it contributes to the welfare of the society as a whole or not.

The distinction between personal and social morality can also be found in Promta's discussion of abortion (Promta, 1998). Clearly, abortion is wrong in Buddhism because it directly involves destruction of life. But according to the perspective of social morality, Promta sees abortion as something necessary even if ultimately wrong for the society because there can be cases where abortion needs to be performed for the good of society as a whole, such as when legalization of abortion leads to reduction or elimination of underground, very unsafe abortion clinics (Promta, 1998).

End of Life

End-of-life issues tend to be more controversial than beginning-of-life issues (except for abortion, which obviously straddles the two). There are already a lot of literature on euthanasia, definition of death, organ transplantation (which is closely related to end-of-life issue), and a growing number on palliative care (See, for example, Keown, 2005). According to Damien and John Keown, Buddhism is opposed to both active and passive euthanasia because it believes in the sanctity of life, and here the Keowns believe that Buddhism is not different from Christianity in this respect (Keown and Keown, 1995). They cite a text from the *Vinaya*, which is one Basket in the *Tripitaka*, the main canon of Buddhism, where a monk is expelled from the order because he advocates death to a terminal patient. By "making death an aim," which means praising death and persuading another to prefer it rather than life, the monk violates the basic monastic rule against killing a human life, and the Keowns take this text as supporting the conclusion that in Buddhism sanctity of life is maintained and euthanasia is forbidden. However, the Keowns also argue that in the case where all hopes of medical help are lost, one should not fight against death to the last minut, but should resign to the inevitable, and it is here that the Keowns say that Buddhism would approve of palliative care in general.

Keown's argument here is disputed by Roy Perrett (1996), who argues that since motive is of crucial importance in deciding the value of an action, one should look closely at the motive behind a particular act of euthanasia to see whether it is pure or not. Motive is pure when it is free from the defilements of greed, anger, or delusion and when it is performed with the intention of benefitting the whole rather than just oneself. Hence, if there was an altruistic motive behind an act of euthanasia, such as to end a patient's life that is clearly terminal and full of intense pain, then such an

act would not be objectionable. However, the dispute between Perrett and the Keowns is couched in term of the debate between the Theravada and Mahayana, with Perrett taking the Mahayana position and the Keowns the Theravada. This is unfortunate because both traditions do share the same core doctrines together. It seems that Buddhist scholars tend to emphasize the differences between these two main branches of Buddhism rather than the similarities. However, key Buddhist doctrines, such as compassion, interdependence, and emptiness of the self and of phenomena, can be found both in Theravada and Mahayana. Thus, instead of scholars adhering themselves to one tradition and debating among themselves, they should focus more on the core teachings that are already shared by all the Buddhist traditions and base their own interpretations of contemporary bioethical issues from there.

Viewed in this light, it can be said that even within the Theravada tradition adhered to by Keown, a support can be found for euthanasia as an act of love and compassion. The whole idea of sanctity of life makes full sense in the context of a theistic religion like Christianity, where life is created by the creator and human life especially is created in the image of the creator himself. While the Buddhist's injunction against killing can certainly be used as a support for the view that Buddhists view life as sanctified, the very concept of sanctity or sanctification is a theistic concept and as such finds no place in Buddhist thought. Thus, one can only talk about life being "sanctified" in Buddhism in a roundabout way where the root meaning of "sanctity" is somehow left behind. This in any case would imply that Buddhist thought somehow follows that of the theistic religions. On the contrary, a nontheistic religion such as Buddhism, in strict literal sense, would forego all talks about "sanctity" or "dignity" all together and instead talk about the value of each form of life in samsara and its capacity for realizing the ultimate goal, which in this case a human being is in a more advantageous position than, say, a hungry ghost or even a deity in heaven, because only a human being not distracted as much by the intense pains or pleasures that beings in the lower and higher realms suffer, respectively. Thus a human being is more valuable in Buddhism than a heavenly deity. This is different from the position of theistic religions, where the heavenly beings are more valuable because they are closer to God.

Furthermore, even in the case of explicitly "making death one's aim," it can be argued that if the purpose of making death an aim is to benefit beings, then the act can become a great self-sacrifice and thus is ethically commendable. A well-known story is that of a bodhisattva, who came across a sick and very hungry mother lion who had to take care of her cubs. Being sick and weak, the lioness was in no position to hunt for herself and for her cubs. Seeing the lioness and her cubs, the bodhisattva felt great compassion and offered his own body to the lioness so that it could gain strength and was thus able to feed her cubs. Viewed from one perspective, this is clearly an act of suicide, but in fact the bodhisattva was praised for his self-sacrifice, in fact the highest form of altruism. It is clear, however, that scarcely anyone alive today would be as self-sacrificing as the bodhisattva in the story, but the story points to the ideal of total self-sacrifice, of who does not have any regard at all for the interest of his own being. In the case of euthanasia, the story seems to

show that making death one's aim does not have to be wrong in all circumstances. There can be some circumstances where doing so can be a form of altruism and highly compassionate act too.

Another important issue in end of life concerns how the concept "death" should be defined. In the past, such as during the Buddha's time, this was not a problem because it was easy to find out who is actually dead. However, with the advent of modern technologies that can keep someone breathing for a very long period who would have been dead otherwise, there has arisen a controversy as to how death should be exactly defined and what the Buddhist perspective should be on this. The issue surrounding definition of death is also connected closely with organ transplantation. Carl Becker (1990) argues that the Buddhist perspective on death is that as long as the body is still warm, the person should not be declared dead. He cites a passage from the *Visuddhimagga*, an early Theravadin commentary, to support this point. Since warmth is necessary for life, it is conceptually impossible for there to be a body which is dead and warm at the same time. This precludes any possibility of declaring someone dead (because he is brain-dead), while his body is still warm because of the respirator.

How death is defined is clearly associated with the issue of organ transplantation. However, even if there were no controversy in defining death, there are much more ethical conundrums regarding organ transplantation itself. The problem centers on how the organs should be distributed. Since there are much more patients who are in need to organs to be transplanted than the number of organs available, how are the organs to be distributed? How should the patients be selected, according to their worth or on a first-come-first-serve basis? On the supply side, should there be the principle of "presumed consent" or "opt-out" system?

The Buddhist principle of compassion can play a clear role here. Potential donors who are also Buddhists need to be reminded that stating their intention as organ donors is a very generous and compassionate act to do and is actually in accordance with the rightful path which will lead eventually toward the ultimate goal of achieving Nirvana. Thus if they make their intention clear as an organ donor, it would be ethically permissible for the doctors to take the organs from them even though they are only brain-dead because through this act they have made a very generous act of compassion. Since the deceased obviously cannot take away their organs to their next lives, they should make the organs available to those who still need them in this life. As for the "opt-out" or presumed consent system, the compassion principle would say that it is rather difficult to presume that everybody is as compassionate as another. Thus, presuming that everybody would agree to be a donor unless they explicitly indicate otherwise might not be tenable because many might not want to become a donor but do not take the trouble of registering their intention. As for the problem of how patients should be selected to receive the donated organs, the principle of equanimity (*upekkha*), which as we have seen is one of the four immeasurables, would mean that distribution out of compassion should be blind. That is, it should not take into account any specific properties that separate one being from others at all. There should not be any kind of discrimination either in form of excluding certain individuals or groups or favoring some

groups or some individuals over others. As a result, the only viable form of distribution here would be something like drawing a lottery or using the first-come-first-serve basis. However, since time spent in waiting is of crucial importance for the patients, the first-come-first-serve basis is fairer than the lottery one. This first-come-first-serve basis, nonetheless, cannot be used at all times without any exception because there can be cases where a patient needs an organ much more than another because the former is in a more serious stage of her disease but may have registered herself on the waiting list later than the other whose disease is not as serious. In this case, it seems that the principles of compassion and equanimity would say that the patient whose disease is more serious should get the organ first even if she comes later on the waiting list.

Another end-of-life issue that has become talked about more in recent years is palliative care. Here, Buddhism can make positive impacts by caring for patients in palliative care centers (Garces-Foley, 2003). Spirituality naturally plays a large role in these centers, as the patients there are moving closer toward death. Being closer to death, they should be reminded that death is inevitable not only for them but also for everybody, who in fact never knows when they will die. Buddhist monks, nuns, and practitioners can help palliative care patients prepare for their end in this lifetime without struggling against it at all costs. Buddhism teaches that death is not the final end where everything will be extinguished forever. On the contrary, death is only a transformation. It is a transition from one lifetime to another, if one still wanders in samsara, which is the case for most people. In such a case, then, another lifetime can be expected. According to the law of karma as stated in the *Abhidhammattha Sangaha*, the quality of the next lifetime very much depends on the quality of life spent in this lifetime, and more importantly, it is the quality of the state of mind at the very moment of death that actually determines what kind of life the person will have to face after he or she is dead (Bodhi, 2007, p. 201). For example, if the person is relaxed and is in a meditative state when she dies, then it can be expected that she will enjoy a rebirth in one of the higher realms. On the contrary, if the person is angry or depressed at the moment when she dies, then it is very likely that she will be reborn in a lower realm. Consequently, it is of utmost importance that the person is in a state of wholesome mind (*kusalacitta*) when she dies, and the palliative care center can arrange for an atmosphere that is most conducive to this.

Vulnerability

The concept of vulnerability has become prominent in recent years as a counterweight to the concept of autonomy. A standard view in mainstream bioethics has been that a person is autonomous and is only vulnerable when conditions befall her in such a way that she cannot function as she normally could. Thus, a disabled person is vulnerable because she cannot function as well as an able bodied person. An elderly is also vulnerable in this sense because she is more susceptible to illnesses and injuries than a youth in the prime of her life.

Viewing a person only as an autonomous agent seems to miss this important aspect of being a human, where vulnerability can be also seen as pervading an entire aspect of being a human. Being a human in this sense is in itself vulnerable, as a human is susceptible to disease, is in a frail condition relative to the environment, and so on. As a vulnerable person deserves and needs active protection, categorizing every human being as vulnerable then can function as a guiding principle in bioethics where each human being is accorded with a special status that emphasizes the need for protection and special care. This dimension, however, appears to be lacking in the normal characterization of humans only as autonomous agents. Jan Solbakk (2011) writes that the concept of vulnerability can be seen from two different angles. One is that every human being is vulnerable. This conception leads to a realization of the concept of human rights where every human being regardless of their ethnicities, nationalities, gender, age, physical condition, etc. deserves and is entitled to special care and protection because of his or her status, qua a human being, as being vulnerable. Another angle of how vulnerability is viewed is that one is vulnerable in this sense only when one happens to be in a certain condition that prevents one from being able to function or perform as well as a "normal" person. In this sense, being vulnerable is not a universal condition; a "normal" human being is not vulnerable in this sense, and only someone who has lost some kinds of abilities or lacks certain features of a normal person can be vulnerable. This second sense sounds rather strange, however, when the concept is applied to women for it implies that being a woman is a "normal" condition for a human being. These two angles of the meaning of "vulnerability," taken together, can provide a foundation for a whole set of bioethical guidelines, one that emphasize not the isolatedness of individuals or their individual capacities to perform as presupposed by autonomy but human solidarity and capacities that each human has in relating to one another, helping, and caring one another.

The text of Article Eight of the UNESCO Declaration on Bioethics and Human Rights states: "In applying and advancing scientific knowledge, medical practice and associated technologies, human vulnerability should be taken into account. Individuals and groups of special vulnerability should be protected and the personal integrity of such individuals respected" (Universal Declaration, 2005). According to Solbakk (2011), the text of the article appears as a result of a compromise. The first sentence of the article, which refers to "human vulnerability" as a whole, points to the first angle of the meaning of vulnerability where vulnerability is a characteristic of humanity as such. In this case, research and development in medical technologies should pay special attention to the fact that every human being is vulnerable. Knowledge and technologies should be developed with the understanding that humans are frail and need special protection. Thus any kind of development that would result in any threat to the survival or flourishing of humanity needs to be stopped. In the second sentence, the emphasis is more toward vulnerability in the sense of loss of normal capabilities, and clearly, these are the groups that need special protection relative to those who are stronger because they have not lost these capabilities. Women, children, the elderly, and the disabled

people are especially vulnerable in this sense, and hence, they need special protection and care.

Buddhism would agree strongly with the principle of vulnerability presented here. The emphasis that the concept of vulnerability has on human solidarity and on their need for special care and protection accords well with the Buddhist precept on compassion and interdependence. Since all human beings are interrelated, no human being can stand alone apart from every other. In this sense, the fact that all humans are interrelated means that everyone is vulnerable, and this fits well with the Buddhist teaching on interdependence, which says that all things, not only humans, are what they are because of their interrelatedness with their total surroundings. When the concept of vulnerability is viewed according to the second sense, the Buddhist concept of compassion can play a key role in emphasizing the fact that these vulnerable groups need special protection and care. They need to be protected and helped simply because their conditions are such that they arouse spontaneous acts of compassion from everyone and actual, concrete help from those who are able to help. Just as a child arouses the feeling of compassion from an adult, the vulnerable group arouses compassion from all humans. It is important to note, however, that compassion here is not to be confused with pity. Pity has a sense that one who feels pity may also feel that he or she is somehow superior than the one to whom the pity is directed. But that is an unwholesome attitude according to Buddhism. When one feels that one is superior to others, a vicious separation between self and others arises, and it is this separation, this bolstering of the ego, that is directly inimical to the realization of the ultimate goal. Hence, the compassion needs to be purely altruistic and universal. It is a feeling that is based ultimately on total loss of any sense of the ego that only serves to separate oneself from the world.

Conclusion

One of the more controversial points within Buddhist bioethics is the question whether there can be any act which is right or wrong in and of itself, and the position taken in this article is that any act is right just in case it is done with compassion and the other immeasurables, and wrong otherwise. Compassionate act arises out of the realization that one's own sense of ego always stands in a way of pure and universal compassion and that any act that arises with this egoistic tendency cannot be fully compassionate, hence should be judged as ethically wrong. Even an act aiming toward death can be a prime example of a pure and universal compassionate act, such as the bodhisattva's dedication of his own body for the hungry lioness alluded to earlier. In this sense, then, it could be seen that there is a sense in which an act cannot be right and wrong in and of itself. Telling a lie, viewed in this light, can be a good act if by so doing the words uttered can create harmony and can lay a path toward eventual realization of the goal in the minds of the listeners and when the one who utters the words fully intend these results without any egoistic motive at all. However, these are viable only in very

exceptional circumstances, and in normal situation, those who have just started their journey toward the realization should instead focus on following the precepts which are aimed at disciplining their own body, speech, and mind, which means that in almost all cases one should not tell a lie. Buddhist ethics, then, cannot be fully separated from other aspects of Buddhist teachings, all of which are concentrated upon demonstrating that samsara, or this experienced world, is unsatisfactory and full of sufferings, that there is a cause of these sufferings in samsara, that the ultimate goal of total liberation from samsara does exist, and that there is a way leading toward final realization of the ultimate goal. These are the four noble truths, which comprise the most fundamental and important part of the Buddha's teaching to his students.

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Catholicism

22

Gerard Magill

Introduction

Roman Catholicism has developed a sophisticated system of morality, both theoretical and practical, that involves multiple tiers of interaction, including official church teaching with specific directives about what is permissible or prohibited, academic discourse by scholars, outreach by professionals in health care, and the daily practice of the moral life by the faithful. To understand varying Catholic teachings on morality in general and bioethics in particular, it can be helpful to begin by discussing different levels of authority in the Catholic church.

Teaching Authority of the Catholic Church

The Catholic Church teaches that God's covenant of salvation is revealed in Holy Scripture with a living transmission of biblical revelation through the Holy Spirit across history, creating a divinely inspired tradition in the church. The authentic interpretation of God's revelation in scripture and tradition is the responsibility of the church's magisterium of bishops in communion with the pope. However, the faithful guided by the church magisterium, shares this responsibility for the living tradition of revelation that undergirds the continuing mission of the church through salvation history. The church magisterium of the pope and bishops teaches on matters of faith and morals, including bioethics, with a range of authority from official Vatican doctrine to its implementation in practical directives for bioethics by national conferences of Catholic bishops.

Because of the extraordinarily large size of Catholic health care in the United States, the teaching from the *United States Conference of Catholic Bishops* (USCCB) is adopted here as an example of how Vatican teaching on morality is implemented at a national level to guide bioethics. Catholic health care in the United States provides approximately one-sixth of the nation's health care, serving

G. Magill
Center for Healthcare Ethics, Duquesne University, Pittsburgh, PA, USA
e-mail: magillg@duq.edu

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approximately 600 hospitals and 1,400 care facilities (long-term care). Because of the size of Catholic health care in the United States, it has a professional organization called the *Catholic Health Association* (founded in 1915) with its own journal (six issues annually), *Health Progress*, that has regular contributions to bioethics discourse. Moreover, in the United States, there is a National Catholic Bioethics Center that publishes a quarterly journal, *The National Catholic Bioethics Quarterly*, as well as an extensively adopted newsletter, *Ethics and Medics*. Also, the USCCB has developed a set of directives to implement Vatican teaching on bioethics, the *Ethical and Religious Directives for Catholic Health Care Services*, now in its fifth edition (USCCB, 2009). Although these *Directives* are designed for and only have jurisdiction over health care in the United States, they implement Vatican teaching in a manner that can have relevance for Catholic bioethics universally.

This discussion of the teaching authority of the Catholic church moves from a broad to a narrow explanation with three distinct components. The first component discusses the comprehensive and systematic teaching of Catholic morality found in the *Catechism of the Catholic Church* (Catechism, 1994) and the church's *canon law* (Canon Law, 1983). The second component examines the foundations of Catholic morality that are explained in the only Papal Encyclical dedicated exclusively to morality so far, *Veritatis Splendor, The Splendor of Truth*, issued by Pope John Paul II in 1993. The third component bridges church teaching on Catholic morality with Catholic bioethics by discussing the *Ethical and Religious Directives for Catholic Health Care Services* from the United States Bishops (USCCB, 2009).

The first component of this discussion of the teaching authority of the Catholic church discusses the *Catechism of the Catholic Church*, authorized by Cardinal Joseph Ratzinger and approved by Pope John Paul II (Catechism, 1994). The *catechism* presents official Catholic teaching on all matters of faith and morality, providing a comprehensive and systematic reference for understanding Catholic morality in general and bioethics in particular. Church doctrine in the *catechism* is consistent with the church's *canon law* (Canon Law, 1983) that also was approved by Pope John Paul II. These documents provide the authoritative foundation for official Catholic teaching on matters of faith and morality.

The highest level authority of church teaching pertains to Papal Infallibility and the magisterium of bishops. In July 1870, the doctrine of Papal Infallibility *ex cathedra* was defined at the First Vatican Council (1869–1870) in Rome in a doctrinal constitution titled, *Pastor Aeternus*, number 3074. Nearly a hundred years later, the Second Vatican Council (1962–1965) in Rome promulgated many doctrinal constitutions. In particular, the *Dogmatic Constitution on the Church*, number 25, clarified the role of the magisterium of bishops over the centuries. This constitution explained that beyond the *ex cathedra* infallibility of the pope in matters of faith and morality, the ordinary magisterium of bishops has authentic teaching authority (Sullivan, 1983).

This understanding was reiterated in teaching from the *Congregation for the Doctrine of the Faith* in 1990 titled, *Donum Veritatis, Instruction on the Ecclesial*

Vocation of the Theologian. The document explained that teachings presented by the bishops in a definitive way must be firmly accepted. These levels of authority in Catholic church teaching reflect a hierarchy of truths, as discussed in Vatican II's *Decree on Ecumenism*, number 11. Also, Catholic church teaching includes the contribution of Catholic theologians. The Papal Encyclical, *Veritatis Splendor*, number 110, explained that the role of theologians includes this responsibility regarding church teaching: "to develop a deeper understanding of the reasons underlying its teachings to expound the validity and obligatory nature of the precepts it proposes." In other words, given the relation between the Catholic magisterium of bishops and the hierarchy of truths taught by them, theologians have a legitimate role as collaborative partners in full communion with the church (Happel & Walter, 1986; O'Donovan, 1982).

The second component of this discussion of the teaching authority of the Catholic church examines the Papal Encyclical, *Veritatis Splendor*. On specific issues of morality, there has been no *ex cathedra* infallible teaching bearing the full and explicit weight of Papal Infallibility as was taught in Vatican I. However, there has been one Papal Encyclical dedicated exclusively to Catholic moral theology, *Veritatis Splendor*. Many Papal and Vatican documents mention particular issues related to moral theology and bioethics, and they will be discussed later. The approach to Catholic moral theology that is explained in this encyclical is consistent with and calls upon the teaching of the *catechism* and *canon law* mentioned above. The following summary of *Veritatis Splendor* presents the foundations for morality in Catholic teaching.

The purpose of the encyclical *Veritatis Splendor* was to address fundamental questions regarding Catholic moral teaching, based upon the traditional doctrine of natural law with its universally and permanently valid precepts, while recognizing that the church's *catechism* provides a complete and systematic exposition of church moral teaching (number 4–5). After a reflection upon the teachings on morality in the bible (Chap. 1), the encyclical addressed four foundational issues in morality to highlight the principles underlying church teaching (Chap. 2).

The first foundational issue in *Veritatis Splendor* is the understanding of human freedom and rightful autonomy in morality in a manner that integrates the ethical realm with the realm of salvation. Here, the encyclical alludes to the traditional teaching of natural law that recognizes the role of human reason in discovering and applying the moral law. The encyclical explains that human reason draws its truth and authority from the eternal law, reflecting divine wisdom itself (numbers, 35–53). As explained by St. Thomas Aquinas, the natural law is the participation of the eternal law in the rational creature (Rhonheimer, 2011).

The second foundational issue in *Veritatis Splendor* deals with conscience whose imperative character formulates moral obligation in light of the natural law and constitutes the proximate norm of personal morality (numbers 54–64). The third foundational issue explains that in the relationship between the person and specific actions, an individual's fundamental option in life cannot be disconnected or separated from concrete behavior. Here, the church explains that there is a substantive integrity or personal unity of moral agents in their body and soul (65–70).

The fourth foundational issue in *Veritatis Splendor* deals with the meaning of moral action that entails the rational ordering of the human act to the good and the voluntary pursuit of that good. Here, the encyclical explains that moral life is inherently teleological in the sense that it consists in the deliberate ordering of human acts to God as the supreme good and ultimate end (*telos*) of humanity. Again, the encyclical turns to Aquinas to explain that the morality of the human act depends on the object being rationally chosen by the deliberate will (the moral object). The object is to be understood as the proximate end to a deliberate decision which determines an individual's act of willing. Hence, there are moral actions that can be described as intrinsically evil (*intrinsice malum*) insofar as the object of the human act involved is incapable of being ordered to God, independently of ulterior intentions or circumstances of the individual. This reflects the Catholic tradition's understanding of three sources of morality: the chosen object, the intention, and the circumstances. Examples of intrinsically evil acts include abortion, euthanasia, torture, slavery, prostitution, and human trafficking (numbers, 65–81). The final section of *Veritatis Splendor*, Chap. III, discusses how the moral good integrates faith and morality, presenting universal and unchanging moral norms as being in service to true freedom.

To bridge Catholic teaching on morality in general with bioethics in particular, the third component of this discussion of the teaching authority of the Catholic church considers the *Ethical and Religious Directives* from the United States Conference of Catholic Bishops (USCCB, 2009), which for brevity is referred to as *Directives*. The *Directives* are now in the fifth edition published in 2009. The preamble and introduction explain that the purpose of the *Directives* is to reaffirm ethical standards of behavior in health care based on church teaching and to present authoritative guidance about specific moral issues. There are six main parts, each with two sections: there is an expository introduction that provides the context for each of the main categories and there is a series of prescriptive directives about the truths of Catholic faith and their significance for the categories discussed. The six parts discuss a different category. Part one discusses social responsibility of Catholic health care services. Part two examines the pastoral responsibility and spiritual responsibility of Catholic health care. Part three considers the professional-patient relationship. Part four analyzes the beginning of life. Part five analyzes the seriously ill and dying. Part six deliberates on forming new partnerships with other than Catholic organizations and providers.

The above points about the teaching authority of the Catholic church present several components: a component that deals with the comprehensive and systematic approach to morality, a component that addresses the foundations of morality, and a component that bridges Catholic teaching on morality with the specific arena of bioethics. From these components, a general framework for Catholic bioethics can be suggested that relates the sanctity and conscience of the human person with moral actions understood in light of the natural law, as discussed in the next section.

Framework for Catholic Bioethics

The sanctity and conscience of the individual person reflects the integration of the ethical realm and the realm of salvation, with moral actions that shape the person's fundamental option to the good, being enlightened by the natural law. This succinct statement presents a framework for Catholic bioethics by considering two related aspects, discussed below. Of course, there are many excellent studies on Catholic bioethics that explore theoretical and practical issues in depth, (Kelly, Magill and ten Have, 2012; Kelly, 2007; Shannon & Kockler, 2009; Walter & Shannon, 2005). This analysis seeks to present a simple framework to address principles and problems in Catholic bioethics.

The first aspect of the framework for Catholic bioethics relates the dignity of the individual with the sanctity of the person in the context of the common good. The Catholic tradition holds that religious and moral truths in faith are not beyond the grasp of reason. The dignity of the human person is grounded in being created in the image of God. The sanctity of the human person deepens this concept in relation to the redemption of humanity after the fall. The integrative nature of the dignity and sanctity of the human person must be understood within a communal context of social responsibility or the common good that shapes the ecclesial mission of the church. Catholic teaching affirms this reciprocity in its health care ministry especially in terms of respect for life (sanctity) and the right to health care (common good).

On the one hand, the sanctity of human life means that it must be respected and protected from the moment of conception. This teaching is the basis for the church prohibition against direct abortion and euthanasia. However, the sanctity of human life is also the basis for church teaching permitting the withdrawal of futile care at the end of life. Also, respecting the sanctity of human life undergirds the church's teaching about the dignity of marriage and the need to maintain the unitive and procreative meaning of marital intimacy – this is the church's rationale for its teaching against contraception as well as in vitro fertilization procedures, as discussed in the *Instruction on Respect for Human Life in Its Origin and on The Dignity of Procreation* from the Congregation for the Doctrine of the Faith in 1987 (Rhonheimer, 2010). On the other hand, because of the church's commitment to human dignity and the common good, the US Bishops in part one of the *Directives* assert there is a human right to adequate health care, especially for the poor and vulnerable.

The second aspect of the framework for Catholic bioethics relates the meaning of moral truth, moral norms, and moral action with the natural law. Catholic teaching explains that moral truth is gleaned from the natural law, adopting the explanation of Aquinas mentioned above. However, there is considerable debate about what this means precisely with varying emphasis upon physical/biological reality versus personal reasoning as properly reflective of the meaning of natural. The camps in this disagreement over the meaning of natural law are often referred to in terms of physicalism versus personalism. The ethical debate typically divides into a conservative camp, being aligned with a physicalist approach, and a progressive camp, being aligned with a personalist approach, to explain the meaning of moral norms and actions (Kelly, Magill and ten Have, 2013).

Views of moral norms can reflect either a universally determined outlook adopting a physicalist, conservative approach or an outlook that is attentive to historical consciousness adopting a personalist, progressive approach. While there is general agreement between conservatives and progressives that a physical act cannot itself determine morality, insofar as intention and circumstances are necessary components for ascertaining morality that are distinct from the physical action, there is considerable disagreement about the moral meaning of particular actions. The progressive, personalist camp generated a theory called proportionalism that justifies moral action after weighing nonmoral goods in light of the intention and circumstances involved. This theory remains influential in Catholic bioethics, even though proportionalist theories in general were rejected as a legitimate normative method in Catholic morality in the encyclical *Splendor of Truth*, no. 75 and 79. The Catholic debate over artificial contraception amply illustrates this divided understanding of the meaning of natural law and its role in determining moral norms: the physicalist, conservative perspective (as occurs in official Catholic teaching) prohibits artificial contraception, and the personalist, progressive perspective justifies artificial contraception in particular circumstances.

This framework for Catholic bioethics, with the aspect that relates the dignity and the sanctity of the individual in the context of the common good and the aspect that relates the meaning of moral truth with the natural law, enlightens multiple practical issues. The history of Catholic moral theology and of Catholic bioethics is extensive, and it is important to be mindful of the development over two millennia of this robust tradition of church teaching and scholarly discourse (Kelly, 1979; Mahoney, 1987), though the focus of this analysis is upon the principles and issues in Catholic bioethics today.

The sections below address the practical issues in Catholic bioethics that typically elicit most controversy and discussion within the United States but also globally. These practical issues are presented in two clusters: clinical ethics both at the start and at the end of life and professional and organizational ethics in health care. Within each cluster, a specific principle in Catholic bioethics is discussed that helps to resolve the dilemmas that can occur when both good and bad effects accompany moral action. Under the discussion of clinical ethics the principle of double effect, which is developed from the teaching of St. Thomas Aquinas, is discussed to address situations in which an individual action involves good and bad effects. In contrast, under the section "Professional and Organizational Ethics," the principle of cooperation, which is developed from the teaching of St. Alphonsus Liguori, is discussed to address situations in which good and bad actions of two different agents coalesce.

Clinical Ethics at the Start of Life

The teaching of the Catholic church against all forms of direct abortion is well known, protecting human life from the time of conception. Catholic teaching on human life has significant implications for both ethics and politics in the public

square (Lee & George, 2008). To explain official Catholic teaching on abortion, in 1995 Pope John Paul II issued a Papal Encyclical, *Evangelium Vitae, The Gospel of Life*. This encyclical further developed the previous teaching in 1987 from the Congregation for the Doctrine of the Faith, *Donum Vitae. Instruction on Respect for Human Life in its Origins and on the Dignity of Procreation*. It is important to note that although Catholic teaching protects human life from conception, this teaching is an assumptive stance given the high stakes involved. The Encyclical *Evangelium Vitae* acknowledges that while "the Magisterium has not expressly committed itself" to what are described as "philosophical affirmations" about the start of life, life is protected from conception, as explained in number 60: "What is at stake is so important that, from the standpoint of moral obligation, the mere probability that a human person is involved would suffice to justify an absolutely clear prohibition of any intervention aimed at killing a human embryo. . .. *The human person is to be respected and treated as a person from the moment of conception*" (number 60). The core teaching on abortion is that "the direct and voluntary killing of an innocent human being is always gravely immoral . . . and can never be licit either as an end in itself or as a means to a good end" (number 57); "direct abortion, that is, abortion willed as an end or as a means, always constitutes a grave moral disorder" (number 62).

Related to this teaching on protecting human life from conception is the prohibition of creating embryos in the petri dish via in vitro fertilization (IVF) outside of the natural environment of the uterus. This prohibition occurs because the IVF process disrupts the integration of the unitive and procreative aspects of marital intimacy that was at the core of Pope Paul VI's 1968 Papal Encyclical against artificial contraception, *Humanae Vitae* (number 12). The IVF process can be used to create embryos not only for treatment of infertility but for other purposes, such as for embryo testing and selection based upon genetic conditions in the process of preimplantation genetic diagnosis (PGD), or for planning so-called designer babies based on genetic profiling, or for research related to human cloning (Guenin, 2008). Catholic teaching in bioethics forbids all of these.

There is another problem that is raised by this strict prohibition of abortion. Catholic teaching against abortion includes contraceptive devices or pharmaceuticals that prevent a fertilized egg from nidating in the uterus. Insofar as human life is protected from the moment of conception, the fertilized egg is included under this protection, and hence, these contraceptive measures are tantamount to abortion. Given the large numbers of Catholic women using these contraceptive measures, with the concomitant number of contraceptive abortions that can occur in daily Catholic life, the teaching against abortion encounters significant issues of effectiveness or credibility – not least because many Catholic women who identify themselves as being firmly opposed to abortion may find themselves participating in these abortive contraceptive measures, perhaps with surprising frequency.

Catholic teaching against abortion specifically prohibits direct abortion. However, some types of termination called indirect abortions are permitted. Two types of cases elicit continuing controversy in Catholic bioethics that can be construed as

legitimate, indirect abortions. The cases deal with the imminent threat of a woman's death in pregnancy requiring the termination of embryonic or fetal life: ectopic pregnancy and pulmonary hypertension.

Principle of Double Effect: Ectopic Pregnancy and Pulmonary Hypertension

Although the Catholic tradition refers to double effect reasoning in dilemma circumstances as applying the "principle" of double effect, what occurs is an interpretation of permissible or proscribed effects, distinguishing between morally intended acts and their unintended side effects within a particular framework of moral reasoning. This section discusses four issues: first, the principle of double effect with its traditional conditions; second, the application of the principle to the settled case of a pregnant woman with a cancerous uterus; third, the use of the principle to clarify the controversial case of ectopic pregnancy; and fourth, the use of the principle to clarify the controversial case of pulmonary hypertension.

First, the principle of double effect is attributed to St. Thomas Aquinas, and over subsequent centuries its four conditions were developed, formulated specifically by Jean Pierre Gury (1801–1866). The four conditions can be explained in this manner. Condition one: the morally intended action as the object of the act must be either good or morally indifferent. Condition two: the bad effect must not cause the good effect but the bad effect and good effect may occur simultaneously. Condition three: the agent must directly intend the good effect, with the bad effect being unintended albeit foreseen. Condition four: there must be a proportion between the intended good effect and the unintended, though permissible, bad effect.

Second, the application of the principle of double effect to the settled case of a pregnant woman with a cancerous uterus can be described in this manner. Condition one: the morally intended action is to remove the cancerous organ, the mother's uterus, to save her life. Condition two: the harm to the fetus occurs at the most simultaneously with the removal of the uterus: the fetus is not killed as a means to achieve the end of saving the mother. Condition three: the bad effect of the death of the fetus is merely foreseen but not intended. Condition four: the proportion between the good and bad effect is that no other intervention would be possible to save the one life that can be rescued (the mother's) rather than lose both lives (the mother and the fetus).

Catholic teaching, from a generic standpoint, accepts that the principle of double effect can be implemented when the death of an embryo or fetus is foreseen but not intended. The *Directives* of the US Bishops states the following in number 47: "Operations, treatments, and medications that have as their direct purpose the cure of a proportionately serious pathological condition of a pregnant woman are permitted when they cannot be safely postponed until the unborn child is viable, even if they will result in the death of the unborn child" (USCCB, 2009).

Applying the principle of double effect to a pregnant woman with a cancerous uterus is now a settled case in Catholic teaching on bioethics. Pope Pius XII

explained in his "Address to the Associations of the Large Families" on November 26, 1951: "The reason is that, if, for example, the safety of the future mother, independently of her state of pregnancy, might call for an urgent surgical operation, or any other therapeutic application, which would have as an accessory consequence, in no way desired or intended, but *inevitable*, the death of the foetus, such an act could not be called a *direct* attempt on the innocent life. In these conditions the operation can be lawful, . . . provided that it is not possible to postpone it till the birth of the child, or to have recourse to any other efficacious remedy" (Odile & Liebard, 1978).

Further ratification of this settled case of legitimately removing a cancerous uterus from a pregnant woman was documented by the U.S. Bishops' Committee on Doctrine in a statement published on June 23, 2010: "The . . . scenario describes a situation in which an urgently needed medical procedure *indirectly* and unintentionally (although foreseeably) results in the death of an unborn child. In this case the surgery *directly* addresses the health problem of the woman, i.e., the organ that is malfunctioning (the cancerous uterus). The woman's health benefits directly *from the surgery*, because of the removal of the cancerous organ. The surgery does not directly target the life of the unborn child. The child will not be able to live long after the uterus is removed from the woman's body, but the death of the child is an unintended and unavoidable side effect and not the aim of the surgery" (USCCB, 2010).

In this case, conservative and progressive interpretations of natural law reasoning, as well as the official teaching of the magisterium of the church, agree that a cancerous uterus can be legitimately removed from a pregnant woman despite foreseeing the death, unintended but unavoidable, of the fetus. Conservative and progressive views argue their support for the case in different ways. For example, proportionalist reasoning would consider the first and second conditions of the principle of double effect to be dependent on the third and fourth conditions that focus upon proportionality and intentionality. Nonetheless, consensus has been reached on the case. That consensus has yet to be developed in the next two cases.

Third, the principle of double effect in the settled case of the cancerous uterus can be used to clarify cases of ectopic pregnancy. When a fertilized egg nidates in a fallopian tube, it creates a life-threatening circumstance for the mother. At times, the situation resolves itself naturally, but typically medical intervention is required. There are two main options. Salpingectomy involves the surgical removal of part of the fallopian tube with the fertilized egg within. This can be justified in a similar manner to the removal of a cancerous uterus from a pregnant woman, insofar as the conditions of the principle of double effect would be exactly similar, most especially that the death of the embryo is merely foreseen but unintended. The more controversial intervention is a salpingotomy involving the removal of the embryo and its surrounding trophoblast but leaving the fallopian tube intact. The advantage here is to preserve the fertility of the fallopian tube while resolving the underlying pathology. The dilemma, however, is that the moral action appears to target the embryo directly, either by use of the drug methotrexate or by surgical intervention.

There are three contrasting ways of justifying this more controversial approach of salpingotomy. The first argument involves a progressive perspective reflecting a proportionalist approach that would weigh the relevant goods, recognizing that the embryo is destined to die whatever transpires. The argument would be that salpingotomy, saving the mother's life and preserving the fertility of the fallopian tube in question, is a more proportionate intervention (causing the most good and least harm) than salpingectomy that involves removal of the fallopian tube with concomitant compromise of the woman's fertility in that fallopian tube (Kelly, 2004). Of course, if the embryo could be removed and otherwise saved, a proportionalist analysis would support doing so, but that is not yet medically feasible. However, as mentioned previously, Catholic teaching does not accept proportionalist approaches.

The second argument involves a conservative perspective arguing that salpingotomy could be permitted, physically removing the embryo while adhering to the Catholic prohibition of direct abortion. The argument is that the meaning of the moral action is to save the mother, albeit foreseeing but unintentionally causing the death of the embryo by physically removing it – the emphasis here is upon physically removing the embryo, recognizing that it will inevitably die rather than directly killing it. The conservative moral philosopher Martin Rhonheimer, among others, makes this nuanced argument by presenting a moral action theory based on Thomistic virtue ethics (Rhonheimer, 2011). He recognizes that the intervention involves killing the embryo insofar as the intervention is aimed at the embryo in a physical manner, but this is not tantamount to a morally direct action. The physical action is not morally decisive. For example, if the embryo could be removed physically and transferred to life support, then that should be done (just as the proportionalist approach would argue), but it is not yet medically feasible. Because saving the embryo is not possible does not mean that the intervention to save the mother entails morally direct killing of the embryo. He makes a similar argument to justify the historical intervention of craniotomy as the necessary physical action to save the life of the mother when otherwise both mother and fetus will die (Rhonheimer, 2009).

It is interesting that both the conservative moral action theory and the proportionalist analysis agree that the physical removal of the embryo cannot determine the moral meaning of the intervention. However, the conservative moral action theory refuses to justify the intervention based on a weighing of goods, such as is argued in a proportionalist analysis. However, distinguishing between these theories with regard to the practical analysis involved can appear like making a technical distinction without a substantive difference. The weighing of goods that characterizes proportionalist analysis involves the identical points upon which conservative moral action theory justifies the removal of the embryo: the embryo cannot survive whatever occurs (of course, the embryo would be saved in both approaches if it was medically feasible), the life of the mother can be rescued, and the physical removal of the embryo is not sufficient to determine the moral meaning of the action. In other words, it appears that complex cases of moral analysis like ectopic pregnancy can bring conservative and progressive approaches

together both with regard to the conclusion of directly removing the embryo and also with regard to the points made to justify the conclusion.

The third argument on ectopic pregnancy involves the use of the principle of double effect, such as argued by the Catholic moral theologian John Touhey. He justifies salpingotomy as the removal of the embryo in an indirect manner. He explains that an intervention may be justified, such as by the drug methotrexate, insofar as the physical intervention deals with the trophoblast that develops into the placenta, thereby not directly or physically removing the cytoblast (within the trophoblast) that develops into the embryo and fetus. He explains that removing the trophoblast with the cytoblast inside is akin to removing the cancerous uterus with the fetus inside using the traditional principle of double effect (Touhey, 1995). This argument differs from the proportionalist analysis and the conservative moral action theory insofar as those approaches justify the direct physical removal of the embryo. In contrast, the purpose of applying the principle of double effect is to avoid the direct, physical removal of the embryo itself. The double effect reasoning is that the removal of the embryo is an indirect and unintended, albeit unavoidable and foreseen, side effect of legitimately removing the trophoblast, within which the cytoblast that becomes the embryo is contained.

Each of these three arguments draws the same conclusion in Catholic bioethics: that salpingotomy can be justified even though it entails killing the embryo (either directly or indirectly). Of course, a conservative argument can be made against salpingotomy as constituting a direct abortion insofar as the embryo is removed from the fallopian tube. However, official Catholic teaching has not yet taken a definitive stance on this case. The above analysis has been presented in detail to illustrate how the normative approaches in Catholic morality and Catholic bioethics function, especially with regard to the foundational teaching on protecting life from conception.

Fourth and finally, the use the principle of double effect can clarify controversial cases dealing with pulmonary hypertension caused or exacerbated by pregnancy. The clinical situation can arise when there is an imminent threat of death to a woman, often around the 11th week of pregnancy, due to pulmonary arterial hypertension that can cause cardiogenic shock resulting in cardiac arrest. The cause of the pathology is the placenta (as a shared organ between mother and fetus) that becomes hypoxic. In such cases, akin to ectopic pregnancy, the fetus is destined to die whatever transpires, and the only life that can be saved is the mother's life.

The same analysis that pertains to ectopic pregnancy can be applied to this case. First, using proportionalist analysis, removing the fetus can be justified by weighing of goods (causing the most good and least harm) – but this theoretical approach has been rejected by Catholic teaching. Second, adopting conservative moral action theory, removing the fetus can be justified by distinguishing between its physical removal and the moral meaning of the action. In this case, as in ectopic pregnancy, a progressive approach involving a proportionalist analysis and a conservative approach involving moral action theory make the same points to justify removing the fetus: the fetus cannot survive whatever occurs, the life of the mother can be

rescued, and the physical action of removing the fetus is not sufficient to determine the moral meaning of the action.

In contrast to these two approaches, a third argument involves the use of the principle of double effect to justify the death of the fetus as an indirect side effect, as follows. The underlying pathology causing or exacerbating the pulmonary hypertension of the mother is the placenta that has become hypoxic. The placenta, as a shared organ between mother and fetus, must be removed. However, the removal of the placenta can only occur by evacuating the uterus with the amniotic membranes containing the fetus, such as by dilation and curettage (D and C). The direct, physical action of removing the amniotic membranes containing the fetus is akin to the removal of the cancerous uterus with the fetus contained within. In the case of pulmonary hypertension, the death of the fetus is unintended, though foreseen and unavoidable. An additional point should be noted in this case. Even if the fetus was already dead in the uterus, the placenta can continue as a functional organ for some time, even weeks. Hypothetically, action in this case to resolve the underling pathology by removing the fetus alone would not be sufficient – only the removal of the placenta can achieve that purpose. In sum, the principle of double effect in Catholic bioethics can be applied to this case (Magill, 2011).

Clinical Ethics at the End of Life

The principle of double effect also can be used to resolve dilemmas in end-of-life care in which withholding or withdrawing treatment (between which there is no morally significant difference), including medically assisted feeding, is deemed to be futile. Because Catholic teaching recognizes that the life of the body is not an absolute good, there is no moral obligation to keep a patient alive whatever the circumstances or cost. The Catholic tradition has developed a working principle that permits allowing patients to die when futile measures are legitimately withdrawn. That is, withdrawing futile measures lets patients die of their underlying pathology and does not constitute killing them: the intent to withdraw futile treatment is distinct from intending the inevitable and foreseen death of the patient. However, any form of direct euthanasia or assisted suicide is prohibited in Catholic teaching, as explained in the 1980 *Declaration on Euthanasia* from the Congregation for the Doctrine of the Faith.

There has been considerable debate over the treatment of patients in a persistent vegetative state (PVS), and the US Bishops updated their teaching on this matter in the 2009 fifth edition of their *Directives* in number 58, where they made these points. There is an obligation, but only in general principles, to provide medically assisted feeding (nutrition and hydration) to patients in chronic and irreversible conditions, such as PVS patients. However, in specific cases medically assisted feeding is morally optional, not morally obligatory, if it cannot reasonably be expected to prolong life or it is excessively burdensome or it causes significant physical discomfort to the patient, such as when a patient draws close to death.

This teaching reflects a more basic distinction, discussed in *Directives* number 56–57, that guides decision-making in health care by differentiating between proportionate and disproportionate means, reflecting the longstanding distinction in the Catholic tradition between ordinary and extraordinary means (Hamel & Walter, 2007). The distinction revolves around the crucial conjunctives *and*/*or*, as follows: "A person has a moral obligation to use ordinary or proportionate means of preserving his or her life. Proportionate means are those that in the judgment of the patient offer a reasonable hope of benefit *and* do not entail an excessive burden or impose excessive expense on the family or the community" (*Directive*, 56, emphasis added); "A person may forgo extraordinary or disproportionate means of preserving life. Disproportionate means are those that in the patient's judgment do not offer a reasonable hope of benefit *or* entail an excessive burden, or impose excessive expense on the family or community" (Directive, 57, emphasis added). That is, ordinary or proportionate means have a much higher bar to meet (benefit *and* burden analysis) than extraordinary or disproportionate means (benefit *or* burden analysis).

Moreover, the Catholic tradition is supportive of organ and tissue procurement after a patient has died. Catholic teaching retains an open stance on donation after cardiac death (DCD). This practice raises a controversial issue. DCD occurs with nonheart beating cadavers (NHBCs) using cardiopulmonary criteria for death rather than brain death. Technically, for a small period of time after using cardiopulmonary criteria for death before brain death occurs, patients could be artificially resuscitated. In theory, such patients are beyond the point of self-resuscitation but technically could be artificially resuscitated, though there would be immense brain damage. In other words, the patient is not completely dead but will never be resuscitated – that is a condition of initiating the process of DCD.

Professional and Organizational Ethics

In addition to issues in clinical ethics at the start and end of life in which the traditional principle of double effect can be so helpful to resolve dilemmas about patient care, the Catholic tradition also engages issues related to professional and organizational ethics for which another ethical principle, the principle of cooperation, can be helpful to resolve dilemmas. The relation between patients and clinicians is foundational in Catholic bioethics, such as explained in part three of the *Directives* of the US Bishops. In addition to respecting patient rights, autonomy, and consent, this relationship provides the context for fostering professional virtue (Pellegrino & Thomasma, 1993). In health care today, there are increasing conflicts of interest that compromise both the health care professional and health care organizations. From the perspective of individual professionals, ethical dilemmas arise, for example, from financial incentives or partnership with device manufacturers. From the perspective of organizations, ethical dilemmas arise, for example, when mergers occur between Catholic and other than Catholic organizations that

provide services prohibited by the Catholic tradition, such as elective sterilizations that contravene Catholic teaching on contraception.

The Catholic tradition has developed a sophisticated principle of cooperation to guide professionals and organizations through these moral dilemmas. The principle functions in situations where an individual or organization as a moral agent is connected with the wrongdoing of another agent. For example, in a merger between a Catholic hospital and a community hospital that performs sterilizations, the principle is applied to make arrangements that keep the Catholic facility at a sufficient distance from the sterilization procedures and profits of the community hospital while having closer affiliation on other morally legitimate aspects of the merger. This type of arrangement using the principle of cooperation was explained by the United States National Conference of Catholic Bishops in a *Statement on Tubal Ligation* (USCCB, 1983) as well as in an appendix to the earlier third edition of the *Ethical and Religious Directives for Catholic Health Care Services* (USCCB, 1995). Subsequent editions of the Directives have removed this appendix on "The Principles Governing Cooperation."

There are two basic distinctions that need to be made. First, formal cooperation is never permitted whereby an individual or organization is morally complicit by directly participating in or intending the wrongdoing of another individual or organization. For example, if a Catholic hospital partnered with a community hospital in order to provide sterilizations and share the resulting profits that arrangement would intend the wrongdoing as formal and illicit cooperation.

Second, material cooperation is permitted in situations of duress that permit material connection between two moral agents: the wrongdoing of one is not intended by the other, and there is sufficient distance between the two moral agents to avoid one being perceived as morally complicit in the wrongdoing of the other. For example, if a politician is proabortion, Catholic citizens may vote for that candidate provided they do not support the candidate's proabortion stance. Furthermore, Catholic politicians may vote for proabortion legislation in government provided they indicate they are opposed to abortion and that the law being passed further limits the harm of previous abortion legislation.

Pope John Paul II, in his 1995 Encyclical *Evangelium Vitae*, wrote the following (number 73): "when it is not possible to overturn or completely abrogate a pro-abortion law, an elected official, whose absolute personal opposition to procured abortion was well known, could licitly support proposals aimed at *limiting the harm* done by such a law and at lessening its negative consequences at the level of general opinion and public morality." In the subsequent paragraph (number 74), the pope summarized the principle of cooperation in this manner, using action against innocent human life as an example: "it is never licit to cooperate formally in evil. Such cooperation occurs when an action, can be defined as a direct participation in an act against innocent human life or a sharing in the immoral intention of the person committing it." Many organizational arrangements in health care employ this principle of cooperation to resolve ethical dilemmas that involve conflict of interest or organizational complicity in wrongdoing (Watt, 2005).

Emerging Issues in Catholic Bioethics

The framework for Catholic bioethics that enlightens clinical, professional, and organizational issues in health care also is helpful for considering emerging issues in bioethics. These three substantive issues illustrate the moral landscape that Catholic bioethics will have to traverse for many years ahead.

Since the sequencing of the human genome, the accomplishments of cloning, and the creation of human embryonic stem cells, science and biotechnology present enormous challenges to Catholic bioethics (Shannon & Walter, 2003). At a foundational level, technological enhancement may change the meaning of human identity, the species, and the ecological environment. Hence, religious bioethics must keep apace to scrutinize and guide foundational changes to the human condition and global environment (Cole-Turner, 2011).

More particularly, the manipulating of pluripotent stem cells raises profound ethical and ontological questions about when human life actually begins and what type of research may be morally permissible at the earliest stages of embryogenesis. For example, insofar as adult stem cells can be turned into pluripotent stem cells that can then be used for procreation (as has occurred in mice experiments), the moral status of human pluripotent stems cells needs to be clarified for research purposes, even though it would be immoral to use these cloned cells for human procreation (Magill & Neaves, 2009).

Furthermore, because embryonic stem cell research is inherently controversial due to the unavoidable destruction of the human blastocyst when procuring these cells, there will be increasing pressure to use excess blastocysts that remain in cryopreservation in IVF clinics. There are approximately 400,000 excess IVF embryos in the United States. Perhaps the Catholic tradition can shed light on the possibility of using these embryos by deploying its principle governing letting patients die and its principle governing organ procurement from dead patients, as follows.

The standard of care in IVF clinics now is to freeze 5-day embryos after they have developed into blastocysts because they subsequently implant more effectively to the uterus. At the blastocyst stage, the embryonic stem cells have already developed. Frozen blastocysts cannot live forever in a state of cryopreservation. Catholic teaching permits them being withdrawn to thaw and die – akin to withdrawing life support from an adult patient (cryopreservation being the embryo's life support). Moreover, just as organs can be procured after a patient dies while the organs are still viable, a similar process is feasible for blastocysts. There is a molecular marker that identifies the point at which the blastocyst cannot recover, yet the embryonic stem cells remain viable. That molecular marker for the blastocyst is akin to the criteria of death used for organ procurement. In other words, the Catholic tradition could deploy its principles governing letting patients die and organ procurement to obtain embryonic stem cells in a morally legitimate manner from unwanted, excess frozen embryos (Magill, 2009). This remains an open question.

Finally, excess embryos in cryopreservation present another opportunity for an imaginative approach in the Catholic tradition. Official Catholic teaching,

for example, in the *Instruction on Respect for Human Life in Its Origin*, forbids surrogacy, understood as a woman carrying a pregnancy for an infertile couple. Perhaps Catholic teaching can be developed to permit a specific type of surrogacy. The condemnation of surrogacy was in the context of assisting infertility. But a different context may elicit a more acceptable meaning for surrogacy. Given the pro-life teaching in Catholicism, there are families in which the mother would be willing to accept a frozen embryo, have it implanted in her womb, and gestate it to birth – as a form of early adoption. If official Catholic teaching makes such a change, it would constitute another example of the capacity for doctrinal development in the Catholic tradition, in this case making a significant contribution to Catholic bioethics.

Conclusion

Catholic bioethics has developed a remarkably nuanced and comprehensive approach to health care, especially to resolve complex moral dilemmas. The teaching authority of the church and a general framework for Catholic bioethics guides discussions at the practical level. The principle of double effect helps to resolve dilemmas in clinical ethics, such as at the start and at the end of life. And the principle of cooperation helps to resolve professional and organizational dilemmas, such as regarding conflicts of interest or mergers between organizations. These practical topics will continue to elicit much discussion, as will emerging issues in biotechnology that will dominate the landscape of Catholic bioethics for years ahead.

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Confucianism

23

Erika Yu

Introduction

As one comes to the era of globalization, it appears that the need to search for and promotion of universal ethical principles are never more pressing and justified. The Universal Declaration on Bioethics and Human Rights is a notable initiative of such endeavor in the field of bioethics. Adopted by the Member States in the General Conference of the United Nations Educational, Scientific, and Cultural Organization (UNESCO) in 2005, the Declaration addresses States with a universal framework of bioethical principles for their legislation and policies formulation. It avows that a universal bioethical consensus has been reached despite cultural and moral diversities. Moreover, pluralistic dialogue, while it should be promoted, is justified only insofar as it is not in conflict with the most fundamental moral commitments that the global community shares (Article 12).

Yet, as globalization opens up the possibility of pluralistic dialogue among different moralities, it brings one no less opportunity to recognize irresolvable disagreements among contending moral communities upholding diverse perspectives. In the field of bioethics, examples of prominent issues include the moral controversies of abortion, embryonic stem cell research, euthanasia, and just allocation of healthcare resources. Appeal to the moral commitments that the Declaration avows to be fundamental to all – human dignity and human rights, or maximization of benefit and avoidance of harm, or individual autonomy – could hardly yield much conclusion in these bioethics issues.

Rather, what is commonly found are different levels of deadlock. On one level, moral debates persist because competing moral communities understand those values differently (Engelhardt, 1996). For instance, respect for human dignity is often the central value that both advocates and opponents of euthanasia defend in their debates, yet they disagree profoundly with each other on whether euthanasia should be morally justified (Somerville, 2009). On another level, moral

E. Yu
Department of Public and Social Administration, City University of Hong Kong, Kowloon, Hong Kong SAR
e-mail: erikayu@gmail.com

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communities also differ in their views on how various values should be prioritized. For example, should individuals have equal rights to healthcare or should those who could benefit the most be given priority (see e.g., Daniels, 1981 & Brock, 2001)? Should individuals be free to sell their organs or should organ selling be banned since commoditization of body parts violates human dignity (see, e.g., Taylor, 2009 & Kerstein, 2009)?

The Declaration, nonetheless, may be read as advocating a "thin" liberal view that aims just to break the deadlock. Instead of supporting a particular moral account of human dignity, human rights, or fundamental freedoms that is central to a certain approach to bioethical issues, a thin liberal view may propose that respect of individual dignity, rights, and freedom necessitates individuals to respect each other's moral choices equally. Fundamental to this proposal is that individuals, as moral agents, are characterized primarily by their capacity to make independent and autonomous choices, including which morality they want to commit. The Declaration is a framework that serves to protect individuals from political authority to restrict their choices of moral life that they want to pursue. Thus read, however, one wonders if the Declaration is a consensus arrived by diverse moral communities on any substantial ethical commitments that they share or on an acknowledgement that there is a lack of it. After all, while the Declaration recognizes and gives regards to cultural diversity or pluralism, the respect is only secondary (Article 12).

Indeed, the Declaration holds a clear and strong stance on the practice of informed consent to medical intervention and scientific research. For persons with the capacity to consent, sufficient information must be given for them to make independent decision on whether to undertake any medical intervention or research (Articles 5 and 6). However, as the Declaration celebrates the value of self-determination and leaves considerable room for independent moral agents to decide on what should be central to their decisions, it falls short to offer specific guidance on various contentious bioethical issues that involve entities without the capacity to consent, such as abortion and embryonic stem cells research. Such issues are often narrowed down to disputes over the moral status of the entities involved as this affects if the key principle of respecting human rights and human dignity should concern them. Yet, this may result in overlooking other ethical concerns that should also be taken into consideration.

To what extent the Declaration can be fruitfully and universally practiced should thus call for further exploration. For one thing, if the Declaration is to be practiced, it does not take place in a vacuum. It must be applied within a specific sociocultural context that inherits a certain established orthodoxy, which presupposes a particular moral vision of good life and human flourishing. Such specific morality offers rich though often taken-for-granted resources that are not only central in fostering solidarity among members of a social community, but are also fundamental to the ethical reasoning behind one's specific understandings and prioritization of values. Much as procedural justice characterizes the formulation of legislation and public policy in modern societies, moral vision is crucial in justifying the substance of legislation and public policy and hence must be given serious consideration.

Insofar as the practice of the Declaration is concerned, due recognition of a moral vision shared by a social community is important to understand what specifically do the values of human dignity, human rights, and fundamental freedoms account for in their bioethical decision making. Besides, it also reveals that for members of moral communities that do not uphold individual rights and self-determination as the most fundamental values, the Declaration may even appear to them as begging the question of why they should compromise their moral commitments to that of the global community should they be in conflict. Instead of being a neutral moral authority, the Declaration may well be deemed as yet another moral community that defends a particular moral perspective in the pluralistic world, albeit a perspective that offers limited moral guidance.

The aim of this chapter is to question the universality of the Declaration from a Confucian perspective. Specifically, it exemplifies its contention by highlighting a different medical decision-making approach that is widely practiced in societies which are under the influence of Confucian culture. In contrast with physician paternalism that was common in the past or patient self-determination that is widely practiced in modern liberal societies, distinctive in this approach is the prominent role played by the family in medical decision making in addition to the patient and the physician. It entails a dynamic interplay among the patient, the family, and the physician that aims at reaching a harmonious decision. This chapter points out that although this Confucian shared decision-making approach might be rationalized by the values of individual rights and autonomy, it is justified by Confucians based on rather different ethical reasoning. Moreover, it further contends that the attempt to justify the Confucian shared decision-making approach with the values of individual right and autonomy is at odds with the Confucian morality.

While this chapter does aim to validate the Confucian practice of medical decision making, it does not assert that it ought to be a universal practice. Besides, nor does it advocate moral relativism. Rather, this chapter intends to reveal the challenge to universalize bioethics in moral pluralism and the concern of moral disorientation and impoverishment resulting from the pursuit of universal bioethics. It hopes to show that ongoing moral dialogue should be given precedence over the mere pursuit of a universal morality if one is to truly appreciate and respect the diversity and richness of human values and civilizations in the age of globalization.

To this end, the next section of this chapter will first outline some salient moral elements of Confucian ethics. It aims to highlight a conception of personhood and moral agency that is significantly different from the one presupposed by the mainstream bioethics. The rest of the chapter will exemplify the contention by focusing on the practice of informed consent. It will first bring into light a medical decision-making approach that is commonly practiced in Chinese societies rooted in Confucian tradition. It points out the typical roles that are played by the physician, the patient, and the family in the medical decision-making process. It will then discuss from the Confucian perspective the ethical justification of this common practice and its moral significance for pursuing a Confucian vision of flourishing life. In the subsequent section, the common challenges to the Confucianism approach are examined. It shows that even though it may appear

that the Declaration could also accommodate the Confucian practice of informed consent, the moral assumptions and justification that it argues for are in fact different and in potential conflict with the Confucian morality. It reveals that while the Declaration promotes individual independence and self-determination, Confucians value shared life experience and harmonious interdependence as they hold that this is crucial for human flourishing. This chapter concludes with a reminder of the importance of open intercultural dialogue.

Confucianism and Bioethics

It is well known that Chinese societies have strong family culture. This is supported by a conception of personhood and moral agency that is deeply rooted in Confucian tradition that is quite different from the one advanced by the Enlightenment movement in the West. While a comprehensive understanding of Confucian teaching would require an explanation of its metaphysical belief in the order of things in nature, this chapter will confine its discussion on the earthy aspect of Confucian teachings and its key implications to bioethics. It aims to explain the ethical significance of Confucianism in contemporary society and why its Western counterpart, even without committing to the metaphysical belief held by Confucianism, may appreciate the insights offered by this long-standing tradition, just as Confucians may learn from them based on the moral experience that is common to humanity.

Central to Confucian ethics is how to pursue human flourishing by living a way of life that would enable virtues cultivation according to the human nature. In the Confucian view, human beings are by nature social, interdependent, and related to each other (Tao, 2004; Hu, 2002 and Yu & Fan, 2007). A flourishing human life, consequently, is not primarily characterized by individual freedom and independence, but by perfection of personal character that allows one to form proper human relationships with others in a harmonious (*he*) manner. This entails personal effort and commitment to pursue a life-long process of virtues cultivation by developing the capacity that is naturally endowed within every human. Mencius, an eminent early Confucian master, holds that anyone is capable to become an exemplary person with perfect character (*junzi*) if one makes the effort (see *Mencius* 6B:2). Yet, he also warns that "slight is the difference between man and the brutes. The common man loses this distinguishing feature, while the *junzi* retains it." (*Mencius* 4B:19) And such distinguishing feature is "understood the way of things and had a keen insight into human relationships. (Shun) (a well-acknowledged ancient sage) followed the path of morality. He did not just put morality into practice" (*Mencius* 4B:19). Key to Confucian ethical teachings is thus the path of morality, i.e., the way of life that human beings should pursue in order to cultivate and practice their virtues, and the social structures that society should sustain to promote human flourishing.

Family is valued by Confucians as the most fundamental social structure where self-cultivation begins and is thus of crucial importance to human flourishing. Among the five basic types of human relationships identified in Confucianism (i.e., parent–child relationship, sibling relationship, husband–wife relationship,

superior–subordinate relationship, and friendship), three of them are familial relationships. Moreover, the familial relations are also the prototypes of the nonfamilial ones. Hence, in the Confucian classic *The Great Learning*, it teaches that "the ancients who wished to illustrate illustrious virtue throughout the kingdom, first ordered well their own states. Wishing to order well their states, they first regulated their families. Wishing to regulate their families, they first cultivated their persons." (Legge, 1975, pp. 4–5) For Confucians, family is the basic building block of society and family order is the foundation of social order. Through properly serving one's roles in the family, one not only cultivates oneself with the virtues that are prerequisites for undertaking other social roles, one also contributes to social stability from the bottom-up by building a harmonious family. Hence, when being asked why he does not take part in government, Confucius replied that "simply by being a good son and friendly to his brothers a man can exert an influence upon government … How can there be any question of his having actively to 'take part in government'?" (*Analects* 2:21, see also *Analects* 1:2).

Family is thus central to a Confucian way of life because it is the locus of virtues cultivation throughout a human life. Specifically, for family to be regulated, one first needs to learn and practice within the family how to properly relate to one's fellow members in accordance with rites. And as one grows up, one reciprocates the family and carries on the good of family by cultivating the young and serving the old. Instead of individual autonomy and independence, in Confucian societies, adulthood is characterized by competence in taking good care of one's family. Moreover, whereas adult children may get married and thereby starting up a new family life, yet this is considered as a continuity and growth of the families of the married instead of departure from them. Their participation in family affairs, especially the important ones, would always remain.

In particular, Confucianism holds that the parent–child relationship which every human is born with and the natural affection (*qin*) embedded in it are the root of morality. The strong affection that parents have toward their child drives them to be highly attentive to the well-being of their dependent child. Among other things, they show their child the significant human good of love and interpersonal bond. For Confucians, it follows that as one grows up, one ought to reciprocate the good by being a filial child. Filial piety (*xiao*) thus entails not only provision of material goods, but also serving one's parents with a caring and reverent attitude (See *Analects* 3:26, 4:18 and 2:8). Yet, it is also important to be aware of the rather common mistake to construe filial piety as requiring absolute obedience and children should always be submissive to their parents. Instead, one should follow what is morally right. If parents require children to do wrong, a filial child not only should not follow, but even has an obligation to correct the parent though one should do so in a tactful way (Nuyen, 2004). It is with this understanding that filial piety is regarded as the root of the cardinal and all-encompassing Confucian virtue *ren* (See *Analects* 1:2, *Mencius* 4A:19 & 4A:27), which in one simple but important sense means "love your fellow men" (*Analects* 7:22, see also *Mencius* 4B:28). And it is also often referred as a moral force that comes with one's ability to show benevolence and kindness toward others (see, e.g., Chan, 1963).

In the Confucian view, cultivation of virtues starts with the family because it recognizes the anthropological fact that one naturally feels more deeply and emphasize for those who are intimately related to us. It follows that it is by developing and extending one's familial affections to distant others that one cultivates the virtue of *ren* (see *Mencius* 1A:7). Hence, when his student Tsai Wo commented that the ancient Chinese rites that requires children a three-year morning period for their late parents as their filial duty was too long, Confucius questioned if Tsai Wo had not been given 3 years of love by his parents and denounced him as "unfeeling" (*bu ren*) (*Analects* 17:21). This is because Confucius acknowledges that "the different rules for the mourning rites were established in harmony with (men's) feelings . . .The more pain it gives, the more slowly is it healed. The mourning of 3 years, being appointed with its various forms in harmony with the feelings was intended to mark the greatest degree of grief." In contrast, the mourning period for those who are less related should be shorter (Legge, 1976, pp. 391–394).

Besides, it is important to note that Confucians recognize the family as an organic social reality that has its own intrinsic moral value and autonomy. It has interests that are common to its members and deeply intricate with their personal ones, yet its interest is not just a sum of its individual members' interests (See Brennan & Fan, 2007). Much as family plays a significant role to its members' personal welfare, the value of family is not merely instrumental. Family is not a joint venture set up by voluntary individuals but a social reality that everyone is born into for better or worse. While some are fortunate to be with a well-functioning family, some have to make more effort to foster and maintain one. The ancient sage Shun, for example, is well known to have a rather difficult family life to begin with. Yet, in either case, Confucian morality holds that given the human nature, assuming the familial roles and responsibilities properly is central to cultivation and practice of virtues. This entails not weighting the interests of each member equally, but accommodating with other members in an appropriate way that will serve the best interest of the family and the members. Hence, it is important to note that while Confucianism appreciates the ethical value of family, it is not ignorant of challenges that individuals may face in fulfilling their family obligations. Quite the contrary, it acknowledges them but contends that both individuals and society have their roles to play in pursuing human flourishing. For individuals, this is how they become autonomous moral agents. Insofar as public policy is concerned, this implies that its formulation should take into account the value of family in human flourishing and sustain this moral good accordingly (Fan, 2002).

In Confucian societies, the primacy of familial relationships, virtue of *ren* and interdependence, are thus presumed in the discussion of bioethical issues as moral agency is characterized by these moral goods. Instead of emphasizing individual's right to one's own body and the liberty of independent decision making, healthcare decisions and policies are oriented toward fostering meaningful human relationships that are marked by virtues and interdependence to meet the human social needs. In this alternative ethical framework, the family is assumed to be the primary caretaker of its members and is naturally involved in their healthcare decision

makings by taking into account the interest of the family as a whole. Bioethical issues such as end-of-life decision making, surrogate reproduction, abortion are seldom discussed as a matter that concerns only the dying patient, the gametes donor and recipient, or the pregnant woman and fetus. For Confucians, these issues entail significant familial obligations and implications on the family's existing and future life that ought to be given due regard. Moreover, the Confucian approach to bioethics is often context specific and it calls for dynamic interactions between family members to arrive at ethically appropriate decisions. It is a lively process in which individuals cultivate and practice virtues by assuming their proper roles in light of the context.

To more fully explain the implications of Confucian teachings to bioethics, the next section will focus on discussing the usual practice of medical decision making and informed consent in Confucian societies that is rather different from the one commonly advocated by the mainstream bioethics. It aims to show that participations of the family and the physician in the patient's medical decision making are justly presumed in Confucian societies just like the right of the patient to make autonomous and independent medical decision is often assumed in the Western liberal societies. This is because they are founded on their respective prominent conception of moral agency that is quite different from the other. The subsequent section will then evaluate common challenges to the Confucian practice of medical decision making. It acknowledges the ethical significance of individual right to autonomous medical decision making as a remedy for the Confucian practice in some contexts though by no means it should be a substitute for it.

Medical Decision Making in Confucian Societies

In societies where Confucianism is at home, most notably in China, Taiwan, and Hong Kong, the practice of informed consent is marked by shared decision making among the patient, the patient's family, and the physician. While their degree of participation in the process may vary in different specific contexts, the typical roles played by the physician, the family, and the patient are as follows:

The physician is not only a source of information but sometimes also a facilitator to consensus building in the medical decision-making process. He/she is responsible for providing and explaining the diagnosis, prognosis, and potential benefits and risks of each available treatment option to the patient and his/her family members. While the physician is still a highly regarded professional in Confucian societies, physician paternalism is no longer a common practice. Informed and written consent is legally required for the physician to undertake any major medical intervention on the patient. In mainland China and Taiwan, consent can be given by competent adult patients and/or their families (Cong, 2004 and Tai & Tsai, 2003). Although informed consent by competent adult individual patients was formally introduced in mainland China in recent years, family participation in important medical decision remains the widely accepted norm (See Chen & Fan, 2010 and Cong, 2004). In Hong Kong, though the competent adult patient should be

the legal authority to consent, it is customary for the physician to disclose critical information to the family (especially the adult children of the elderly) before the physician and the family share the information with the patient (see Chan, 2004). Involving the family in medical decisions and consensus building is recommended by the Hong Kong Hospital Authority, a statutory body that takes care of over 90 % of inpatient services of the Hong Kong population (Hospital Authority, 2010), as a "good practice" unless the patient objects the practice (Hospital Authority, 2002).

Nonetheless, the physician is still entrusted with safeguarding the best interests of the patient based on professional judgment, particularly in cases involving medical emergency or patients without capacity to consent. For instance, in the guidelines issued by the Hong Kong Hospital Authority on withholding or withdrawing life-sustaining treatment for incompetent and terminally ill patient, it advises that much as healthcare professionals should arrive at a consensus with the patient's family, they should also consider if the family's decision is in apparent conflict with the best interests of the patient. Moreover, the physician is legally empowered to provide life-sustaining treatments to the patient in emergency even without the family's consent (Hospital Authority, 2002).

The substantial role of the family in medical decision making is distinctive in Confucian societies. As explained in the last section, for Confucians, the family is considered as an autonomous moral agent that has the responsibility to take care of the well-being of its members. Hence, if serious illness is diagnosed, the family is often informed and consulted even before the patient. The family can then evaluate the extent of psychological burden the medical information may place on the patient, and the best way to break the bad news to the patient. In addition, the family may even request the physician to cooperate with their decision on how to convey the information to the patient (Fan, 2000). In mainland China and Taiwan, this is reflected by the family's authority and responsibility to decide what medical information the patient is psychologically and intellectually capable to receive and the physician's cooperation with the family. While the preferences and wishes of the patient should be taken into account, likewise the patient should be aware that the medical decision is not only about his/her individual well-being but also those that are dear to him/her. Confucian societies acknowledge that the interests of a family and its individual members are deeply intricate. Thus, even though in Hong Kong, respecting the patient's autonomy is one of the guiding ethical principles in making decision on forgoing life-sustaining treatment, no less emphasized is that the decision should also be a "consensus-building process between the care team and the patient and the family" and this entails "*involvement of the patient when he/she is mentally competent, and his/her family regardless of the mental capacity of the patient*, *unless a mentally competent patient refuses to have the family involved*" (Hospital Authority, 2002, pp. 7–8, emphasis original).

Hence, in contrast to the requirement of informed consent advanced by the Declaration, a prominent feature of the shared medical decision-making approach in Confucian societies is that it is far less individualistic. In the Confucian view, the family has the major responsibility to take good care of its ill member, and healthcare policy in Confucian societies should facilitate the family to

fulfill this role. This entails that the family not only should be able to participate in making the patient's medical decisions, but also to learn about the diagnosis and prognosis even prior to the patient. Being the most closely related, there is a prima facie case that the family is in the position to know not only what would be the patient's wishes, what would serve the patient's best interest, and what would be the possible impacts on the family, but also how to strike a balance among them should they are in conflict. Besides, more importantly, the shared decision-making process is also a good opportunity for the family members, including the patient, to understand each other's concerns from different perspectives and discuss what would be the best for all involved. For Confucians, illness is not only suffered by the patient, it is a misfortune of the whole family. The Confucian approach to shared decision making is a consensus-building process that not only serves to arrive at a unified and harmonious decision, but also to maintain family integrity (Fan, 2011).

In contrast with the mainstream bioethical principle of informed consent as advanced by the Declaration, individual autonomy is not presupposed to be of primary importance for Confucians. The patient is not primarily characterized by independence or self-sufficiency. Quite the contrary, the patient would be excused from his/her usual responsibilities regardless if he/she has the capability to discharge them. It is widely accepted that the vulnerable patient should be taken care of by the family and physician (Cong, 2004). In particular, it is an important filial obligation of adult children to look after their elderly parents in the Confucian tradition, and the elderly is naturally most commonly found to be critically ill or needing long-term healthcare. Instead of the fear of losing individual autonomy and independence as health declines, quite the contrary, the Confucian elderly deem that it is a blessing to be taken care of by their adult children (See Tao, 2007 and Chan, 2007). In fact, this is an achievement for the elderly to be pound of as it implies that they have duly fulfilled their parental obligation in cultivating their children. Of primary importance for Confucians is thus the cultivation and practice of virtues that allow individuals to live well interdependently. Such interdependence would not result in the fear of losing the self for Confucians because human relations constitute an important part of the self for them (see Hu, 2002).

Virtue is also central to the practice of medicine. Medicine is an esteemed profession in Confucian tradition not only because it requires a high level of knowledge and skill, but also kindheartedness. The practice of medicine is well known as an "art of *ren*" (*yi nai ren shu*) in Confucian societies and a Confucian physician should aspire to be a "*ren* practitioner of the art of *ren*" (*ren sin ren shu*) in addition to be knowledgeable and skillful in medicine. The virtue of *ren* is of crucial importance to the practice of medicine as it informs the physicians that their primary subjects are not diseases or disorders, but their patients and their primary concern should be the welfare of their patients.

The Confucian teaching thus reminds that the physician is also in a significant interpersonal relationship with the patient. A Confucian physician is expected to have the heart of benevolence like a parent (*yi zhe fu mu xin*) when treating one's patient as the physician–patient relationship is modeled on that between

parent and child. The physician thus has the duty to look after the welfare of the patient that often goes beyond simply observing the patient's right to self-determination. Apart from offering advice to the patient, as mentioned, a Confucian physician is also entrusted with the duty to protect the medical interests of the patient in the practice of shared medical decision making. Moreover, the virtue is also essential for physicians to be compassionate toward their patients' sufferings, which is particularly important when the physician and patient are confronted by the limitation of medicine. In contrast, although such understanding of medical professionalism is also advocated in the Hippocratic tradition, the value of benevolence is construed in a markedly different manner in modern bioethics. For example, the influential work of Beauchamp & Childress defines benevolence in two principles. One is the "principle of positive benevolence," which "requires agents to provide benefits." And the other is the "principle of utility," which "requires that agent balance benefits and drawbacks to produce the best overall results." Both principles, it is important to note, are to be distinguished from "the virtue of benevolence, various forms of care, and nonobligatory ideals of benevolence" (Beauchamp & Childress, 2009, p.197).

As pointed out by Chan (2004), Tse and Tao (2004), Fan and Tao (2004), and Chen and Fan (2010), the participations of the patient, the family, and the physician may result in a lack of definite locus of decision making in the Confucian approach. Depending on the context, the input from the patient, the family, and the physician may carry different weights in the decisional outcome. The multilateral decision-making process requires the physician, the family, and the patient to exchange their perspectives on what would be the optimal choice. Undoubtedly, this may result in indeterminacy characterized by unclear locus of decision making (Chan, 2004 and Tse & Tao, 2004) that could be avoided by unilateral decision making, where individual autonomy of the patient and thereby his/her choice is pivotal. Yet, Confucian recognizes that there is no fast and hard rule to follow because sensible medical decision making must take into account various specifics such as the urgency, the nature of the medical information, the respective psychological and intellectual capacities of the patient and the family members, the character of familial bonds, etc. Spared by the indeterminacy is the necessary room and flexibility for apt and harmonious decisions to be possible. It entails a reciprocal process of exchanges between the patient, the family, and the physicians, during which the virtues of them are practiced and cultivated.

Challenges of the Confucian Practice of Shared Medical Decision Making

While shared medical decision making is widely practiced in Confucian societies, it is certainly not without objections. This section outlines the common challenges against the Confucian approach and evaluates the extent to which the principle of informed consent that is advocated by the Declaration may be useful to address the concern.

The fact that unfortunate and tragic cases happen under the current practice of shared medical decision making in Confucian societies prompts question about the ethical legitimacy of the approach. For example, the family may choose not to disclose to the patient that he/she is seriously ill but consent to a surgery of limited chance of success for the patient, and the patient eventually dies on the surgery table. Or the family may refuse aggressive treatment even if it might be the only possible remedy. There are two major objections which hold that shared medical decision making is the cause of such cases. First, some may attribute such medical tragedies to unintelligible or even harmful decisions made by the family for the patient. Second, some may argue that it is dubious what the family regards as the best decision would indeed be the same as that of the patient since they may uphold different values (see, e.g., Wear, 2003). It is possible that the patient would have made a different decision, had there been an opportunity for him/her to decide independently. In either objection, it is contended that the mainstream practice of informed consent should replace the shared decision-making approach.

It is important, however, to distinguish between the above two objections as the primary concern of them is different. In the first objection, the fundamental ethical concern is whether a decision is indeed in the best interest of the patient. It does not criticize a particular medical decision-making approach per se but the decisional outcome. It hence does not in essence challenge the Confucian practice of shared decision making or support the requirement of informed consent, for even under the practice of informed consent, the patient is free to consent or refuse to a treatment regardless if this would be in his/her best interest. The formality of informed consent hence does not necessarily address the first objection, though there is a widespread presumption in the mainstream bioethics that individual is the best defender of his/her interest.

Yet, some may contend that the fundamental value of informed consent, in fact, is such self-determination. This is also the primary ethical concern of the second objection to the practice of shared decision making. It argues that the patient's decision should be absolute even if others disagree the decision would be in the best interest of the patients, let alone if it is of the family. The involvement of the family, however, may deprive the patient of sufficient medical information to choose for oneself without the interference of others. Besides, it may further suggest that if the patient does value contribution from the family or the physician in his/her decision, he/she may invite their participation in the process. Yet, even so, informed consent must be given by the patient when major medical intervention is to be performed on him/her. Likewise, for refusal of intervention, the patient should have the right to decline medical intervention even against medical advice, provided that he/she is well informed of the possible consequence.

There is certain an appeal of the second objection that justifies the requirement of informed consent. For one thing, it may protect the patient from being deceived or harmed by others. Although there is a prima facie case that the family would look after the welfare of the patient, conflicts between family members do exist and some may be intense and difficult to resolve. The fact that the interests of family members are deeply intricate in some cases may unduly undermine the individual

wishes and interests of the patient. Moreover, even though the family may intend to lessen the patient's psychological burden, the deceived patient may question the need for undergoing aggressive treatments, hold false hope or fear, or miss the opportunities to carry out his/her last wishes (Wear, 2003).

Yet, the fact that the shared decision-making approach may not apply well in some cases does not mean that it should be replaced entirely. The problems may not be caused by the decision-making approach as such, but by improper application of the same. (See Li and Wen (2010) for a case study that serves to illustrate the distinction.) Although the Confucian approach does not support that only the patient's individual interests and wishes should matter, neither does it hold that they can be overlooked. Instead, the approach respects the family, which includes the patient, to have the room and authority to decide what would be the best all things considered, subject also to the professional judgment of the physician that the decision is not in apparent conflict with the patient's medical interests. This entails effort from both the family and the physician to look into the contextual details and the dynamics at different stages of decision making, such as the diagnosis and prognosis, the psychological reaction of the patient, and the resources available. It is an interactive process among the family, the patient, and the physician. In the Confucian view, being fully informed and self-determined would not alleviate the anxiety over undergoing aggressive treatment, ease concern about treatment outcome, or ensure one could carry out one's last wishes, if what in fact needed are care and assurance from those whom one has a close and trusting relationship with.

Hence, even though the option of informed consent as advanced by the Declaration should be available to safeguard the individual interests of the patient, it should not be adopted as the default practice in Confucian societies. Rather, what Confucians may learn from its western counterpart is that such a principle of informed consent can be introduced as a corrective available for the patient to initiate should he/she find that the shared decision-making approach fails in his/her circumstances. This means that unless the patient requests otherwise, the physician may presume that he/she could inform and consult the family about the patient's healthcare. Given the cultural background, this is a respect for both the patient and the family because it acknowledges the value of the family and being a family member is an important identity to the patient. This is comparable to the respect of individual right of self-determination in societies where individual autonomy and independence are upheld as fundamental values.

It is thus also of crucial importance not to rationalize the Confucian approach of shared decision making by the values of individual right and autonomy, for this would undercut the values and way of life that are truly fundamental to Confucian ethics (Fan, 1997). In fact, as informed and written consent becomes more formally required in China in recent years, its ethical implication also surfaces. As the physician becomes more watchful of his/her legal liability that is founded on the rights of the patient or the family, the relationship between the physician and the patient or the family turns more contractual in nature. For the physician, cultivating and practicing the virtue of benevolence becomes secondary to honoring the right of

self-determination of the patient, and safeguarding the medical interests of the patient becomes less pressing than protecting oneself from being sued (see Cong, 2004 and Hui, 2005). The significant role of the physician in the shared decision-making process may as a result be threatened since virtue is no longer recognized as central to the practice of medicine. Moreover, although informed consent is founded on the value of individual autonomy in the West, Cong (2004) noted in his study that in China, physicians barely considered the requirement for them to seek formal informed consent from the patient is due to the value of autonomy. What the physicians were rather conscious of, instead, were the legal implications of the formality of informed consent.

The value of the family in Confucian way of life may likewise be disoriented by the liberal rationalization. Confucianism appreciates family as a given social reality that every human being inherits. It provides both moral contexts and resources that cultivate individuals to be moral agents based on a vision of human flourishing that is characterized by interpersonal care, connectedness, and dependency. Correspondingly, for Confucians, the participation of the family in the patient's healthcare is the default. While it does presume that the participation is valued by the patient, this should not be reduced as conditional upon invitation from the patient as the mainstream principle of informed consent suggests. Instead, in Confucian societies, the principle is more aptly to be regarded as a measure available to protect the patient should the family become dysfunctional. On the one hand, this would ensure that individual interests and preferences would not be sacrificed against the patient's wishes. Yet, on the other hand, this also recognizes that in Confucianism, moral priority is given to a way of life where interdependence, familial life, and harmonious human relationship are valued over one that advances independence, individual choices, and rights. This is analogous to the ethical orientation implied by the Declaration toward a way of life where individual autonomy is given precedence over other ethical values. While individuals may place family as central in their lives, this is justified insofar as this is their free choice.

Concluding Remarks

Whereas this chapter confines its discussion on informed consent from a Confucian perspective, what it aims to show is the challenge posed by moral pluralism to the endeavor to identify a set of practical bioethical principles that are universally binding. While human dignity, human rights, and fundamental freedoms may well be widely shared values, the Universal Declaration on Bioethics and Human Rights should also note that diverse moral communities have different prioritizations and specific understandings of those values. It is of crucial importance to recognize that this entails more than what the Article 12 maintains where cultural diversity and pluralism are "acknowledged" to be secondary to the rest of the Declaration. When faced with complex bioethical issues, societies must develop their policies not only by taking into account the values that are advanced by the Declaration, but also

those that are central to their ethical traditions and deeply embedded in their people's daily lives. This is not to argue for moral relativism or to invoke cultural exceptionalism, but to remind the importance of open cross-cultural pluralistic dialogue in attaining better understanding of the richness of human ethical commitments and to call for room for such exchanges.

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Judaism

24

Aaron L. Mackler

Introduction

This chapter begins by introducing key terms that are important to understanding the Jewish ethical tradition, then surveys authoritative documents of the tradition, and briefly sketches varied approaches or "streams" in contemporary Judaism. It then examines central Jewish values in comparison with those found in the UNESCO Universal Declaration on Bioethics and Human Rights. Major issues near the end of life, and at the beginning of life, are considered.

Ethical concerns have always been central to Judaism and have been understood within the broad context of Jewish life (this chapter draws extensively on Mackler, 2003). Basic concepts in Judaism include God; Torah or "Teaching"; and the community of Israel, the Jewish people. For Jews and Jewish thinkers across a wide spectrum of beliefs, both individuals and the Jewish community as a whole participate in a covenantal relationship with God. Torah is central to this relationship and basic to Jewish life. God in love gave the Torah to the Jewish people, and through them to the world. In its narrowest sense, Torah refers to the first five books of the Bible, Genesis through Deuteronomy, traditionally termed the "Written Torah." More broadly, Torah includes the extensive "Oral Torah" and refers to all Jewish traditional teaching – in fact, all authentic Jewish thought and practice.

Jewish ethics has been understood within this context, not sharply distinguished from other spheres of life. One example of this holistic approach may be found in the Holiness Code of the Book of Leviticus (Ch. 19). This passage includes numerous ethical responsibilities, including the mandate to "love your neighbor as yourself," (Lev. 19:18) intermixed with ritual commandments. All represent aspects of the general injunction of this section: "You shall be holy, for I, the Lord your God am holy." (Lev. 19:2) Both ethical and ritual perspectives are important in answering the question, "What ought I to do?" For this code, as for the Jewish tradition in general, all aspects of human activity meld together holistically in a life of service to God and one's fellow.

A.L. Mackler
Theology Department, Duquesne University, Pittsburgh, PA, USA
e-mail: mackler@duq.edu

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Two additional features of the Holiness Code represent views that have continued in Judaism's development. First, the passage is introduced by God instructing Moses, "Speak to the whole Israelite community, and say to them..." (Lev. 19:2). The call to holiness and all that follows are not understood exclusively or even primarily as pertaining to individuals, but to an entire community. Second, the commitment to holiness entails particular behavioral norms that are expected of individuals and the community. Such norms are traditionally termed *mitzvot* (singular, *mitzvah*, "commandment"). A *mitzvah* is a shared normative practice, expressing what members of the Jewish community may expect from one another, as well as an action significant in covenantal relationship to God.

Each *mitzvah* contributes to a system of *halakhah*, a word literally meaning "path" or "way" and signifying Jewish normative practice, often translated as "Jewish law." Supporters argue that *halakhah*'s role as a legal system provides for cohesion and a sense of community among Jews worldwide, as well as within local communities. It offers continuity with the past, maintaining continuity of the covenantal community over time and affording contemporary individuals the benefit of accumulated wisdom of the past. *Halakhah* traditionally has been understood to express both God's will and God's wise and beneficent counsel. It thus provides a means for the expression of God's love and of the Jew's love for God. Finally, the very fact of the centrality of *halakhah* to Jewish ethics over the millennia might be seen as itself carrying normative weight. A *halakhah*-centered approach simply is the Jewish way to do ethics; to use Wittgenstein's image, such are the rules of the language game of Jewish ethics.

While *halakhah* has been central to Jewish life and thought, it has not been the only ethical guide. Accompanying *halakhah* has been *aggadah*, or narrative. This term broadly refers to Jewish theological reflection, lore, articulation of values, expressions of meaning, and cultivation of virtues. Returning to the Holiness Code of Leviticus 19:2, Moses Nahmanides (1194–1270) writes that the opening call to holiness is not merely an introductory phrase but an injunction in its own right. Without this, a person might observe all rules and yet be a "scoundrel with Torah license" (commentary to Lev. 19:2). The call to holiness includes, but also goes beyond, the specific norms of *halakhah*. Classically, the relationship between *halakhah* and *aggadah*, between the letter and the spirit of the law, is essentially symbiotic. In the image of Abraham Heschel, *halakhah* is like a body, while *aggadah* is spirit. *Halakhah* without *aggadah*, its animating spirit, is like a corpse. *Aggadah* without *halakhah*, its worldly concretization, is like a ghost, too ethereal to be realized (Heschel, 1955, 341).

Judaism

Foundational Sources: Scripture and Tradition

Judaism values both Scripture and tradition. For Jews, the Bible is the Hebrew Bible, also referred to as *Tanakh* or "Old Testament." A special status is recognized

for the Torah, Genesis through Deuteronomy. Some believe that this was presented by God to Moses, word by word and letter by letter, in a form identical to contemporary printed texts. Others see the Torah as largely written by humans, perhaps with Divine inspiration. A range of thinkers understand the Torah to be divine in its origin but shaped significantly by human reception, transmission, and interpretation.

For traditional Judaism, Scripture and tradition represent distinct but complementary aspects of God's revelation. Central to tradition is the Oral Torah, which is classically understood both as the interpretation and development of the written Scripture and as a parallel oral communication from God that was faithfully transmitted in oral form through many generations.

Since late antiquity, numerous works of "Oral Torah" have been given written form. Together, these constitute central resources for deliberation in bioethics and other areas (see Feldman, 1998, pp. 3–18). The *Mishnah* (meaning "study") was compiled in the early third century by Rabbi Judah Hanasi, presenting material that developed and was transmitted orally over the preceding centuries. The *Talmud* (like Mishnah, a term meaning "study") is in many ways the central work of the tradition. It records commentary on and discussion stemming from the Mishnah, developing over succeeding centuries. The Babylonian Talmud, compiled in Babylonia (currently Iraq) in the sixth and seventh centuries, is often referred to simply as "the Talmud".[1] Three types of post-Talmudic literature offer the most significant contributions to the fabric of *halakhah*. One genre represents commentaries on the Talmud. A second major genre is that of responsa, in Hebrew *teshuvot* (singular, *teshuvah*, "responsum" or "response"). These are the *halakhic* decisions of rabbinic authorities, addressing specific issues or cases, and collectively constitute the case law of Judaism. A third genre is represented by legal codes. Codes are not formally enacted, but come to be recognized as authoritative, similar to the way in which the *Oxford English Dictionary* or *Encyclopaedia Britannica* have come to be recognized as authoritative. The first major systematic codification was produced by Moses Maimonides (Rambam, Rabbi Moshe ben Maimon) in the twelfth century and is known as the *Mishneh Torah* ("repetition of the teaching"). The most authoritative code of law is the *Shulhan Arukh* ("set table"), written by Rabbi Joseph Karo in the sixteenth century, published with interspersed glosses of Rabbi Moses Isserles, termed the *Mappah* ("tablecloth" for the set table).[2]

Classically, individuals seeking to follow Jewish ethics would be guided by a variety of influences, including narratives, rituals, exhortations to virtue, maxims, and communal customs, and significantly by *halakhah*. Traditional *halakhah*, like secular case law, utilizes analogies with precedent cases to decide new cases.

[1]Passages from the Mishnah traditionally are identified by the name of the tractate, followed by the number of the chapter and paragraph within the chapter; e.g., *Sanhedrin* 4:5. References to the Talmud are given by the name of the tractate and the page on which the reference may be found (e.g., *Sanhedrin* 37a).

[2]References to the Shulhan Arukh are given by the name of the section (or its abbreviation), followed by chapter number and paragraph within the chapter (e.g., *Yoreh Deah* [*Y.D.*] 339:1).

Compared to other legal systems, *halakhah* is markedly open ended, decentralized, and religiously sensitive, but it is a legal system nonetheless. The paramount authority in discerning *halakhic* guidance in a given case is the rabbi, and religious authority for the community as a whole is provided by rabbinic leadership. For most of the past two millennia, leadership has been decentralized, resting with various rabbis in local communities. Classically, positions are articulated by individual rabbis whose authority comes to be recognized by their colleagues and by communities. Leaders of various academies and rabbis of cities and communities all enjoyed significant authority, most generally deferred to tradition and current consensus.

The balance of subjective and objective authority is a point of contention among Jewish writers. Almost all would agree on the importance of the individual taking account of objective norms in formulating his or her own judgment. At the same time, tradition acknowledges significant authority of each individual in exercising his or her stewardship of health and well-being.

Streams Within Judaism

Judaism does not recognize a central human authority, and different Jews differ on numerous issues. One may speak of different "movements" (or "streams") in Judaism. These are not tightly defined denominations, but help in describing the range of views. The three largest movements are generally termed Orthodox, Conservative (or Masorti, "traditional"), and Reform (or Progressive). All three have their roots in responses to modernity in nineteenth-century Germany. Representatives of each movement tend to see their movement as in many ways the most authentic Jewish approach, as well as the path offering the best prospects for the future. Each movement is complex and includes a broad range of stances, although some generalizations can give a sense of tendencies common within each.

Reform Judaism as it emerged in the nineteenth century understood the essential truths of Judaism to be unchanging: monotheism and a universalist ethic of love of neighbor. Ethical truth was largely defined by liberal thought and progressive Western culture, in particular the ethics of reason of Kant. Other aspects of Judaism, including *halakhah* and traditional expressions of the Oral Torah, were at best secondary and readily changeable. Throughout the history of Reform Judaism, autonomy has been central to the articulation of Jewish ethics. Autonomy has taken various forms: a Kantian sense of the individual following dictates of universal reason; an individual liberty right of choice; a complex Jewish self, authentically making choices that reflect an identity that is significantly shaped by community and covenant with God. In recent decades, some Reform thinkers have accepted an increased role for *halakhah* in offering guidance to individuals, but individual autonomy remains predominant.

Orthodox Judaism developed as a movement in response to Reform. While modernity may bring benefits, the Enlightenment and modern thought pose threats to the integrity of Judaism. Orthodox Judaism tends to present itself as continuing the unchanged Judaism of the past. Torah in general and *halakhah* in particular are

essentially unchanging. As noted above, the text of the Written Torah is seen as identical to that presented by God to Moses. Oral Torah is understood primarily in terms of its articulation in the Talmud (based on material communicated by God to Moses) and received now as tradition from the past. While new situations may call for thoughtful application of past precedents, Orthodox leaders tend to stress the need for caution and a desire to minimize change. Tendencies to emphasize the role of received tradition over reason, *halakhah* over *aggadah*, and stringency over flexibility are common in Orthodoxy. The rabbi, articulating traditional consensus, is the primary authority.

The Conservative movement also developed as a traditionalist response to Reform, but of a more centrist sort. Conservative thinkers agree with their Orthodox colleagues that *halakhah* plays a definitive role in Jewish life and Jewish ethics. At the same time, *halakhah* has historically developed over time, through gradual evolution and by means of textual and judicial interpretation. Such development, by such means, should continue; the model is one of "tradition and change." The determination of which developments are appropriate is primarily made by rabbinic leadership, but there is also an appeal to broader communal insight. Conservative writers characteristically attend to the historical development of *halakhah*. While Torah is in some sense eternal, it develops in a way that manifests its strength and vitality as a living tradition. Past sources are read diachronically, tracing streams within the tradition and often finding divergent tendencies as well as ongoing development. Development has been, and should continue to be, organic, gradual, and evolutionary. Conservative writers generally seek a balance between the authority of the individual and that of his or her rabbi.

A smaller Reconstructionist movement developed originally as a tendency within Conservative Judaism but shares much with Reform/Progressive approaches. Reconstructionism tends not to think of a theistic or personal God, but to emphasize the culture and practices of the Jewish people.

Jewish Values and the UNESCO Universal Declaration on Bioethics and Human Rights

Traditional Jewish values and principles accord powerfully with those expressed in the UNESCO Universal Declaration on Bioethics and Human Rights (UNESCO 2005). The Mishnah (*Sanhedrin* 4:5) interprets the first chapter of Genesis:

> Therefore was a single man [Adam] created, to teach you that anyone who destroys a single person from the children of man is considered by Scripture as if he destroyed an entire world, and that whoever sustains a single person from the children of man is considered by Scripture as if he sustained an entire world; and for the sake of peace among people, that no one could say to his fellow, my ancestor was greater than your ancestor; . . . and to proclaim the greatness of the Holy One, blessed be He, for man stamps many coins with the same die and they are all the same as one other, but the King of the kings of kings, the Holy One, blessed be He, stamps every man with the die of the first man and not one of them is the same as his fellow.

Like the UNESCO document (Arts. 2–3), this foundational text of Judaism affirms the intrinsic dignity and value of each individual. For Jewish tradition, respect for people (*kevod habriyot*) represents a powerful obligation. Saving and preserving life (*pikuah nefesh*) justifies virtually any action that would otherwise be prohibited and is commanded as a positive obligation by Leviticus 19:16, "do not stand idly by the blood of your neighbor."

Judaism sees healing as an important way to help others and save life, as the UNESCO statement values health throughout, explicitly in articles 14–15. Historically, some Jewish thinkers have raised a theoretical question regarding the compatibility of human attempts to heal with respect for divine sovereignty. The Bible, indeed, depicts God as purposefully causing illness (as well as famine and other forms of human suffering) and providing healing. It is clear for the tradition, though, that God expects humans to assume the responsibility of active stewardship and to help others. Healing is grounded in biblical mandates to heal the injured (Exodus 21:19), to restore that which has been lost (including lost health) (Deuteronomy 22:2), and to love one's neighbor as oneself (Leviticus 19:18). As expressed in the *Shulhan Arukh* (*Y.D*. 336:1), "The Torah gave permission for the physician to heal. That is a *mitzvah*, and is in the category of saving life [*pikuah nefesh*]." As an expression of this mandate to heal, Jewish writers strongly support medical and scientific research – as with UNESCO – provided that it is directed toward human benefit and in accord with ethical commitments and prudent judgment (Articles 2, 15).

All Jewish thinkers acknowledge a role for reason and experience in shaping ethics. The understanding of this role and its relation to tradition vary widely. In classical Judaism, appeals to universal reason and human experience are less central than are appeals to sacred texts and tradition. At the same time, Judaism has viewed all of humanity as participating in a covenantal relation with God, understood as the covenant of God with the "children of Noah." This covenant entails basic moral responsibilities that are incumbent on all human persons, such as prohibitions against murder and robbery. The extent to which these norms should be viewed as natural law, and in what sense of the term, has been vigorously debated (see Novak, 1998).

The Mishnah proclaims the fundamental equality of all people, as none can boast of superior ancestry. Jewish ethics historically focused on the responsibilities of Jews to fellow Jews. This focus reflected not only a theoretical valuing of the community but also the practical social conditions under which Jews lived. For most of Judaism's history, Jews lived in independent Jewish communities or semi-autonomous communities within a broader corporate state. For most of the past two thousand years, Jews were discriminated against to one extent or another, oppressed, or at best tolerated by what was experienced as an external non-Jewish world. The tradition includes some discussions of the ethical responsibilities of all persons. Most theologians have endorsed the Talmud's statement that not only Jews but righteous individuals of all nations will enjoy the salvation of a portion in the world to come (*Sanhedrin* 105a). Historically, ethical responsibilities of Jews toward non-Jews were recognized; these tended to fit a model of a responsible but distant ethics of strangers, reflecting the real-life context of the time. Traditional

sources instructed that non-Jews together with Jews should receive financial support for the poor, visiting of the ill, and other works of philanthropy. The extent to which these mandates were carried out, and relations between Jews and non-Jews generally, varied greatly.

Since about 1800, large and growing numbers of Jews came to have the status of individual citizens within secular states. The advent of modernity entailed both radically new ideas and a radically new life situation. Modern thinkers increasingly came to see in the Bible's account of "having God begin humankind with but one pair of people an early intuition of the truth that all ethics is necessarily universal. Put symbolically, one Divine Parent meant that all human beings have familial obligations to one another" (Borowitz, 1990, p. 99). Most contemporary thinkers recognize important responsibilities for all of humanity, in addition to special responsibilities for members of one's community – the Jewish community, as well as local and national communities. Judaism strongly supports UNESCO's valuing of equality and solidarity (Articles 10, 13).

Jewish tradition teaches that all belongs ultimately to God. God has granted humans authority over the use of resources with the expectation that we will use these resources responsibly and to help those in need. The Bible proclaims: "God favors no person, and takes no bribe; He executes judgment for the fatherless and the widow, and loves the stranger, giving him food and clothing" (Deut. 10:17–18). Over the centuries, Judaism developed the Hebrew Bible's value of justice and institutions for support of the poor into a system of *tzedakah*, literally meaning justice and signifying support for the poor and needy. Justice is also affirmed in the UNESCO declaration (Article 10).

The Mishnah provides a strong foundation for pluralism and respect for differences among people. For many Jews, most powerfully in Reform Judaism, this supports the importance of individual autonomy and the requirement for informed consent (Articles 5–6). Orthodox rabbi Irving Greenberg likewise declares that "the patient himself must have a role in therapy. The patient is in the image of God; thus the greater the role in the patient's own therapy, the greater the patient's own dignity" (Greenberg, 1986, p. 142). Most Orthodox authorities, however, emphasize the requirements of objective norms. Providing benefit and avoiding harm significantly constrain individual choice. Differing Jewish writers articulate differing specifications and balancing among these values.

End of Life

Judaism's commitment to life and healing tends to support the provision of treatment to sustain life. For some Orthodox authorities, the obligation to maintain life-sustaining treatment is virtually absolute. Humans are mandated to sustain life, and any continuation of life, even when marked by suffering, is esteemed as a benefit for the patient, as well as a requirement of God's sovereignty. Most Orthodox authorities are even more reluctant to withdraw treatment than to withhold it because they construe "withdrawing" as an action. Even these thinkers acknowledge that

treatments often entail risk, or may be only questionably effective, allowing some room for decisions about providing treatment. Still, in virtually all circumstances, all treatment that is effective in prolonging life must be provided.

Many Jews agree that life is intrinsically good but allow a greater scope for treatment decisions. Ethicist Benjamin Freedman argues that, even assuming the obligation to pursue healing, a patient retains significant authority and responsibility for medical decisions. The norm of clinical practice is that choices must be made between different treatments with different side effects, different risks, and different possible benefits. Real choices must be made about which treatments to pursue. In such cases, traditional Judaism should agree that the patient should listen to guidance from health care professionals, and then the patient should make the choice as steward of his health (Freedman, 1999).

A central text regarding decisions to forgo life-sustaining treatment is found in the commentary of Moses Isserles in the *Shulhan Arukh* (Y.D. 339:1):

> It is forbidden to cause the dying person to die more quickly. For example, if one is a *goseis* (dying person) for a long time and is unable to expire, it is forbidden to remove the pillow or mattress from underneath him,...and one does not move him from his place. However, if there is something causing a hindrance to the soul's departure, such as if there is a noise near the house such as a woodchopper, or if there is salt on his tongue, and these are delaying the departure of the soul, it is permitted to remove them–this is not a [significant] action, but is *only removing an impediment*.

While physiological details are unclear, many have seen in this passage a recognition that it is not always possible or appropriate to artificially postpone death. Conservative rabbi Avram Reisner argues that mechanical respirators and transfusions may represent impediments. A dying patient could refuse these, so long as the intention is not to achieve death, but to avoid burdens and to allow death to occur naturally (Reisner, 2000, pp. 265–69). Conservative rabbi David Feldman offers a more general interpretation: "A clear distinction is thus implied between the deliberate termination of life and the removal of means that artificially prolong the process of death....While physicians, then, may not disconnect life-support systems where they shorten life thereby, they may do so to shorten the dying process." (Feldman acknowledges that since "it is difficult to tell the difference between shortening life and death, the principle is a moral one more than a practical one." Feldman also differs from the Orthodox claim that withdrawing treatment is far more problematic than withholding. "At the outset, the physician should connect the support systems of respiration or circulation; he should not decline to do so on the grounds that this may be prolonging death. He must give the patient every chance for life. Having connected the systems conditionally, however, he may remove them if he then determines that their function was not prolongation of life but of death" (Feldman, 1986, p. 95)).

Conservative rabbi Elliot Dorff advocates an approach of evaluating benefits and burdens for treatment decisions regarding terminally ill and permanently unconscious patients. Appealing to texts as well as experience, Dorff argues "that we should use the benefit to the patient as the primary criterion in determining a course of action rather than our ability to accomplish a limited medical goal (such as

keeping one or more organs functioning)." (Dorff 2000a, p. 312) A variety of medical treatments may be forgone based on "our compassionate attention to the best interests of the patient" (as defined primarily by the patient, to the extent possible). A presumption supports the provision of artificial nutrition and hydration, but this presumption is rebuttable: these measures may be forgone for a terminally ill patient (at the request of the patient or surrogate) if they are seen not to serve the patient's best interests (Dorff, 2000b, pp. 344, 348–54).

A statement from the Reform movement develops a different rationale to support views similar to those of Dorff. "Once a medical treatment ceases to be effective and beneficial it ceases to be 'medicine' as that practice is conceived by Jewish tradition. . . .Treatments which do not effect 'healing' are not *medicine* and thus are not required" (Plaut & Washofsky, 1997, p. 348).

Some Reform authorities would accept any refusal of treatment articulated by an individual on grounds of patient autonomy. A minority are even willing to accept active killing when autonomously chosen by a suffering patient. Generally, however, Reform and other Jews reject suicide, assisted suicide, and euthanasia. Most judge that such acts exceed the scope of legitimate stewardship. As well, acceptance of euthanasia and assisted suicide is likely to threaten and harm vulnerable patients. In appropriate cases it may be legitimate to decide to forgo treatment. When medical treatment offers hope to cure and save life, it should be pursued. However, many Jews argue that life-sustaining treatment may be forgone if it merely prolongs the dying process, if it offers no hope for cure, or if it imposes burdens or fails to benefit the patient.

Beginning of Life

There is wide agreement among Jewish writers that a fetus has value and that elective abortion generally is wrong. However, if there is a conflict between the life of the fetus and the life of the woman, the imperative to protect the woman's life takes precedence. Writers express diverse views about whether and to what extent the woman's health and well-being also could justify abortion. A precedent from the Book of Exodus (21:22–23) has been influential in the Jewish tradition. "When men fight, and one of them pushes a pregnant woman and a miscarriage results, but no other damage ensues, the one responsible shall be fined. But if other damage ensues, the penalty shall be life for life...." The Hebrew Bible also contains passages that reflect the value of the unborn child and God's relationship with individuals before birth. In ascertaining concrete responsibilities, however, the clear distinction between the status of woman and fetus in Exodus 21 has exerted greater influence and provides a touchstone for the later development of Jewish law and ethics.

A central text in rabbinic deliberations about abortion is found in the Mishnah (*Oholot* 7:6): "If a woman is having [life-threatening] difficulty giving birth, one dismembers the fetus within her and brings it forth limb by limb, because her life comes before its life. Once the greater part has emerged, one may not touch it, for one may not set aside one life (*nefesh*) to save another." All Jewish authorities agree

that the fetus has a lesser status than that of the woman, though there is debate as to whether this status is virtually equivalent to hers or significantly lower, according greater scope for permissible abortions. All Jewish authorities agree that abortion is permitted to save the woman's life, though the permissibility of abortion for other reasons is contested.

Most authorities agree that abortion is mandated to save the pregnant woman from significant threats to her health. Many accept abortion in some circumstances to avoid the woman's suffering, even when her health is not directly threatened. The abortion of a fetus with a serious genetic disease, such as Tay-Sachs disease, is often approached in these terms. Jewish writers typically do not claim that the future suffering of the child after birth would make his or her life not worth living, but rather justify such abortion when it would save the woman from anguish that she would find unbearable.

Some further stretch the rubric of therapeutic abortion. Precedents allowing abortion to guard the woman's psychological health may be expanded to include such variables as physical strength, stress, and personals needs. Some, especially among Reform Jews, emphasize that the tradition does not consider the fetus a person, and so the value of the woman's autonomy is decisive, not only legally but morally as well. Even these writers acknowledge a need for thoughtfulness in making moral decisions about abortion.

A perspective on abortion may be provided by framing the issue in terms of the intrinsic dignity and value of human life, sometimes expressed as the sanctity of life. All Jewish authorities are committed to this principle but specify and balance this principle and others differently. For Jewish thinkers, the life of the fetus or unborn child has value and deserves respect, but somewhat less so than the woman. According to some authorities, the status of the fetus is virtually equal to that of the mother; commitment to the sanctity of life demands abortion to save the woman's life but condemns abortion in any other circumstance. For other Jewish thinkers, the imperative to preserve the life of the woman is more broadly construed, entailing a commitment to preserve health. This approach reflects leniency with regard to fetal life but also stringency to preserve the woman's life and health. Yet other Jewish writers emphasize that the sanctity of life and respect for human dignity involve more than safeguarding biological existence. There are limits to the sacrifice and suffering a pregnant woman is obligated to undergo, even to preserve the life of the fetus.

For Judaism, the fetus must be respected as potential personal life, but does not have the full status of a person at any stage of gestation. All Jewish writers would permit abortion when necessary to save the mother's life. Most Jewish authorities would permit abortion to avoid a serious threat to the mother's health. Many Jewish thinkers would accept abortion in some other circumstances to avoid significant personal suffering for the mother.

Jewish writers tend to accept the use of reproductive technologies when desired by an infertile couple. Concern must be paid to the physical and personal well-being of all involved, especially children. Many express great caution regarding the use of donor gametes, though some accept this in appropriate cases.

Conclusion and General Values

Judaism attempts not only to address particular medical issues but to help shape a way of life that reflects core values such as respect for persons, life, healing, and justice. Jewish tradition affirms the intrinsic value and dignity of each human person. Each individual and the community as a whole are responsible to support others and to provide for basic needs, including health care. The *Shulhan Arukh* (Y.D. 335), following earlier sources, describes visiting the sick (*bikkur holim*) as not only an act of loving-kindness but a personal obligation incumbent on all. Visitors are expected to care for the tangible needs of the patient as well as engage in conversation and prayer. The community is responsible to provide for health care as a matter of justice, *tzedakah*. This responsibility is not unlimited, for individuals and communities legitimately pursue other concerns. While Jewish norms are not incumbent on modern nations, justice is required; Jewish understandings of justice may contribute to broader national and international dialogue.

Diverse Jewish writers would agree on the important value of reverence for human life. One clear implication of this value is that, as a moral matter, abortion is at least prima facie wrong, that is, the moral prohibition against abortion is binding unless outweighed by competing ethical considerations. As well, reverence for human life supports attention to problems of poverty and attitudes of selfishness, which contribute to the prevalence of abortion and harm human well-being in many other ways.

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Orthodox Christianity

25

Florea Ştefan

Introduction

Bioethics finds a new type of anthropological approach. In nuce, this means, from a Christian perspective, a circumstantial, profound approach, in all the cases that concern the defense, the protection, or the development of life as a special and inestimable gift of the Creator. In this sense, it is better understood why the Church considers itself a defender ex officio of life, as it is the servant of life, the servant of the Living God. Having appeared during the last decennia of the twentieth century, bioethics has triggered an increased interest for the study of moral rules of life not just in the medical or juridical world, but also in the Christian ecclesiastical area. The Church Fathers have condemned from the very beginning abortion and suicide, as bioethical approaches avant la lettre. At the same time, they have encouraged scientific knowledge and research, medicine, and everything that is useful for man, starting from the premise that man was created by God with the purpose of contributing, in the Holy Spirit, to the perfection of His creation, of being a collaborator of the Creator, who is supporting and developing the human creativity, ingenuity, and creative fantasy. Actually, the healing of any suffering, the curing of any human incapacity, according to the saving and regenerating example of the Redeemer, is part of what is called the apostolic mandate, the sacramental priesthood. While in the Catholic and Protestant area there have been concerns for the domain of bioethics since the first scientific debates appeared in this regard, at the middle of the last century, in the Orthodox area, despite a sporadic interest and openness to this issue, it was only at the beginning of the 1990s that the Orthodox theologians, especially those belonging to the Churches from behind the Iron Curtain, were able to come into contact with the preoccupations of bioethics and began to research such topics. The explanation of this gap is obvious, as the great Orthodox Churches (the Russian and the Romanian ones) were not in the position to have much information on this new domain and their main concern was to support ecclesial perspective that has in its center the respect and life protection as much as

F. Ştefan
Faculty of Orthodox Theology, Valahia University Targoviste, Targoviste City, Romania
e-mail: pr_floreastefan@yahoo.com

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possible. It was only during the age of freedom that these Churches were able to penetrate into the area of bioethics in all the due depth (Astărastoae & Trif, 1998, 17). The concerns of the Orthodox Churches that had not been within the sphere of influence of any communist state had been rather directed toward dogmatic, pastoral, missionary, or doctrinal issues and only sporadically and occasionally to bioethical issues. This domain was a new one and, prudently, the newcomers first studied the how Catholic and Protestant Christians – with a profound modern and especially postmodern experience – had extended their pastoral and missionary experience and the traditional rules of respecting and promoting life on this new scientific field. For the Orthodox theology, it is an obvious thing that man has been created in the image of God and with the destiny of an unlimited resemblance to Him; that is why man is a completely special being, with a particular cosmological dignity and position (Engelhardt, 2003, 65). Sure, along with the theological, Christian, and theistic vision, today, there is also a humanist, secular, or atheist bioethical vision. Approaching the specifics of bioethics in the Orthodox area, it will be referred to the Christian Orthodox bioethics, to its fundamental principles, to the way in which it approaches life and the contemporary challenges in relation to life. Being really a science with a subtle definition, bioethics is permanently exposed to the risk of losing its meanings and values or of having them distorted by a secular, utilitarian approach although other approaches exist such as virtue ethics.

The Specifics of the Orthodox Bioethical Perspective

Christian bioethics aims to provide a reliable light on the way of life, so that man, using the divine gift of his mind, creativity, may act in good faith from the perspective of the evangelical prescriptions and in relation to His Creator, as it is stated by its classical definition, which affirms that it is a "new discipline, combining biological knowledge to the knowledge of the system of human values" (Potter, 1971, 1; Macer, 1995, 29). The solutions proposed by the Christian bioethics are fully true to human life, to the Creator, and to the entire creation, highlighting the limits of human science, courage, and reason. Christian bioethics puts the respect and protection of life in relation with the search for salvation, from an eschatological perspective, and to the protection, respect, and promotion of human dignity, being inspired by care for man, by love and respect for the human being (Vicol, 2006, 16). The specifics of the Orthodox bioethics consist in a deep respect for human life, for the manifestation of the living and of man in all his fullness. That is why any bioethical approach, from an Orthodox perspective, has in view to support and to protect life, to consolidate the principle of love and respect toward the great gift of life made to us by God, and the lens through which an Orthodox bioethicist looks at everything is not usefulness, but serving God by serving man, promoting good, solidarity, and philanthropy. In the official documents of the Orthodox Church, in relation to bioethics, a few aspects have received particular attention: promoting life and human dignity in any situation; avoiding any personal profit following therapeutic interventions; discerning mind and lucidity in any medical

decision, which has to rely on a deep respect for the patient, as a perfect image of God; a deeper understanding on the medical responsibility toward supporting and defending life, catechizing the clergy and the believers concerning the medical interventions of any kind, etc. The suffering person, who is in need and hurting, is seen as Christ the pilgrim or as a concealed Christ (who is to be recognized in the image of the brother who is in pain). Any man, especially a man who is in difficulty, is considered and evaluated as an expression of the Redeemer's kindness, and basis of the final and eschatological judgment, according to which what is done to the sick person is appreciated in the terms: "You have done it to Me" (Mathew 25, 40). The Christian doctor is a doctor who serves his suffering fellow, being always a merciful Samaritan. The Orthodox bioethics speaks about Jesus Christ, "the Doctor of our souls and of our bodies, the One Who can heal any disease and infirmity, Who can turn suffering into a hymn of praise and can transfigure joy in the light of His resurrection. This beautiful expression does nothing else except to put the incarnated Son of God – as He really is – in the centre of the medical world, of hope and of healing" (Astărastoae, Scripcaru, & Scripcaru, 1994, 12). Christian bioethics helps not to destroy the human civilization, not to mock the divine creation, but to provide the society we live in with an authentic axiological system.

The Principles of the Romanian Orthodox Bioethics

Not everything that is possible is also allowed. Even though, due to the present amazing technical progress, man has numerous possibilities of scientific quest, not everything his powers can accomplish also has a moral end. Man is not the creator of life; he is just one of its beneficiaries and has the divine duty to administrate the creation in agreement with the divine moral laws. The reason is simple: life must be protected under any circumstances and everything that is contrary to it or endangers or deforms it is forbidden. What does not preclude is not opposed to the human right to freedom, because, as it is well known, not everything that is possible is also good, and one's freedom ends where the other's freedom begins. From an Orthodox perspective (B.O.R. Documente. 2004. Pozitia Bisericii Ortodoxe Române faţă de transplantul de organe), bioethics is grounded in the divine Revelation. That is why respect for life, as a precious divine gift, as it was stated before, lies at the heart of any debate and at the basis of any approach. The premise from which the Orthodox bioethical approach starts is that God – the Creator – is the absolute master of life and death. That is why sovereignty over life belongs exclusively to him, man having only the obligation to contribute to defending and supporting it (according to Gen. 1:21,27; 9:6; Deut. 32:39; Ex. 20:13; Job 1:21; Acts 17:28;). Naturally, this is the basis of the idea that man is not allowed to act on private foundations of life by means of medical techniques so as to radically transform it or even to initiate a new human type (Geisler, 1989, 45). Bioethics has for its main source the revealed will of God, because it is only in this way that it can promote life in the best and most correct way, maintaining its relation to the Creator of life. When Christian bioethical

discourse would be outside the revealed doctrine, it would grow speculative and would turn to ideology, i.e., to artificial and false ideas. Another point refers to the fact that at the heart of the human research should be the respect for man's life and dignity, as man is a being with a special role in creation, being created in the image of God. The dignity of life comes from the fact that its source is God Himself, that man has been created by means of a special act by the Creator, being in the image of God and having the perspective of a permanent similarity to Him, so that any act that degrades life is an act of disrespect toward God Himself. God has created nothing for destruction and He supports life providentially, which encourages us to be promoters of life, for by defending life we honor our Creator and respect the great and beautiful gift of life and dignity (Breck, 2003, 15–16). Another principle has in view the fact that human life has a sacred character, because it has been created by God and God Himself is sacred and a source of sacredness (cf. Lev. 20, 26). Human life is sacred through its origin and destiny, that is why it is inviolable and lies at the heart of man's interests. The sacredness of life relies on the fact that man was created by the All-holy God in His image, and God is a model, promoter, and supporter of holiness. At the same time, the holiness of life involves values such as image of God, human person, dignity, respect, and perfection (Lossky, 1993, 144). Human life is a gift; humans have done nothing to come into existence and whatever they do they cannot make it perfect or make it longer beyond God's will. Coming from God and having for one's destination the relation with God, through one's return to the Father, man acquires value by reflecting the divine value; his entire life acquires light and value through its very connection to the Creator; that is why it can be said that human life has an inner value, given by its eternal origin and destiny. God, Who is love, has given men the existence as a gift of His endlessly overflowing love; He has given it to them so that they may live in an eternal loving communion with Him (Col. 1, 12, Ephes. 1, 18). The sacred gift of life is the most important component of human life, the only really precious gift that man has ever received. That is why a human person can by no means be the instrument of purposes that are foreign to his development, as man finds his total and definitive fulfillment only in God and in His redeeming plan. One can state that the sacredness and inviolability of human life is the only universal principle that has no restriction and no exception (Maximilian, Milcu, & Poenaru, 1994, 69). The principle of naturalness rejects everything that goes against the natural development of life or stops the natural development of man in harmony to the laws God has engraved in the creation. This is also one of the reasons why euthanasia, for instance, is fought against and refused, not just because life is the gift of God and what you cannot give you also cannot take, but also because the earthly human life must end naturally, according to the Creator's decision and according to one's biological infirmities, and not according to one's arbitrary will. Natural is everything that comes from God, and forgery and artificiality is everything opposed to the divine will or to the laws of nature, which are also of divine origin. Artificiality is opposed to life through its alterity in relation to life and to life's purpose; that is why Christian bioethics rejects any artificial thing that is directly or indirectly opposed to life. The eschatological

principle holds that everything human persons do in support of life has to take into account the fact that this earthly, biological life does not represent everything, is not a purpose in itself but is just a preparation for the eternal life, an exercise preparing men for the eternity, a time of trial and edification of one's perfection. That is why the human life and man's deeds have to be directed to eternity, to immortality, which saves from idolatrise the culture of life itself, which otherwise – in theory – would draw near the vitalism of the ancient, pagan religions, or to the contemporary consumerism and materialism. "Live fully, here and now"– this would be man's best slogan, the most correct one, were he not meant for deification, spiritualization, and transfiguration (Yannaras, 1996, 55). The eschatological principle gives force to faith, gives wings to hope, and chases away the temptation to divert the actions in favor of promoting life from their true meaning and purpose. The dominant principle that should characterize all the human actions is that of solidarity and love, the biggest Christian commandment, the very essence of the Creator and of man's perfection (according to Mt. 22:37–39). Man was not created alone; in order to be able to become perfect, he was given the opportunity to live in community and in communion; that is why, the manifestation of human solidarity is natural as equal beings in front the Creator, but as persons who love one another and manifest their mercy to each other, according to God's model. Solidarity supposes not just supporting the universal human effort, but also sacrificing human persons for their fellows, every moment of their life, up to the sacrifice of their own life. It is out of love for their fellow men that all the social work and mutual assistance among people have come. It is also out of love for people that there are innumerable persons serving their fellows' needs, even to the point of sacrificing their lives for their fellows' sake. The incarnated Son of God gives humans the supreme example of love and solidarity, receiving a human body for their sake, suffering, dying, and being resurrected, for their salvation, for their good, out of His great love and in order to show his solidarity with them. God's arrival into the heart of the human history is the active principle animating all humans, too, to serve their fellow men in need through their friendship. According to this logic, any medical intervention should be carried out with the fully informed consent of the respective person, who should be aware of all the moral, spiritual, or medical implications of the respective act. When this consent cannot be expressed, the only actions allowed should be those that maintain life. It is a human duty to prevent somebody's death, by any legal and moral means, but also to contribute to treating, curing, or correcting the imperfections of man's biological life (Atkinson, 1985, 205). A being of joy and of hope, the Christian celebrates life, serving the God of life, appreciates biological life, along with the eternal one, as a marvelous gift of God, promoting the idea that man should rise above different ideologies and doctrines, and man's life is truly a good thing, a value in itself and a sacred gift (Breck, 2003, 19). Life is a *talent* that was entrusted to men so that they may transform it and increase it, turning it into a gift for the others. No person is an iceberg floating uselessly on the oceans of history. Any human person is part of a large family in which each one has his own place and role. Science can change life, but it cannot transform it. What men need is

a change of Life and Death. This is the calling of the Church. Beside all the things above, one should take into account as well the fact that the Church values the concept of person, namely, of living entity created for communion, creative, open for dialogue, who finds one's purpose only in communion, is indivisible, capable of relations and self-reflection, free, unique, with the vocation of a distinct contribution to the world's soteriological progress, but especially with a great moral responsibility (Stăniloae, 1997, 359). Christian personalism has in view the fact that between part (man) and whole (mankind) there are fine, multiple, and complex intrinsic connections, so that a man cannot express entirely the whole of humanity, and that can be assumed and saved only with each and every man. In this sense, one should understand that what is good for just one man should be good for the entire mankind and the other way round. Namely, all that can support life in a particular case becomes norm for the whole. It is not just the soul that has value, in the case of man, but man as a whole, because man, body and soul, material and spiritual, is a being with a subtle definition, a mediator between the two worlds and having value as a whole. It can be said that man is a special being, and the body is his interface for space and time or the way of manifestation of his spirit under these conditions of existence. The extremely special value of man is also given by the fact that for him, God Himself arrived in the human history, received a human body, and became a Man. And to save a man is to save his divine dignity, to fully honor God the Creator. God is the One who saves man; that is why man should also be someone through whom God acts, an *alter Christus*. The morality of the medical act can only be appreciated by relating it to a transcendent principle; otherwise, it is changeable in a permanently fluctuating environment, depending on the will, knowledge, and ideology that mark – at a certain moment – man's life. Man's intrinsic, absolute value in front of any ideology, turns any medical intervention – from a Christian perspective – into an intervention that concerns the human body, not like a piece of meat, like something ordinary that can be found in large quantities on Earth, but as a special material individualization, as a personal way of relating with one's fellows, and especially as a special environment for the manifestation of God's presence. That is why saving the integrity of a man's body is an instance of praising God, and a way of contributing to the accomplishment of His Creation.

Bioethical Structures Within the Orthodox Church

From an inter-Orthodox viewpoint, on the level of the world Orthodoxy, on the occasion of the Meeting of the First Hierarchs of the Orthodox Churches from Constantinople (Istanbul) in 2008, it was decided to create an Inter-Orthodox Bioethical Commission, so that it may express a common Orthodox viewpoint in matters of bioethics. This agreement has been substantiated through the meeting organized by the Ecumenical Patriarchy, between May 23 and 26, 2011, at the Orthodox Academy of Crete in Kolimbario. The event was presided by the Eastern

Orthodox Metropolitan Ioannis (John) of Pergamon (Zizioulas) and debated the main contemporary issues related to bioethics.

In the Romanian Orthodox Church, the most open out of the churches from former communist space, the interest for bioethical topics became obvious after the 1989 events, when the communist regime in Romania was stripped of power and a democratic journey of the country began, more precisely, even since 1992, when the Holy Synod of the Romanian Orthodox Church approved the creation of a Consultative Commission of Bioethics, meant to provide specialized expertise on current matters in the domain. Important is also the decision of the same forum, which in the year 2001 decided that bioethical topics should be a priority on the agenda of the high forum. At the same time, a proposal of the Committee for the elaboration of the principles and methodologies for the approach, study, and evaluation of this topic was approved, namely, that the four large university centers of the country (Bucharest, Iaşi, Cluj, and Timişoara) would function a local bioethics commission, made up of five theologians, five scientists, and a lawyer, dealing with bioethical topics, and the results of the research may be handed over to the National Consultative Commission of the Romanian Orthodox Church on Bioethical Issues, which was created on the same date, with members from within the four subcommissions. This commission elaborates conclusion and hands them over for approval to the Holy Synod. The Commissions functioned since 2001 until 2003, they handed over their proposals to the Consultative Commission and then to the Chancery of the Holy Synod, their expertise being felt in the decisions of the high Romanian Orthodox forum on organ transplant (2004), abortion (2004), and euthanasia (2005) (Iloaie, 2009).

Within the Orthodoxy, a notable preoccupation is also the concern for bioethics of the Russian Orthodox Church, which has expressed its position concerning different topics in the domain on the occasion of the well-known document entitled *Fundaments of the Social Concept of the Russian Orthodox Church*, expression of the Jubilee Episcopal Synod of the Russian Orthodox Church, Moscow, August 13–16, 2000.

The American Orthodoxy, closer to the top scientific research has, through its different jurisdictions, very clear positions on a set of bioethical matters covering a large array of problems. Locally, each autonomous Orthodox Church has its own consultative bioethical structures and expresses knowledgeable viewpoints, on different occasions, concerning bioethical issues under debate.

Along with the Romanian and the Russian Orthodoxy, the Greek one is very active in supporting – from a social viewpoint and in the media – the perspective of the Orthodox Church on the main bioethical issues. From this viewpoint, it can be said that the Greek Orthodoxy highlights the need of an ethics concerning procreation and the need to eliminate abortion from the preoccupations of its own believers, but also the need for a major ecotheological vision, while the Russian Orthodoxy is concerned by matters related to the ethics of the work and of the techniques of genetic manipulation, while the Romanian Orthodoxy is preoccupied by the interdisciplinary, technological-scientific approach and the substantiation of the bioethical issues.

The Position of the Orthodox Church on the Main Bioethical Themes

Abortion

The ecclesial writings from the beginning of the second century, the Holy Fathers' and church writers' works of the third century, as well as the ecclesiastical rules and canons state the concomitance of the body and soul even since the moment of fertilization, as they are formed both at once, which shows that even since the conception stage, it can be talked about the existence of a concrete and true human person.

The entire Orthodox Christianity considers abortion as deliberate murder, as it starts from the belief that human life begins with procreation, namely, at the moment of the fertilization that gives birth to the unique zygote, the unique cell made up of two gamete cells. This conviction relies on scriptural texts (Ps. 138, 13–16; Is 49, and so on; Luke 1, 41, 44) as well as on the scientifically established fact that even since the moment of conception, there is genetic uniqueness and probably cellular differentiation that, if the embryo is allowed to develop normally, will produce a living human being. Man's life is considered sacred even since the beginning, since it is clear that it is dealing with the existence of a soul even since the moment of conception. The fetus has always and constantly been considered a complete human being. The artificial interruption of a pregnancy has always been considered a crime, a homicide, in the orthodox tradition. By abortion, one ends a human life, a human existence, even though it may have been in the beginning stages. The fetus, in his personal life, is an autonomous human being and a complete human person, living and developing independently from his maternal environment. So, ending a pregnancy is not the right of the person bearing him. The fact that the pregnancy does not yet concern the fully developed person does not mean that it can be reduced to a thing, becoming an object – good for property, for sale, or for storage. At the same time, it does not mean that the pregnant person may freely take any action concerning the fetus, as she can do concerning any other part of her body. The fetus is not a thing or an object or a simple part of the woman's body, but gene with life in evolution, united to the life of the pregnant person. This special particularity of the fetus as person in evolution cannot be contested. Consequently, the fetus is and has to be protected by the civil law as something special. From this results the intransigence of Orthodox bioethics concerning abortion: man exists as man since the moment of his conception until the moment of his biological death. So, during any moment of man's life, if there is an intervention against man's survival, it is considered homicide. Extrapolating, children are not therefore their mother's property, their parents' property, or even the society's property for any of them to take any action concerning the children even since their mother's womb. The orthodox Church has always been – in all the times and places – against abortion, which it considered a crime against human life, and which it situated among the outrageous sins, which diminish and annihilate the communion of its perpetrators with God. It is true that there are some nuances,

like when a woman is raped, however, the child has no fault and mother should keep him; also when the mother's life is threatened, the choice is hers. It is about saving a life and losing the other without being able to keep them both. Being an act directed against human life, the abortion is comprised and forbidden by the sixth commandment of the Decalogue: *Thou shalt not kill* (Deut. 5, 17). The principle against abortion (and not only) could be best synthesized in the following words: all that is committed against the human being is committed to a certain extent against God's will.

Organ and Tissue Transplant

By tissue and/or organ transplant is understood the complex medical activity that, for therapeutic purposes, replaces tissues and/or organs no longer working from a morphological and functional viewpoint, from the body of a human subject, with other similar ones, proved as being healthy. The organ transplant represents a really laudable techno-medical performance of today's science. It is a performance of the medical science and practice that the Church blesses as long as through the transplant, one solves the crisis determined by the lack of other healing solutions and the normal life of one person is restored without taking the life of any other person: no one should be killed for someone else to live. To carry out a transplant is to implant in a certain part of the body a tissue or an organ taken from another part of one's own body or from someone else. From a living donor can be drawn one of his double organs (e.g., kidneys) or tissues (skin, bone marrow, blood). When living tissue is transferred from one part to another of the same organism, it is called an onto-plastic (autograft) transplant. When dealing with the transplant of a tissue or an organ from one individual to another belonging to the same species, it is called a homoplastic transplant. A heterologous transplant, finally, is a transplantation of tissue from an animal to a human being. The drawing and the transplant of human tissues and organs are carried out for therapeutic reasons. The Orthodox Church agrees to organ transplant as long as it is carried out not for a material interest, but out of love, if the donor consents and the respective transplant does not endanger either his life or that of the receiver. A problem is raised by organ and/or tissue drawing and transplant from persons experiencing cerebral death. The Orthodox Church has established a few criteria concerning the carrying out of this practice: one should respect the dignity of the person (donor, receiver, doctor); the operation should have a therapeutic purpose; it should be for the benefit of one's fellows; it should respect the life and even the death of the human person; it should respect human rights and the spiritual dimension of the human existence, from the very moment of its conception; it should not be determined by political or economic opportunism, by medical curiosities, which are in fashion in the present secularized world. At the same time, the donation should rely on the spirit of sacrifice, should not be the object of a financial deal, should be carried out in order to cure or treat a disease, should be the only solution at that moment, should benefit of the agreement of both parties, and should not be part of a human embryo, who is

a being with rights and cannot express his consent, and a drawing would mean his destruction. The receiver of the gift has the chance of continuing his life, while the giver no longer has that chance in the terrestrial area. There are critical situations in which the organ transplant comes as a saving solution, and here one can refer to the people born with malformations or other congenital diseases and who otherwise would not have any solution for survival. Organ donation can be considered as well as a gift out of human solidarity, the individual's moral obligation concerning the respect for life and saving human life being superior to keeping one's physical integrity. So, tissue and organ transplant, on the one hand, helps save the life of those who otherwise would not have had any chance of survival, and, on the other hand, offers to the one who gives the joy of prolonging a life, following in this way the example of one's Redeemer Jesus Christ. The Orthodoxy is flexible concerning this aspect, criticizing and being opposed to the situations of organ traffic, of high-quality medical assistance refusal in order to get a person into the situation of becoming a donor, even unintentionally, or to the situations in which this solution does not have a minimum theoretical success. As sacrifice and as a way of diminishing human suffering, the organ transplant benefits of the approval of the Orthodoxy, being seen as a form of love for human fellow.

Cloning

There is no synodal document with a determined position concerning cloning. However, the opinions expressed by the Orthodox theologians help to support a unitary viewpoint. The Church does not agree with the idea of cloning because this technique of genetic manipulation supposes the creation of copies of DNA fragments (molecular cloning), of cells (cellular cloning), or of organisms. Cloning is a piece of evidence of human power going over its limits, substituting itself to the divine power, because the cloned organism is identical from a genetic perspective with the ancestral cell or organism he came from. So, between the original and the cloned person there is genotype identity, as they share the same genetic patrimony, yet there is no phenotype identity. Between the two organisms there is no bigger identity than between two twins, who also share the same genetic patrimony, yet each one has his identity, his personality, his destiny, which differ depending on their environment, on their education, on their culture, on their own free choices and decisions, each one being endowed with will. So, cloning is not a process of procreation, but is reproduction on an animal breeding level, being, namely, an offense against the dignity of the person obtained through cloning. A clone has no father and mother; it is not the fruit of an act of love between parents, but a laboratory product, obtained using a serial man-making-machine, an object produced on order. The moral issue that arises is that this procedure can create errors, is highly susceptible to failure, produces many abnormalities, can create significant misbalances in the ecosystem, nullifies the individuality and uniqueness of the human being, and can create significant juridical and identity-related complications. At the same time, it violates man's fundamental rights, hurting the

dignity of man and of the divine creation, creates the suspicion of the immediate possibility of racial selection, puts man in God's place, introduces stereotype and repetition in the uniqueness of life, undervalues the body, which is a temple of the Holy Spirit (I Cor. 3, 16), and may even create true biological bombs or may be used as racial weapon. That is why the Orthodox theologians do not accept this procedure and do not find any moral justification for it. The attempts made to obtain human beings without any connection to love and to family should be considered contrary to ethics, as they go against the dignity of both human procreation and of the conjugal union. In 1998, the Romanian Parliament voted in favor of a law that forbids cloning. However, the debate continues, especially as the atheistic moralists or those belonging to different secular groups, relying on a so-called right to progress and research (a Marxist-Darwinist projection, an ideological distortion), support the view that no legislative restriction should exist concerning cloning. Orthodoxy, through its theologians, considers this technique unnatural and not useful for the common love and good, but rather a technique supporting petty economic or racial interests. Thus, it rejects cloning with determination. Only organisms created naturally, respecting the laws of creation, can be viable and sustainable. And then, can someone guarantee that no genetic errors are introduced in the creation, without having the possibility of eliminating them? So, it would be better to stop playing God. The issue of cloning is an actual piece of evidence that science without solid spiritual and moral principles is positioned against man.

Euthanasia: Assisted Suicide

By euthanasia, which in Greek means "beautiful death" or "easy death," one understands the medical help meant to put an end to the life of someone suffering from an incurable disease. The practice of euthanasia supposes the ceasing of the medical treatment, which subsequently leads to death, or even the ingestion of deadly substances or the use of lethal techniques. It is used especially in the case of those who say that they have incurable diseases or an age they consider sufficient for life and so they wish to put an end to their earthly existence. Those who support euthanasia start from the following premises: the ill person's right to a decent death, the presumption that the diagnosis is always a correct one and cannot be changed, the idea that there is no other alternative for helping the incurably ill person. What is neglected, however, is the fact that death should intervene naturally and not artificially, that no one cannot establish the certitude of the diagnosis, but can only approximate it. At the same time, there are enough cases in which, despite an extremely unfavorable diagnosis, the patient either completely recovered, or his health condition considerably improved. One cannot forget that the Nazi practice of programmed euthanasia, meaning by it a means to ensure the supremacy of the white and "strong" race, constituted the first applied political program concerning euthanasia. Death for the believer indicates his relationship and his primary dependence on God; he puts his life into God's hands in an act of total submission. The euthanasia and the suicide constitute the sign of the vindication by man of the right

to dispose of himself, of his own life and death. Any legislation should recognize and consecrate and defend the fundamental right to life, but not to death. Because, granting the right to life and death, the legislation turns to absurd and annuls itself. Life is sacred and inviolable. There is no life devoid of meaning, of value, of dignity, just as there is no death devoid of dignity except for that caused by suicide or euthanasia. The Orthodox Church clearly and firmly states its position against euthanasia – under any form – considering it deliberate murder and asking for the punishment of those who make themselves guilty of it. A doctor must save lives, not end them, and in any situation human life has an indestructible and indelible dignity. Euthanasia is not a natural process, as it involves a choice. The life that a man cannot give should not be ended by man, even if it is his own life. Only God is the master, the source and the author of life, and only He has the right to take it. What is not yours cannot constitute a subject of choice or transaction. Orthodoxy rejects any action or accident by which one could try to end someone's life and any way by which someone could try to end his own life, recommending the administration of all the natural treatments meant to ease the patient's pain. Suffering has, for an Orthodox Christian, a soteriological sense; it has a sense, and death is the most important moment of this life, as it is the passage gate to the world of eternity; that is why illness and death have something mysterious in them, as they do not lack the presence of God in them. When man artificially intervenes to hurry death, he goes against the Creator's will and becomes an opponent even of his own humanity. At the same time, no medical or economic reason can justify euthanasia, this being a barbarian act and a sign of behavioral and civilizational estrangement.

Contraception

In the Orthodox perspective, the family governed by authentic love cannot be infertile; of course this is not an infallible rule, for love and marriage can occur where, for various reasons, the family cannot have children. But its fruits can be either material or spiritual. The purpose of a marriage is the accomplishment of the two married people through a complete love, which can lead them to get closer to God and to salvation. When among the family fruits there are children as well, they are a great gift and blessing from God. Orthodoxy does not want to intervene in the intimate life of its believers, considering the marriage holy under all its aspects, including its bodily aspect. At the same time, man's purpose is to grow in his likeness with God, in perfection, but also to perpetuate the human species. It is true that, in principle, man has reason and can decide if and how many descendents he shall have, although, in the end, the One who decides is the Creator. However, the Church accentuates the priorities – perfection, salvation, and the perpetuation of the species – thereby it recommends abstinence for the natural regulation of different situations. Some theologians associate abstaining from procreation by different means to the sin of Onan. Others, in exchange, without any approval of some ecclesiastical decisional forum, accept any non-abortive contraceptive means. Normative remains, however, Saint Paul's recommendation: commonly

agreed-upon-abstinence for a while (I Cor. 7, 5). Even though Orthodoxy has not clearly stated its position by means of a synod so far, the tendency goes, however, toward the promotion only of the teaching preached by the Holy Apostle Paul – temporary commonly agreed-upon-abstinence.

Artificial Insemination

Here as well Orthodoxy also does not have any normative document, yet the bio-moralists and Orthodox moralists consider that if the insemination occurs with biological material from the two spouses, who are totally, partially, or temporarily infertile, or have any other medical problem and the birth can occur only through artificial insemination, then, because it serves love and the family, this thing is blessed. The condition is that both of the spouses should agree to it, and the biological material should belong and should be used only within the same couple. The import from somebody else is seen as a form of technicized adultery and is not accepted.

Experiments with Human Beings and Consent

The Orthodox Church does not have any synodal document concerning this issue. The historical experience shows that through medical experiments was discovered the antidote for many human diseases and sufferings, but, at the same time, some of them only served some people's pride, folly, or stupidity, being true experiments of torture (Clement, 1996, 23). Theologians, philosophers, people in the service of culture, or politicians have gradually pronounced themselves in time on the need, the use, or the rules that should accompany the medical research, many of them being opposed to the medical experiments on man, these means being considered as violating man's dignity and serving rather human vanity than mankind's welfare. At the same time, it is considered that medical experiments on man create suffering and humiliate the human being, taking away some of its physical or psychological integrity, terrorizing the future of the respective persons. It is a noble and moral thing to wish the welfare of mankind and to do everything to cure the different ailments affecting man's physical or spiritual life, but, in this approach, one must take into account a few rules. Any medical experiment needs to be carried out with the consent of the subjects after having previously informed them correctly on the respective scientific research, on the risks that they run and on the consequences of these experiments. At the same time, any experiment on man should not mutilate or create damages hindering the adequate functioning of the human body, and so the total or partial destruction of some healthy organs for the sake of research would be even more unacceptable. The latter should have a unique purpose – namely, to serve man, not someone or the other's ambitions, pride, or will for power (Fiori, 1996, 1123). Informing the subjects undergoing the tests is obligatory, in any situation, always before the beginning of any form of medical treatment, the only ethical exception being that of a major emergency that does not allow for such procedures.

Increasingly stronger voices ask for the forbidding of the experiments on animals, as part of God's creation, with its own dignity and meaning, the animals being unable to express their agreement. Numerous theologians see in these experiments a diabolical form of humiliation for the creation and a source of useless suffering, stating that good scientific medical results can be obtained using other means as well.

Conclusion

Bioethics is a big challenge for our contemporary society that implies promotion of human dignity and ecclesiastical community responsibility with liability and caution.

It is truly a science of life, of the rules of human life lived according to the natural divine principles, according to the providential and redeeming plan of the Creator. Ethical clarifications have no other purpose but to impose respect for life, for human dignity, for man's inalienable and divine rights. The dialogue between science and faith can be realized by means of reason, which is common for both of them. From here comes the need for a philosophical-moral reflection in the medical and biological domain as well. So, bioethics is understood as a discipline with a rational epistemological status, opened toward theology seen as a suprarational science, final instance, and "horizon of meaning." Bioethics is situated in the vanguard of science and of the means for promoting the transformation of one's world; it is the very guard of one's mentalities' purification and the keeper of life's treasure, protecting human beings from violating the sacredness and holiness of life. The Orthodoxy, through its different local Churches, by means of the agreement of some pan-Orthodox meetings, has formulated certain positions concerning the main bioethical issues, which it sees as norms meant to guide the believers on their way to salvation. By respecting them, the Orthodox believer enters the communion of love of the ecclesiastical community. By not respecting them, however, he creates not only suffering and disorientation, but also estrangement from the ecclesiastical body. An important role in this guidance goes to each priest in his own parish, in his spiritual relation with his parishioners. Personalist Christian bioethics is engaged in the defense and in the promotion of man's life, from birth to man's natural end, and invites all the Christians and all the good-willed people to participate to the realization of the great project of a new culture of life. Christian bioethics, in the light of the Orthodoxy, is truly a science of life, of the rules of the human life lived according to the natural divine principles, according to the providential and redeeming plan of the Creator.

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Protestantism

26

Evert van Leeuwen

Introduction

Protestantism is the collective name of the religious groupings in Christianity which arose from the sixteenth century on. It is the third flow of religious thought and belief in Christianity, besides (Roman) Catholicism and (Eastern) Orthodoxy. The scope of this article makes it impossible to deal with all the varieties of Protestantism which developed during the last 500 years. The main characteristics can however be given by five Latin phrases starting with an S: *Solus Christus* (i.e., only in Jesus Christ can salvation be founded; He is the Redeemer of mankind), *Sola fide* (i.e., only by faith mankind can be saved from sin), *Sola scriptura* (i.e., only the Bible can be regarded as the Word of God; nature or tradition cannot be regarded as such), *Sola gratia* (i.e., only Divine Grace can yield salvation), and *Soli Deo Gloria* (i.e., only God receives honor and glory). These characteristics have been interpreted in many ways with respect to moral actions and their evaluation in terms of good and bad or with regard to the question of human responsibility. It is hard to cover all of them, but a systematic historical overview can give some insight into the main religious, political, and economical key points that need to be understood when dealing with specific moral views of a stream of Protestant moral thinking.

Systematic Historical Overview

The name Protestantism was coined at the Reichstag (Diet) of Speyer in 1529 in Germany, when a part of the German princes protested against and rejected the withdrawal of an earlier agreement (1525) on the freedom of religion. The Emperor of the Holy Roman Empire, Charles V, tried to bring back order in the German parts of his empire after the war with Frans I of France. He therefore reconfirmed the

E. van Leeuwen
UMC St Radboud, Radboud University Nijmegen Medical Centre, Nijmegen, HB, Netherlands
e-mail: e.vanleeuwen@iq.umcn.nl

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Edict of Worms of 1521 in which the reformer Martin Luther was condemned, outlawed, and the combustion of his writings ordered. Protestantism therefore arose not so much out of a religious dispute as well as through a political act with a considerable moral weight. Later, in 1555 a settlement was reached through application of the slogan "Cuius regio, eius religio" (Whose realm, his religion). Understanding the roots of Protestantism requires understanding of this intertwinement of religious thought and moral and political action. Max Weber has given a clear explanation of the intertwinement in his famous essay "The Protestant Ethic and the Spirit of Capitalism" (1905). Still, the intertwinement is more complicated than one between economical strategies and virtues based on religion. It also entails the rise of citizenship and individual freedom as moral and political factors. The rise of commerce in Medieval and Renaissance Italy and France, and the ways in which the Catholic Church had indulged itself in politics and trade, already initiated in the twelfth-century heretic lay movements like the Albigensians (or Catharism) and the Waldenses. In both cases material wealth and prosperity were denied in favor of spiritual and personal salvation or purity. The movements reflect the need of spiritual and personal development of faith as can also be seen in the works of, for instance, the Cistercian Bernard of Clairvaux and the Dominican Meister Eckhart. In the United Kingdom (Ockham, Wycliffe) and in Bohemia (Jan Hus), similar movements arose a century later with the aim of reforming the Catholic Church. In their development these reformers, like the later Protestant leaders, the Augustinian monk Martin Luther, the lawyer John Calvin, and the pastor Huldrych Zwingli, stressed the difference between faith as the source of moral behavior and morality as a system of rules of conduct. They also preached soberness and poverty as a Christian lifestyle and were in conflict with the practice of indulgences as the partial or full remission of penance of sinful behavior. In this way the reformers reflect partly St. Augustine and his De Civitate Dei or City of God, stating that the Earthly City should be subordinated to it. For another part they rely on the rise of individual conscience and the strengthening of personal faith in moral matters. In this the reformers did not try to support or stimulate economical prosperity but instead denounced the striving for wealth. Sola fide, together with Sola Scriptura as the only source of the Word of God, can be considered as their offspring.

The work of St. Augustine has been influential on the rise of Protestantism in another sense as well. St. Augustine fiercely combated Pelagius who preached that human beings could perfectly perform good works on their own, without Divine Grace or intervention. In this Pelagius denied the doctrine of the original sin in which mankind is condemned by the sin of Adam. Pelagius proclaimed that free will is sufficient to fulfill the Divine Law and that man is capable to avoid sinning. St. Augustine defended according to Pelagius Manichaeism in his doctrine of the original sin and the Fall of Adam. St. Augustine, however, though a follower of Mani in his youth, had also denounced the fatalistic ways of belief of Manichaeism, in which the struggle between the spiritual world of Light and the material world of Darkness, Evil, has a main place. St. Augustine therefore defended both predestination as the belief that God is omniscient and eternal and the free will of human beings, who are created after the image of God and therefore can make decisions

without any cause forcing them. According to a strict interpretation of the doctrine of predestination, nothing happens, has happened, or will happen that is not willed by God at the moment of creation. This interpretation seems to leave no room for the personal free will. St. Augustine did however uphold the notion of free will but under the condition of the original sin. Therefore, mankind is able to strive for the good, but is dependent on Divine Grace in order to succeed. Moreover, predestination implies that God has elected already before the beginning of time those who will be saved by God's Grace. The tension between the doctrines of free will and predestination is therefore not altogether solved. Within Catholic theology the debate on free will returned especially between 1200 and 1400, in the works of St. Thomas, St. Bonaventura, and Duns Scotus. Gradually it was acknowledged that the good works of humans could be preparatory to salvation. Scotus argued against St. Augustine that humans are basically good and not sinful and that goodness can facilitate reconciliation with God. The Catholic Church developed more and more to recognition of free will as a ground for moral action and moral responsibility. The Protestant theologians of the sixteenth century radically broke with that development. Luther and even more Calvin claimed that only faith could be a starting point for salvation and not free will. Luther even denied free will in his early works. Above faith, Calvin also believed in the double doctrine of predestination, meaning that God in His omniscience did not only ordain the course of happenings in this world but in His Wisdom has also decided beforehand who will be saved and who will be eternally condemned. The room of personal free action is therefore very limited, and reconciliation of man with God is only dependent on Divine Grace (Sola Gratia). Opponents of the strict view on predestination and the limitation of free will were severely attacked by Calvin. Michael Servetus, for instance, a Spanish physician, inventor of the pulmonary circulation and pharmacologist, was first betrayed by Calvin to the Inquisition and then, when Servetus fled to Geneva, trialed and burned alive by orders of Calvin. Servetus was an outspoken opponent of the doctrine of predestination as well as the role of Divine Grace in Calvin's work. Another opponent, the Savoyard Sebastian Castellio, was banned from Geneva and considered as an instrument of the Devil. Castellio defended free will as the ground for moral respect and as a force to perform good works. In his acknowledgment of free will and the possibility to be good, he became a forerunner of the later Armenians and the Rotterdam philosopher Pierre Bayle.

The common restriction to three main reformers of Protestantism, Luther, Calvin, and Zwingli, has not only to do with their theological work, preaching, and writing. It has also to do with their ambitions as makers and managers of new religious entities and political strategies. Luther supported the German princes in their struggle with King Ferdinand and the Emperor Charles V, Calvin had his strong ambition to be the ruler of Geneva, and Zwingli supported the Swiss farmers in their struggle. On a bigger scale, Protestantism mainly broke through in countries which wanted to liberate themselves from the Habsburg dynasty and the authority of the Catholic Church. In the United Kingdom, the Anglican Church or Church of England was founded to enable Henry VIII to divorce and remarry. The King became the head of the Church of England. In the Netherlands, Protestantism played a major role in the

revolt against Spain, a revolt which started over a dispute about taxation. In France things turned out otherwise. Henry IV, leader of the French Huguenots, could only become king of France when he would return to the Catholic religion. France had already seen bitter and bloody fights between Catholics and Huguenots, and when he accepted his conversion to Catholicism, he allegedly spoke the famous words "Paris vaut bien une messe" (Paris is worth a mass).

The wars, fights, and political ambitions concomitant with the establishment of a recognized religion easily do forget that many forms of Protestantism are based on communality. Instead of the authority of the Pope and the Catholic Church as the organizing institution, Protestant Churches act as local communities with a council as its main authority. The strength of the communal organization has been especially clear in the movement of the Anabaptists and Baptists. The Anabaptist movement originated in Switzerland during the days of Zwingli. Zwingli, like Calvin and Luther, defended the baptism of infants, but one of his main followers became convinced that conversion and confession should give reason to rebaptize (Anabaptism). The movement associated itself partly with the Peasants' War (1523–1526) in Germany, led by the spiritual Thomas Müntzer. Müntzer, like Zwingli, stated that each human being could find his own way to heaven, without or within the church. He actively supported the farmers in their financial demands and their request of human rights. Luther however distanced himself from this worldly business and stated that he strived for a reformation of the church. Only later he notched with the demands of the princes. The belief of the Anabaptists that the human free will is sufficient to establish heaven on earth rapidly gained influence, and some of the Anabaptist leaders did not eschew violence to transform their beliefs into reality. Jan van Leiden started in this line of thinking a New Jerusalem in the German city Münster. The community lasted 1 year after which the radical Anabaptists were killed. Most of the Anabaptists however are known for their peacefulness, their willingness to share goods in the community, and their avoidance of governmental authority. After the expulsion from Zürich, they fled over Europe and tried to live a pure life and avoid earthly power in organized society. In this way they broke with the Catholic tradition which considered society as an organized Christian body. The Hutterites, the American Amish, and the Mennonites are examples of this communal way of life. In England the Puritan movement gave later birth to Baptist Churches. Baptists stand for the belief that the profession of faith should be prior to being baptized. It then signifies the purification of sin by God's Will. Like in case of the Anabaptists, the statement of personal faith is elementary for baptism as well as belonging to the community of believers. Because of their rejection of the sacrament of infant baptism, both Anabaptist and Baptist believers were prosecuted in Europe for many years. Many of the communities decided to emigrate from Europe to America. Both North and South America have active religious communities that sometimes go back for more than 400 years.

Within the further development of Protestantism, the communal life and the five S's hold their leading position. When Lutheranism led into dogmatic ruling within the German Churches, a new flow came up in the seventeenth century, called Pietism. Soon the movement was followed in the United Kingdom by the Methodist

movement, which was also inspired by the Dutch theologian Arminius who rejected the strong form of the double predestination. In the Netherlands the Calvinistic reform had chosen to follow another theologian, Gomarus, at the synod meeting of 1619. But soon after the meeting, a movement for further reformation started, mainly under the influence of the theologian Gisbertus Voetius. All these movements have in common the claim that the dogmatic rulings of the Protestant Churches and their political influence are considered imperfect and should be complemented by a morality and lifestyle in which the Bible, especially the New Testament, is followed as close as possible. Emphasis was thus given to the individual ethics of behavior and personal, methodological study of the Scripture. More radicalized movements took the communal life very seriously, and they started communities both in Europe, like Jean de Labadie, and in the Americas. German Mennonites (Anabaptists), for instance, established a village in Brazil's province Santa Catarina, called after the birthplace of Menno Simonsz, Witmarsum. Besides emphasis on a communal life (for instance, by calling themselves "Brethren"), on personal faith, and on the study of the Bible, many of the pious movements shared a sense of living in the End Time in which disasters occur and during which man should be prepared for the return of Christ. The Holy Spirit is also active in this period of time which led in the nineteenth century to Pentecostal Churches following Methodist and Baptist beliefs in the purification of all sin, through the gift of the Holy Spirit. Individual belief is brought in these churches to its maximum, together with the belief in Divine Presence and the restoration of Christianity in its pure way. Jehovah's Witnesses came, for instance, out of the nineteenth-century pious thinking, stating that the End Time has come and rejecting many aspects of Catholic and Protestant belief, because of their willingness to adjust to former gentile concepts such as the immortality of the soul. The communal tradition again is very strong in their organization. As such the developments in the seventeenth towards the twenty-first century can be seen as stressing the faith of the individual together with a strong commitment to the life in the community.

Protestant Ethic and Morality

From the need, already felt in the early seventeenth century, to restore the original intentions of the Reformation and to develop a pious lifestyle and strict morality, it may be concluded that the mainstream of the Protestant Churches adopted general rules in accordance with the politics of the region, state, or country. Economical factors, like the freedom to trade in the Netherlands and in the German harbors like Bremen, or the ownership of land in North America; political ideas like those of Benjamin Franklin; and social demographic factors and differences, like those between the Latin and francophone languages and the Saxon and Celtic languages, helped to shape Protestant ethic and morality. Differences in perspective with respect to the original sin, predestination, the freedom of the will, and the possibility to reconcile or even reunite oneself with the Divine Presence furthermore differentiated the moral perspectives in personal behavior. Nowadays a large

variety of moral views coexist in Protestantism and it is hard to summon some common key views. The belief in the Divine Trinity, for instance, has been rejected, not only by Servetus or the Cathars but also by churches ranging from the Unitarian Churches to streams of Pentecostal religion and Jehovah's Witnesses. Servetus was executed by Calvin, Isaac Newton had to keep his Unitarian beliefs for himself, Charles Darwin was raised as a nonconformist Unitarian, and Swedenborg influenced both Charles Sanders Peirce and William James with his views. The dispute on the theory of evolution and Divine creation has roots in a long tradition of divergent Protestant views on man and nature in relation with Divine Governance. Some issues seem however to give a common ground to the diversity and they will be discussed here.

Individuality. Protestantism arose together with the growing conscience of citizens and farmers that they could act morally based on their freedom. Personal responsibility cannot be evaded nor traded against indulgences or payments to the church. Although the freedom of the will is counteracted by the doctrine of predestination, Protestantism as such recognizes the freedom of the will in matters of ethics and morality. Mankind has the choice to decide between good and evil. Differences have to do with the question whether or not mankind is able to overcome the original sin with or without Divine Grace or by accepting Christ's sacrifice.

The brokenness of nature. In contrast to the Catholic Church, nature is considered to be broken since the Fall of Adam. Even when the doctrine of original sin is rejected, one has to see that nature is not good in itself. Differences have to do with the possibility to overcome the brokenness. Mankind has the task to preserve the partial goodness of nature and to repair it when possible. Within disputes about genetic modification or the use of stem cells, the issue of how far mankind has the task of being a cocreator plays an important role.

Communalities. Protestants belong to churches which form the core of their communities. These communities can be highly organized, like in Calvinism, but can also take looser forms like in brotherhoods. Participation in the community is more important than citizenship or belonging to a state. The separation between the church and state is prepared and stimulated by many forms of Protestantism, but not by all. Especially in pious and Calvinistic circles, a theocratic conception of the state, implying that the rules of Christianity should be the starting point of legal thinking, still survives. One should not forget that both Calvin and Luther studied law before becoming reformers.

Salvation. In moral matters mankind should strive to do what is considered good and to avoid evil. This does however not imply that good works will be sufficient to be saved. In ethics there is no final reward given in the afterlife. Only Divine Grace can save man, and differences continue to exist on the question whether reconciliation with God can be reached in earthly life.

Health, disease, and death. It is man's task to preserve health as much as possible. Disease and death signify the brokenness of nature after Adam's Fall. Within Protestantism it is a matter of dispute how far preventive measures based on medicine can go. Some Calvinistic Churches hold, for instance, that mankind has to

accept what has been ordained by God's Will. Vaccination is therefore rejected as an inacceptable means to avoid predestined fate. Others stimulate medicine as a means to restore the original goodness of nature and as a task given to mankind. Healing is however not always considered as a result of medicine and scientific human thinking. In many churches miracles are still accepted as well as the powers of prayer and devotion. Healing then means a form of reconciliation with God's Will. If one believes that the brokenness of nature cannot be overcome by human deeds, then it follows that every healing in the end is the effect of Divine Grace.

Abortion. Whether or abortion can be allowed at all, or in some circumstances, has been a recent dispute in Protestantism. Especially the more pious types of Calvinism, Lutheranism, and the churches that arose from the Methodist and Baptist movements reject abortion in any case. The churches that adjusted themselves to the changing political and social environment tend to accept abortion in some circumstances, making the pregnant woman responsible for her own life and body. In general Protestant morality has mostly considered birth as the moment in which a new fellow human being comes into existence, instead of the moment of fertilization.

Suicide, euthanasia, and physician-assisted suicide. Suicide has always been condemned by Protestants, but opposite to the Catholic views, the act of suicide does not imply eternal condemnation. After all, Divine Grace will decide who will be accepted or rejected after death. Martyrs in ancient times as well as those who fell in the hands of the Inquisition in later times are revered, even when they consciously risked their lives for the sake of their religious views. Physician-assisted suicide and euthanasia are accepted by some churches but rejected by many others. The dispute has to do with the freedom of the will to end one's life, when one sees no future left than unbearable suffering while human means are exhausted and also with the belief that God may have reasons to let someone suffer which man cannot understand but should accept.

Health insurance. Insurances as such have always been a matter of dispute within Protestantism. Because of predestination and the reliance on the community, sailors and fishermen did not insure themselves. They relied on their community to take care of their relatives in case of accidents. Some churches still reject the idea of health insurance as a violation of their beliefs and the morality that follows from it. They consider charity as sufficient within the community to take care of every kind of disaster.

Protestantism and the UNESCO *Universal Declaration on Bioethics and Human Rights*

From the small overview of Protestantism above, it is possible to deduce the main points of concordance with the UNESCO Universal Declaration on Bioethics and Human Rights. The first ten articles of the declaration are in accordance with the recognition of personal, individual conscience and responsibility and with the communal aspects of Protestant religion and its emphasis on justice and being

equal in the eye of God. Several points of discussion are still there and need to be discussed in the Protestant communities. First, health and disease are not simply the result of human and scientific endeavor. They can also be considered by communities as being given by God's command and therefore need to be accepted by the individual. That requires a balance to be settled between what is considered God's command on the one hand and human rights and freedom of research on the other. The declaration takes the latter as fundamental, while in many branches of Protestantism, human rights and the freedom of research are not taken to be fundamental but subjected to the Divine Law. Limits that follow from the Divine Law have to be respected, and although human beings are created in the image of God, their capacity to repair and cocreate will always be subjected to the brokenness of nature that follows from the original sin. Prudence in the progress of science and moral consideration of the goals of scientific endeavor are therefore constantly needed to avoid human hubris or recklessness. Death and disease are considered to be unavoidable and need to be accepted as part of the imperfectness of this world. Discussion of these matters in the international community could very well take place with other Christian Churches, like the Catholic and the Orthodox Church, but also in dialogue with Judaism and Islam. Within those religions the discussion on how the Divine Law limits human rights and the freedom of research also has been a fundamental debate over the centuries with similar but also dissimilar outcomes.

Second, respect for autonomy as the expression of the responsibility of the individual before God is mostly related to the demands of the community. "Love thy neighbor" is considered to be a rule that trumps autonomy in many ways. The declaration asks for human solidarity in this regard, but the communal dimension of Protestantism on the one hand does not simply endorse a system of healthcare insurance, while it on the other hand commands that one should help those who are in need without any restraint. The diakonia, or diaconate, has always had an important place in Christian Religion and has been regarded in Protestantism in some of its branches as a more prominent religious way of dealing with the sick and the poor than a system of healthcare insurance which is based on reciprocity. Ultimately the perspective of how the religious community should relate itself to the secular authorities in nations and states is at stake when it comes to justice in healthcare.

Third, transnational practices are within Protestant communities not without dispute. Besides support given on the ground of charity, the conviction that everyone's destiny and salvation is either determined by God's Will or by the morality of the individual person has traditionally implied that missionary works should be supported, while on the other hand, a certain kind of indifference towards the fate of people with other religious beliefs has been expressed. A dialogue in which all religions can take part as the starting point of a global community in which people take care of the sick and the poor has been started in many places of the world after the Second World War, but as yet has not resulted in a commitment in which all different Protestant Churches are united.

Conclusion

Protestantism in its earliest forms has paved the way in many respects of the secular perspective of human rights and respect for personal autonomy. On the other hand it stresses the lack of human capacity to overcome the brokenness of nature and consequently warns for the hubris in scientific endeavor. The intertwinement of religion and secular authority or politics is expressed in the dominant place of the concept of the Divine Law that needs to be obeyed. Discussion on that concept and the perspective of human rights and freedom of research needs to be started with many of the Protestant Churches.

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Taoism

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Hong-wen Li

Introduction

Taoism (also Daoism) is a somewhat hybrid religion that is developed in close relationship with other spheres of Chinese culture. Its unique characteristics include the creative force of Tao, multiple heavens, and the potential of human transformation toward immortality. This makes it difficult to classify Taoism under a single framework. Taoism has never been a unified religion and has constantly consisted of a combination of teachings based on a variety of original revelations (Kohn, 1991).

From Shang dynasty (c. 1600–1028 B.C.E) documents and artifacts, Taoists have inherited its belief of ancestor worship and divination, its emphasis on the written language in ritual, and its hierarchical organization system into their religious beliefs and practices. The *Yijing* or *Book of Changes* is another important source of Taoism. As a divination manual, it plays a key role for the guidance and support in Taoist cosmological speculation and alchemy. In cosmology and alchemy, the eight trigrams show the directions and dimensions of the universe while the hexagrams signify subtle stages and times of cultivation (Kohn, 2009, p. 1–8).

Although Taoists do not share the doctrine of lifelong learning emphasized by Confucians – they are likely in favor of unlearning with the goal of a more natural state of mind *wu-wei* – they do agree with Confucians concerning the importance of cosmic harmony and social virtues. Confucianism focuses on ritual formality (*li*), sees society as hierarchically structured, and proposes a set of virtues that have imposed a great impact on Taoist communities and practice (Kohn, 2009, p. 14).

H.-w. Li
Department of Philosophy, Peking University, Beijing, China
e-mail: hongwinlee@gmail.com

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What Is Tao?

The basic principle of Taoism is, of course, Tao, which is normally regarded as beyond description and human perception and understanding – "the Tao that can be told is not the constant Tao" (Laozi, 2008, p. 1). But the manifestation of the Tao can be perceived.

The word "tao" is usually translated as "path," "way," "road," "method," or "principle." Basically, the nature of Tao has a twofold structure: the "eternal Tao," which is the mysterious and inaccessible Tao at the center of the cosmos, and "the Tao that can be told," which is at the periphery, visible and tangible in the natural and known world. As a philosophical concept, Tao is the most important idea in the philosophical Taoism (tao-chia) and religious Taoism (tao-jiao).

Tao as the Origin of Universe

In the cosmological sense, Tao is the origin of the universe, the basis of all existing things, the law governing their development and change, and the ultimate god of Taoism. Tao is fundamentally the void or nothingness yet encompassing everything. Right at the beginning of *Tao Te Ching*, Tao is defined as "the origin of Heaven and Earth" and "the mother of myriad of things." "Heaven and Earth" in Chinese means nature or the universe; "the myriad things" means all the beings in the world (Wang, 2010, p. 7). Tao is the creator and sustainer of everything in the Universe. It is described as follows: "There was something undefined and complete, coming into existence before Heaven and Earth. . ." (Laozi, 2008, p. 62). Hence, Tao is the origin of universe and the root of all things, which precedes God in time.

Tao as the Reality

Tao as ultimate reality is at times characterized as the origin and source of all things (Lai, 2008, p. 76). *Dao Te Ching* Chap. 1 suggests that *chang tao*, conceived of as the entirety of reality, is greater than the sum of its individual parts. This is a metaphysical understanding of the concept Tao. *Tao Te Ching* tells:

> The Tao gives birth to One. One gives birth to Two. Two gives birth to Three. Three gives birth to all things. (Laozi, 2008, p. 117)

The Tao has two essential aspects discriminated as *Wu* (Being-without form) and *You* (Being-within-form). The former is the state before Tao comes down to its actuality, which is invisible and abstract, while the latter is the state of Tao manifested in the things, which is visible and concrete. Wu and You are thus regarded as the two sides of one coin. They are dialectical and interdependent opposites, perhaps best understood as aspects of Tao. Wu and You are interdependent in the same way that reality and its manifestation are interdependent (Lai, 2008, p. 77).

Tao and De

The concept of Virtue (De) is closely related to Tao, both of which are served as the basis of Taoist doctrines. *Dao De Jing* relates, "All respect Tao yet value Virtue" (Laozi, 2008, p. 137). One common explanation of Virtue is that it is the specific manifestation of Tao in specific things. Taoists think Tao and Virtue as the general principles and guidelines for their beliefs and behavior. In practice, they both cultivate Tao but also cultivate Virtue. A set of principles for Taoist everyday action and behavior are derived from the Tao and Virtue. These principles include nonaction, nonpassion, nondesire, nonstruggle, and the pursuit of simplicity and truth.

Tao and Wu-wei

The Tao follows the way of naturalness, which means *wu-wei* in Taoist philosophy. Particularly, Tao is the model of conduct to be followed by the Taoist disciples, and it is linked with *wu-wei* (nonaction) and *wu* (empty, noting) in this respect. Taoists believe that without nonaction, nothing can be achieved. Nonaction is not a refusal to go against nature but rather an acceptance of nature's laws, which is to reasonably and effectively use the laws of nature. It is in line with nature rather than in contradiction with it (Zhao, 2010, p. 64–65).

Many people may misunderstand nonaction as a passive philosophy. The simplest interpretation of *wu-wei* is that it means doing nothing or as little as possible. This can be understood politically or metaphysically. However, *wu-wei* does not mean doing nothing but rather doing significant things, that is, *wei-wu-wei*. As Laozi says: "Do nothing and do everything" (Laozi, 2008, p. 90). In this sense, nonaction is the precondition of action. It demands the abandonment of the inferior but gaining the key. Leaving alone one thing, one can do other things. Doing nothing, one can be free from worry. Thus, nonaction is the secret to preserve one's health and keep inner happiness. If one is ignorant of nonaction, and works feverishly and blindly, one is like *Kuafu* chasing the sun, who died on the road because of exhaustion and thirst according to an ancient Chinese fable (Zhao, 2010, p. 66).

Philosophical Taoism and Religious Taoism

Taoism is deeply embedded in Chinese culture and has incorporated several important elements that are present in Chinese history even before the beginnings of Taoism. It forms an integral part of Chinese culture and contributed greatly to the cultural development. Basically, various cultural perceptions and religious practices were established and had an everlasting impact on Taoist philosophy, cosmology, ritual, and religious practices.

Philosophical Taoism

Philosophical Taoism is tao-chia (Daojia), which was a school of philosophy dated back to Laozi and Zhuangzi. Religious Taoism is tao-jiao (Daojiao), which is the traditional religion in China. The distinction between "philosophical Taoism" and "religious Taoism" is much like the distinction between contemplative Taoism and the kind of Taoism seen as "purposeful" and "practical" Taoism (Robinet, 1997, p. 3). In Western languages, "Taoism" encompasses the meanings of both tao-chia and tao-jiao. Even Chinese are confused about their differences. They often use the two terms interchangeably, which have different dimensions of meanings besides similarities and close relations to each other in the long history of Taoism.

Li Yangzheng discriminates Daojia and Daojiao clearly in the following aspects: (1) they differ in ultimate goals: the former aims to realize a spiritual transcendence for its followers, while the latter aims to immortalize by means of arts; (2) differ in the principle to follow: the former advocates nonaction, while the latter appeals to the divine agents; and (3) differ in the ways of demonstrating forms of existence: the former states felt the presence only in the intellectual world, while the latter through its clergy and popular arts (Li, 2009, p. 12).

Tao Te Ching (*Daode jing*) is the earliest and best-known text of philosophical Taoism, which is associated with the philosopher Laozi, who was a contemporary of Confucius and later divinized and grew into the Highest Lord Lao, a major deity of the Taoist religion still worshiped widely today. The book *Tao Te Ching*, a short text in about 5,000 Chinese characters, 81 chapters, has been translated almost into all the languages in the world. People found that it not only serves as a philosophy of life but also as a guidance in areas like economy, military affairs, science, politics, and even the stock market. *Tao Te Ching* is written in verse, a stylized prose that has strong parallels and regular patterns. It is a complicated and confusing riddle of philosophy.

The second major text of philosophical Taoism is the *Zhuangzi*, named after the philosopher Zhuangzi (c. 370–290 B.C.E.). The text *Zhuangzi* consists of 33 prose chapters that also contain materials from other early Taoist strands. The philosophy of Zhuangzi focuses on perfect happiness or free and easy wandering, the state of utmost spontaneity that is reached when one fully realizes one's inner nature and destiny as given by Tao and stops trying to evaluate and judge things or strive for unsuitable situations beyond one's reach. To achieve this mental state, one should detach from society and practice making all things equal, fasting the mind, and sitting in oblivion. The result will be a life that is perfected, unhindered by concepts, and completely at ease in the world, plus exceedingly skillful at all tasks (Kohn, 2009, p. 50).

Religious Taoism

Taoism is normally regarded as an indigenous traditional religion in China. It is generally accepted that Taoism organizations were established by Celestial Master

Zhang Daoling during the Eastern Han Dynasty 1,900 years ago. However, there is common reference to the Three Ancestors: the Yellow Emperor, Laozi, and Celestial Master Zhang. And the original Taoist doctrines can be dated back to Laozi in the Spring and Autumn Period (TAC, 2002, p. 7).

Ancient Taoists were enthusiastic alchemists, who attempted to produce immortality pills by smelting minerals such as aluminum and mercury. Early Taoists attached great importance to minerals, mainly lead, mercury, sulfur, gold, and silver, from which they believed elixirs could be made. They had hoped that these elixirs could free them from the terrors of death. Of course, no immortality pills were ever made. The experiments in alchemy, though irrational from a modern science perspective, greatly promoted advances in science and technology in ancient China, including the development of ancient chemistry and production of gunpowder. Their records of experiments became valuable documents in ancient Chinese chemistry.

Moreover, Taoism has made great a contribution to traditional Chinese medicine. A folk saying says, "Nine out of ten Taoists are doctors." Taoists' pursuit of longevity and health leads to many Taoists practicing in medicine. Some renowned senior Taoists, like *Ge Hong* in Jin Dynasty, *Tao Hongjing* in Southern and Northern Dynasty, and *Sun Simiao* in Tang Dynasty, were all well-known doctors and pharmacists.

Modern Taoism begins with the Song dynasty in the tenth century. Its main representatives are the ritual masters, unorganized by lay practitioners who perform various rituals and service for the people. As Chinese society is dominated more by the merchant and the educated elite, religious concerns shift toward exorcism, fortune-telling, and healing. One school is notably different in this period: Complete Perfection, founded by Wang Chongyang in 1170, is monastic, ascetic, and focused on personal self-cultivation. With the support by the government rulers and emperors, it becomes the second leading school of modern Taoism. In this sense, the fate and shape of Taoism is closely connected with the imperial court.

The fate of Taoism today is closely linked with politics. It was suppressed from the founding of the People's Republic of China, in 1949, until 1978. Since then it has made a major comeback but remains under tight control and administered through various government agencies. As Lai Chi-Tim has pointed out, modernization, antireligious policies, and government officials' misunderstanding of Daoism still present a great challenge to the survival of this indigenous religious tradition in China (Chi-Tim, 2003). People choose the Taoist life for different reasons: to take refuge from civilian life, do community service, rise in the official hierarchy, become a hermit, or establish a Taoist-based business (Kohn, 2009, p. 188).

In the course of long history, Taoism has been transmitted and adapted beyond China. Especially Taoist thought and long life practices have spread in several East Asian countries, notably Korea, Japan, and Vietnam. In the West, the *Tao Te Ching* is widely known, and people gain benefits from its concepts of nonaction, softness, and naturalness. Taoist health practices, typically taiji quan and qigong, are becoming popular in the West.

Basic Beliefs of Taoism

The ideological system of Taoism is said to be complicated to cover a wide range of contents. Generally speaking, it evolved into a religious culture based on three main original resources: the worship of heaven and ancestors, Taoist theories and beliefs regarding immortality, and ethical Confucianism and folk religious customs. So Taoism as a religion is strictly different from Taoism as philosophy. The latter is only beheld as a resource of the Taoist doctrine.

Deities and immortals, as models of achieving Tao, are worshiped by followers of Taoism. Tao gathers to form the Three Purities, that is, the Celestial Worthy of Primordial Beginning or Jade Purity, the Celestial Worthy of Numinous Treasure or Highest Purity, and the Celestial Worthy of the Way and its Virtue or Supreme Purity. Below the Three Purities, the emanations of Tao are a mass of deities such as the Jade Emperor, the Four Heavenly Emperors and the Five Emperors of the Five Directions, and immortals who humans can become through self-cultivation (TAC, 2002, p. 12).

Taoists believe deities and immortals dwell in the sacred mountains, which provide tranquil environment for their self-cultivation. Early Taoist priests mostly lived on sacred mountains. Later, some Taoist priests accepted appointments at the imperial court at the orders of the emperors and lived in temples built for them in cities. With the development and flourishing of Taoism, many large sites of Taoist activity were built in sacred mountains and cities, some of which are called "palaces" because of their palatial dimensions (TAC, 2002, p. 78).

Taoist priests gather together for morning and evening prayers each day. They hold prayer rituals to give blessings on the birthdays of deities and conduct rituals to expiate the sins of the dead. Such rituals can also be held at the request of followers. They also hold large-scale rituals, such as Grand Universe Ceremony, to pray for prosperity and peace in the nation, good weather for crops, and world peace. Besides these, Taoist priests are mainly engaged in self-cultivation (TAC, 2002, p. 30).

The Taoist Body

Basically, Taoism does not share the idea of the Western philosophical dualism of body and mind. Rather, it is a theory that takes life to be the unity of body and spirit. J.W. Freiberg's in-depth analysis provides a reconstruction of Taoist notions of spirit, ontology and consciousness by the archaeological method (Freiberg, 1975).

Physical Immortality of Body

The highest ideal of Taoism is to acquire immortality. To achieve this goal, one must practice Taoism both inside and outside one's physical existence. Inner practice involves physical and breathing exercise, concentrated contemplation,

and the taking of elixirs. Later, this type of practice gradually came down to refining the interior elixirs (*neidan*). The basic principle of this practice is to cultivate the self both spiritually and physically. External practice involves doing good deeds and helping others so as to acquire more merit and virtue. If one succeeds in both aspects, one could enter into the world of immortals (TAC, 2002, p. 9). Immortals are similar to magical practitioners, but the latter use their skills in service for society and may or may not eventually ascend to the paradises. Many immortals' tales recount stories of their wondrous feats.

It is commonly believed that extrication from the predicament of the worldly worries is the fundamental concern of every religion, and there is no exception for Taoism. As Qiang Yu pointed out, what makes the difference is that, while other religions appeal to afterlife for the realization of the ideal life, Taoism cares about how human beings can live forever and never die and how freedom and extrication can be achieved in one's life time (Yu, 2006, p. 134).

The Taoist belief of immortality of human beings reflects an ontological existence paradox: pursuing infiniteness in a finite life. The eternal life was attained in one of two modes: as an ecstatic going-along with the transformations of the universe or as an ecstatic union with the Tao. The belief of physical immortality of body demonstrates that the meaning and value of human beings lie in the release of potentiality of individual life and the accumulation of energy equaling that of the Heaven and Earth. Only in this way can the timely finiteness of an individual be surpassed and freedom be achieved.

Body and Qi

Taoists believe that the body is Dao in its concrete, manifest, and individual form, made up of *qi*, the cosmic vital energy that pervades all (Kohn, 2009, p. 52). Qi is the material force of universe and the basic stuff of nature. In ancient sources, it is associated with mist, fog, and moving clouds. It is contained in the food one eats and the air one breathes.

But basically, *qi* is the life force in the human body and as such forms the basis of physical vitality. Without *qi*, one cannot survive. As Zhuangzi said: "Human life is the accumulation of *qi*; death is its dispersal" (Chen, 2007, p. 524). Qi animates life and furnishes the functional power of events; its quality and movement determine human health. Everyone receives a certain amount of *qi* from the nature. If he uses out all of it, then he will die.

It is natural that everyone needs to survive and keep healthy through *qi* cultivation. In order to do so, one needs to draw *qi* into his body from air and food, as well as from other people through sexual, emotional, and social interaction. One can get ill if he breathes bad air, overburden his body with food and drink, get involved in negative emotions, or engage in excessive sexual or social interactions.

The basic ideal of *qi* cultivation is to create harmony in the body and keep a balanced state of being in the person. If one achieves this proper state in the body and person, then he keeps the upright *qi* (*zhengqi*), which without moral sense is

quite different from the basic idea of *zhengzi* conceived by Confucians. This harmonious state is matched by health in body, defined as no illness; health in nature, defined as regular weather patterns; and health in society in the peaceful coexistence among families, clans, villages, and states. In the same token, perfection of *qi* means its optimal functioning in the body.

The opposite of this balanced state is wayward *qi* (*xieqi*), also called deviant, pathogenic, or even evil *qi*. Whereas upright *qi* moves in a regular, steady, and harmonious rhythm, benefiting health and long life, wayward *qi* is disorderly and dysfunctional, violating the normal order of the nature and human body existence and creating harm to human body and person. In this sense, wayward *qi* loses the balanced pattern of flow and cannot keep the normal dynamic forces of change. Wayward *qi* appears when *qi* moves either too fast or too slow or becomes excessive or depleted. This can happen either out of outside influences such as too hot or too cold or internal irregularities such as strong emotions or anxiety (Kohn, 2009, p. 53–54).

The Honor of Death

Taoism believes that the Heaven and the Earth are everlasting, but life is accidental and death is certain. Life is transitory, but the universe is endless. In this sense, Laozi said that Heaven and Earth are ruthless. Life floats briefly in the limitlessness of space and time, just as Zhuangzi said: "if you use what is limit to pursue what has no limit, you will find yourself in danger" (Chen, 2007, p. 113). So, life is temporary and accidental, and death is eternal and certain. It is a natural transformation from life to death. Death means a return to the eternal world. It seems that death does not amount to much, so the Taoist attitude to death is to be indifferent to it.

Zhuangzi showed a deep contempt for death. There was an interesting story about Zhuangzi's philosophy of death. When his wife died, he sang songs and played drums on a basin. He celebrated her return to nature, while most people think death as the end of individual existence seems tragic. His reason was that human body as the form of *qi* is the demonstration of Tao, and the death of body is the constantly changing of forms of Tao. Indeed, one does not necessarily mourn on the death but should willingly, actively, and joyfully participate in this change.

It is not right to make a conclusion that this reflects a negative attitude to life by Zhuangzi, who is neither an optimist nor a pessimist and thinks of joy and sorrows as alternating and inseparable like day and night or birth and death (Zhuangzi, 2001, p. 23). According to Zhuangzi, the liberation from selfhood is seen above all as a triumph over death, grasping the Way/Tao through accepting one's dissolution as part of the universal process of transformation without horror of physical decomposition and mortality.

Death cannot be avoided. Then it is better to regard death as normal and matter of necessity. Only in this way, one can keep a peaceful mind and not worry about death too much. If death comes, it is no use mourning, and it is better to follow the nature and keep calm. Laozi knew that misfortune and happiness as a unity of two

opposites: "Happiness is where misfortune lies lurking; misfortune is what happiness depends on" (Laozi, 2008, p. 151).

In Taoism, death is but one stage in the transformation of life. While the Indians abhor such endless transformations and invented ways of release from the cycle of rebirth, Zhuangzi says: "What incalculable joy this is!" (Chen, 2007, p. 519). The Taoist so identifies himself with the transformative aspect of Nature that, notwithstanding the pains and sufferings, he regards life as joy, freedom, and spontaneity. In the celebration of the transformative life of the Mother, death exists no more, and it is swallowed up by life (Chen, 1974).

Self-cultivation and Religious Practices

Taoism believes that one can achieve immortality through self-cultivation. It is easy to get confused that there is seemly a tension between religious Taoist attitude to death, enthusiastically pursing immortality and longevity, and that of philosophers as Zhuangzi, seeing death as a natural process neither optimistically nor pessimistically. The tension makes it right to distinguish philosophical Taoism and religious Taoism.

The Taoists created many methods of self-cultivation, such as sitting motionless, concentrating the mind, promoting the flow of *qi*, breathing, combining of controlled breathing and physical exercises, and practicing martial arts (*gongfu*). Most traditional Chinese methods of health preservation and promotion, including *qigong*, martial arts, and traditional Chinese medicine, have close links with Taoism. It is said that *taijiquan* (Chinese shadow boxing) was invented by Zhang Sanfeng, a Taoist priest of Mount Wudang.

Nourishing *qi*, or *qi* cultivation, refers to a kind of state of self-preservation and relaxation, using the *qi* to achieve a harmonious communication between spirit and body. The control of *qi* means the power to guide the energetic process to one or the other part. Laozi said: "Can you control your mind so that it never strays from the way of Tao? Can you control your breathing so that it is soft and gentle like a newborn babe? Can you cleanse your inner vision until you see noting but the light?" (Laozi, 2008, p. 22–23). Some scholars interpret these quotations as "three steps of nourishing *qi*" (Zhao, 2010, p. 103).

The earliest documented form of *qi* cultivation is guiding it through the body in a combination of deep breathing and visualization. Described also in inward training, it allows people to come closer to Tao and create harmony in and around themselves. Healing exercises are the physical component of Taoist body cultivation, which serve to heal diseases, enhance vitality, and create a sense of connection to Tao. All these practices can lead to a state of ultimate transcendence, called immorality. Immortals overcome natural patterns, live forever, move freely through Heaven and Earth, and execute various magical feats (Kohn, 2009, p. 64).

Taoist religious practice includes meditation and ritual. They both require a period of purification, a strong self-control, a healthy body, good mental focus, and visualization practice. Meditation involves various methods of concentration, such as quietist simplicity and inward training; certain types of observation or

insight, such as sitting in oblivion and inner observation; and some forms of visualization, such as nourishing the inner organs, actualizing the gods and engaging in relations with divine beings. Taoist rituals may be sponsored by the state, a temple, a community, or a family, in each case serving a specific purpose. In the ritual, the Master, assisted by other helpers, invites the gods to participate with petitions for good fortune, and creates a level of harmony.

Taoists believe that, through the adjustment of an individual's inner energy or the complement of the outer material elements, one can restore damage to the initial inherent harmony caused in the course of perception and practice and can regain a rebirth and become "the absolute" that never fades (Yu, 2006, p. 136).

Taoist Bioethics

A New Perspective for Bioethics

It is declared that one lives in the face of robust moral pluralism with profound and at times angry disagreements in the form of conflicting metaphysical accounts. Many once coherent traditional accounts have fragmented, if not fallen into incoherence. One confronts the postmodernity of numerous competing accounts, with a loss of focus within once-dominating accounts. It appears that controversies among irresolvable moral and metaphysical views define the human condition. Different traditional and competing accounts are different genres of perspectives, with incommensurable paradigms, life worlds, and thought styles. The deep disputes and disagreements among moral and metaphysical strangers are said to be the stuff of the culture wars (Engelhardt, 2007).

With a strong sense of a need to respond to the moral pluralism, many people, who regard traditional accounts as intact and coherent, attempt to extend or recover the vigor of traditional accounts often rooted in religious commitments with deep metaphysical explanations. The traditionalist way of response to moral pluralism and cultural diversity is a disposition to a cultural counterrevolution. Traditionalists attempt to criticize and even reform the modern liberal lifestyle and values – free choice and autonomy – which are deemed as the core ideas of bioethics discourse.

Taoist bioethics, thus coined, is a new perspective beyond Confucian bioethics, Christian bioethics, Islamic bioethics, and any other competing theory of bioethics. Taoism, as a philosophical school and a religious belief system, has its cultural identity and position in the long history of Chinese philosophy and religion. Actually, this traditional way of thought has many implications for bioethical issues, for example, a naturalistic way of life and harmony of body and mind.

Criticism of the Principle of Autonomy

The dominant modern North American and Western European models of bioethics are radically criticized by Confucian bioethicists who claim that these models

regard individuals as ideally atomic persons to make decisions themselves autonomously, ignoring the deeply family-centered character of social reality that is appreciated by Confucianism (Fan, 2007). While it is right to claim that Confucianism as a Chinese philosophical school is at odds with the take-for-granted principle of autonomy, it is short-sighted to take Confucianism as the only cultural pattern in China to resist the Western bioethical values. Needless to say, Taoism with Confucianism and Buddhism stands at the center of Chinese culture, always shaping the Chinese lifestyle and thought style. Thus, it is necessary to identify the Taoist bioethical thought concerning the principle of autonomy, confirming its cultural identity in this period of moral pluralism.

Specifically, Zhuangzi's intrinsic idea of freedom is comparatively different from the principle of respect for autonomy. This difference demonstrates that the principle of respect for autonomy is based on individual subjectivity and consciousness, while Zhuangzi's idea of freedom aims to dissolve them by the way of losing self (Li, 2008). Zhuangzi demands human beings go back to the inner mind and heart, where the true freedom lies in. As one knows, the principle of autonomy basically derives from the Kantian deontology theory that defends freedom, reason and dignity of human being. According to Kant, moral responsibility originates from practical reason rather than from God or authority. The autonomy of free will is self-legislation of reason.

Unlike Immanuel Kant, Zhuangzi does not pursue subjectivity based on pure reason and practical reason. He claims freedom of human life, which means freedom of physical body and mind, through dissolution of individual subjectivity rather than the Kantian way of pursing freedom, which means practical reason of free will. In a word, Zhuangzi insists on the unity of body and mind through the practice of Tao: losing self. This is totally different from the Western way of dualism: the separation of body and mind. Therefore, Taoism, Zhuangzi as its representative, objects to the principle of autonomy that is popular among academics (Beauchamp & Childress, 2001).

Core Values and Basic Ideas

Taoism as a traditional Chinese philosophy and religion does not have any close relationship with global bioethics principles which is made in the context of modern ideology. However, Taoism as a cultural background does have effects on Chinese practice and application of global bioethics principles. In the UNESCO Universal Declaration on Bioethics and Human Rights, a set of global bioethics principles are declared to be respected: human dignity and human rights, autonomy and individual responsibility, respect for human vulnerability and personal integrity, privacy and confidentiality, equality, justice and equity, respect for cultural diversity and pluralism, solidarity and cooperation, etc. These principles are what modern people think about human life and human health practice. Although Taoism has a different model with these ideas, it is quite reasonable to think that Taoism has a basic philosophy of respect for human life from the perspective of naturalism.

Taoist ethics focus on the creation of harmony within the community and the larger universe. All Taoist activities are closely connected to Heaven and Earth, who signal their disapproval through disasters, personal misfortunes, sickness, and harm. Thus, Taoism advocates the Tao's way in accordance with the law of Nature, with the core value of harmonious coexistence between human and nature.

In order to live properly in the Tao, Taoists have to realize that all beings are an integral part of the whole nature and universe, which functions in accordance with Tao and thus is fundamentally good. The universe, with the force of Tao, manifests a perfect goodness of cosmos – goodness can be learned by human beings as a guideline to reach well-being and inner harmony in moral and social rules. The goodness, once realized, is the ultimate goal for Taoists to purse Tao.

Thus, Taoist rules and community structures as social life are basically set to serve the individuals to realize the perfect goodness – universal connectedness with Tao. Taoists get to know that while the universe is essentially perfect, single beings can be involved in this process to a certain degree. Ideal Taoists have realized their inner nature to the peaceful and harmonious state, with the body and mind spread by the purity of Tao. On the contrary, people living in conflict and trouble cannot realize their true potential and inherent harmony, resulting in disharmony and immoral and harmful actions which are at odds with Tao and the nature of Heaven and Earth.

Take Taoists' food as an example. The monastic food is usually vegetarian. The food should neither be too hot nor too cold, too spicy or too bland, nor should it contain any harmful stuff. It aims to harmonize the body, supporting health and long life. Besides, every taking of food is conducted with a special ritual of sharing it with all beings, from the gods above to the demons below, from the emperor to all people on earth.

Another good example concerns alcohol and sex in daily life. In order to become immortals, Taoist monastics had rules against intoxication and sexual behavior. Both could impede the flow of energy in the person and harm Heaven and Earth. Alcohol is blamed for offensive behavior, rule violations, causing accidents, and getting lost on the road. It is best to stay away from wine completely and create one's own inner liquor from *qi*. Sexual activity is forbidden for Taoist monastics because it will cause harm to human body and reduction of *qi*.

In a word, Taoists are required to keep in mind the harmony and benefit of the cosmos, avoiding all activities that could cause disturbance among personal life, families, villages, country, and state. The goal of Taoist religious life is the universal vision of harmony in the world.

The Value of Life and Universal Love

Taoism has been emphasizing the value of life since it was founded. For Taoists, true and full love means the acceptance and rejoicing in whatever life brings. This philosophy is held by Zhuangzi who celebrates life in all its transformations – every

form of life, long lived or short lived, ugly or beautiful, all receive affirmation. A true Taoist willingly submits himself to the process of change, letting Mother Earth take him back to Her womb.

Being a true Taoist, one should integrate and sublimate his personal love for wife, mother, and friend in the transpersonal love for life, Nature, and all transformations (Chen, 1974). If death is merely one stage of life's endless transformations, the loved ones have not been lost to a person. In this sense, the love of Tao – the unchanging way of life – is universal love, which transcends selfish love for the average person in everyday life.

Ziran and Naturalist Life

The Taoist ethical system derived from the conception of ziran, which is often translated "nature" to designate entities in the natural world and the relations between them. The natural way of ethical response corresponding to a world of ziran is wuwei: noninterference, or letting things be. Noninterference has many significant ethical implications, including an avoidance of inflexible, absolutist ideals and unilateral and dictatorial methodologies. Ziran-wuwei describes an ethical framework that is grounded in respect for individual spontaneity, regarding the practice of ziran-wuwei as natural to humanity and therefore comes as the natural essence of human being (Lai, 2008, p. 107). In this sense, ziran is identified by some scholars as the core value of Taoist ethics, in which interpersonal relationships are characterized by naturalness and peace (Liu, 1999).

With regard to the relationship between human beings and nature, Taoism advocates respect for nature and follow nature to lead a naturalist life. "People conform to the earth. The earth conforms to heaven. Heaven conforms to the Tao. The Tao conforms to its own nature" (Laozi, 2008, p. 64). Taoists pursue a natural life, a calm psychology, a pure style, and a simple life. A calm mood can promote health, longevity, and prosperity. The naturalistic Taoist attitude toward life includes the following aspects.

First, imitate nature. Life lies in movement. But the movement is at best exercised at a uniform speed as stillness and nonaction. Taiji shadow boxing (tai ji quan) is a good example. Second, eat and drink naturally. Light food, such as beans, vegetables, and fruits, is marvelous for one's health. Third, merge into nature. "People conform to earth." This requires that one returns to a state of being a son of the Earth, breathing fresh air, swimming in the sea, visiting a forest, and living on a high mountain. Fourth, think naturally. A healthy body is dependent on a healthy mind. Open-minded people are healthy. Thinking naturally can lead to a peaceful and happy life. Fifth, understand nature. "Empty your mind of all thoughts. Let your heart be at peace. Watch the turmoil of beings, but contemplate their return. . . Immersed in the wonder of the Tao, you can deal with whatever life brings you, and when death comes, you are ready" (Laozi, 2008, p. 35–36). In a word, the best way of life is follow nature (Zhao, 2010, pp. 119–122).

Taoist Attitude to Technology

One lives in a time when technology has profoundly influenced every sphere of one's life and fundamentally changed the quality of one's body, existence, and modes of behavior. It is widely recognized that bioethics is such a research discipline that aims to make an ethical response to the issues arising in the application of modern biotechnology to medicine. Thus, the attitude to technology, broadly speaking, shapes bioethicists' answers to the ethical problems concerning with biotechnology use. And it was claimed that Asian countries and regions have shown a somewhat different pattern of response to such biomedical innovations (Lee & Ho, 2007). Though Taoism is almost overlooked by bioethicists to discuss the related bioethical issue, it is one of cultural pattern behind the dynamics of such responses.

Zhuangzi, as a Taoist philosopher, has come up with a very enlightening philosophical idea about technology: Technology is the demonstration of Tao. His concept of technology demands that the development of technology conform to the essence of Tao. Undoubtedly, the technological activities should aim for truth, but what is more important is the seeking for Tao. The fact that Zhuangzi examined technology within the framework of Tao is actually a representation of an outlook on value and ethics, which has a deep influence over the development of technology in ancient China (Zhang & Wang, 2004).

It is claimed that the major danger issuing from a rapidly globalizing biotechnology lies in the relation of medicine to human nature. Stephen Erickson worries that human beings are very much *in*, but they are not altogether *of* the world. The biotechnology model of medicine colonizes all aspects of human nature, reaching the capacity to manufacture specifically designed individual human nature. Moreover, biogenetic engineering will further encourage tendencies toward depersonalization with the high values of productivity and efficiency. The economic lenses of biotechnology industry rationalistically drive the world and reinforce the domination of technology, while human beings are marginalized in this process. It is likely that the metaphysical dimension human nature will be erased and replaced (Erickson, 2007).

Taoist philosophy criticizes the alienation of human nature, which is caused by overuse of technology including biotechnology in medicine. From Zhuangzi's philosophy of technology, it is natural to indicate that the strong intervention to human body and life by modern biomedicine violates the basic principle of Tao: *ziran-wuwei*. At the same time, the overuse of biotechnology in medicine has gone against the basic bioethical principle of nonmaleficence, which is said to be one of four basic principles of bioethics.

Conclusion

The construction of Taoist bioethics is an academic endeavor to respond to the cultural diversity that shapes bioethical thoughts and clinical practitioners and an

attempt to define a Chinese cultural identity in the process of globalization of global bioethics. Bioethics has been developed in a cultural diversity background since it was introduced to China in the 1980s. Any efforts aiming to construct and reconstruct a model of global bioethics should not overlook the great impact of Taoism on Chinese lifestyle and thought style that shapes the basic ideology shared by Chinese on bioethical issues.

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Section V

Specific Issues from a Global Perspective

Bioethics Education

28

Henk A. M. J. ten Have

Introduction

Bioethics is the discipline that is focusing on ethical issues in medicine, health care, and associated technologies (see ▶ Chap. 1 on "Global Bioethics" in this handbook). Today, it is taught in many countries around the world. Everyone is nowadays confronted with moral questions concerning disease, disability, dying, and suffering. Doctors and nurses need to know about these ethical issues and how to respond sensibly and with compassion to questions and worries patients might have. Ethics teaching is, therefore, required by every medical school in countries such as the United States, the United Kingdom, and Bulgaria. This is not the case in many other countries where ethics teaching is either nonexistent or grossly deficient. Also, the quality of the teaching can be very different.

Several years ago, the author visited a medical school in Côte d'Ivoire. An enthusiastic colleague was teaching medical students a course on patient's rights. The general rationale for the course was that people need to be informed about their health condition, they need to give permission if they are treated, and they can refuse to be included in a research project. This is true for developed countries and equally true in developing countries. The circumstances for the course were awful. Students were cramped into a small room without furniture and glass in the windows; educational equipment was lacking as well as electricity, let alone internet connection. The teacher was standing in front of an antiquated whiteboard that had lost its utility long ago. While the temperature was tropical and humid, students recognized the importance of the subject: these are basic democratic rights of citizens and they seemed eager to learn about it. Somewhat later and in similar circumstances, the author observed a course in Senegal. A medical doctor in a white uniform was reading a text about medical secrecy. The students had no possibility to make notes (no space, no chairs), books were too expensive, and computers unavailable. The reading was dull and did not seem to inspire many students. In Togo, another colleague tried – unsuccessfully – to convince the dean of the

H.A.M.J. ten Have
Center for Health Care Ethics, Duquesne University, Pittsburgh, PA, USA
e-mail: tenhaveh@duq.edu

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science department that bioethics nowadays is an important discipline and that it should be taught in the university. Similar experiences can be obtained in many other countries. Bioethics education is extremely diverse; its significance is often, but not always, acknowledged but its implementation varies enormously.

In this chapter, the focus will be first on how and why bioethics education has developed rapidly in the last five decades. Nowadays, bioethics teaching is practiced in many settings and there is a plethora of publications on this subject. The second section will discuss the ongoing issues and controversies in bioethics education. Due to its relatively recent history, bioethics education is still lacking a solid body of experience and is facing many challenges. These challenges become particularly evident when the focus is on the global perspective, which is the purpose of the third section of this chapter. International organizations such as UNESCO are increasingly interested in promoting bioethics education at an international level. International cooperation and exchange of experiences can contribute to solving some of the quandaries of bioethics education, as will be argued in the fourth section, focusing on the problems of implementing and improving education in bioethics as well as the various modalities to address and ameliorate these problems. The final section of this chapter will conclude with reflections on education in general. Education has always been a major concern of philosophers, and present-day bioethics education should take these philosophical concerns into account.

The Development of Bioethics Education

The emergence of bioethics in the 1970s was immediately associated with growing interest in ethics education. The medical curriculum in many countries was the first to introduce professional ethics teaching. This was unavoidable since the revolutionary changes in medical science and technology after World War II as well as the innovations in diagnosis and treatment significantly impacted medical education; the new moral quandaries of these changes could not be ignored in professional education. In the early 1970s, there was a rapid growth of ethics teaching programs in the United States. In 1972, ethics teaching programs could be identified in 12 medical schools, growing to 95 in 1976 and 114 in 1980 (out of 125 existing schools) (Pellegrino & McElhinney, 1982). In these efforts, more than 1,000 faculty members have been involved. This situation has been stabilized since 30 years (Eckles, Meslin, Gaffney, & Helft, 2005; Goldie, 2000). In order to be certified, all medical schools are now required to include bioethics in their curricula (Persad, Elder, Sedig, Flores, & Emanuel, 2008). It is clear that in other countries, developments followed later but with a similar pattern of dissemination and institutionalization. In the 1980s, bioethics education expanded in Western Europe. Before that time, there was no formal medical ethics teaching, although in some (particularly Mediterranean) European countries, medical ethics was already taught in incidental courses in "medical deontology" (emphasizing the duties of medical doctors), often in connection to law, forensic medicine, or history of medicine.

In the United Kingdom, recommendations to develop medical ethics teaching were only launched by professional bodies (General Medical Council, British Medical Association, and Institute of Medicine) in the mid-1980s. In 1993, the General Medical Council made bioethics a core subject in the UK medical curriculum, and ethics teaching has now an accepted place in the medical curriculum (Mattick & Bligh, 2006a). In the Netherlands, although the first chair of medical ethics had been established in 1974, it took almost two decades before all medical schools had introduced ethics courses in their curriculum (Ten Have, 1995). In the Nordic countries, formal courses in ethics were introduced in medical curricula in the 1980s (Nordic Committee on Bioethics, 2002). Bioethics teaching now has an established place in the medical curriculum within the European Union (Claudot, Alla, Ducrocq, & Coudane, 2007). Countries in Central and Eastern Europe followed in the 1990s. Before the collapse of the communist system, ethics has been taught as part of mandatory ideological training for health professionals. This context made it difficult later to introduce bioethics education, particularly since in a number of university courses in Marxism have been transformed into courses in bioethics. With substantial international support, many countries, however, were able to achieve significant improvement and expansion in bioethics education (Borovecki, ten Have, & Oreskovic, 2006).

The gradual expansion and dissemination of bioethics education in medical schools was associated with an ever-widening scope. First, ethics teaching was initially introduced in undergraduate medical education but later it is expanded into the graduate curricula as well as specialization programs, emphasizing clinical ethics but also continuing education (Pegoraro & Putoto, 2007). In 2004, the number of medical schools in North America with ethics education in the clinical years had doubled compared to 1985 (Lehmann, Kasoff, Koch, & Federman, 2004). Bioethics education had also rapidly expanded in residency programs in several specialties (e.g., internal medicine, pediatrics, family medicine, psychiatry). Current US data show that 99 % of surgery residencies now include some mode of explicit ethics education while it was nonexistent in 1997 (Grossman, Posner, & Angelos, 2010). Second, bioethics education was no longer confined to future medical practitioners but also included in the professional training of other health professionals. There was a specifically rapid development of ethics education in nursing (Fry, 1989). Third, bioethics education was advocated for other scientific disciplines, for example, biology, biochemistry, genetics, and the life sciences (Dawson, 2009). This was in line with the wider notion of bioethics coined by Van Rensselaer Potter, combining scientific knowledge with philosophy and ethics in order to better understand the contemporary problems of applying new knowledge and emerging biotechnologies. Fourth, bioethics education was regarded as essential for young scientists and professionals studying in university but increasingly also for graduate and more experienced colleagues in health-care practice, research facilities, and laboratories. The increasing number of hospital ethics committees, for example, created a need for specific postgraduate courses and programs to better equip its membership. Quandaries and controversies in research often resulted in encouragement of specific ethics programs for researchers.

Fifth, bioethics education has become relevant for the general public and policy-makers, demonstrating that bioethics is no longer regarded as a merely academic discipline but as a major driving force for public debate and policy-making in present-day societies. Sixth, the number of online ethics courses and programs for various health professions is rapidly growing (Stoddard & Schonfeld, 2011).

Global Outreach and Cooperation

Most recently, bioethics education has become the focus of international activity and cooperation. In 1993, the World Summit on Medical Education recommended that ethics should always receive full attention in medical school (World Summit, 1994). The World Medical Association is since long involved in promoting medical ethics. In 1999, it passed a resolution recommending that all medical schools should make teaching of medical ethics obligatory in the curriculum (Claudot et al., 2007). In 2005, it has launched a medical ethics manual as a guiding teaching aid in medical schools around the world (WMA, 2005). Since 2002, the World Health Organization is focusing on ethical issues related to global health and health care, particularly in research ethics. Although it has published many relevant documents, it has not specifically addressed bioethics education. In 2000, the Fogarty International Center, part of the National Institutes of Health in the U.S., launched the new International Bioethics Education and Career Development Award Program. It is funding bioethics training initiatives in developing countries but specifically focused on research ethics. The most extensive and broad effort has been undertaken by UNESCO (the United Nations Educational, Scientific and Cultural Organization) that has launched its ethics education program in 2004. This program aims at the integration of ethics into scientific education in all member states. It has been built up in several steps (Ten Have, 2008). The first step is focused on providing information. Policy-makers at governmental level but also in universities and academies of science do not often have adequate information about what exist and what is lacking in the field of bioethics education. It is, therefore, necessary to identify existing ethics programs as well as expertise and to exchange experiences. In order to establish a database of ethics teaching programs, standardized forms have been developed to describe teaching programs, so that the substance of each program can be examined and various programs analyzed and compared. Within a group of countries, experts are identified who actually are teaching within a university setting. The experts are invited to take part in a regional meeting; in advance, they are invited to provide data on their programs and to return the descriptive forms so that existing programs can be discussed during the meeting. Often, it is the first time that experts have insight in the programs taught by their colleagues in the same and neighboring countries. In the meeting, information can be clarified, difficulties identified, and problems discussed with colleagues. With the empirical data obtained and clarified, it is easier to subsequently explore what will be necessary for the future and how international collaboration can help to promote ethics teaching. Regional expert meetings have been organized in

Budapest (October 2004), Moscow (January 2005), Split (November 2005), Muscat (November 2006), Istanbul (March 2007), Marrakesh (June 2008), Abidjan (December 2008), Dakar (March 2009), and Kinshasa (July 2009). Currently, 235 teaching programs have been validated and entered into the UNESCO Global Ethics Observatory database, covering 43 countries, mainly from Central and Eastern Europe, the Arab region, and Africa. The advantage of this database is that detailed information concerning each teaching program is available in comparative format (www.unesco.org/shs/ethics/geobs).

One common finding so far is the vulnerability of ethics teaching programs. Often, the programs are taught by enthusiastic teachers, but there is no firm institutional basis, nor any systematic effort to create a future generation of ethics teachers.

As a second step, an ethics teacher training course has been set up to remedy these problems and to make sure that a new generation of professionals and scientists will be encouraged to teach ethics in a professional manner. This ethics teacher training has taken place in Romania (2006), Kenya (2007), Slovak Republic (2007), Saudi Arabia (2007), Belarus (2008), Croatia (2010 and 2011), and Serbia (2011). The focus of the courses is on didactic skills required for ethics teaching rather than on content issues of bioethics.

The third step in the ethics education program has been the development of a proposal for a core curriculum in bioethics, on the basis of the *Universal Declaration on Bioethics and Human Rights*, adopted by all member states of UNESCO in 2005. Because there is consensus on the fundamental principles of bioethics in the declaration, this can be considered as a basis for what should be minimally included in a bioethics course. An Advisory Expert Committee on the Teaching of Ethics, composed of members of the International Bioethics Committee and the World Commission on the Ethics of Scientific Knowledge as well as representatives of the UNESCO Chairs in Bioethics, the Academy of Sciences for the Developing World (TWAS), and the World Medical Association (WMA), has developed the proposal with teaching units related to the principles of the declaration. For each unit, the possible objectives and contents are described and proposals for teaching materials, resources, and assessment methods are provided. The proposal has taken into account the recommendations of a consultation meeting with 30 experts, mainly from developing countries. The proposal has also been tested in a number of universities all over the world (Argentina, Armenia, Belarus, Israel, Japan, Moldova, and the Russian Federation). Based on these experiences, the proposal has recently been revised. It is currently in translation into Arabic, French, Russian, and Spanish. The core bioethics course can assist scholars who want to establish teaching programs in bioethics in various cultures and regions. Also, books with cases from various countries are available to be used in the units of the course.

Finally, UNESCO is the only UN organization with the possibility to establish university chairs that can help to implement its program in a specific country or region. UNESCO chairs in bioethics are currently located in Argentina, Brazil, Israel, Kenya, Mexico, Portugal, Spain, and USA. Regional documentation centers

are also an important resource for future activities since they will make information and documentation from the region itself available and distribute information materials from other regions and UNESCO. Centers have been established in Vilnius University (Lithuania), Egerton University (Kenya), and the Academy of Sciences in Cairo (Egypt).

Controversies

The impressive proliferation of bioethics education in many countries and for multiple audiences is reflected in the vast body of literature on the subject that can be consulted nowadays. However, the most striking characteristic of this literature is its enormous heterogeneity (Claudot et al., 2007; Eckles et al., 2005; Goldie, 2000). Even within the same country, there is ample variety, not only in the type of programs offered and didactic approaches used, but also in quantitative terms. The reported number of teaching hours can vary from 5 to 200 (Silverberg, 2000). A recent survey in the USA showed that in medical schools, the required hours of instruction in bioethics averaged 35.6 but ranging from 9.0 to 125 h (Persad et al., 2008). In the Netherlands, all eight medical schools have ethics courses but the number of teaching hours is varying substantially. The same is true for the degree of integration in the core curriculum (Ten Have, 1994). In a study carried out in 18 European countries, the number of teaching hours was ranging from 0 to 107 h (Claudot et al., 2007).

Reading the scholarly literature, one gets a bewildering impression of variability. Methods of bioethics teaching are wide ranging. Some programs are primarily based on plenary lectures while others use a variety of methods, from patient consultations, case discussions, simulations, role-playing, and games. Many teaching programs consist of specific courses while others are fully integrated in other components of the curriculum. Though most programs are assessed, evaluation methods and instruments vary considerably. This variability creates a perplexing situation. Almost anyone and every significant organization seem to agree that bioethics teaching is necessary and should be mandatory for contemporary and future health practitioners and scientists. At the same time, there is no consensus on the relevant core ethical contents, processes, and skills necessary for medical practice. Controversies seem to exist in major dimensions of teaching programs.

Objectives

Why is there bioethics teaching? What does one hope to achieve with education in bioethics? In most of the scholarly literature, distinctions are made between three types of objectives: knowledge, skills, and attitudes. For example, if the focus is on informed consent, students should know what it is; they should have information

and facts about this concept, but they should also learn how to apply it in practice and why it is important to establish relations with patients and research subjects. The skills objective is most often mentioned but in different formulations. An essential skills component related to the first objective is that of learning to recognize ethical issues. Since medicine itself is a moral profession, value judgments are pervasive in clinical decisions (Pellegrino & McElhinney, 1982). Because moral concerns are inseparable from technical concerns, it is not always easy to identify the normative dimension of clinical decisions. Students should, therefore, learn how to identify which aspects of decisions are technical in nature and which are ethical, and they should be able to assess how technical and ethical aspects are related to each other (Ten Have, 1995). Other skills often mentioned are formal and analytical. Skills should be developed in identifying relevant moral principles, analyzing the normative dimension of clinical decisions, critically analyzing moral arguments, or justifying personal decisions regarding ethical issues. Skills can also focus on critical reflection and self-criticism. A different approach was taken by a consensus meeting in the USA in 1983 identifying more substantial skills such as the ability to obtain a valid consent or knowing how to proceed if a patient refuses treatment (Culver et al., 1985). The third objective claims that the attitudes of students should be influenced. Bioethics education should make them more sensitive to ethical questions and, especially the values of patients, to elicit a sense of moral obligation and personal responsibility, to tolerate ambiguity, and to respect different moral views (Callahan & Bok, 1980).

The UNESCO database shows that the overwhelming majority of programs are focusing on the first type of objective: providing knowledge and information as well as identification of moral issues. Skills objectives are also important, ranging in frequency from (1) analysis and reasoning to (2) understanding and explaining to (3) justification and argumentation. Influencing attitudes is less common but still half of the programs aim at producing good conduct. The basic controversy in fact is whether bioethics education should aim at improving medical decision-making (and, therefore, emphasize the skills of ethical analysis) or at producing better physicians (and thus aim at attitude formation and good conduct). The underlying assumption of both aims is that better decisions as well as better physicians both will lead to enhanced quality of patient care.

Methods

How should bioethics be taught? A variety of didactic approaches are presented in the literature ranging from plenary lectures, small-group discussions, movie-triggered debates, and role-playing. The majority of medical schools in the USA are using four teaching methods: discussion/debates, readings, writing exercises, and lectures (DuBois & Burkemper, 2002). Most medical schools in the United Kingdom use a combination of large and small-group teaching

(Mattick & Bligh, 2006a). The UNESCO database shows that in non-Western countries, lectures are the most commonly used method while case discussions are used in 50 % of the programs. Lectures are commonly used to transmit knowledge and key concepts and to introduce topics. Small groups are focused on interactive debate and discussion. Many teachers emphasize the need for case-based learning (Fox, Arnold, & Brody, 1995; Ten Have & Essed, 1989). Cases relate the teaching to real-life situations. Cases also are best discussed in group sessions and practical exercises. This makes the teaching more relevant for the students; it is also closer to what is going on in medical practice in distinction to the classroom. Barnard (1988) has criticized the trend to use cases. The focus on cases suggests that ethics is a tool for problem-solving rather than an approach to cultivate professionalism and humane approaches that could prevent similar cases in the future. In general, too much emphasis on pragmatism and relevancy can undermine the perception of ethics as a broader perspective of values and virtues that invites to recognize ethical problems in the first place.

There is also discussion about whether it is more desirable to have specific courses on ethics or ethics education integrated in other courses (Fox et al., 1995). Since separate courses are often isolated and marginalized, it is better to showcase that ethics is an everyday component of good medical practice (Goldie, 2000). What is often recommended is team teaching, combining expertise in ethics, medicine, and humanities. This reflects the interdisciplinary nature of bioethics. It furthermore shows that professional competence includes moral qualities.

It is obvious that the discussions on teaching methods reflect the evolution of bioethics education. In the early stage, ethics educators came from other disciplines such as theology and philosophy. They continued to use the methods of plenary classroom teaching with cognitive aims and formal lectures that were common in their own disciplines (Goldie, 2000). In this stage, ethics was taught as a separate course in the preclinical years. The traditional model of bioethics education, therefore, emphasized particular teaching methods: lectures, small-group discussions, and reading. Nowadays, more alternative models are flourishing, using a broader range of methods such as student presentations, movies, patient interviews, panel discussions, mock trials, and emphasizing more active learning through games, role-playing, and interviews with simulated patients (Fox et al., 1995). Widening the range of teaching methods is also dependent on the goals of teaching. If a broader range of aims is introduced, there is a concomitant need for a variety of teaching methods throughout the curriculum (Goldie, 2000). Shaping attitudes and virtues as well as enhancing moral development will require different methods than promoting knowledge and cognitive skills. This will also stimulate the initiating of more teaching activities in the clinical phase of the curriculum, with grand rounds, ward rounds, case conferences, and simulated patients. A similar change in teaching methods over time was noted in the United Kingdom: programs have become more oriented toward student experiences, clinical problems, and integrated teaching, with less emphasis on ethical theory (Mattick & Bligh, 2006a).

Content

What should bioethics educators be teaching? The subject matter of teaching programs depends on how narrow or broad the notion of "bioethics" is interpreted. It also depends on the setting in which the teaching takes place. The topics will vary whether the teaching is focused on medical students, residents, nurses, or science students. But the topics will also vary according to the cultural and social context in which bioethics education is developing. In the first stage of its development, the main setting was the undergraduate medical curriculum. This is reflected in several surveys showing that the content areas for bioethics teaching, at least in medical schools in the USA, are rather limited. The majority of teaching programs is focused on six areas: informed consent, health-care delivery, confidentiality and privacy, quality of life/futility/provision of treatment, death and dying, and euthanasia and assisted suicide (DuBois & Burkemper, 2002). For preclinical courses in North American medical schools, the focus is even more restricted: all programs cover consent, end-of-life issues, confidentiality, and truth-telling (Lehmann et al., 2004). But again, there is wide variety. Both Silverberg (2000) and Goldie (2000) present in their surveys a long list of topics addressed in bioethics teaching programs. What is not mentioned are issues of social justice, access of health care, and equitable distribution of health-care resources – issues that are important in a European perspective (Gillon, 1996). Teachers of medical ethics and law in the United Kingdom issued a consensus statement in 1998 outlining the core content of a minimum basic curriculum. They mention 12 topics: informed consent and refusal of treatment, the clinical relationship (truthfulness, trust, and good communication), confidentiality, medical research, human reproduction, the new genetics, children, mental disorders and disabilities, life/ death/ dying and killing, vulnerability, resource allocation, and rights (Consensus Statement, 1998).

The focus on identifying more or less exhaustive lists of topics that need to be covered in bioethics education is one approach to substantiate bioethics programs. Another approach is to structure the teaching program around different ethical perspectives such as deontological theories, utilitarianism, care ethics, and virtue ethics (Ruyter, 2004). The advantage is that this will provide the students with a framework to understand and interpret specific ethical problems arising in practice. When ethical theories rather than concrete experiences or cases are the basic structure of the program, it is also less relevant to cover all possible topics in contemporary bioethics. The topics will function as examples for the application of the theories so that students will learn how to approach new and emerging topics later. In comparing case-oriented and method-oriented programs, it was found that case conferences, although positively received by the students, lack a general theoretical framework for case analysis and interpretation (Ten Have, 1995). At the same time, a focus on methods (or theories) does not sufficiently engage the practical experiences of students. Combining the advantages of both approaches will result in a two-tiered approach of interconnecting the theoretical and practical perspective: clarifying important normative positions and methods of case analysis in the preclinical program followed by a regular sequence of ethical case conferences in the major clerkships.

Evaluation

What are the best ways to assess bioethics teaching programs? Here again, there is almost universal agreement that teaching programs need to be assessed. Otherwise, the effect of the programs remains unclear and there is no indication how they can be improved. There is also widespread agreement that the outcomes of the programs need to be assessed in the students. Otherwise, it is not clear what the students have learned. Programs that are not evaluating students are not taken seriously and have a marginal status in the curriculum as a whole. Nonetheless, in educational practice, students are not always evaluated. A survey among North American medical schools found that only half of the schools formally evaluate students. If there is evaluation, it is focused on moral reasoning abilities. Only a third of the schools assess students' behavior in ethically difficult situations (Lehmann et al., 2004).

This discrepancy between ideal and practice is related to controversies about what evaluation should take into account and how it should be performed. If there is no consensus on the goals and methods of bioethics education, it is difficult to determine what exactly should be assessed: knowledge, skills, attitudes, or behavior? Of course, each individual program can be assessed depending on its goals, but this does not allow comparison between programs so that finally it remains unclear what are more and less effective approaches in education.

There is not a lack of assessment methods as such. The literature provides examples of written assessments (multiple-choice questions, essays, case vignettes, short-answer questions), oral assessments (presentations, simulations, standardized patients, clinical observation exercises, direct observation of patient interactions), self-assessment reports, and portfolios (Campbell et al., 2007; Eckles et al., 2005; Wong & Cheung, 2003).

In assessment studies, two basic questions can be asked. One is what is the effect of bioethics education; the other is what teaching method is preferable. The first question is often addressed in technical terms: how can we measure the effects of teaching? The selection of an appropriate assessment method depends on the goals of the teaching programs (Goldie, 2000). For evaluating cognitive aspects, one can test dimensions such as ethical problem-solving, constructing rational arguments, recognizing moral problems, and understanding concepts (Wong & Cheung, 2003).

The problem is that knowing does not imply doing. Various assessment strategies are, therefore, performance-based. Quite a few studies are focused on the development of moral reasoning skills. Some studies indicate that bioethics education contributes to an increase in moral reasoning (Self, Wolinsky, & Baldwin, 1989; Smith, Balint, Krause, Moore-West, & Viles, 1994). Another focus is on ethical sensitivity, using case vignettes to measure the ability to recognize moral issues. Studies show a decline in ethical sensitivity after the first year of undergraduate medical training (Hébert, Meslin, & Dunn, 1992) but it is unclear whether and how bioethics education can remediate this trend.

Certain skills are difficult to measure, for example, interactional competence. Ethics teaching apparently improves confidence of residents in dealing with ethical

issues, but the conclusions are based on questionnaires and not on observed actual behavior (Sulmasy, Geller, Levine, & Faden, 1993). Studies also show that small-group ethics teaching is more effective than lectures and large-group seminars in promoting "students' potential ethical behavior" (Goldie, Schwartz, McConnachie, & Morrison, 2001), but this conclusion is based on whether or not their written replies to case vignettes came close to the professional consensus judgment regarding the cases. Even more difficult to measure is the goal of moral development and producing virtuous professionals. Although different methods are available (observation, videotaping, structured clinical examinations, simulated patients) (Wong & Cheung, 2003), it is questionable whether qualities and virtues such as compassion and integrity will be quantifiable and measurable at all. The focus of assessment efforts apparently is on evaluating process issues, procedures for decision-making, skills, rather than on understanding the problems and their context or on good professional conduct. Empirical outcomes research, although fashionable, has serious shortcomings, not only because the current instruments are inadequate, but also because it presupposes that only those goals that are practical and measurable need to be taken into account. The fact that most assessment studies are focused on moral reasoning and ethical sensitivity suggests that ethics is only a "competency" that is necessary to facilitate medical decision-making.

The second basic question in assessment studies is which teaching methods are preferable. The simplest way to answer this question is to ask students and to measure satisfaction or preferences about usefulness or relevance of the teaching. Recently, more comparative studies of teaching methods have been done. But there are only few studies that show that any teaching method is superior to others. Most studies compare a lecture-based curriculum (more passive learning) with a case-based curriculum (active learning). The traditional seminar proved superior to case-based teaching using standardized patients in terms of knowledge and performance (Robb et al., 2005). Group discussions added to case-based teaching will enhance students' abilities to recognize and analyze ethical issues (Smith, Fryer-Edwards, Diekema, & Braddock, 2004). In nursing education, traditional classroom teaching was less effective than small-group problem-based learning in ethical discrimination ability (Lin, Lu, Chung, & Yang, 2010). Similar conclusions were reached for first year medical students (Goldie et al., 2001). Case-based education improved the overall awareness of ethical issues, but remarkably also led to a 50 % reduction in duration of stay for patients in the surgical intensive care unit (Holloran, Starkey, Burke, Steel, & Forse, 1995). Comparing online delivery of bioethics education to traditional classroom delivery, Stoddard and Schonfeld (2011) found no difference except for scoring multiple-choice questions that was higher in the traditional approach.

Two Different Philosophies of Bioethics Education

The different views on objectives, methods, content, and evaluation reflect essentially two diverging views of bioethics education.

Modest View

In most of the literature, the view of bioethics education is modest. Ethics is introduced in the medical curriculum in order to better assist health professionals. The focus is on facilitating the practice of clinical medicine or research. Ethics teaching is a way of learning skills for analyzing and resolving the ethical dilemmas that will confront health professionals in their future practices. Ethics teaching can help them to be better prepared for dealing with problematic patient cases and make them more confident in decision-making and more effective in communicating with patients, families, and colleagues.

This view of bioethics education is also pragmatic. One should focus on what is practical and measurable. It is assumed that it is not realistic to expect that ethics education can create moral physicians or make ethical scientists. How can a limited number of courses bring about a change in behavior or character of health professionals? Moral character is already there when students enter the university. The best purpose of bioethics education, therefore, is teaching skills (Eckles et al., 2005). Gillon (1996) is very explicit: medical ethics teaching was not intended to improve the moral character of future doctors. It is not the role of bioethics instructors to inculcate virtues such as empathy, honesty, and integrity.

It seems, however, that the philosophy of bioethics education is moving towards a broader conception. The focus on identifying and analyzing ethical issues is characteristic for the early stages of bioethics education but now there is movement beyond the traditional model with many alternative models aiming to influence students' attitudes, behaviors, and characters (Fox et al., 1995). Apparently, there is growing consensus that the ultimate goal of bioethics education is to produce good health professionals and scientists (Goldie, 2000).

Broad View

In this view, bioethics education is basically a long-term effort to create virtuous health professionals and scientists. It is moral education aimed at character formation, integrity, and professional virtues. The assumption is that only in this way bioethics teaching can contribute to enhancing the quality of patient care. Bioethics education was introduced and promoted to counteract dehumanizing and objectifying tendencies in contemporary medicine and health care. It is not just there to facilitate medical decision-making but it should contribute to making medicine more humane. For this reason, bioethics education has a broader focus on the humanities, liberal arts, social sciences. and philosophy, so that medical activity is located in a wider human context. This broad perspective on bioethics education is endorsed in several ways. For example, the accreditation standards of the American Association of Medical Colleges require that undergraduate students demonstrate scrupulous ethical principles in caring for patients, for example, honesty, integrity, and respect (LCME, 2004). This implies that these ethical principles must be taught and evaluated but also that future physicians must show

these principles in their professional behavior. The same approach is taken in the United Kingdom. The majority of British medical schools now state that the aim of ethics teaching is "instilling ethical behavior in medical students" (Mattick & Bligh, 2006a, p. 182). More so, they claim that they are successfully accomplishing this goal. Also the UK consensus statement of bioethics educators underlines that ethics teaching should reinforce the aim of medical education: the creation of good doctors. The current emphasis on professionalism reinforces this point of view. Rather than transmission of information and knowledge, the learning of values and attitudes is important, since they constitute an identity which is an intrinsic component of professionalism.

It is remarkable that the need for teaching ethics is reemphasized every time when professional behavior turns out to be problematic. An example is the case of Harold Shipman, an English doctor who most probably murdered about 250 patients. One of the recommendations of the government investigation report in 2004 was to improve the teaching of ethics (Mattick & Bligh, 2006b). Ethics teaching is regarded as a remedy against lack of virtuous behavior. A similar approach was taken in scientific research. The last two decades have witnessed a cascade of cases of scientific misconduct, plagiarism and falsification scandals, and many ethical problems due to financial conflicts of interests. In the USA, the National Institutes of Health and the National Science Foundation have required as of January 2010 that graduate and postdoctoral researchers funded by grants must receive education in responsible conduct of research. Ethics education should promote research integrity and research ethics. Apparently, one course of ethics is considered as an effective antidote to social and cultural tendencies that allow and even encourage scientific misconduct. Although it is assumed that the aim of ethics teaching is to produce better physicians or researchers, such view of ethics as instantaneous prescription is obviously misguided. Public trust in science cannot be restored with a single bioethics course (Salerno, 2008). Bioethics education is not a medication that can be provided or a remedy that can be injected when the whole body is affected. Bioethics is not like other disciplines contributing to medical education: it is an intrinsic part of medicine itself as a moral enterprise. It is focused on understanding and transmitting the basic values of the profession. This transmission is continuous and not the result of an incidental or supplementary educational intervention. Medical education is a process of socialization and of "moral enculturation," transmitting a distinctive medical morality (Haffert & Franks, 1994). This is not a process visible in formal ethics teaching, but a substantial part of the "hidden curriculum." Studies of the hidden curriculum show that it has substantial ethical impact, for example, loss of idealism, emotional neutralization, acceptance of hierarchy, and competition rather than cooperation (Lempp & Seale, 2004).

Such a view of medical education implies that there is a continuous transmission of values and virtues framing and shaping professional identity. Ethics is not a tool that can be added from the outside but it is already there, intrinsic in the culture in which medical training operates. Formal and explicit bioethics education runs the risk of not only being extraneous to the internal morality of medical education

(as a peripheral course) but it can even be antithetical to the values emphasized in the hidden curriculum. These values may make health professionals more cynical. But articulating ethical skills will not be a remedy. Haffert and Franks (1994) recommend acknowledging that ethics is permeating medical education, though in an implicit and not articulated way. There is a difference between what is taught and what is learned. Three practical steps will follow. First, bioethics education needs to establish an overall value climate, recognizing that ethics teaching is a responsibility at organizational level. Second, all faculty is involved in ethics education, not merely in the classroom but rather at the bedside and in the laboratory; it is, therefore, important to teach the teachers. Third, bioethics education is already based on virtues before it even starts to be explicit and formal and before it addresses facts and skills. This answers the often raised question: can virtues be taught? They are continuously taught in the process of professional formation. But one course alone will not do the job. Teaching virtues is an institutional mission (Branch, 2000; Shelton, 1999).

The two philosophies of bioethics education formulate different perspectives, a broad one aiming at virtuous professionals and a narrow one aiming at ethically skilled practitioners. Both perspectives cannot be isolated from the fundamental question why there is bioethics education in the first place. If bioethics education was primarily introduced to counter the "dehumanizing" effects of modern science and technology in the context of health care and science, reiterating a reduced image of patients as subjects of technical-ethical skills, and a focus on the human body and biology, teaching has to move beyond a purely analytic and cognitive model of education. Otherwise, it would merely reinforce the myopic views and problems that necessitated the introduction and expansion of bioethics education in the first place. But at the same time, the impact of bioethics education should not be overestimated. Most ethics formation is taking place throughout the hidden curriculum. The best bioethics education can do is to make this informal education explicit so that the harmful effects of the hidden curriculum can be counteracted. This requires a sustained and long-term effort, creating "an educational climate that positively influences medical students' moral development" (Branch, 2000, p. 505).

Problems and Challenges

The growth of the scholarly literature on bioethics education is fueled by the persistence of problems and challenges.

- The overwhelming number of publications, statements of interest, and declarations of importance notwithstanding, there is not an impressive lot of bioethics teaching in practice in most countries. Persad et al. (2008) point out that in the US bioethics education, although required, comprises only 1 % of the medical school curriculum. Many educational activities are sporadic and occasional. In Europe, most hospitals have only short-term initiatives, not longer courses or programs, while nobody seems to take responsibility for the activities (Pegoraro & Putoto, 2007).

- There is a serious lack of qualified teachers. Not even half of the bioethics instructors in the USA have published a single article in bioethics (Persad et al., 2008). For many teachers of bioethics, this is not their primary academic focus. A survey in 2004 showed that 20 % of medical schools in the US and Canada did not even fund teaching in ethics (Lehmann et al., 2004). In general, there is almost no faculty development in bioethics education. There are only a few efforts to teach the teachers and to create the next generation of bioethics instructors.
- Resources for bioethics education (teaching materials, funding for library resources, program examples) are generally insufficient for teaching. More than 50 % of medical schools in the United Kingdom are inadequately resourced for teaching medical ethics (Fulford, Yates, & Hope, 1997).
- There is not a lot of international exchange of information. It will be helpful if detailed information about syllabi and teaching experiences would be available. The UNESCO database is currently the only comparative database but it provides information for a limited number of countries. This lack of cooperation is resulting in absence of coordination or strategic planning.
- It is difficult to know the quality of teaching programs. Since detailed information is generally not available and assessment studies scarce, there are no criteria to compare and evaluate the quality of education.
- The expansion of bioethics education has reintroduced the issue of interdisciplinarity although bioethics itself was conceived as an interdisciplinary effort. In bioethics teaching, medical ethics is usually taken as a paradigm since it has the longest history. The presupposition of educational interventions often is that students involved in bioethics teaching are medical students. Nowadays, more and more students from other disciplines, for example, the natural sciences or social sciences, are involved in bioethics education. The question arises how to teach for heterogeneous groups of students coming from different disciplines and with heterogeneous backgrounds and interests.

Growing Consensus

Controversies and challenges have not prevented that over the last few decades, areas of consensus seem to have emerged. Many scholars now agree that certain approaches of teaching are preferable, that there is a need of comparative studies, and that a common core of programs can be defined.

Preferable Teaching Approaches

The most successful teaching program is vertically and horizontally integrated in the curriculum (Stirrat, Johnston, Gillon, & Boyd, 2010). Pellegrino and McElhinney (1982) already advocated early on that an educational program should start with an introductory course in the first year, followed by integrated teaching in

the clinical years. This will have the advantage that in the preclinical years, the fundamentals of bioethics and the moral point of view can be explained but that the teaching will be integrated in courses in subsequent years and applied during the specific rotations later on (Ten Have, 1994). This approach demonstrates that ethics is a continuous activity during medical education. Bioethics education is not isolated but part of the daily routine. Integration usually requires team teaching, cooperation between clinicians and ethicists. This mode of teaching has been regarded since a long time as the optimal way of ethics instruction (Pellegrino & McElhinney, 1982). However, most medical schools in the US do not provide an integrated bioethics curriculum (Silverberg, 2000). Another point of agreement is that active learning is better than passive learning. A student-centered approach is preferable, especially in bioethics education since it will encourage reflection and critical thinking. This also explains the popularity of the case method. When students can select cases and examples for ethics instruction, the learning process can focus on real-life experiences.

Comparative Studies

The majority of publications on bioethics education are from North American authors. Relatively little is known, therefore, of the experiences in other countries and cultures. Comparative studies of programs can help to identify what is effective and what is not and to identify what would be an ideal program. Most studies compare teaching programs in the same country, for example, case-oriented and method-oriented programs (Ten Have, 1995). A precondition for such a comparison is that extensive descriptive studies are published of specific programs. Here also, there is a lack of information. A review of mainly US literature found only five descriptive studies of ethics curricula (Eckles et al., 2005). Much more comparative information is currently available in the UNESCO database but this is not used so far in the scholarly literature. Ethics teachers usually have little idea about what is going on in other countries. Their programs are focused on the ethics debates in their own states. Nonetheless, it might be useful to take note of ethics teaching elsewhere. Educators will be surprised how much there will be in common in teaching worldwide. It illustrates how much bioethics has become a global endeavor. People far away are in fact very close to us in aspirations, values, and rights.

Defining a Common Core

An interesting recent development is the determination of a common core for bioethics teaching programs. American authors are usually skeptical. They argue that there is no ideal bioethics curriculum: “there is nothing like a common core curriculum in medical ethics at present” (DuBois & Burkemper, 2002, p. 437). Lehmann et al. (2004) are more optimistic. Although they conclude that there currently is no common standard for ethics education, they stress that there is

a need for a model curriculum. The same need for a consensus statement on specific topics to include in a core ethics curriculum is recently expressed by Lakhan, Hamlet, McNamee, and Laird (2009). In Europe, several efforts have been undertaken to define a core curriculum. In the Netherlands, at the instigation of the medical association, all teachers of bioethics agreed on the structure of a core program in medical schools, identifying the contents, the goals, and the evaluation methods (Ten Have, van Wijmen, & van der Ploeg, 1994). However, this proposal was a voluntary commitment without any measures to implement or enforce it. It is unclear today whether there is any common core in the programs actually taught. In the United Kingdom, all teachers of bioethics and law made a consensus statement in 1998 on a model core curriculum. The statement mentioned specific topics that should be included in bioethics curricula. Studies later showed that only 4 of the 12 topics recommended were covered in the teaching programs of most medical schools (Mattick & Bligh, 2006a). Thereupon, a revised version of the core proposal was published in 2010 (Stirrat et al., 2010). Comparison of UK and US curricula makes clear that all medical schools in the UK cover at least a number of similar topics (e.g., informed consent, clinical relationships, confidentiality, the new genetics) (Mattick & Bligh, 2006b) while American programs can differ widely. Two European projects were focused on formulating a common core curriculum. Dickenson and Parker (1999) report on agreement on a core curriculum with common workbooks for several European countries. Pegoraro and Putoto (2007) stress the need to formulate a common base for the provision of bioethics education; there are too many gaps, too many varieties, and too haphazard activities in a survey on bioethics education in hospitals in ten European countries.

A different approach is taken by Thornton and colleagues. Rather than identifying specific topics that should be included in a common core, they refer to areas, for example, history of medical ethics and bioethics, theoretical foundations and methods of analysis, and the cultural context of bioethics (Thornton, Callahan, & Nelson, 1993). At an international level, the recent proposal for a core curriculum in bioethics launched by UNESCO demonstrates that agreement is possible regarding specific topics, modules, and objectives.

Efforts to define a core curriculum are not uncontested. It is argued that the need for standardized curricula will result in a quest for uniformity in order to reduce variance in health-care practices and in order to guarantee that students can be objectively assessed. This tendency is favoring numbers over values, transforming bioethics education in a quantifiable enterprise (Fins, 2010).

Conclusion

In the year 405, St. Augustine was consulted by a young colleague about the best approach to teach an introductory course in Christianity. In his treatise on catechetical instruction, Augustine addressed the issues of subject matter, objectives, and methods of instruction. The crucial question is: what is good education? In Augustine's view, education is not successful if it is not passionate and inspired.

All starts with the spirit, that is, the enthusiasm, devotion, and concentration of the teachers. Their tongue should be guided by their heart. Education is not merely focused on knowledge or skills but it should motivate and inspire. Teachers and learners are united in the same endeavor; they all want to be better persons (Christopher, 1946).

These ideas are reiterated in a recent reflection on education (Jackson, 2012). The ultimate aim of education is transformative. Its goal is "to effect beneficial changes in humans, not just in what they know and can do but, more important, in their character and personality, in the kind of persons they become" (O.c., p. 94). Education is fundamentally a moral enterprise. It is, what John Dewey has called, the manifestation of humankind's responsibility to conserve, transmit, rectify, and expand "the heritage of values we have received" (Dewey, 1934, p.87).

Bioethics education has a similar though more restricted mission. It invites students to participate in a specific professional community, grasping and shaping what is valuable in being a professional. Ethics teaching is not a remedy or antidote that can be injected into the medical curriculum to compensate, complement, or supplement lack of virtues and values or to provide a dimension of "humanitarianism" or "professionalism" to unidimensional persons focused on science, rationality, and objectivity. On the contrary, it is focused on constructing professional identities and shaping character. In building and reinforcing professional identity, knowledge and practice are linked.

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Bioethics and Human Rights

29

Thomas Faunce

Introduction

The corpus of international human rights (as textually established by instruments such as the *Universal Declaration of Human Rights* (UDHR), the *International Covenant on Civil and Political Rights* (ICCPR), and the *International Covenant on Economic, Social and Cultural Rights* (ICESCR)) developed after the Second World War as an expression of the commitment of governments and the peoples they represented to principles sustaining three great social virtues: justice, equity, and respect for human dignity. It was also, though this was less well recognized or acknowledged, a profound reaffirmation of an idealist view of reality and the norms humans create to function within it. Nations incorporated judicially enforceable social and economic human rights in their constitutions that provided, for example, guarantees about access to health services and medicines as well as civil and political freedoms of speech, association, and prohibitions on torture or arbitrary and unlawful detention or death. Hope grew that such commitments would mark the start of a process whereby governments would not only provide physical security but maintain social structures that allowed their citizens to flourish in good health. Expectations were that states would prioritize programs (such as those implementing the United Nations *Millennium Development Goals*) that aimed to gradually reduce warfare, poverty, corruption, childhood and maternal mortality, and lack of equitable access to health services and essential medicines. UN human rights institutions and non-governmental organizations began to play crucial roles in this process. So, too, did the expanding capacity for individual citizens to petition human rights committees and courts concerning violations of human rights.

Bioethics arose as an academic discipline in roughly the same period. Bioethics may usefully be described as the application of moral philosophy to ethical problems in the life sciences (Harris, 2001). Prominent manifestations of bioethics included guidelines produced by groups of eminent persons in controversial areas

T. Faunce
College of Law and College of Medicine, Biology, and the Environment (Joint Appointment), Australian National University, Canberra, ACT, Australia
e-mail: fauncet@law.anu.edu.au

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such as reproductive and end of life issues, as well as genetic testing, manipulation, and data storage (Faunce, 2005; Jonsen, 2000; Pellegrino, 1995). Norms of bioethics have also been devised to regulate the conduct of scientific research, access to, and quality and safety of technology, medical services, essential medicines, and other preconditions for health (Harris, 2001).

This chapter discusses the normative origins of bioethics and human rights. The view presented here is that the normative systems of bioethics and human rights are idealist in that they attempt to shape human conduct according to principles derived (like our understandings of time and space) a priori so that true statements are capable of being made about them that do not necessarily correlate with common experience. This chapter then analyzes the intersections of bioethics and human rights in the context of their responding to two great contemporary challenges: the policy influence of supranational corporations and their capacity to relate to the emerging preeminent social virtue of environmental sustainability.

Normative Origins of Bioethics and Human Rights

Many scholars of bioethics and human rights endorse the view that the principles underpinning those normative areas (as well as legislative and judge-made law) arrived in liberal democracies by a process (chiefly among policy and lawmakers) of what is termed "reflective equilibrium" or "coherence reasoning" from the hypothesis that societies, like individuals, when properly oriented strive to maintain foundational virtues, such as justice and fairness (Dworkin, 1977; Nussbaum, 1999; Rawls, 1976). Respect for human dignity is another such a virtue particularly associated with international human rights law (Faunce, 2005). According to this model, consistent application of foundational principles sustained those virtues, and the normative systems could in turn be reinvigorated by seeking to make new principles and laws coherent with that base, or by calibration between the normative systems (Faunce, 2005). Others distrust such ideas as having uncertain and quasi-mystical natural law elements that can be exploited by messianic totalitarian leaders (Hart, 1979; Kelsen, 1948).

Closely allied with the idea of foundational social virtues as a normative foundation for bioethics, laws, and human rights was the well-established intellectual notion of a hypothetical social contract. This concept seemed less mystical in part because it seemed to link to national legal texts such as the *Virginia Declaration of Rights 1776*, the *American Declaration of Independence 1776*, the French *Déclaration des Droits de l'Homme et du Citoyen 1789*, and other constitutional arrangements derived from them. Many see the global culmination of such ideals and world conscience in the United Nations' *Universal Declaration on Human Rights* of 1948. This is particularly true of Article 1:

> All beings are born free and equal in dignity and rights. They are endowed with reason and conscience and should act towards one another in a spirit of brotherhood.

International human rights itself undoubtedly remain highly suspect, particularly in Islamic societies, for its lack of connection with religious law as expressed in the

Quran or *Sunnah*. In such societies, norms of international human rights are consistently qualified by *shari'a*-based Islamic criteria and by suspicions that the primary norm-creating bodies in international human rights are dominated by the representatives of developed, northern countries or large corporations with alien social values (Abdullahi Ahmed, 2005).

What appears to have been less thoroughly considered, however, is whether what is manifesting in the development of governance systems like bioethics, law, and human rights is an emergent pattern of ordering from low-level rules toward greater complexity characteristic of all life (as revealed by a considerable volume of good research into the organization, for example, of simple organisms such as slime mold or ants to brains, cities, and computer programs) (Johnson, 2001). This leads to the hypothesis, explored here, that it is an illusion to regard normative systems like bioethics and human rights as entirely arising from core documents driven by influential groups or personalities, or being denigrated. Rather, bioethics and human rights may be emergent expressions of a unique human contribution to the perception and heightening of order in the universe – conscience. Let us trace some philosophic origins of this idea.

The philosopher Benedict de Spinoza in his seventeenth century *Ethics* (Bk II, Prop. XLIV) wrote that it is the nature of reason properly applied to perceive things truly, that is, as they are in themselves not as contingently existing in past, present, or future circumstances revealed to us by sensory experience. This pronouncement and its implications have often been ignored or dismissed as a peculiar type of idealist rhetoric. How, for example, could it make us view things any closer to reality or more ethically to regard them as not bound by forward-flowing time? Such a position was contradicted by our sensory experience. Yet Spinoza's profound realization (and others following on from it) paved the way for major scientific as well as ethical breakthroughs in thinking – the realization that there could be true statements about reality that did not appear to correlate with common sense.

Immanuel Kant took Spinoza's insight a few steps further in his eighteenth century *Groundwork of the Metaphysics of Morals* and his *Critique of Pure Reason*. Kant influentially contended that the capacity to form ethical concepts in the form of goals or end points for future actions based on principles applicable to all rational beings is a core distinguishing characteristic of the well-developed human mind. It arises, he maintained, proportionally with our capacity to view our place in the world more objectively, including viewing ultimately our understanding of time and space as arising a priori as necessary preconditions for sensory experience (rather than being determined by it). The freedom of individuals to set conceptual goals presupposes a capacity to reject them, and Kant reasoned that laws (backed up by official enforcement) provide an external constraint upon persons whose selected end points would otherwise unduly interfere with the capacity of other rational beings to choose their own goals.

Kant's was an optimistic moral philosophy about human nature, and it set the tone for what became known as the Enlightenment Tradition with its implicit understanding that humanity's increasing use of rationality would shape more

peaceful and harmonious social structures. Ethics, Kant saw as permitting rationalization of voluntary self-constraint by minds seeking to consistently apply principles capable of general application and becoming virtuous. The more people acted from a concept of duty (often against the opposition of their own sensual inclinations) to consistently apply such principles, the more humanity was morally developing toward a type of collective enlightenment. Those principles also rose in ethical value the more they facilitated the capacity to flourish equally in all other rational beings. Kant summarized this by stating (in his *Introduction to the Doctrine of Virtue*) that virtue arises from consistent voluntary decisions to act (despite internal or external obstacles) upon principles capable and worthy of application by all rational humans. Martha Nussbaum has convincingly demonstrated how it is an error to claim that the works of the central "enlightenment" theorist, Immanuel Kant, reveal an obsession with idealized duty and principle to the exclusion of character-formation and the training of the passions (or to make the same claim against seminal utilitarians such as Henry Sidgwick, Jeremy Bentham, and JS Mill) (Nussbaum, 1999).

Yet thinking like that of Spinoza and Kant, discussed here, had implications not only for ethics but for the emerging science of physics. In his *Critique of Pure Reason*, Kant wrote that "we can never represent to ourselves the absence of space, though we can quite well think it as empty of objects." (Kant, 68) Likewise, he stated that "appearances may one and all, vanish; but time (as the universal condition of their possibility) cannot itself be removed." (Kant, 75) The twentieth century physicist Albert Einstein, who studied Kant's ideas in his youth, probably drew upon this insight (that space and time might exist in ways that seem at odds with everyday sensory experience) to ponder what physical laws (such as the general and special theories of relativity) might answer physical anomalies such as why the speed of light is constant regardless of the speed of its source (Faunce, 2011a).

A corollary of such "pure" reasoning, as Kant perceived, was that knowledge (including moral truths about the role of principles and virtues in constraining free will) could also arise from a suprasensible part of nature that has the potential to be true, despite not necessarily correlating with common experience. Such realization may have been a critical factor in development (particularly by other enlightenment philosophers such as John Locke, physician, philosopher, and founding father of human rights jurisprudence) of the concept of inalienable human rights (granted by nature to all people) even though such a position had no foundation in sociological facts about governance of the time. John Locke was a physician pupil of Sydenham, a great clinical empiricist inheritor of the Hippocratic tradition. It is interesting to speculate that a major factor promoting both the corpus of human rights norms, as well as the norms of bioethics deriving from the *Hippocratic Oath*, was loyalty to the professional virtue of relief of individual human suffering (Faunce, 2007).

In any event, though the constitutions of nation states increasingly incorporated (particularly as a result of Locke's philosophic influence) the claim that the basis of human rights obligation could reside in an ideal applicable to all people as part of

the "nature of things" rather than be entirely constrained by the interests of a King or religion, the origins of that principle were never fully explored or appreciated.

Overlap Between Bioethics and International Human Rights

Historically, the systems of bioethics and international human rights have many intriguing historical parallels. Medical ethics, for instance, provided the original core of bioethics, and its basic principles may be viewed as derived from the tradition represented by the Hippocratic Oath (Davey, 2001).

Proving a breach of the *Hippocratic Oath's* ethical obligation to "do no harm" was central to the conviction of the Nazi doctors at the Nuremberg Trials after the Second World War for nonconsensual, brutal experimentation; sterilization; and active nonvoluntary euthanasia. Those proceedings spurred creation of a tripartite collection of documents that remain central to medical ethics: the *Declaration of Geneva* (or the modernized *Hippocratic Oath*), the *Nuremberg Declaration on Human Experimentation*, and the *International Code of Medical Ethics*. These international medical ethics documents can be viewed as synergistic with the tripartite international Bill of Human Rights: the *UDHR*, as well as the latter *ICCPR* and the *ICESCR*. A major distinction, however, was that the former bioethics instruments were unambiguously directed at relationships between individuals, the latter human rights documents chiefly with relations between individuals and states.

Particularly overlapping with norms of bioethics in the *UDHR* were provisions requiring respect for human dignity and equality (articles 1 and 2), as well as the human right to life (article 3). Others resembled components of medical ethics in prohibiting torture or cruel, inhuman, or degrading treatment or punishment (article 5), requiring nondiscrimination (article 7), freedom from arbitrary interference with privacy (article 12), and progressive realization of the human right to a standard of living adequate for health and medical care (article 25). In the same category was the human right to share in scientific advancement and its benefits (article 27) (Claude & Issel, 1998).

Consent to medical treatment and experimentation is one area of explicit overlap between bioethics and international human rights. Article 7 of the *ICCPR* provides that "no one shall be subjected without his free consent to medical or scientific experimentation." Under general comment 20, the United Nations Human Rights Committee has interpreted this to require "special protections" – for example, no institutionally nominated surrogate decision-making – for persons "under any form of detention or imprisonment," or those hospitalized on grounds of necessity or involuntarily due to mental illness. It could extend also to protect patients from doctors who were institutionally prevented from providing such "free consent," even where such physicians were not considered state agents (Faunce, 2007).

Contemporary international human rights and bioethics clearly overlap in the regional *European Convention on Human Rights and Biomedicine*. In force since 1997, the regulatory impact of this convention has been more significant than its

limited ratification might at first indicate; the European Court of Human Rights having referred to and taking into it in dealing with the cases where the countries were involved that did not ratify or even sign it. This convention covers matters such as equitable access to health care (article 3), consent (Chap. II), private life and right to information (Chap. III), the human genome (Chap. IV), scientific research (Chap. V), and organ and tissue removal from living donors for transplantation (Chap. VI) (Council of Europe, 1997).

In considering the intersections between bioethics and human rights, it is important to take into account article 38 of the *Statute of the International Court of Justice*. This provision identifies international conventions and customary international law, among others, as the sources of international law. Thus, as a Declaration, rather than an international convention, the *UDHR* did not directly create binding human rights norms under international law upon signatory states.

International humanitarian law, as an aggregation of customary and treaty-based norms concerned with the treatment of the wounded, civilians, and prisoners of war, has many areas of overlap between bioethics and human rights law. The *Geneva Conventions* in 1949, the *Hague Convention* of 1907, and the *Genocide Convention* (what year?) and *Nuremberg Charter* (what year?) all impose upon states positive duties to permit and negative duties to hinder the exercise of medical professionalism amid armed conflict. These have now achieved status as customary international law. Medically related NGOs, such as the International Red Cross, Physicians for Human Rights, and Médècins Sans Frontières, though staffed by professionals required by bioethics to owe distinct obligations to their patients are increasingly involved in monitoring, preventing, alleviating, and even defining state violations of international humanitarian law. Along with nonphysician groups such as Amnesty International and Human Rights Watch, many of their members view themselves as at the vanguard of a cosmopolitan world order normatively governed more by human rights than by bioethics (Faunce, 2005).

The UNESCO *Universal Declaration on the Human Genome and Human Rights* (1998) and UNESCO *Universal Declaration on Bioethics and Human Rights* (2003) are other instances of texts with clear overlap between bioethics and human rights (Nys, 2005). The former pronounces that the human genome symbolically represents part of the common heritage of humanity, while forbidding practices contrary to human dignity, such as human reproductive cloning. The latter instrument, though also nonbinding under international law, arguably provides, if not a codification, then a promotion of bioethical norms onto the global normative stage. Particularly important are norms of technology transfer and social responsibility in relation to essential medicines that specifically apply to corporations (Faunce, 2007). Article 14(2) of the *Universal Declaration on Bioethics and Human Rights* provides:

> Taking into account that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, and economic, or social condition, progress in science and technology should advance:

(a) Access to quality health care and essential medicines, especially for the health of women and children, because health is essential to life itself and must be considered to be a social and human good
(b) Access to adequate nutrition and water;
(c) Improvement of living conditions and the environment;
(d) Elimination of the marginalization and the exclusion of persons on the basis of any grounds
(e) Reduction of poverty and illiteracy

Article 15 – sharing of benefits provides:

1. Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries. In giving effect to this principle, benefits may take any of the following forms:
   (a) Special and sustainable assistance to, and acknowledgement of, the persons and groups that have taken part in the research
   (b) Access to quality health care
   (c) Provision of new diagnostic and therapeutic modalities or products stemming from research
   (d) Support for health services
   (e) Access to scientific and technological knowledge
   (f) Capacity-building facilities for research purposes
   (g) Other forms of benefit consistent with the principles set out in this Declaration
2. Benefits should not constitute improper inducements to participate in research.

There are now many tribunals both at national and regional levels, authoritatively interpreting norms of bioethics at least partially in terms of international human rights. These include the English Court of Appeal and House of Lords, as well as the European Court of Human Rights. In *Case of D v United Kingdom*, for example, the European Court of Human Rights held that deportation of an HIV/AIDS-infected patient to his developing country of origin was state conduct which violated his human right to be protected from inhuman or degrading treatment or punishment. The judges reasoned that such deportation would result in his being denied adequate medical treatment and exposed to poor public health conditions (*D v. UK*, 1997). In many other jurisdictions around the world, judicial cases concerning new reproductive technologies, end of life decisions, privacy, and informed consent are now heavily influenced by international human rights norms, either because of parliamentary or judicial incorporation of human rights into domestic law, or to remedy a common law lacuna, or legislative ambiguity or obscurity.

The international right to health (as specified in article 12 of the *ICESCR* and in over a hundred national constitutions) also provides an important area of overlap between bioethics and human rights. The international right to health, for example, has core obligations to provide the basic preconditions for existence (food, water, sanitation, housing, nontoxic environment) including reasonable access to essential health services and products (Toebes, 1999). Approaches to the implementation of the international human right to health have involved defining universal outcome measures that measure compliance with the core state obligations of the human right to health, establishing systematic reporting to responsible international bodies to monitor progress on implementation and compliance with international

human rights obligations, and highlighting civil rights violations, such as discrimination against protected groups, that inhibit access to healthcare services (Kinney, 2001). A UN special rapporteur has been appointed to work on these issues, but has been largely symbolic in function owing to an understandable reluctance to confront some of the main corporate and sovereign obstacles to implementing the right.

The human right to health, particularly in domestic constitutions, indeed has often been interpreted as a largely symbolic, non-individually enforceable, progressively realizable concession to normative decency or attempt to claim political legitimacy. Technical and financial, as well as conceptual limitations, currently prevent it involving a justiciable guarantee for each person of a minimum level of actual health. Progressive realization of such a right requires effective use of available resources. The minimum content of this core, which cannot be set aside on grounds of progressive realization, may be conceptualized as a responsibility to reduce serious threats to the health of individuals, or the state's population, according to international standards (Ngwena, 2003).

Effective state infectious disease control and equitable provision of essential medicines as well as taxpayer-funded health services in medical emergencies comprise a compelling and justiciable minimum core public health component of the right to health. Courts have enforced the right to health in domestic constitutions to make states, for example, provide basic treatment to HIV/AIDS patients. In 2002, the South African Constitutional Court unanimously found the government in breach of s 27(1) ("right of access to healthcare services") and 27(2) ("progressive realization" of the right to health) in that Constitution. It held that the government's policy of restricting the anti-HIV drug "nevirapine" to 18 sites was unreasonably rigid and inflexible, denying babies of HIV-infected mothers outside those sites a potentially life-saving therapy. The Court took note of the fact that the drug was apparently affordable, easy to administer, and recommended by the WHO (*Minister of Health v. Treatment Action Campaign*, 2002).

The Challenge of Supranational Corporations

So, after the Second World War, the peoples of the world through their governments seemed set on a course of prioritizing ideals such as those expressed in the normative systems of bioethics and human rights – ideals that seemed strongly to emerge from a commitment to conscience as well as foundational social virtues such as justice, equity, and respect for human dignity. Yet something went badly wrong.

The governments of the world started to prioritize a different set of international legal commitments to people lacking in any fundamental or necessary commitment to conscience or foundational social virtues. These were increasingly politically and normatively powerful artificial persons in the form of transnational corporations. What commenced to cut across the ideal of bioethics and human rights was a process of private sector lobbying of state officials and indoctrination of

politicians into the so-called neoliberal free market ideology. This manifested in World Trade Organization (WTO) agreements that created huge financial penalties for nations seeking to reestablish taxpayer control over areas such as water, food, power, telecommunications, or health services and investor-state dispute mechanisms that allowed supranational corporations to sue governments when legislation or policies (though otherwise coherent with bioethics or human rights) impeded their investments.

Pertinent examples included the WTO agreements such as that on *Trade-Related Aspects of Intellectual Property Rights* (TRIPS) and the *General Agreement on Trade in Services* (GATS). These did have provisions that allowed exemption for government policies necessary to protect public order and morality (articles 27(2) and XIV (a), respectively). Public order or morals, however, were not defined in such agreements, and trade dispute panels had to rely on dictionary definitions such as that which defined public morals as "standards of right and wrong conduct maintained by or on behalf of a community or nation." Naturally, such a definition implied varying cultural, religious, and other national contexts, rather than the notion that there was or could be consensual and clearly defined systems of global bioethics or human rights. Indeed, since the 1990s in particular, the WTO has been able to create a politically influential, profit-driven global corporate agenda for global governance in healthcare policy with no explicit requirement to consider norms of bioethics or human rights (Abbott, 2005).

A state can now elect, for example, as have many OECD countries, to place "hospital services" on its "schedule of commitments" to be covered by the "liberalizing" rules of the WTO GATS agreement. This executive action (mostly no specific parliamentary scrutiny or democratic mandate is constitutionally necessary) facilitated a reorganization of ownership and management of public hospitals towards a "for fee" private insurance-oriented model. Under this patients with insurance were increasingly exposed to the moral hazard (contrary to basic bioethics and human rights norms) that an assessor at their insurance company (specifically tasked to do this) would find it more lucrative to find a reason to deny their claim than honor their premium. Likewise, under the GATS "market access" requirement, subsequent (more bioethics and human rights-minded) governments were hindered from legislating to regulate the total number or market share of foreign private healthcare services or suppliers.

The GATS rule of "national treatment" additionally required that a "liberalizing" government could not provide, even unintentionally, more favorable conditions to domestic healthcare companies than to foreign corporations. The most favored nation (MFN) rule obligated such administrations to also ensure that most favorable treatment, in terms of trade, granted to any foreign company was extended to all foreign companies wishing to enter this "liberalized" sector. The "domestic regulation" rule likewise made domestic laws and regulations, including those which protected the public's health and safety, subject to challenge and possible elimination if they were determined to be "unnecessary barriers" to trade, or more "burdensome than necessary" to assure the quality of a service. These changes often facilitated a brief influx of foreign venture capital, but created

a one-way policy agenda toward global privatization of healthcare services regardless of adverse population health impacts and infringements of basic bioethics and human rights norms.

The WTO TRIPS agreement created a process of influencing the way states used bioethics and human rights norms to balance intellectual monopoly privileges (IMPs). This can be seen, for example, in its express exceptions to IMP protections over pharmaceuticals such as compulsory licensing by governments to allow generic manufacture of medicines (after payment of reasonable compensation to any patent holder) if such medicines were required to be cheaper and more readily available for public health reasons. Yet, a so-called "data exclusivity" requirement (allowing prolonged withholding from generic competitors of data revealed by pharmaceutical patent holders to drug regulators for safety, quality, and efficacy assessment prior to marketing approval) seemed designed to undermine compulsory licensing. Indeed, any nation (such as Brazil or Thailand) that has attempted to invoke WTO TRIPS compulsory licensing to provide essential medicines (particularly to treat HIV/AIDS) in fulfillment of its bioethics and human rights obligations has been threatened with trade sanctions by nations such as the USA at the behest of their patented pharmaceutical corporations.

The WTO TRIPS agreement has actually inhibited the capacity of governments to deal rationally with the global burden of disease in accord with core components of bioethics and the international human right to health. This interpretation is supported by the 2001 TRIPS clarification known as the *Doha Declaration on TRIPS and Public Health*. This Declaration symbolically affirmed the capacity of WTO members to use the full exceptions in the TRIPS agreement to promote public health by facilitating access to affordable medicines while implicitly acknowledging their lack of capacity or will to do so (Abbott, 2005; Correa, 2002).

Bilateral and regional preferential trade agreements have additionally facilitated the plans of multinational pharmaceutical and managed care corporations to exploit "liberalized" markets and challenge universalist (taxpayer-funded and egalitarian) domestic health and medicines policies, often on the grounds that they created nontariff trade barriers, or insufficiently rewarded "innovation" or "research and development" (Faunce, 2007).

Supranational corporations continued to lobby governments under the thrall of the neoliberal ideology that market forces (though often monopolistic or collusive in operation) would provide a viable alternative to normative systems like bioethics and human rights in providing for the essential needs and flourishing of citizens. When international civil society defeated the Multilateral Investment Agreement (MIA) these corporations turned to regional deals (Chap. 11 of the North American Free Trade Agreement between the USA, Canada, and Mexico) and bilateral investment treaties (BITs). These allowed those corporations to sue for damages (before a panel of trade arbitrators with a vested financial interest in perpetuating such a system) governments that impeded investments by legislation otherwise coherent with bioethics or human rights. Governments were sued, for example, by corporations in Canada (when they legislated to prohibit toxic lawn chemicals or gasoline) and in Uruguay and Australia (when they tried to reduce

smoking in young people by introducing plain packaging of tobacco products) (Faunce, 2011b).

Thus health policy debates began to rationalize widespread deaths among increasing numbers of poor, uninsured patients and those who could get access to essential medicines (because of fiercely protected patents or lack of corporate R&D interest in that area) as temporary market failures or "adjustments" (Holmer et al., 2000). The corporate sector ascribed the causes of this lack of consumer capacity, for example, to government policies fostering unemployment or restricting business innovation, as well as to high costs of rent, food, and education (Kinley & Chambers, 2006).

Particular challenges created for bioethics and human rights by global governance via supranational corporations include protecting in priority to shareholder profits the interests and welfare of the million or so women and girls under 18 trafficked yearly for prostitution, 10 million refugees, or 5 million internally displaced persons; the victims of any one of the 35 or so wars currently raging across the earth, of state-promoted torture, or rape in the guise of "ethnic cleansing"; or any of the 250 million children exploited for labor, sexual gratification, or as soldiers, as well as the 1.2 billion people living in severe poverty, without adequate obstetric care, food, safe water, or sanitation. Gender discrimination, poverty, famine, and displacement by warfare are significant factors in large numbers of children in African countries still failing to receive basic information from health professionals about how to avoid infection with HIV/AIDS, despite often over 20 % of the population being seropositive (Fidler, 1998).

The Challenge of Environmental Sustainability

The virtue of environmental sustainability has been linked to the idea that this planet should be treated as a distinct living entity (James Lovelock's Gaia Hypothesis) (Lovelock, 1991). It has become a symbolic rubric focusing public and governmental attention on the interaction between human health, technological development, and sustainability of the biosphere (McMichael, 2002). In this emerging discipline, anthropogenic climate change and environmental degradation as well as poverty and lack of necessary fuel and food are targeted as intrinsically global environmental pathologies the resolution of which requires concerted efforts to implement a wide range of not just renewable energy technologies (such as those using nanotechnology) but bioethical principles including those related to protecting the interests of future generations and preservation of biodiversity. By logical extension the application of renewable energy technologies, for example, utilizing nanotechnology to improve solar energy conversion to electricity, or to purify soil or water, can be regarded as forms of planetary nanotherapeutics.

Salutary facts driving academic and policy interest in planetary medicine are not only the greenhouse-gas-driven increase in severe weather events, but the projected increase of global human population to 10 billion by 2050 with associated energy consumption rising from ≈400 EJ/year to over 500 EJ/year beyond the capacity of

existing fossil-fuel-based power generation. The research underpinning planetary medicine also emerges strongly from influential commentaries such as the Intergovernmental Panel on Climate Change (IPCC, 2007) and the Stern report (Stern, 2007) as well as the United Nations *Millennium Development Goals*.

Environmental sustainability as a primary social virtue can be linked with so-called "ecocentric" or "biocentric" bioethics. This is also known by terms such as *Deep Ecology* and expressed in documents like the *Earth Charter* or *Earth Manifesto*. It involves two key ethical principles. The first is that the flourishing and diversity of nonhuman life forms has intrinsic value requiring protection by policies and technologies that reduce the number of humans along with their demands on those other species. The second holds that human flourishing itself requires a deepening respect for right relations with ecosystems which should be reflected in the choices our species make about the use of new technologies.

It is difficult to discern environmental sustainability as a clearly defined ethical virtue or principle in contemporary media and policy debates between those with Christian, Islamic, or secular perspectives; those enmeshed in securing the embellishments of institutional or corporate financial power; and those (such as the "Occupy Wall St." protestors) critiquing the desuetude of that power in the face of moral crises. One finds, for example, little if any reference to environmental sustainability in ethical works derived from religious traditions, or from academic schools such as utilitarianism ("act on principles maximizing the greatest good for the greatest number") or deontologic idealism ("act on principles capable of universal application"). It could, of course, be argued that the concept of environmental sustainability is present implicitly in such doctrines or in core religious concepts like Buddhist compassion, Christian conscience, or Islamic *taqwa*.

Those supporting environmental sustainability as an emerging foundational social virtue alongside the human-focused justice, equity, and respect for human dignity could argue that the "virtue ethics" position supports the social virtue of environmental sustainability because its achievement is one of the central altruistic goals of good people in our age. Such goal-oriented virtue-based approaches to ethics have been criticized as too readily subjugating individual liberties and flourishing to the attainment of ostensibly wider social aims (Crisp & Slote, 1997). On the other hand, non-goal-oriented virtue ethics theories are commonly subjected to objections emphasizing their circularity and failure to provide determinate guides to action particularly in pluralist societies.

The less human-centered social virtue of environmental sustainability (as a normative basis for bioethics and human rights) can also be viewed as an extension from moral concerns in related areas such as protection of animals, based on their common capacity to suffer and the primacy of norms preventing suffering as far as practicable for the majority of our interactions. This focus on the normative primacy of "suffering" creates conceptual difficulties for those who rely upon it to argue that ecosystems (such as wild rivers or rainforests) deserve ethical status or legal rights. Why should expanding the circle of empathy require proof that an entity can suffer because it possesses a nervous system that we can readily discern as comparable to our own?

Attempts have been made by some economists to frame the bioethics of sustainability chiefly in terms of the fictional notion of perpetual growth in gross domestic product (GDP). Such formulations often pay obeisance to the fictional power of deregulated markets and the "invisible hand" of entrepreneurial self-interest to ethically regulate demand upon earth's resources. Other economists, however, have striven to factor our moral responsibilities concerning the finite and fragile resources of the biosphere much more centrally into their economic calculations. The virtues of ecological sustainability and environmental integrity, for instance, were influentially propounded by eco-economists such as the EF Schumacher (with his concept of "small (and local) is beautiful") and Kenneth Boulding (with his idea of "Spaceship Earth" as a closed economy requiring recycling of resources). In doing this, the former drew upon Buddhist ethical principles and virtues, while the latter relied upon those resonating with the Quaker tradition.

The economist Herman Daly similarly drew on the laws of thermodynamics and the tendency of the universe to greater entropy (dispersal of energy) to champion the idea of "steady-state" economics that financially values maintenance of ecosystems equally with production and profits. Such an approach could be extended to suggest that bioethics, human rights, and economic principles be coherent not just with thermodynamics, but with physical laws and patterns of symmetry such as those underpinning electromagnetism, gravity, general relativity, and quantum physics, as well as other principles that are nonfalsifiable, without necessarily correlating with our sensory-oriented experience of the world.

Many economists interested in developing greater moral and scientific credibility for their discipline are investigating the bioethics of sustainability through the lens of human population and ecosystem science. One such approach, for example, defines sustainability as involving the persistence of diversity and ethical ideas of human flourishing among human communities, as well as the preservation and regeneration of ecological systems.

Case Study: Global Artificial Photosynthesis

In its present technologically unenhanced form, photosynthesis globally already traps around 4,000 EJ/year solar energy in the form of biomass. Nanotechnology researchers now are actively redesigning photosynthesis to achieve, for example, low-cost, local-domestic conversion of sunlight, water, and carbon dioxide into fuel for heating and cooking (Hurst, 2010). Nanotechnology is not only facilitating the capture of electromagnetic radiation from the sun but helping its transfer to improvements of the reaction center where it splits water to produce hydrogen (for fuel) and oxygen and then to reduce atmospheric carbon dioxide via the enzyme RubisCO to make carbohydrate food. Those methods seek to replicate how plants perform a single quantum computation, sensing many states simultaneously and so enhancing the efficiency of the energy capture and transfer at physiological temperatures (Gray, 2009).

Numerous competitively funded research teams have dedicated artificial photosynthesis-related projects already underway in many developed nations (Sanderson, 2008). Enhanced artificial photosynthesis, if applied consistently with bioethics and human rights, could assist crop production on marginal lands; reduce atmospheric CO2 levels; lower geopolitical and military tensions over fossil fuel, food, and water scarcity; and create carbon-neutral hydrogen fuel for domestic, community, and industrial storage. Practical "artificial leaf" systems have been developed and are on the threshold of commercial rollout (Reece et al., 2011).

Establishing how bioethics and human rights meet the twin challenges of corporate globalization and environmental sustainability will be equally important with facilitating the scientific collaborations that will allow global artificial photosynthesis to take place in time to address the major societal and environmental challenges that the expanding human population and its dependence on fossil fuels are currently creating (Faunce, 2012).

The essence of a bioethical or human rights principle conceived in an ideal sense (and thus not merely derived mechanistically from a written religious or legal code, guideline, or declaration) as meeting these challenges is that it should be widely or even universally applicable (for example, depending on context, extend to protecting, respecting, or fulfilling the interests of all human beings, or animals, lifeforms, or ecosystems). The traditions of bioethics and human rights derive from profound consideration of the relations of humans with each other and nature. They should provide a calibration system against which can be critiqued for example the behavior of those artificial corporate persons currently self-interestedly dominating domestic and international trade law and policy in ways likely to be inimical to global artificial photosynthesis.

At present, the foundational social virtues and ethical principles likely to underpin any rollout of a new source of renewable energy and basic food will be perceived by many policy makers as likely to derive from corporate-driven free market ideology, religious authority, or indirectly through confronting the necessities of survival – an understanding that without such norms or rules of behavior the majority of humans could not live well with each other, or for very long.

A macroscience project to promote equitable global use of artificial photosynthesis represents an excellent opportunity to create a high profile awareness of nanotechnology, bioethics, and human rights as positive joint-contributors to overcoming major contemporary public health and environmental problems (Faunce, 2011a). One particular area of looming conflict will be between such a vision will be IMPs such as patents. Many of the nanotechnological techniques and structures, as well as the artificial proteins involved in artificial photosynthesis will be the subject of patents. The process of photosynthesis is as central to life on earth as DNA; thus, there are likely to be major debates over whether patents should be allowed over any part of the photosynthetic process. Such debates will be unlikely to inhibit patents being taken out over all aspects of artificial photosynthesis, but if excessive patents cause artificial photosynthesis ownership to become fragmented, "follow-on" research may be hampered by the high cost and difficulty in negotiating contracts with large numbers of patent owners (Faunce, 2011b).

Creating governance principles consistent with bioethics and human rights to deal with such issues will be an arduous and complex process. A good point of departure for such a governance journey might be a UNESCO *Declaration on the Bioethics and Human Rights of Global Artificial Photosynthesis*. Such a document would not have the force of law (under article 38 of the Statute of the International Court of Justice). However, it might become important as a symbolic utterance that guides ethical debate and law reform at international and domestic levels.

The UDBHR has many features that would be relevant to shaping the bioethical and human rights principles governing global artificial photosynthesis. These include, first, application to individuals, communities, and private corporations as well as states (article 1) and, second, a focus on "access to adequate nutrition and water," "improvement in living conditions and the environment," and "reduction in poverty and illiteracy" (article 14). The UDBHR also emphasizes the need to recognize the importance of freedom of scientific research and equitable access to medical, scientific, and technological developments (article 2); sharing its benefits with particular attention to the needs of developing countries (article 15); and safeguarding and promoting the interests of the present and future generations (article 2). UDBHR article 21.3 likewise relevantly requires that states and public and private corporate actors should recognize the "importance of research contributing to the alleviation of urgent global health problems" (Faunce, 2011b).

There are however bioethical issues much more specific to global artificial photosynthesis that could be raised by means of a specific UNESCO Declaration. These include whether photosynthesis in its natural form should be considered a subject to common heritage of humanity principles (as under specific United Nations Declarations and Conventions are the human genome, the moon, the outer space, the deep sea bed, our natural or cultural world heritage) or indeed a part of a new category of ethical and international law principles in the category of planetary common heritage. A statement in such a UNESCO Declaration that photosynthesis (in either its natural or artificial forms) was the common heritage of humanity could be important in wider governance moves to restrict corporate ownership through intellectual property rights or misuse by nation states for strategic or military purposes. Other questions may involve developing specific principles by which artificial photosynthesis technology can best address within defined time pressures critical problems of global poverty and environmental degradation (Faunce, 2011a, 2012).

One specific outcome of such normative intersections could be provisions supporting science-based assessment of the cost-effectiveness of such new technologies before government subsidy. Another might involve a commitment to withdraw investor-state dispute settlement rights once a nation has achieved a specific score on a rule of law index. Yet another might be a provision that supranational corporations, as a legal requirement of their registration, be ineffect 'married' through a requirement to undertake obligations to global public goods (annually selected by a regulatory authority) and restrain salaries for chief executives within a set proportion of those of political leaders. Sustainable government support for new renewable energy options like solar fuels could derive from a tax on global financial transactions

(Faunce, 2007). The treaty creating such a Tobin tax could include provisions preventing fraud through financial incentives to informants and their lawyers on the model of act us False Claims Act (Faunce, 2011b).

It is an act profoundly coherent with bioethics and human rights to imagine a world where every road, building and vehicle is "doing" photosynthesis more efficiently than plants and where each household could generate its own basic carbohydrate food and ethanol fuel for cooking, heat, and light simply and cheaply from a roof unit that required as inputs only photons, water, and carbon dioxide. It is also ethical to consider the pressure that thereby would be taken off the natural environment to provide land for crops or sources of fuel.

Conclusion

We have seen that there are now two powerful normative systems intersecting (and not necessarily in the public or environmental interest) with bioethics and human rights – domestic law (constitutional, judge made, as well as legislative) and international trade and investment law. The idea has been advanced that bioethics could be evolving toward justiciable and enforceable international human rights as part of a functional global social contract and this implies a combination of both self-assurance about the latters regulatory and symbolic importance, as well as mistrust of governments to otherwise uphold the principles and virtues that sustain them.

The conceptual heart of any global social contract can no longer be considered to involve contractual-type guarantees involving rules about when any one person's freedom can be interfered with by another's, when the aims of the state should not unduly infringe those of its citizens and guarantees of basic social, cultural, and economic support. The obligations of supranational corporations and the capacity of citizens and the environment to be protected from them must also be part of a hypothetical global social contract and the national constitutional norms derived from it.

Both bioethics and human rights carry the promise of enlarging the objects of human sympathy and so the applicable range of principles and rules available to decision-makers. One such emerging social virtue is "environmental sustainability" and it is critical for the survival of our civilization and our planet that it takes its place alongside justice, equity, and respect for human dignity in the normative foundations of bioethics and human rights. Global artificial photosynthesis may emerge as the technology best able to shape the moral revolution that places environmental sustainability at the heart of the world's governance arrangements.

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Biobanking

30

Darren Shickle

Introduction: What Is a Biobank?

The Organisation for Economic Co-operation and Development (2009: 1) defined human biobanks and genetic research databases as "structured resources that can be used for the purpose of genetic research, which include: (a) human biological materials and/or information generated from the analysis of the same; and (b) extensive associated information."

However, there is no consensus on a definition for biobanks. Some, for example, the Council of Europe (2006), only use the term biobank population collections and have a separate definition for other collections of biological materials biobanks. Thus, the former would be applied to large cohorts (some such as UK Biobank are as big as 500,000 people) recruited from the general public, while the latter tend to be smaller collections of samples and associated data obtained from patients with a specific disease cohort of patients.

Population cohorts are prospective, collecting detailed information on lifestyle, exposures, and demographic risk factors and then following up the cohort over time to observe what diseases they subsequently develop. They allow researchers to examine the associations between genetic and environmental risk factors for a range of diseases. They tend to be expensive because of the number of subjects to be recruited but also because of follow-up over many years. Even with their large size, there may only be sufficient disease outcomes to study the more common diseases.

For rarer diseases, disease-specific collections are more appropriate. These are retrospective and seek out individual who already have the disease and then look for markers associated with particular genes and other risk factors by comparing with a control group who do not have the disease.

D. Shickle
Academic Unit of Public Health, Leeds Institute of Health Sciences, University of Leeds, Leeds, UK
e-mail: d.shickle@leeds.ac.uk

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There are various funding models for biobanks:

- Piggybacked onto hospital clinical services, usually pathology departments
- Funded by grants from research funding bodies as part of their open calls for applications, rather than specific advertisements for biobank proposals
- Funded via specific calls for proposals to support biobanking initiatives to enable or accelerate biobanking research
- Initiatives by governments or large funding bodies, to set up a resource for their research community
- Private sector funding

The term biobank also need not be restricted to human biological material, so, for example, there are biobanks containing samples from other animal species, plants, microbes, etc. However, for the purpose of this chapter, the main focus will be on human biobanks.

Shickle, Griffin, and El-Arifi (2010) proposed a classification for different sorts of biobanks to facilitate a more focused consideration of the ethics and governance issues with each. However, for the purpose of this chapter, the principles of the United Nations Educational, Scientific and Cultural organization (UNESCO) Universal Declaration on Bioethics and Human Rights will be discussed in the context of all the categories of biobank.

It should be noted that that are two other relevant UNESCO documents:

- International Declaration on Human Genetics Data (2003)
- Universal Declaration on the Human Genome and Human Rights (1997)

However, it is outside the scope of this chapter to describe the similarities and differences between these various documents, and the issues relevant to biobank are adequately highlighted by considering the generic Universal Declaration on Bioethics and Human Rights.

Universal Declaration on Bioethics and Human Rights

Articles 1 and 2 are general provisions relating to the scope and aim of the Declarations. The principles themselves are specified within Articles 3–17. Articles 18–21 describe application of the principles. Promotion of the declaration is described in Articles 22–25. Final provisions are laid out in Articles 26–28.

Human Dignity, Equity, and Respect for Cultural Diversity

This section relates the principles as stated within the Universal Declaration on Bioethics and Human Rights (UDBHR) to biobanks. Some of the principles contain broad statements of values which while uncontroversial, without in-depth exploration of their meaning, have limited utility when applied to policy or legislation. Thus, for example, human dignity and human rights (Article 3) and respect for human vulnerability and personal integrity (Article 8), while important concepts to underpin a review of the ethical issues relating to biobanks, will not be discussed in

detail in this chapter, as they have been addressed elsewhere within this Compendium and Atlas of Global Bioethics.

Article 10 (equality, justice, and equity) states that "[. . .] the fundamental equality of all human beings in dignity and rights is to be respected so that they are treated justly and equitably." This is expanded upon in Article 11 (nondiscrimination and nonstigmatization) which requires that "[. . .] no individual or group should be discriminated against or stigmatized on any grounds, in violation of human dignity, human rights and fundamental freedoms." Article 12 emphasizes respect for cultural diversity and pluralism although "[. . .] such considerations are not to be invoked to infringe upon human dignity, human rights and fundamental freedoms, nor upon the principles set out in this Declaration, nor to limit their scope."

Article 17 deals with protection of the environment, biosphere, and biodiversity. While there are biobanks involving other animals and plants, the focus of this chapter has been on human biobanks. The Secretariat of the Convention on Biological Diversity (2002) has also produced guidelines on access to genetic resources and fair and equitable sharing of benefits although the scope explicitly excludes human genetic resources.

The Human Genome Organisation (1996) (HUGO) has recognized that the Human Genome Project, the Human Genome Diversity Project, and other genetic research have given rise to a number of concerns:

- Fear genome research could lead to discrimination against and stigmatization of individuals and groups and be misused to promote racism
- Loss of access to discoveries for research purposes, especially through patenting and commercialization
- Reduction of human beings to their DNA sequences and attribution of social and other human problems to genetic causes
- Lack of respect for the values, traditions, and integrity of populations, families, and individuals
- Inadequate engagement of the scientific community with the public in the planning and conduct of genetic research

The Human Genome Diversity Project (HGDP) (Cavalli-Sforza, 2005) is a resource that is aimed at promoting worldwide research on human genetic diversity, with the ultimate goal of understanding how and when patterns of diversity were formed. In the collection of the lymphoblastoid cell lines from worldwide populations, the HGDP was acutely concerned with ethical, legal, and social issues. At its founding meeting, HGDP adopted ethical guidelines (Greely, 2001), the key points of which were as follows:

- The HGDP and its participating researchers must always respect the humanity of the sampled individual and the cultural integrity of the sampled population.
- Informed consent is both an ethical imperative and a legal requirement.
- Researchers should actively seek ways in which participation in the HGDP can bring benefits to the sampled individual and their communities.
- One way to avoid bringing harm to the sampled individuals or their communities is by protecting the confidentiality of those sampled and, in some cases, of their entire community.

- Although very unlikely, it is nevertheless possible that the results of the HGDP might lead to the production of commercially beneficial pharmaceuticals. Should a patent be granted on any specific product, the project must work to ensure that the sampled population benefits from the financial return from sales.
- Human history – and the human present – is full of racism, xenophobia, hypernationalism, and other tragedies, stemming from beliefs about human populations. In the past, some of those tragedies have been perpetrated by, or aided by, the misuse of scientific information. All those involved in the HGDP must strive, in every way possible, to avoid misuse of the project data.
- Many people in the world have, at best, a limited understanding of human genetics. Some fear the consequences of human genetic research, in part because of the limits of their understanding. It is essential that a worldwide "public awareness" program is included within the project to educate people about its aims, methods, and results.
- The ethical issues faced by the project will evolve over time and must therefore be kept under continual review.
- The transfer of technology to developing regions of the world, which is an integral part of the proposed project, should contribute positively to the development of self-sufficiency in these regions. The help given should not be superficial and of only short-term usefulness.
- There should be a feedback of information to populations that participate in the HGDP.

Cell lines were only included within the resources if donors have provided informed consent to permit use of sample in studies of human history or evolution. A protocol for confidentiality protection for donors of samples was also established. Other information may have been collected by the various researchers who contributed to the collection, but the only information about ethnic and geographical origin (in degrees of latitude and longitude) and sex was stored within the HGDP biobank.

Autonomy and Consent

Autonomy and individual responsibility (Article 5), in the context of biobanks, have received considerable attention in ethics literature in particular in relation to consent (Articles 6 and 7) and, to a lesser extent, privacy (Article 9).

The first paragraph of Article 6 (consent) applies to preventive, diagnostic, and therapeutic medical interventions and hence is not relevant to biobanks as there are no interventions directly associated with the biobanks, although data and samples stored within the biobanks may have been generated as a biproduct of such interventions. However, paragraph two requires that:

> Scientific research should only be carried out with the prior, free, express and informed consent of the person concerned. The information should be adequate, provided in a comprehensible form and should include modalities for withdrawal of consent. Consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage or prejudice.

Beauchamp and Childress (2001) identified the following elements of the process leading to informed consent:

1. Threshold elements (preconditions)
   (a) Competence (to understand and decide)
   (b) Voluntariness (in deciding)
2. Information elements
   (c) Disclosure (of material information)
   (d) Recommendation (of a plan)
   (e) Understanding (of 3 and 4)
3. Consent elements
   (f) Decision (in favor of a plan)
   (g) Authorization (of the chosen plan)

Usually, potential biobank participants will have the mental capacity to give consent. As with other forms of research, there is the potential for concern when research subjects are in a dependent relationship with the research, for example, when a patient is asked to provide consent by a health profession responsible for their clinical care. Thus, the request for consent should usually be made by someone independent of this dependent relationship or at least who has a more junior role.

Article 7 lays out special protections to be given to persons without the capacity to consent. In particular, there are requirements to act in the best interests of the person lacking mental capacity and to involve the person concerned to the greatest extent possible in the decision-making process of consent, as well as that of withdrawing consent. It is difficult to demonstrate that participating in most research (unless when there is therapeutic benefit from an intervention that is only available within a clinical trial) is in the best interest of the participant, even if they have full mental capacity. The key is recognized in paragraph (b) when the caveat is introduced of only exposing the person to minimal risk and minimal burden AND if the research is expected to benefit the health of other persons in the same category. These requirements are consistent with many examples of national legislation, for example, the Mental Capacity Act 2005 in the United Kingdom (Shickle, 2006a). Thus, a person lacking mental capacity should not be recruited into a population biobank or for a biobank for a disease where there would be other patients who have mental capacity to give consent. But in principle, there would be no impediment for establishing a biobank to collect samples for conducting research on conditions that cause mental incapacity.

As Hoeyer (2008) has pointed out, human tissue has been stored and used for research on a regular basis for more than 80 years, and then suddenly during the 1990s, collection of human tissue, under the label of biobanks, started to attract considerable debate in the ethics literature.

There are three categories of consent that could be required within a biobank (Shickle, 2006b):

- Consent to collect data/samples directly from the data subject
- Consent to use data/samples collected for other purposes
- Consent for research to be performed on the data/DNA

Consent to collect data/samples from the data subject within a biobank should not, a priori, be ethically problematic as long as Beauchamp and Childress' elements are addressed. Explaining to potential biobank participants the aim of the biobank, what they are being asked to do, what sorts of questions they will be asked, and what samples will be collected is not dissimilar to the information that should be disclosed for any other research study (Shickle, 2006b). For most biobanks, in particular the retrospective case-control biological sample collection, it should also be relatively easy to explain what analysis will be performed on the data/samples and by whom, for example, in order to look for linking between sequences of DNA and particular risk factors among people with or without the disease. There are also no a priori ethical problems with prospective studies and longitudinal collection of data: many nonbiobank research studies do this. The consent problem with DNA biobanks arises when the information that ought to be disclosed during the consent process becomes increasingly uncertain. For example, unlike most research studies, where the research is performed by those who collect the data/samples, within biobanks this is not usually the case. At best, it is only possible to say that researchers will be vetted for legitimacy, but that they could be from not-for-profit or commercial sectors, may be from the country where the data/samples are collected, or could be international. Similarly, there could be reassurances that (other than exceptional circumstances, such as under a court order) the biobank will only be used for research approved by an independent research ethics committee. Given that most biobank participants are relatively healthy at the time of recruitment, it is also not possible to specify which diseases will be explored. It is this uncertainty that has caused particular debate.

Various solutions have been proposed, which have moved away from an absolute requirement to obtain informed consent (Shickle, 2006b). For example:

- Blanket consent, in which biobank participants assent to their data/samples being used for all forms of future medical research
- Preauthorization models in which participants are able to specify particular sorts of research that may or may not be performed using their data/samples
- Waived consent, in which an independent third party decides whether future uses of data/samples are appropriate

Johnsson, Hansson, Eriksson, and Helgesson (2008) conducted a survey of biobanks in Sweden to find out the incidence of cases of patients withholding their consent for samples to be stored within a biobank. Patients refused consent to either storage or use of their samples in 1 in 693 cases, and 1 in 1,580 confirmed this decision by completing a dissent form. One in 19,059 withdrew their consent. They therefore thought the consent process represented a minimal threat to the quality of research. However, they concluded that:

> A complex and costly administration has been set up to protect the small minority of patients who do not want their samples to be stored in biobanks or used in research. (Johnsson et al., 2008: 3)

They recognized that the findings might not be generalizable to other contexts or cultures and that the right to say "no" might be justified, no matter how small the

minority utilizing it. However, they thought the means to protect this right seemed flawed and that the lack of dissent in an explicit opt-in consent system justified a move to presumed consent as part of an "opt-out" system. In response to this paper, Laurie (2008) thought that Johnsson et al. had overlooked:

> [. . .] the costs of establishing a defensible opt-out system that gives patients adequate information about who might have access to their samples or information, and for what purposes. (Laurie, 2008: a337)

Laurie argued that a stronger evidence base is required in order to better understand:

> [. . .] what patients and public understand about samples, records and research; how well informed they are; and whether low opt-out rates truly reflect well placed trust or simply poorly informed apathy. (Laurie, 2008: a337)

Ludman et al. (2010) contacted 1,340 people for reconsent for transfer of previously collected data to the US federal database of Genotypes and Phenotypes (dbGaP). Interviews were conducted with 365 of the 86 % of the sample who reconsented. Respondents said that it was very (69 %) or somewhat (21 %) important that they were asked for permission. Many thought that alternatives to consent, such as notification-only or opt-out to be unacceptable (67 % and 40 %, respectively).

Article 9 requires that "[. . .] the privacy of the persons concerned and the confidentiality of their personal information should be respected. To the greatest extent possible, such information should not be used or disclosed for purposes other than those for which it was collected or consented to, consistent with international law, in particular international human rights law."

Many studies exploring public attitudes to participating in biobanks have highlighted that potential biobank participants have concerns about privacy and confidentiality (Shickle et al., 2003). For example, in a representative survey of 4,659 US adults conducted by Kaufman, Murphy-Bollinger, Scott, and Hudson (2009), 91 % would be concerned about protecting their privacy if they were part of a biobank, although this should be set against a high concern (79 %) about privacy of their medical information more generally. Respondents were more content to allow academic/medical researchers access to their data than government-funded researchers. They were most concerned about pharmaceutical companies accessing their data, although the study authors were unclear whether this was due to privacy concerns or disapproval of the industry's profit motive. Thirty-seven percent would worry that the study data could be used against them and most wanted guarantees that their data could not be accessed by insurers, employers, or law enforcement officials. However, despite these concerns, 60 % would participate in a biobank.

The question therefore arises whether there is a particular problem relating to biobanks and an Article 9 right to privacy? Are people more concerned about the data and samples that they may donate to a biobank compared with the data or samples that they may be asked for as part of a standard research project? While it has been suggested that there are features of genetic/genomic test information that mean that it should have additional protections (McGuire et al., 2008), most of the

data contained in biobank is information that could be collected within other forms of medical research and indeed research in other academic specialties. Similarly, blood, urine, etc., could also be collected in nonbiobank research. The public do seem to perceive genetic information as being more sensitive because genetic information is perceived as being an integral part of who they are (Melas et al., 2010). Do they perceive data controllers and data protection procedures to be intrinsically more untrustworthy than within other studies? There is no reason to suspect this, but it is a consistent research finding that the public consider certain data users to be more untrustworthy or are concerned that their DNA could be used to identify them (Shickle et al., 2003; Melas et al., 2010). This is despite the fact that most genetic data generated from a biobank has limited or no clinical or predictive value and most biobank participants are law abiding. Of course the privacy concerns about biobanks may just be an artifact of academics going out and asking people whether they are concerned about privacy and biobanks. Given that people do agree to participate in biobanks, it may be that the concern about breach of privacy is outweighed by their perception of the worth of the research and hence the importance of them participating.

As Hoeyer noted from his review of the literature on the ethics of research biobanking, there is a:

> [...] clear discrepancy between the concerns of donors, legislators and ethicists. The academic debate and legislatory action tend to focus on informed consent, and most of the concerns that donors have remain unattended to. (Hoeyer, 2008: 429)

While there were no clear trends, Hoyer made the following tentative observations:

- The type of tissue asked for and the position of the donors in relation to the research project seem to be important: the more people feel they need medical research results, the more likely they seem to donate.
- Only a minority would never participate in biobank research, but the social groups most likely to abstain differ between national contexts.
- A majority, or at least a substantial minority, think the donor should have a say concerning retention of tissue. This is generally interpreted as support of a consent requirement, but whether people prefer broad or specific consent and when and under which conditions differs remarkably between the surveys.
- Commercial access to public biobanks is accepted by a majority, although it is viewed more as a necessary evil than as the preferred research infrastructure.
- Mostly, donors are interested in getting access to research results, particularly of relevance to their own health, but the conditions differ widely.

Solidarity and Cooperation

The HGDP ethics guidelines recognized that it was unlikely that the HGDP would lead to commercially valuable products. Article 4 (benefit and harm) required that "[...] in applying and advancing scientific knowledge, medical practice and associated technologies, direct and indirect benefits to patients, research

participants and other affected individuals should be maximised and any possible harm to such individuals should be minimised." Direct benefits for an individual from participating in a biobank are negligible, and harms are more likely to arise in relation to dignity, integrity autonomy, etc., rather than harm to physical or mental well-being. Indeed, population benefits may be unclear when a biobank is first established, but rather they are created as a resource for researchers to use in order to conduct research that may generate benefits downstream. Individual patients and members of the public are asked to join this enterprise and make altruistic donations of their personal data and tissue.

Article 13 (solidarity and cooperation) suggests that "[. . .] solidarity among human beings and international cooperation toward that end are to be encouraged." "Solidarity" and "altruism" are concepts that underpin much of the publicity materials for biobanks. For example, the strap line for UK Biobank is "Improving the health of future generations."

Notes of the UK Biobank consultation meeting with industry described UK Biobank as:

> [. . .] a long term endeavour and the altruistic contribution of participants will benefit future generations . . . The contribution of participants to the project should be seen as a gift to biomedical science in the public interest. (UK Biobank, 2003: 5)

The language within the UK Biobank Ethics and Governance Framework went further:

> Participation will be presented as an opportunity to contribute to a resource that may, in the long term, help enhance other people's health. (UK Biobank, 2007: 5)

The use of the word "opportunity" suggests that participation is something that a citizen would want to do, if not ought to do, as part of an obligation to improve the health of future generations.

The UK Human Genetics Commission (2002) went further and used the language of "duty":

> Genetic knowledge may bring people into a special relationship with one another. We lead our lives as members of large and small communities and we have certain duties to other members of these communities. Such duties can include not causing harm to others and doing things to help them. Sharing our genetic information can give rise to opportunities to help other people and for other people to help us and we have a common interest in the benefits that medically-based genetic research may bring. We have, therefore, set out a concept of *genetic solidarity and altruism*. This supports the idea that, for example, although nobody should feel pushed into taking part in genetic research, when they make this decision people should be aware that by taking part they might help those suffering from disease. (Emphasis in original) (Human Genetics Commission, 2002: 6–7)

Petersen (2005) explored use of the language of citizenship within published documents pertaining directly or indirectly to UK Biobank. Petersen felt that words and phrases such as "altruistic," "gift," "sharing," "opportunities to help others," "common interest," etc., have a strong resonance in liberal democracies, especially with a widening of the concept of social citizenship and an emphasis on the duties of citizenship. However, he felt that the term "genetic solidarity" represented

a significant modification of the concept of social solidarity, which in its conventional usage implies cohesion, shared aims, and interested and single-minded unity of purpose. He saw the conjunction of "genetic" and "solidarity" as being consistent with:

> [. . .] the increasingly prominent worldview of 'genetic welfare', whereby genetic considerations tend to prevail over social ones and there is a change in our perceptions of rights, responsibilities and duties. It is the language of an emergent biological citizenship, involving the linking of biology and identify. (Petersen, 2005: 284)

Obligations for protecting future generations are specifically addressed with Article 16 which requires that the impact of life sciences on future generations, including on their genetic constitution, should be given due regard.

The main genetic issue in relation to protection of future generations would be impact on the gene pool. The gene pool can be affected in various ways:

- Prolonging the life of individuals with genetic conditions who would otherwise not reach reproductive maturity or who would be unable to reproduce
- Manipulation of the genome within inheritable material, for example, via gene therapy
- Selective termination of pregnancy for particular genetic disorders or traits
- Introducing evolutionary pressure on partnership and reproductive choices of individuals

Biobanks may lead to downstream interventions that could theoretically lead to the first of these. While any genetic research can add further to the pressures driving the latter three, the association between biobanks with these is likely to be tenuous.

Article 14 (social responsibility and health) suggests that "[. . .] the promotion of health and social development for their people is a central purpose of governments that all sectors of society share." This is unlikely to be contested. However, Article 14 goes on to suggest that "[. . .] the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition" and that progress in science and technology should be directed to advance this aim. Including "highest attainable standard of health" as a fundamental human right is however likely to be contested and indeed unattainable. A critique of this is outside the remit of this chapter on biobanks, but suffice to say that all healthcare systems involve some degree of rationing and hence suboptimal health for its service users. However, while the general direction of this article is important, it is not relevant to most biobanks. The aim of biobanks is to facilitate research that would lead to the highest attainable standard of health, but there are lots of intermediate steps between biobanks and final product and benefits and probability of success are often exaggerated.

Sharing of Benefits

Article 15 (sharing of benefits) proposes that "[. . .] benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries."

The Human Genome Organisation Statement on the Principled Conduct of Genetic Research (1996) was based on the following principles:

- Recognition that the human genome is part of the common heritage of humanity
- Adherence to international norms of human rights
- Respect for the values, traditions, culture, and integrity of participants
- Acceptance and upholding of human dignity and freedom

It went on to recommend that:

> Undue inducement through compensation for individual participants, families and populations should be prohibited. This prohibition, however, does not include agreements with individuals, families, groups, communities or populations that foresee technology transfer, local training, joint ventures, provision of health care or on information infrastructures, reimbursement of costs, or the possible use of a percentage of any royalties for humanitarian purposes. (Human Genetic Organisation, 1996: 3)

A subsequent statement by the Human Genome Organisation Ethics Committee (2000) dealt specifically with this issue of benefit sharing and how to distribute profits that may accrue to commercial enterprises, governments, or academic institutions on the basis of the participation of particular communities. The Committee recognized that there are different definitions of community and that communities may have different beliefs about what constitutes a benefit. However, prior discussion was needed with groups or communities on the issue of benefit sharing. They also recognized that as a species, we all share in essence the same genome and at this collective level, the genome is the common heritage of humanity. However, at specific places within the genome, individuals (with the exception of identical twins) exhibit significant variation. At a minimum, all research participants should receive information about general research outcomes and an indication of appreciation. The Committee recommended that all humanity share in, and have access to, the benefits of genetic research and that benefits should not be limited to those individuals who participated in the research. Even in the absence of profits, the Committee recommended that immediate benefits as determined by community needs could be provided. But profit-making entities should dedicate a percentage of their annual net profit (1–3 % was suggested) to healthcare infrastructure and/or to humanitarian efforts.

Many of the smaller biobanks do not have the resources to consider issues relating to intellectual property rights (IPR), but even within the larger population biobanks, IPR issues are often poorly addressed, or the policy is deferred until after the collection phase is complete. For example, UK Biobank is probably the largest biobank with the highest international profile and most often used as a gold standard for other biobanks to follow (it has recruited 500,000 people aged between 40 and 69 years from across the United Kingdom). UK Biobank completed sample collection in 2010 but did not finalize its access procedures until the end of 2011 (UK Biobank, 2011).

Pathmasiri, Deschênes, Joly, Hemmings, and Knoppers (2011) identified three phases within the life cycle of a biobank in which IPR may be relevant: creation, collection, and access phases. They proposed that scope for IPR within the first two of these phases is limited. Within the creation phase, the biobank may wish to

copyright logos, software for interviews, or new health questionnaires. Patents may be sought for innovative equipment developed for storage of samples. However, only in exceptional cases would these intellectual property (IP) protections be financially lucrative. Within the collection phase, the main focus is privacy and protection of access to data and samples. The emphasis is on contractual and procedural mechanisms rather than IPR. The main scope for IPR is in relation to research that accesses the data and samples contained within a biobank, leading to patents for new diagnostic tests, new applications of existing medications, new medications, or copyrights in publications.

Pathmasiri et al. (2011) raised the question as to whether publically funded biobanks should claim any ownership of IPRs that are developed as a result of access to biobank data and samples. They did recommend that biobanks acknowledge the possibility of "downstream IPRs" and that these ought to be clearly and preemptively specified within IP policies and access agreements before granting access to the biobank to mitigate future misunderstandings and litigation. Pathmasiri et al. conceded that a biobank, and of course the public that paid for it, might wish to benefit from downstream IPR as there was considerable time, energy, and money involved in collecting, processing, and storing of samples. However, they pointed out that biobanks only provide the raw material for the research and do not take part in the inventive steps to develop patents, and hence, they argued that biobanks should not have rights in patents, etc. The main argument of their paper was that publically funded biobanks should be satisfied with benefits "in kind" rather than financial. Underpinning this argument is the recognition that aim of the majority of publicly funded biobanks is to promote the development of new knowledge by giving the research community access to data samples. It is further argued that the most efficient way to acquire these benefits is to, firstly, maximize the use of the biobank in research and, secondly, maximize the dissemination of knowledge developed by the research projects that used the biobank. Pathmasiri et al. claimed that the need to negotiate additional potential IPRs before obtaining access to the biobank resource translates into added access procedures, approvals, and delays and hence additional hurdles that put of use of the biobank and be counterproductive to the aims of the biobank owners.

In addition, Pathmasiri et al. (2011) suggested that the financial return from downstream IPRs for the biobank may be an unpredictable source of income, and biobanks would be better advised to ensure that the funding needed for maintaining the biobank is secured from access fees. They also pointed out that the additional administrative burden of negotiating and monitoring IPR would need to be offset against any income. While it is true that for smaller biobanks the likelihood of generating significant and reliable IPR income would be low, larger population biobanks are likely to attract significant interest from international research groups, and hence, the extra work in setting up robust access and IP arrangements would be warranted.

Most of the costs associated with a biobank are upfront, relating to the collection phase and to a lesser extent the creation phase. The case is usually made to funders on the basis for the need for establishing the biobank as an infrastructure for

research. The funding is made on this basis without an expectation that that the funding will be returned, although the initial grant often does not give sufficient attention as to how the resource will be funded on a long-term basis during the access phase. For most biobanks, there is an expectation that access fees would cover at least the cost of retrieving and processing the data and samples for each request and that this income would also offset the cost of maintaining the biobank itself. The main IPR concern for most biobanks is to set up a mechanism to prevent exclusive licensing practices which lead to higher prices for diagnostic tests and pharmaceuticals developed from utilizing the biobank and hence adversely affect the public who freely donated the samples that facilitated the patent-creating research in the first place. The most infamous example of this (although not directly related to a biobank) was when Myriad Genetics marketed predictive genetic tests for breast cancer, as prices that were considered by some to be excessive, on the back of patents it held for sequences within the BRCA 1 and 2 genes (Marsh, 2010; Park, 2010).

The patent system and other intellectual property rights were enacted in recognition of the need to reward the investment of individuals leading to innovation, and that innovation, generally, is in the public interest. Thus, researchers, especially within the for-profit sector, will need to be afforded some IPR protection as incentive for doing the research, but at the same time, providing some guarantees for society that the patented innovations are not priced out of the reach of parts of society who have capacity to benefit. The US National Institutes of Health [NIH] (2005) and the Organisation for Economic Co-Operation and Development (2006) have both produced guidelines for best practice for the licensing of genetic inventions. The NIH guidelines discouraged exclusive licensing:

> Whenever possible, non-exclusive licensing should be pursued as a best practice. A non-exclusive licensing approach favors and facilitates making broad enabling technologies and research uses of inventions widely available and accessible to the scientific community. When a genomic invention represents a component part or background to a commercial development, non-exclusive freedom-to operate licensing may provide an appropriate and sufficient complement to existing exclusive intellectual property rights. (NIH, 2005: 18415)

The NIH guidelines go on to state that:

> PHS [Public Health Service] encourages licensing policies and strategies that maximize access, as well as commercial and research utilization of the technology to benefit the public health. For this reason, PHS believes that it is important for funding recipients and the intramural technology transfer community to reserve in their license agreements the right to use the licensed technologies for their own research and educational uses, and to allow other institutions to do the same, consistent with the Research Tools Guidelines. (NIH, 2005: 18415)

In addition to more specific principles and examples of best practice, the OECD guidelines contained four general principles and recommended that licensing practices should:

- Foster innovation in the development of new genetic inventions related to human healthcare and should ensure that therapeutics, diagnostics, and other products and services employing genetic inventions are made readily available on a reasonable basis

- Encourage the rapid dissemination of information concerning genetic inventions
- Provide an opportunity for licensors and licensees to obtain returns from their investment with respect to genetic inventions
- Have reasonable certainty over their rights and the limitations to those rights in relation to genetic inventions

Given its size, both in terms of size of cohort and budget, UK Biobank is proposing to take a more robust approach to IPR compared with other publicly funded biobanks, and intends to explicitly retain ownership of the resource:

> UK Biobank's approach to Intellectual Property Rights (IPR) is structured on the basis that it seeks to encourage use of the UK Biobank Resource for health-related purposes by bona fide researchers. To this end, UK Biobank will retain ownership of its rights in the Resource (so that it is available to all other approved researchers), while at the same time facilitating the availability of clinical advances (e.g. diagnostics and treatments) arising from its use. UK Biobank is the owner of the property in the samples and the database (which will be added to, and updated, throughout the life of the Resource) and retains all the intrinsic IPRs in the data in the Resource (notably database rights and copyright). (UK Biobank, 2011: 10)

Pathmasiri et al. (2011) also proposed that one way that biobanks could achieve a goal for wide diffusion of knowledge and applications is to request that biobank users return research findings to the biobank within a designated time frame. These results can then be made available to the wider research community, who could make use of them within other research.

UK Biobank has also given a clear indication that it:

> [. . .] would not expect naturally-occurring genetic sequences, biomarkers, proteins or biochemical processes to be made the exclusive preserve of one party. (UK Biobank, 2011: 10)

UK Biobank proposes to have no claim over inventions and associated IPRs that are developed by researchers as a result of using the resource. However, it is intended to have a "reach-through" provision to restrict the exercise of these rights if IPR is used to restrict health-related research and/or access to healthcare unreasonably. In the event that conduct is considered "unreasonably restrictive," UK Biobank:

> [. . .] reserves the right to require that a licence of such rights is granted back to UK Biobank on an irrevocable, perpetual, global, royalty-free, fully sub-licensable basis so that other researchers who are granted access to use the Resource can exercise such rights to the extent necessary to conduct their research project. (UK Biobank, 2011: 10)

It remains to be seen how UK Biobank operates this proposed approach to IPR once access to the resource has begun. It also remains to be seen whether smaller biobanks would be able to institute similar restrictions. Given the pressure to demonstrate that the resource is being used and hence show to funders that the money spent on establishing the biobank is worthwhile, it would be courageous for a biobank administrator to place barriers to exploitation of the resource, when, for the more common conditions at least, there is a global oversupply of samples.

The Icelandic Health Sector Database was operated under a license by deCODE genetics. In turn, deCODE genetics entered into an exclusive sublicense agreement with Hoffman-La Roche that will give the latter exclusive access to the database to

explore the genetic origins of 12 diseases. This sublicense agreement promises that Iceland will be provided, free of charge for the patent term, any products that are developed using data from the Icelandic database. While the decode model received considerable criticism (Greely, 2000) and the company eventually went bankrupt in 2009, the model of subsidized healthcare costs might be attractive to a country with a cash-limited health economy. Other countries that have established national biobanks have also hoped that it would attract pharmaceutical and biotechnology companies to set up facilities within their country, so earning additional tax and economic activity.

Paragraph 2 of Article 15 states that "[. . .] benefits should not constitute improper inducements to participate in research." While there are rarely any direct financial inducements for donating tissue, within publicly funded biobanks at least, there may be some degree of coercion for patients to participate in disease-specific biobanks, if they believe that this is the best hope of finding a cure.

Support groups for patients with genetic disorders are generally keen supporters of the research community and oppose measures that they perceive might hinder the research process. For example, commenting on the Myriad Genetics case, Sharon Terry, the cofounder of PXE International, wrote:

> A sweeping, broad-brush approach would cause wide-ranging disruption to research and development for innovative diagnostics and treatments to the detriment of individuals and families in need of medical breakthroughs. (Terry, 2010: 24)

PXE International is a support group established by families with *pseudoxanthoma elasticum* (PXE). When Sharon Terry's children were first diagnosed with PXE, Sharon and her husband started exploring research options and in addition to establishing the support group developed their own biobank and retained IPR. When they were approached by two separate research groups for blood samples, they were:

> [. . .] shocked to find out that they wouldn't share [samples] and expected us to allow blood to be drawn from small children twice in 1 week. There was no central repository for the precious blood of people with this rare condition . . . We began to scheme about what we would do if we were managing research on this disease. It seemed to us that not only did PXE need a central repository for blood and tissue, it also needed a large cohort of affected people to give researchers a comprehensive understanding of the condition's manifestations and progression . . . Soon after we started the PXR International Blood and Tissue Bank, the researcher in whose lab we banked our samples actively tried to thwart access to the bank by other researchers. We were appalled, maybe naïvely, that researchers would put their needs for publication, funding, promotions, and tenure ahead of the needs of people living with disease . . . Fortunately, this problem was counterbalanced by interactions with other researchers here and abroad, with whom real collaboration occurred. One of these relationships led to a joint application for the patent on the gene associated with PXE – the first time lay people in an advocacy group have applied for the patent. We consider ourselves stewards of the gene and know that the real issues will be played out in its licensing. (Terry, 2003: 168–170)

Article 15, specifically notes the importance of benefit sharing with developing countries. Sheremeta and Knoppers (2007) recognized that in view of the trend toward population genetic research and the widening gap between the developed

and the developing world, mechanisms are required to ensure that the benefits of this research can be shared equitably. They suggested that if the biotechnological advances derived from genomics are applied correctly, then there is potential to affect a revolutionary transformation in medicine and healthcare over the next few decades. But they also warned that if used "inappropriately and unwisely" the power of genome-related biotechnologies would inevitably exacerbate existing inequities.

Emerson, Singer, and Upshur (2011) noted examples of "scientific-imperialism" and "biocolonialism" in which vulnerable populations had been exploited in research. They believed that this has led to many communities and governments in low-to-middle income countries being understandably reluctant to trust foreign researchers and permit access to human tissues. As a way of rebuilding this relationship, Emerson et al. (2011) proposed a "tissue trust" as a way of promoting host capacity by either requiring that research is conducted within country or charges an export fee that could be used to develop this capacity. The model also includes requirements in terms of governance structures and community engagement.

Moral standards for sharing of research benefits with the developing world have been proposed (El Setouhy et al., 2004). However, the main focus of these frameworks is in terms of fairer benefits to participants and the community in which they live, during the research. As has been mentioned previously, the benefits from participating in a biobank are negligible. Thus, it is the wider global healthcare agenda that is relevant here and not one specific to biobanks, with downstream diagnostic tests or therapies being equitably shared and accessible to deprived populations. That said, the initiatives such as the Human Genome Diversity Project will be important to ensure that the outputs of genomic research take into account different polymorphisms around the world. After all, no developing country would be able to afford the £60 million spent on establishing UK Biobank.

Conclusion: "Biobank Exceptionalism"?

The main focus of the discussion within this chapter has been on Articles 6 (consent) and 15 (sharing of benefits), reflecting the main foci of debate about biobanks within the academic literature. It should be noted that while the scientific (and indeed the ethics) community has paid particular attention to producing solutions to the consent problem within biobanks and the public are presented with arguments why participating in a biobank participant is a way of solidarity, scientists have been less forthcoming with solutions to address the sharing of benefits.

It is true that biobanks provide an infrastructure and a resource for research, rather than being a research enterprise in their own right. It is also true that seeking informed consent for data/sample donation is more complicated because of the uncertainty about how the resource will be used and by whom.

However, this should not mean that biobanks should be automatically exempt from the usual a priori moral obligation to seek informed consent. Of course, there are examples of research where consent is not sought because it is not practicable or appropriate to do so, and if necessary, biobanks should use similar justifications.

It is true that intellectual property rights are more difficult when there are many organizations involved. It is also true, that the funders of biobanks want to encourage research that will benefit the public. However, these difficulties should not mean only the researchers (whether in for-profit or not-for-profit organizations) should only be the ones to benefit from the investment made by those who fund the biobank and those who donate their data/DNA.

Genetic exceptionalism is the claim that genetic information is special and hence should be treated differently from other forms of personal or medical information, based on its ability to predict the future, identify individuals, implications for other family members, and/or scope to discriminate/stigmatize. However, to various degrees, these characteristics are also true of nongenetic information. In any case, the information generated from research on biobank samples could rarely, if ever, be used in these ways. While the particular issues relating to biobanks require specific attention, this should not mean that the principles within the Universal Declaration on Bioethics and Human Rights do not apply.

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Biometrics

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Emilio Mordini

Introduction

Biometrics has passed through its pioneering period and is now increasingly used for people identification and/or authentication online, in border controls, in health systems, e-commerce, e-government, and so on. Rapid decreases in price, better performance, and dramatic improvements in sensor technology and data storage capacity have made biometrics practical both for consumer applications and for governmental purposes.

Any innovative technology program needs a continuous investigation of its possible ethical implications. Biometrics could play a pivotal role in ensuring more reliable identification schemes both at local and global levels. Yet one should carefully balance the benefits with ethical and social risks. The relevance of ethical implications of biometrics is self-evident: it is not only a consequence of the scale of the phenomenon and of the current historical period. Its relevance is mainly a consequence of the deeply rooted ethical significance of some issues raised by biometrics. Many of the problems are related to individual identity such as protection of personal data, confidentiality, individual liberty, and the relationship between individual rights and common good.

This chapter will first provide an overview of the development and the state of art of biometric technology in the wider context of the history of personal recognition. The main ethical implications of biometrics will be then discussed under two main headings, fundamental and specific ethical issues. Fundamental issues concern the central question whether biometrics are per se demeaning and abusive of human dignity. Among specific issues, the focus will be on questions related to privacy and data protection, questions related to surveillance, and questions related to large-scale applications. After confronting ethical issues raised by biometrics with the Universal Declaration on Bioethics and Human Rights, the conclusion will indicate the potential contribution of biometric technology to the development of human rights in low-income countries.

E. Mordini
Centre for Science, Society and Citizenship, Rome, Italy
e-mail: emilio.mordini@cssc.eu

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Biometrics

The Origins

The word "biometrics" comes from the ancient Greek and literally means measure (metrics) of life (bio). It was coined in the late nineteenth century by Francis Galton (1822–1911), an English geographer, anthropologist, naturalist, and pioneer in eugenics. Galton modified a previous Greek neologism invented by Anglican priest and polymath William Whewell (1794–1866) who first used the term "biometry" to mean "calculation of life expectancy" (Whewell, 1831, p. 375). Galton slightly modified the term from biometry to biometrics and changed its meaning by using it with the sense of "application of mathematics to biology" (Galton, 1901, p. 7). According to Galton's original definition, "the primary object of Biometry is to afford material that shall be exact enough for the discovery of incipient changes in evolution which are too small to be otherwise apparent" (Galton, 1901, p. 9). Galton put strong emphasis on quantitative aspects of biological research (Bulmer, 2003). He took inspiration from "The Origin of Species" to focus on the measurement of individual differences among living organisms, but differently from Darwin, he was convinced that evolutionary chance is not gradual but progresses through major breaks in continuity. In particular, Galton focused on mental and physical characters in human beings and to what extent they depend on biological heritage and environmental and developmental conditions.

Further to Galton, the word biometrics was used to mean various methods of measurement of physical and behavioral features of an individual in order to:

1. Study hereditary and environmental factors which concur to determine these features
2. Study variability over time of these features
3. Investigate their possible association with pathological conditions
4. Assess to what extent they are unique for each individual and can be used as identifiers

Biometric applications have included the following applications:

1. Medical applications: medical parameters (e.g., weight, height, body diameters, blood pressure, measurement of biochemical components in the blood). These biometric features are normally used for clinical purposes. By comparing measurements collected from an individual with previous measurements from the same individual, and with average values obtained from healthy individuals, medical doctors may infer information about the state of health of the subject. These measurements could also be aggregated in order to deduce meaningful medical data about physiological and pathological conditions of human communities.
2. Natural science applications: the statistic study of quantitative variance of anatomical and physiological features, in humans, animals, and plants, is a powerful instrument to study the inheritance and evolution of characters and the transformation of species.

3. Social science applications: biometrics were used to provide scientific foundation to the so-called anthropology of human races and to racist theories.
4. Forensic applications: biometric forensic applications have been twofold. On the one hand, in the past biometrics provided foundation to prejudicial scientific discourses such as physiognomy and phrenology; on the other hand, they have been used for criminal identification by exploiting the uniqueness of some biometric features, notably the disposition of epidermal ridges of human fingers which leave an impression called "fingerprint." Galton first noticed that fingerprints have the characteristic of being different in each human being, even in identical twins. From this observation, he proposed the use of fingerprints for the identification of criminals and victims in the course of the police investigation (Bulmer, 2003). Impressions of fingers, invisible to the naked eye (latent fingerprints), may be left behind on a surface at a crime scene and further retrieved, which explains the great relevance of this biometric application in forensic practice.
5. Applications for personal recognition: there is some evidence that in ancient times, biometric features were used for individual recognition purposes: a number of archeological artifacts show that fingerprint impressions have been used as a signature since the Neolithic era. European explorer Joao de Barros recorded the first known example of fingerprinting in China during the fourteenth century. The Spanish explorer wrote that early Chinese merchants used fingerprints to settle business transactions, and those Chinese parents used footprints and fingerprints to differentiate children from one another. In order to be a good identifier, a biometric feature should satisfy four basic requirements: (1) collectability, which means that the feature should be easily measurable; (2) universality, which means that the feature exists in all individuals of a given species; (3) uniqueness, which means that the feature should be present in a distinctive way in each individual; and (4) permanence, which means that the feature should remain stable over time. Many body features have been investigated, yet – till to the introduction on digital biometrics – only fingerprints satisfied all these conditions.

Personal Recognition

Today biometrics are largely thought of as providing ways of managing and authenticating the identities of individuals, and only few scholars remember different biometric applications. How did biometrics come to this point? One needs to refer briefly to the history of methods for personal recognition and their significance in human civilization.

The need for specific methods for identification is presumably connected with the birth of the first urban societies during the so-called Neolithic Revolution. From at least three million years ago, humans have lived by hunting (or fishing) and gathering edible items (such as fruit and insects). Only a few thousand years ago,

the mankind developed a new economic model based on farming (cultivated crops and domesticated animals). The transition from an economy based on hunting and gathering to an economy based on farming implied many epochal consequences, among which the emergence of sedentary dwelling. Human groups gave birth to sedentary communities organized in small villages and towns. Farming economy also meant the creation of food surpluses, which promoted trade of food and food-related products (e.g., salt, which was probably one of the first commodities because of its ability to preserve food). Growing societal complexity, alongside developments in intra – and intersocietal trade, made the identification of foreigners increasingly vital to the normal functioning of these early societies. One has indirect evidence of this, in the Odyssey, whose plot is based on a series of recognitions of a hero who is travelling abroad, far from his own homeland, striving for going back home. Indeed, the reading of the Odyssey allows listing the main identifiers used by early human communities. They include a description of physical appearance (e.g., body size and shape, skin and hair color, face shape, physical deformities and particularities, wrinkles and scars) and artificial and more permanent body modifications (e.g., branding, tattooing, scarification). Finally they include physical (e.g., passes, seals, rings) and mental tokens (e.g., memories, poems, music, recollection of family and tribal links).

As population densities increased, also social hierarchies developed. The birth of the great empires (Egyptian, Chinese, and Assyrian) introduced new important drivers for personal identification, taxation, conscription, and the administration law. The Roman Empire was the first cosmopolitan society in the West providing for a universal identification system through a tripartite codified name scheme, which was related to the birth of the first comprehensive legal system on property and political citizenship. The Roman name scheme remained partly operational in Europe during the Middle Ages, yet most mediaeval "nomadic" individuals – e.g., beggars, pilgrims, merchants, and professional soldiers – were identified only through community membership, certified by passes and safe-conducts issued by religious and civil authorities.

The modern era saw increased mobility associated with new geographic discoveries, urbanization, and, later on, industrialization. The need for more effective recognition schemes emerged in parallel with the development of post-Westphalia polities. The first passports were issued in France by Louis XIV, and the first legislation in the West linking personal identities to birth registration was enacted during the French Revolution. The passage from the mediaeval identification scheme based on community membership (e.g., family, guild, village, manor, parish) to an identification scheme based on a document issued by the state central authority is full of meaning. The new citizen who emerged from this process was an unmarked individual who was distinguishable only through her name, nationality, and place and date of birth. Religion, ethnicity, race, cast, and social conditions became irrelevant in order to identify individuals, at least in theory. Actually the history of how nation states kept on using identification schemes largely based on racial, religious, and ethnic categories is sadly infamous. The most horrible event of the twentieth century,

the Shoah, was made possible chiefly by the existence of an effective, automated, bureaucratic apparatus for certifying racial identities (Black, 2001).

After World War II, a new powerful driver for personal identification emerged: the welfare state. The welfare state, which first appeared in north Europe, was based on the provision of services via redistributionist taxation. In order to be properly enforced, both redistributionist taxation and welfare provision need robust and reliable systems for personal identification, which is witnessed inter alia by the increasing numbers of identity and entitlement documents (e.g., social cards, social insurance number) that are generated by each state which provides social benefits and services.

Finally after the agricultural, the industrial, and the welfare state revolutions, we are now on the verge of a new, epochal transition. The world has reached a degree of interconnectedness never experienced before. Today, about two billion persons are moving each year across large geographic distances (International Air Transportation Association, 2010), about two billion and a half people are connected to the Internet (Internet World Stats, 2013), and the number of active cell phones in the world is exceeding the world population (SI team, 2013). This situation dramatically transcends national control and state regulations and has momentous consequences for traditional identification schemes, which cannot rely any longer only on identification documents issued by nation states. The tourist hoping to use her credit card in any part of the globe, the asylum seeker hoping to access social benefits in her host country, and the banker hoping to move money from one stock market to another in real time – all have the same need. They must prove their identities and be certain of others' on a global level. In such a context biometrics are emerging as the possible answer.

The Birth of Automated Biometrics

Till the 1970s fingerprints were the sole, relevant example of biometrics used for identification purposes. Conventional fingerprinting was based on the comparison between two sets of analog representation, one set obtained in the past from a known individual and one set collected in the present, either on the crime scene or from unknown individuals that should be identified or whose identity should be verified. Until the advent of digital technologies, fingerprints were collected by using ink and a card or by using dark powder and tape (latent fingerprints). Fingerprints were then compared with the fingerprints on recorded files (comparative dactyloscopy). The whole process was time demanding, rather cumbersome, and its accuracy critically depended on expert's competence and experience.

As all repetitive and boring activities, also fingerprinting was waiting for automation, and this became possible in the 1970s, when first the Japanese National Police Agency and then the FBI automated the process of classifying, searching for and matching fingerprints.

The birth of Automated Fingerprint Identification Systems (AFIS) was not a trivial event because it was the starting point of contemporary, digital biometrics.

The discovery that fingerprints could be turned into numbers (i.e., digitalized) and processed as numeric strings opened the way for finding a number of new biometric identifiers, which could not be appreciated by naked eyes, but that could be captured and processed by specific sensors. Beyond fingerprints, other unique and stable biometric features were soon discovered, e.g., iris structure, retina texture, face and hand geometry, body and ear shape, voice, signature dynamics, and gait.

Simplifying greatly, one may think of automated biometric systems as identifying or authenticating individuals on the basis of three steps. (1) Biometric samples are captured by way of sensors which record physical inputs from the biometric traits presented by the subject (e.g., fingers, face, iris). Sensors are mechanical devices which are modified by the input signal, in a way which is proportional to the magnitude of the signal. This generates an electric output. Through the repetitive measurement of the electric output at certain interval of time, the magnitude of the voltage is turned into a proportional number, which is encoded as a binary number, or a gray code, or still in other ways. The overall process is called "analog-to-digital conversion." The analog-to-digital conversion is the occurrence which makes automatic biometrics radically different from any traditional, human performed biometrics. From the moment in which the representation of the relevant properties of an item is turned into digits, one can operate through numbers. This has dramatic consequences. First, the digit format allows collecting, processing, storing, and retrieving a huge amount of data in a short period of time, which was definitely impossible with analog representations. Second, digital representations have different qualities from analog representations; the most important is that digital representations display information in terms of discrete values and consequently can be compared by using quantitative and probabilistic criteria. Data handling and probabilistic comparison are the two events which allow the full automation of the whole recognition process. (2) The next step is the creation of templates, which are normalized representations of the biometric sample. In real life there is a continuous variability, and in order to get a model reliable enough, one needs to merge and normalize signals captured in different moments and under different conditions. Templates can be generated mainly in two ways, either a series of analog signals are combined, creating a compound signal which is then digitalized, or each of the series of analog signals is digitalized individually, and then the results combined. Whichever method is employed, the aim is the same: to overcome variations between individual signals due to contextual factors such as lighting conditions or background noise. Templates are then stored as digital representations (e.g., in a central database or on a card – though central databases are increasingly unpopular and unnecessary). When, on a subsequent occasion, (3) the subject presents their biometrics to the system, it will produce a new template which can be matched with the existing template created on enrolment (i.e., at steps (1) and (2)). This matching of earlier and later templates is not expected to be exact, but will make reference to a given confidence interval, a margin of error deemed appropriate to the particular context in which the biometric system is deployed. When a template is compared with a database (one-to-many comparison),

the process is known as "identification"; when it is compared to a specific existing template (one-to-one comparison) – say, the template stored in a passport – the process is known as "verification." It is important to draw reader's attention on the fact that the database used for identification should not be necessarily centralized. Actually today, there is the tendency – both for privacy and security reasons – to use dispersed, networked databases. A special case is then when one is interested in checking whether an individual is not in a given database (i.e., screening). In such a case one compares the biometric sample against a database with the aim not to match it. In other words, one is not interested in ascertaining the identity of an individual, but in knowing who the subject is not (negative identification).

Engineers usually distinguish between strong, weak, and soft biometric features (Jain, Patrick, & Ross, 2008).

"Strong biometrics" are features that can be considered unique (at least extremely unlikely to be found equal in two individuals) and permanent (at least enduring for very long periods of time). Although no physical property can ever be truly unique or permanent, some properties can be treated as though they were. For instance, in human beings, fingerprints, hand skin patterns, iris structure, hand veins, and the retina texture can be practically considered unique and stable. The same would hold true for DNA, which is however rarely considered a biometric trait, chiefly because of historical reasons and because its usage is often subjected to specific legislations. The early development of biometric technologies has been chiefly based on strong biometrics. Logically speaking, identification based on strong biometrics is hardly different from identification based on artificial tokens. What changes with biometrics is that the token is no longer an external object associated to the person, but it is a bodily feature. This explains the popular aphorism, according to which biometrics are turning the human body into a password, which would be true in any case only for strong biometrics.

"Weak biometrics" are features that are "less unique" or "less stable" than those used as strong biometrics. In humans, weak biometrics include features like body shape, odors, behavior (e.g., gestures, gait, face dynamic), voice, body sounds, and electrophysiological phenomena (e.g., hearth and muscular electrical activity, brain waves). Weak biometrics can be used for identification purposes provided that they are not used in isolation. Given that one can only in part establish a be-univocal correspondence among them and a given individual, they should be used only in context (by considering also space and time coordinates) or in association. This implies that in order to use them efficaciously, one should collect also other details such as geo-spatial localization and the time in which the feature has been collected. One could also fruitfully merge two or more weak biometrics, or different biometric modalities targeting the same biometric feature, or associate weak biometrics with soft biometrics.

With the expression "soft biometrics," engineers refer to features which are too generic to be an identifier. They include categories such as gender; age; race and ethnicity; weight; height; and eye, skin, and hair color. Soft biometrics can be fruitfully used to reinforce strong and weak biometrics. Basically they allow to reduce the number of odds and consequently to refine the identification process.

Next Generation Biometrics

Advances in sensor technologies, which enable different bodily and behavioral characteristics to be captured, have been the main technological driver of next generation biometrics, which is largely based on weak and soft biometrics. Emerging biometrics include technologies which measure "motor skills" (i.e., the ability of a human being to utilize muscles), technologies which measure electromagnetic body signals, and finally technologies which measure human-computer interaction patterns (Mordini & Tzovaras, 2012). Examples of emerging biometrics include gait recognition (analysis of walking patterns); dynamic facial features, eye blinking, lip movements, and smile recognition; voice recognition (analysis of vocal behavior); signature/handwriting or other authorship-based biometrics; electrocardiogram (ECG, records the electromagnetic signals produced by the heart as measured on the skin); electroencephalogram (EEG, records the electromagnetic signals generated by the brain as measured on the scalp); electrooculogram (EOG, records eye movements); electromyogram (EMG, records muscle activity); body odor recognition; keystroke or mouse dynamics; and online behavior recognition. According to Yampolskiy (2011) next generation biometrics could be classified under the common heading of behavior-based authentication mechanisms. Yampolskiy suggests that these authentication mechanisms are characterized by "the incorporation of time dimension as a part of the behavioral signature" (p. 378).

Most new biometrics require less user cooperation and can be run almost unobtrusively and in a way transparent to the subject; they can also capture signals from a distance, or on-the-move. They are consequently the ideal candidate for being integrated in ambient intelligence environments and in any other ambient destined to be constantly automatically supervised. Finally, given their lower discriminatory capacity and lower degree of stability, new biometrics are often integrated in multibiometric systems, targeting a sole biometric feature but using different kind of sensors (multimodality) or several biometric features in parallel or sequentially (multibiometrics).

Ethical Implications of Biometrics for Personal Recognition

Since the 2001 terrorist attacks on the American mainland, many governments have seen in biometrics an opportunity for significant advances and breakthroughs in securing people and their assets. In the United States "Every major piece of post-9/11 federal security legislation included biometrics provisions" (Gates, 2006, p. 417). Despite this, there has been little evidence to suggest that security measures based on biometrics prevented any major act of terrorism, while on the other hand, biometric devices have begun to become commonplace in domains outside the security sphere. Border control, electronic identification and authentication, e-commerce, e-banking, and e-health have all seen significant take-up of biometric technologies.

While biometrics offer certain advantages in many of their applications (e.g., a greater convenience-to-security ratio than traditional authenticators and identifiers such as complex passwords), civil liberties and privacy advocates have argued that these advantages should be carefully weighed against the potential down and dark sides of biometrics. Biometrics, some would argue, are a key component of a pervasive surveillance apparatus, employed by governments, whose primary aim is not specifically the prevention of terrorism, but more generally to monitor and control their citizens. A sharp debate is emerging about whether biometric technology offers society any significant advantages over other forms of personal identification and whether it constitutes a threat to privacy and a potential weapon in the hands of authoritarian governments (Mordini & Green, 2008).

There are two main categories of ethical concerns surrounding biometric technologies: one is related to more fundamental issues while the other is directly related to specific biometric applications.

Fundamental Ethical Issues Raised by Biometrics

What turns bodily properties and behavioral traits into biometric features is their measurability. Only measurable anatomical and physiological features can be considered biometric features. If a human property can be measured, this means that it can be treated as a physical, quantifiable phenomenon. In other words, biometric features are human attributes described in terms of physical quantities, such as length, mass, time, electric current, temperature, amount of substance, and luminous intensity. Per se this is not outrageous, biomedical science has always quantified human bodily features for clinical purposes, but is it ethically legitimate to use this technique for identifying persons? If identity and identification concern the essence of an individual, would biometric identification run the risk to reduce the richness of human identity to a sum of mere physical quantities? Do biometric identification technologies threaten human dignity by denying humanity itself? Would biometrics be inherently demeaning? If this is the case, biometrics should be just banned, no matter what application one is considering.

This fundamental question was clearly expressed by the French National Consultative Ethics Committee for Health and Life Sciences, in the Opinion on "Biometrics, identifying data and human rights," whose importance deserves a full quotation: "Do the various biometric data that we have just considered constitute authentic human identification? Or do they contribute on the contrary to instrumentalizing the body and in a way dehumanising it by reducing a person to an assortment of biometric measurements? Is there not a possibility that this attempt to arrive at a biometric simplification, which cannot ever capture an individual's essence, could in fact lead to misrepresentation, to seeing nothing but the biometric persona, however scientifically determined? They may reduce human beings to an accumulation of data and cartographic criteria" (French National Consultative Ethics Committee on Health and Life Sciences, 2007, p. 3).

Italian philosopher Giorgio Agamben first formulated the argument that is, still today, the reference for all those who contend the ethical legitimacy of biometric technologies themselves. Agamben (2008) argues that the gathering of biometric data is a form of biopolitical tattooing, akin to the tattooing of Jews in Auschwitz extermination camp. "The problem – Agamben states - concerns the juridical-political status (it would be simpler, perhaps, to say bio-political) of citizens of the so-called democratic states where we live. [. . .] There has been an attempt the last few years to convince us to accept as the humane and normal dimensions of our existence, practices of control that had always been properly considered inhumane and exceptional" (p. 201). The arguments runs at it follows, the body features that human beings use in everyday life to identify their fellows are biographical signs, embodied languages, which tell the biography of the subject. This is the case with human faces, body gestures, voices, odors, and even wrinkles and scars, which tell the story of the subject and are inscribed into her biography. Human bodies are truly words made flesh. This is the dimension which would be nullified by biometric identification. Biometrics are pure bodily signatures mechanically extracted from our bodies by impersonal devices. They speak of our biology rather than our biography. In this sense biometrics would not only depersonalize the subject, but they would definitely dehumanize her. Biometrics – concludes Agamben's argument – turn the human persona into bare life, which can be scorned, humiliated, and finally exterminated. Ancient Greeks had two words for life, *zoe* and *bios*. *Zoe* is the life common to animals, humans, and gods, just life. *Bios* is life that is particular to humans, particular because it is life in the human context, with meanings and purposes. Agamben argues that there are times when rulers create indistinct zones between human life (bios) and bare life (zoe). Following Carl Schmitt and Walter Benjamin, Agamben calls these times "states of exception." In states of exception, humans are stripped of all meanings except the fact they have life and that life, like the life of an animal, can be taken at any point without it being considered murder, as happened in the concentration camps.

Specific Ethical Issues Raised by Biometrics

Beyond the fundamental question whether biometric identification is itself demeaning, there are a number of ethical issues that have been raised in the last decade about particular technologies and some specific biometric applications. They can be categorized under three main issues: (1) questions which are related to privacy and data protection, (2) questions which are related to the so-called surveillance society, and (3) questions which concern large-scale applications.

Biometrics and Respect for Privacy and Data Protection. Biometrics have generated several privacy and data protection concerns, most of them are related to the degree of protection to be accorded to biometric data and to the legitimacy of biometric database. Finally, some questions have been also raised in relation with biometric data sharing, notably for security and law enforcement purposes.

Is Biometric Data Personal Data? By definition personal data is any data which is related to an identified or identifiable person. It is important to note that it is still personal data, any data which – complemented by further information – could drive to identify an individual. This specification, which could not pose particular problems in the past, is today quite problematic because of the increasing capacity for data mining processes. As a matter of fact, today almost any detail concerning an individual could be used, at least in principle, to identify her. Personal data is thus destined to become an ever-expanding area. This is quite relevant because most legislations deserve a special protection to personal data, in particular when data is sensitive, say, when it concerns (a) the racial or ethnic origin of the data subject, (b) her political and philosophical opinions, (c) her religious beliefs or other beliefs of a similar nature, (d) her physical or mental health condition, (e) her sexual life or orientation, and (f) her criminal record. In all these cases, personal data can be collected only for one or more specified and lawful purposes and only provided that they are adequate, relevant, and not excessive in relation to the purpose or purposes for which they are processed. Moreover, data should not be kept for longer than is necessary, the data subject should be notified, and she should provide her informed consent to data collection and have the right to rectify and erase data in any moment. It is out of discussion that biometric row data (the analog representation of biometric features as they are captured by sensors) is personal data; what is instead controversial is to what extent they are sensitive data and whether biometric templates should be considered personal data as well. In principle biometric data, although personal, should not be considered sensitive because it does not concern any category of sensitive data. Moreover, most biometric features are public, and it would be bizarre to consider, e.g., face aspect, voice intonation, and body shape as human attributes which deserve special protection. Yet it has been argued – not without reason – that what turns bodily attributes into biometric features is the specific process through which sensors capture the signal and translate it into digital representations. Algorithms generate a new item which is no longer a pure bodily attribute, but it is a new digital entity; what is the ethical and legal status of the digital body? Who owns digital representations of the body? Do they deserve the same protection that the law reserve to flesh body parts? Some have argued that digital body representations should be considered as an extension of the physical body (Rodotà, 2011). Such an extreme position was espoused by the European Group of Ethics (EGE), the ethical advisory body of the president of the European Commission. The EGE Opinion n.20 on Ethical Aspects of ICT Implants in the Human Body reads, "We shall not lay hand upon thee". This was the promise made in the Magna Carta – to respect the body in its entirety: *Habeas Corpus*. This promise has survived technological developments. Each intervention on the body, each processing operation concerning individual data is to be regarded as related to the body as a whole, to an individual that has to be respected in its physical and mental integrity. This is a new all-round concept of individual, and its translation into the real world entails the right to full respect for a body that is nowadays both physical and electronic. In this new world, data protection fulfills the task of

ensuring the "habeas data" required by the changed circumstances – and thereby becomes an inalienable component of civilization, as has been the history for *habeas corpus*" (European Group on Ethics in Science and New Technologies, 2005, p. 29). According to this perspective personal data protection would be the most relevant legal instrument safeguarding individual freedom against any arbitrary state action, notably when data concerns the human body as it is the case with biometrics. Actually in the proposed reform of the European Data Protection Directive, the European Commission has proposed to the European Parliament to consider biometric data sensitive by default, as the same level of data concerning religion, ethnicity, sexual life, etc. (European Data Protection Supervisor, 2013).

A further data protection issue raised by biometrics concerns the ethical and legal status of biometric templates. Templates are not directly and easily linked to any bodily feature. Actually they are normalized digital representations obtained by processing through proprietary algorithms the outputs of biometric sensors. Would it be possible to reverse the algorithm and reproduce the original biometric sample? This is one of the main current controversies surrounding the status of biometric data. The issue is much more nuanced than it could appear (Yanushkevich, Stoica, Shmerko, & Popel, 2005). First of all, there is not only one biometric and one modality, and it makes little sense to tackle this issue in general terms. As a matter of fact, there is evidence that some biometric templates can be partly reversed but it is limited to a few biometric modalities (fingerprints, face, and more recently iris). Moreover, one should understand well what "reversing" means. Many people fear that it is possible to reconstruct the original biological and behavioral characteristic of an individual from a template. This is an urban myth. In some cases templates could be used to re-create artifacts that might be exploited for spoofing the system (e.g., fake fingerprints or a facial mask), which is admittedly a serious security breach. Yet till today, it has never been possible to duplicate faithfully the original body feature as it exists in real life. In addition the current trend is to encrypt templates so making almost impossible to reverse them. Decisions about the ethical and legal status of biometric templates may have important practical consequences because – if template were judged less privacy threatening than row data – legislations could mandate to store only them in biometric systems, so preventing some data protection objections to biometrics.

Biometric Databases. Biometric databases are one of the most controversial areas of biometrics. The main aim of these databases is to prevent citizens from establishing more than one identity by obtaining several identity documents (e.g., passports, ID cards, social security card) with different names. Such a risk is particularly serious in those states which do not possess a general register of residents or are introducing it at the same time as the new identity documents. However, the creation of centralized biometric databases accessible over networks in real time presents significant operational, security, and privacy concerns. Operational and security concerns include:

1. Risk of collapse of the system: if networks fail or become unavailable, the entire identification system collapses.

2. Security risks: in order to prevent system collapse, designers often build in high redundancy in parallel systems and mirrors; this increases security risks and vulnerabilities.
3. Large centralized biometric databases represent significant targets for hackers and other malicious entities to exploit. There are significant risks associated with transmitting biometric data over networks where they may be intercepted, copied, and tampered with, often without any detection. Privacy concerns include:
    1. Function creep: large centralized databases are alleged to be more prone to function creep (secondary uses) and insider abuse.
    2. Proportionality: considering operational and security risks, some argue that there is no proportionality between risks and potential benefits; yet this critically depends on the goal that the users are trying to achieve with the system.
    3. Sensitive data: when large-scale biometric databases store the full and complete images of the biometrics involved in addition to the templates, all privacy risks are exacerbated.

The current situation is mixed and together with countries which have adopted centralized biometric databases (e.g., Finland, Sweden, Norway) or are about to (e.g., France, UK), others did not. In particular, it is worth mentioning Germany, where the Parliament had ruled out the possibility of a biometric nationwide database. According to the German Parliament, a central biometric database would be incompatible with the *Recht auf informationelle Selbstbestimmung* (right to informational self-determination) which forms part of the fundamental rights of the German *Grundgesetz*. In the USA, the main limitation to biometric data collection is provided by the Fourth Amendment which protects against unreasonable searches and seizures.

A further issue raised by biometric databases concerns the creation of multimodal and multibiometric databases, which may embrace several biometrics including DNA, often linked with other databases, such as credit card databases, costumer databases, social insurance databases, and electronic health record databases. Although data linkage is often justified by reasons of efficacy and effectiveness, it is apparent that the capacity for eliciting sensitive personal information of these large data networks is huge. Although some legislations (e.g., in the EU) formally prevent data linkage and fusion, other legislations do not address this issue, and several data fusion centers have been created in the last decade by the US Department of Homeland Security and the US Department of Justice. Actually the only way to prevent data linkage would be to create non-interoperable databases, because if databases are technically linkable, it will be always possible to public authorities to overcome legal barriers by using an executive order (e.g., public health emergency, threat to national security, or any other "exceptional situation").

Biometric databases also increase the risk of function creep. "Function creep" is the term used to describe the expansion of a process or system, where data collected for one specific purpose is subsequently used for another unintended or

unauthorized purpose. Although some examples of function creep are fairly innocuous, function creep has always the potential to erode public trust and destroy confidence in a given system. When function creep results from a deliberate intention, it represents a serious ethical breach. In the context of biometric applications, one should distinguish between two different situations: when biometrics are used beyond the limits for which the system was officially adopted and when biometrics are misused to generate extra, unauthorized information. As regards the former, it is evident that any identification scheme can be carried out with a hidden agenda (e.g., sorting out some social groups, eliciting the feeling of being under observation in the subject) and biometrics are no exception. According to the ISO SC37 Harmonized Biometric, in these cases one should refer to a "subversive use" of biometrics – i.e., an attempt to subvert the correct and intended system policy – rather than to function creep. Biometric systems might also be misused to generate details that are not relevant to personal recognition and which could be exploited for unintended or unauthorized purposes. This holds particularly true when row biometric data (analog representations, such as photographs, tapes, images) is stored in the system. Misuse also entails risks of stigmatization and discrimination against ethnical and religious minorities, persons with disabilities or suffering from any medical disease, and older people. Sensitive information could be elicited from raw biometric data; for instance, faces could be suggestive of ethnicity, religious beliefs, sexual orientation, as well as political/philosophical opinions; most biometrics could also unravel medical sensitive information (e.g., metabolic diseases which alter face or body shape, vessel diseases which make impossible to collect hand vein images); also physical and mental disabilities could be revealed by some biometrics (e.g., demented persons could be unable to follow operator's instructions, people suffering from certain neurological disabilities could be unable to keep their fingers still for the time necessary to keep their fingerprints, blind persons may have difficulty in getting themselves aligned with the iris scanner).

Biometric Data Sharing. There are many reasons for sharing biometric data between different actors and agencies; however, when speaking of "biometric data sharing," one usually refers to sharing biometric data between nations for security and law enforcement purposes. The better known international agreements about biometric data sharing are the "Prüm Treaty" and the "Five Country Conference Protocol." The Prüm Treaty is an agreement about 13 EU member states (Austria, Belgium, Estonia, Finland, France, Germany, Hungary, Italy, Luxembourg, Netherlands, Romania, Slovenia, Spain) for mutual online access to national fingerprint and DNA databases. The Five Country Conference Protocol is an agreement to share biometric data in the form of fingerprints for security and law enforcement purposes. The Protocol includes the UK, Australia, Canada, United States of America, and New Zealand. A similar multilateral initiative is in progress also within the countries of the Association of Southeast Asian Nations (ASEAN). Moreover, there are various bilateral agreements for biometric data sharing between single countries.

Data sharing poses a number of technical problems – which chiefly concern standards and technical interoperability – as well as momentous political and

ethical issues. The main issue is likely to be reciprocity. Provided that all actors in principle agree with the need to ensure a basic level of data protection and respect for informational privacy to these databases, the international community has widely divergent views about acceptable levels of data protection, and to date there is not agreement on common international privacy principles which could provide a framework for the use of biometric data. The EU, for instance, prohibits transferring personal data of EU citizens to a country or territory outside the EU unless that country or territory ensures the same level of data protection of the EU. Official stances of this kind are unavoidably destined to create dead-end situations, as it has happened, for instance, with an endless discussion between the EU and the USA about data sharing of air passengers. On the one hand, in today's globalized and interconnected world, it is simply unthinkable the idea to limit data flow only to a group of country; on the other hand, it is hard to imagine that all countries would share the EU vision on privacy and data protection. The level of privacy protection of biometric data shared also includes the issue whether it is proper – and if so, under what circumstances – for Armed Forces to share biometric data gathered in a combat or peacekeeping mission with law enforcement and immigration authorities of their own country or of other countries. This leads to the main – and probably more worrisome – ethical issue in international biometric data sharing. Basically shared biometric databases consist of a mixed population of data, which includes sentenced criminals, persons only suspected of illegal activities, comprising alleged terrorists and drug traffickers, immigrants, etc. Data collected for noncriminal purposes, such as immigration-related records, is combined with and being used for criminal or national security purposes with little to no standards, oversight, or transparency. The ethical legitimacy to put all these categories of persons together, to share their biometrics, and eventually to treat them as they were all (potentially) dangerous criminals is highly questionable.

Biometrics and Surveillance. The word "surveillance" is a French word which literally means oversight, supervision (*surveiller*). The first attested usage of this word dates back to 1768 (Centre National de Ressources Textuelles et Lexicales, 2013) in the *Éphémérides du Citoyen*, which was the first, and most influential, economics periodical to be published in France. During the French Revolution, a network of Surveillance Committees was set up by the National Convention by a law of 21 March 1793 with the task of monitoring all foreigners, listing and arresting suspects. Interestingly enough they were also in charge of delivering citizenship certificates (Lapied, 2002).

Michel Foucault has been the main contemporary scholar who focused on the relationship between power and surveillance. He was intrigued by the role of surveillance in inducing social conformity and self-discipline. The point of departure for the French philosopher was that power tends to be exerted by controlling bodies, through a widespread surveillance apparatus, rather similar to the network of revolutionary Surveillance Committees (Foucault, 1980). Foucault defines the "disciplinary society" a society in which all bodily aspects of life are carefully monitored by different agencies including law enforcement authorities, the school system, the judicial system, and the public health system.

Later scholars have pointed out that Foucault's disciplinary model has been today replaced by a "society of control" where the political problem is no longer monitoring citizens, but rather managing the endless flow of persons, goods, and personal information. In the society of control, "what is important is no longer either a signature or a number, but a code: the code is a password (. . .) The numerical language of control is made of codes that mark access to information, or reject it" (Deleuze, 1992, p. 6).

Biometric identification technologies not only open the door to an enormous potential for surveillance in more traditional terms, but they seem to be integral to the ideal of the new "society of control." Through biometrics one can identify, trace, and monitor the continuous flow of people which constitutes one of the main elements of globalization. By allowing identification processes on global scale, biometric technologies could in principle even provide a unique and unambiguous identifier to each world inhabitant. "If the international system did embrace extensive use of biometrics or another globally unique identifier, the move could signal the effective end of anonymity. It would become feasible to compile a complete profile of a person's activities – including where the person has gone, what he has spent money on, with whom he has been in contact, what he has read, etc. This death to anonymity would meanwhile be coupled with asymmetry in information: the individual's every move could be monitored, yet he may not have any knowledge of this surveillance. Beyond privacy, such a state of affairs does not bode well for the exercise of other fundamental freedoms such as the right to associate or to seek, receive, and impart information – especially as the intimidation of surveillance can serve as a very restrictive force" (UNESCO. Information for All Programme, 2007, p. 40).

Reliability of Biometric Technologies. A further issue related to biometric surveillance as well as biometric databases and large-scale applications concerns the robustness and reliability of biometric systems. As mentioned earlier, biometric recognition is probabilistic in its nature; it means that there is always a percentage of false positive (people erroneously recognized) and false negative (people erroneously *not* recognized). This could be acceptable provided that the margin of error of each specific application is carefully calibrated according to the particular context in which the biometric system is deployed. This is not a purely technical question; on the contrary, it implies nuanced ethical, legal, and political decisions. Think, for instance, of biometric systems used for surveillance and biometric systems used for forensic purposes. The principle of presumption of innocence is a main tenet of western juridical civilization. This principle dictates that a court should always choose the interpretation that favors the defendant. It implies that in order to be accepted as an evidence, biometric systems should be calibrated in a way to minimize false positive even if this implies a higher rate of false negative (this would not be the case with old, analog fingerprint recognition based on experts' eyes, which were not probabilistic in essence). But if the same system is used, say, for screening air passengers, it should be calibrated in a way to minimize false negative, say, the odds that a terrorist escapes security checks, even if this implies a higher rate of false positive, say, innocent passengers unjustly stopped at

the biometric checkpoint. Moreover, it is almost impossible an (ethically) proper calibration in the case of large-scale applications, where a false (negative or positive) rate of, say, 0.1 % may correspond to many thousands of recognition errors. In any case the number of people affected by biometric errors would be disproportionately high.

Beyond issues raised by biometric errors, there are other aspects related to system reliability that should be considered. The first one is vulnerability to attacks. Generally speaking, there are two types of attacks, direct and indirect. Direct attacks are performed at the sensor level outside the digital limits of the system, and therefore no digital protection mechanisms can be used. In a direct attack, also called spoofing, a person tries to masquerade as another one by falsifying data and thereby gaining an illegitimate advantage. Indirect attacks are performed inside the system and are due to intruders, such as cyber-criminal hackers, by bypassing the template generator or the matcher, by manipulating the templates in the database, or by exploiting the possible weak points in the communication channels. While countermeasures against indirect attacks pose the same ethical and legal problems posed by any measure of cybersecurity, countermeasures to spoofing attacks are more problematic. The typical countermeasures to spoofing attack are aliveness detection that aims at detecting physiological signs of life and consequently prevents identification with dead body parts or artificial copies and multimodal biometrics. The main problem with both these countermeasures is that they increase disproportionately the amount of personal information gathered by, and stored in, the system, which is extremely questionable in terms of respect for privacy and data protection principles. In other words, in order to make the system less vulnerable to attack, one is often obliged to increase its informational intrusiveness to a degree which would be hardly acceptable. This problem is going to become more and more complex. For instance, current research to prevent possible attacks based on unconscious or enforced identification and volition control is investigating the possibility of using biometrics (e.g., electrophysiological biometrics) for intention and emotion detection.

Finally there is a third aspect of reliability of biometric systems, which concerns their security, notably the risk of identity theft. Identity theft occurs when someone uses a person's name and sometimes other parts of their identity – such as their biometrics – without the person's knowledge or consent to obtain services or goods or uses the person's identity information to make false claims for services or goods. In principle biometrics could make identity theft harder. On the other hand, any biometric system can be attacked by stealing the identity of security-cleared users, and only the user himself can know of an identity theft attack is ongoing. The problem with biometric identity theft is that a biometric identifier cannot be easily changed as a PIN or a password. In particular, when a strong biometric feature has been stolen and duplicated, its usability is lost forever. In other words, a stolen biometric feature is a sort of "digital amputation," which makes that biometric feature definitely useless for identification purposes. A possible strategy to circumvent the risk of biometric identity theft is to avoid using strong biometrics and to adopt systems based on weak biometrics and multibiometrics. It is also important to

avoid large databases, which can be easily attacked, and prefer systems based on authentication (one-to-one) rather than on identification (one-to-many). However, the risk that a biometric system – created with the aim to increase personal security – could generate more vulnerabilities both to people and to their assets poses serious ethical and political questions.

Large-Scale Applications. The advent of large-scale applications has been one of the most important events in biometrics. Many countries, including the USA and the EU, incorporate biometric data into passports, ID cards, visas, and other documents for use in large national-scale automatic biometric identification systems. In the USA, for instance, there are two largest biometric databases in the world, each one of them holding more than 100 million records, the FBI's Integrated Automated Fingerprint Identification System (IAFIS) and DHS's Automated Biometric Identification System (IDENT), which is part of US-VISIT program.

Technically speaking, large-scale systems have several requirements, which include high-level scalability, considerable computational power, and support for large databases (tens or hundreds of millions of records). From an ethical point of view, they should respect all privacy and data protection requirements that have been previously discussed. Their potential for surveillance has been also debated and should not be overlooked.

More recently, however, a new category of large-scale applications has emerged, applications for economic, political, and social purposes in low-income countries. The most impressive example is the India's Universal ID program, which aims to provide a unique identity to 1.2 billion residents.

Most low-income people in countries in Africa and South Asia have weak and unreliable documents, and the poorer people in these countries do not have even those unreliable documents. In 2000, UNICEF calculated that 50 million babies (41 % of births worldwide) were not registered at birth and thus destined to lack any reliable identity document in the future. In a world system where nearly all states in low-income countries are not able to provide their citizens with reliable identity documents, biometrics is likely to be the sole hope for most of these people to have trustworthy identity documents. This is critical for many reasons, not the least because identity documents are essential to ensure respect for fundamental rights. "For many—refugees, potential voters or pensioners—some form of official documentation can be an essential step towards security, freedom, entitlement and inclusion (. . .) The utility and morality of identity systems and technologies depend largely on context, perspective and need. The identity gap between rich and poor countries also shapes the debate on identification and the specific role of biometric technology. In rich countries, biometric identification is mainly used in areas relating to security and policing (. . .) In poor countries, biometrics is more commonly employed in developmental applications. This is not always a clear distinction. Some "developmental" identification programs in poorer countries have been influenced or driven by security concerns. Conversely, some rich countries have used biometric identification for broader purposes (. . .) However, the overall picture is an emphasis on surveillance in richer countries and an emphasis on authentication or verification in poorer ones" (Gelb & Clark, 2013, p. 12).

It is important to emphasize that biometrics are the only large-scale identification systems that could also be run by small private actors and independent agencies instead of heavy governmental structures. This would make possible to imagine a global system for personal recognition starting from low-income countries, which would be closer to the Internet than to the Leviathan. The fear that biometrics might lead to a unique, global identifier – a digital cage from which one could never escape – is probably misplaced. On the contrary, biometrics could permit to create separate digital IDs for particular purposes by applying different algorithms to the same biometric characteristic or by selecting different biometric features of the same individual and using weak and multiple biometrics. As well as providing the appropriate level of security for each application, this would make it much easier to revoke biometric templates if they become corrupted or are stolen. Still more important, these processes do not need cumbersome, centralized structures but can be easily implemented by a web of local authorities, as it has been demonstrated by the penetration of biometric technology and applications in Asian and African markets.

Biometrics vis-à-vis the Universal Declaration on Bioethics and Human Rights

As previously mentioned, automated biometrics are "borderland" technologies, in the sense that they are at the intersection between medicine, life sciences, information, and security technologies. While discussing ethical issues raised by biometrics, it is then particularly relevant to consider the Universal Declaration on Bioethics and Human Rights, which specifically addresses "ethical issues related to medicine, life sciences and associated technologies as applied to human beings" (UNESCO, 2005, p. 76).

The main principles of the Declaration that are relevant to biometrics are likely to be Article 3 (Human dignity and human rights), Article 6 (Consent), Article 8 (Respect for human vulnerability and personal integrity), Article 9 (Privacy and confidentiality), Article 10 (Equality, justice and equity), Article 11 (Non-discrimination and non-stigmatization), and Article 12 (Respect for cultural diversity and pluralism).

Article 3 reads that "1. Human dignity, human rights and fundamental freedoms are to be fully respected; 2. The interests and welfare of the individual should have priority over the sole interest of science or society." One should emphasize the central role played by respect for human dignity, which requests a serious ethical scrutiny of dignity issues raised by biometrics, and the priority accorded to interests and welfare of the individual over societal interest. The former point is essential to understand the current debate about security and surveillance technologies. In case of conflict between the interest of the individual and the interest of society, the individual must prevail. To be sure, it is often possible to frame security problems in win-win terms, and many alleged conflicts between individual rights and security needs could be solved by increasing both individual rights and societal security,

yet when a real conflict exists, the Declaration points out that the sole, tenable, ethical solution consists in giving priority to individual rights.

Article 2 (Consent) requires that "scientific research should only be carried out with the prior, free, express and informed consent of the person concerned." This article does not limit the need for informed consent to biomedical research, but extends this principle to "scientific research" in general. This unavoidably implies that research on biometrics, when it involves human beings, should undergo to the same strict regulations which rules the discipline of informed consent in medicine. Of course this should not entail the simple transposition of bioethical rules to biometric research, but it demands that informed consent is carefully considered and tailored on the specific situation of biometric research.

Article 8 deals with respect for human vulnerability and personal integrity and requires that "individuals and groups of special vulnerability should be protected and the personal integrity of such individuals respected." The relevance of this article to biometrics dwells on the actual risk that biometric applications are not properly designed in order to ensure full accessibility to disable and disadvantaged individuals and groups. In particular, in case of large-scale applications, it is paramount that engineers apply principles, methods, and tools to promote universal design of biometric devices and disabilities should not prevent the usage of biometric recognition systems.

Article 9, which focuses on privacy and confidentiality, has an obvious relevance to biometrics. In particular, this article requires that collection of personal information is consistent with "international human rights law." It implies that in the deployment of biometric application, it should be mandatory to carry out a wider human right impact assessment, which includes, but it should not be limited to, a privacy impact assessment.

Article 10 (Equality, justice and equity), Article 11 (Non-discrimination and non-stigmatization), and Article 12 (Respect for cultural diversity and pluralism) collectively draw the attention on the risk that biometric identification could favor discrimination, stigmatization, and racial and ethnic harassment. This is a real risk, notably in large-scale applications and if biometric databases are used for people profiling. This is not, however, the unavoidable destiny of biometrics. On the contrary, as previously mentioned, biometrics could become an important component of developmental policies in low-income countries by facilitating civil identification and, indirectly, promoting equality, justice, and equity.

Conclusion

The need for recognition schemes is inherent to human civilization itself. With biometrics, for the first time in the history of human species, human beings have really enhanced their capacity for personal recognition by amplifying their natural, physiological, recognition scheme, based on the appreciation of physical and behavioral appearances. Complex personal recognition schemes, tattoos, seals, passports, badges, safe-conducts, passes, passwords, PINs: biometrics would

make obsolete all these traditional identification paraphernalia and – at least in the long run – promise to replace all of them. This is not, however, without ethical risks, and a cautious and mindful approach is required.

Real-life applications of biometric technologies – being fundamentally embedded in societal structures, historical narratives, the development of state authority, and so on – are concerned with more than pure biology or pure physicality. As such, the process of abstraction and reification from which the biometric body would emerge according to Agamben and other radical critics is itself a philosophical abstraction. In other words, although rhetorically suggestive, philosophical arguments against biometrics are hardly tenable. Biometrics themselves are not likely to threaten human dignity more than any other modern technology.

People – and sometimes scholars – are victims of the illusory belief that personal identification per se threatens basic liberties and infringes the private sphere. To be sure, any process of personal identification implies that individuals are recognized subjects of rights and obligations, and this could be seen as a limitation of individual liberty. Yet there would be no rights, no liberty, without personal identities. No political, civil, and social right can be enforced on anonymous people. One can claim her rights, including the right to refuse to be identified, only if she is an identifiable subject and if she has a public identity.

In ancient Greece, slaves were called "faceless," *aprosopon*. The word that in Greek designates the face, *prosopon*, is also at the origin of the Latin word *persona*, person. The person is thus an individual with a face; this is to say, out of metaphor, one becomes a person when she is identifiable. Biometrics could contribute to give a face to such a multitude of faceless people who live in low-income countries, contributing to turn these anonymous, dispersed, powerless crowds into the new global citizens.

Certainly, then, there are reasons for the ethical and political concerns surrounding biometrics, and a careful democratic scrutiny of biometric applications is needed; but these reasons are fortunately balanced by some reasons for hope.

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Clinical Research in Resource-poor Settings

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Jan Helge Solbakk and Susana María Vidal

Introduction

This chapter addresses the ethical challenges pertaining to clinical research in resource-poor settings. First, a brief account of the history of biomedical research ethics in four different stages is provided, emphasizing elements of particular relevance in the present context. Second, the impact of the global spread of the neoliberal market model on the conception and organization of biomedical research is analyzed, including key drivers and factors behind the so-called globalization of biomedical research, the dramatic outsourcing of clinical research during the last 15 years to poor and low-income countries, and the implicated deregulation of international ethical guidelines and declarations pertaining to clinical research in resource-poor settings. Third, some key concepts and measures about human development, poverty, and resource-poor settings are introduced, emphasizing the need for implementing comparative measures able to reflect the level of human development in a more fine-tuned way than which is possible by applying the gross national product (GNP) per capita criterion. For these reasons, it is proposed to view the concept of "resource-poor settings" and the characteristics of health systems in such settings in light of the Human Development Index, as well as through other metrics suggested by the United Nations Development Program, UNDP, such as the Human Poverty Index, HPI. Fourth, the conception of social vulnerability is introduced, so as to be able to differentiate between different situations of special

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J.H. Solbakk (✉)
Centre for Medical Ethics, Institute of Health and Society, Faculty of Medicine, University of Oslo, Oslo, Norway
e-mail: j.h.solbakk@medisin.uio.no

S.M. Vidal
Latin American and Caribbean Bioethics Programme. SHS. UNESCO Montevideo Office, Especialista de Programa. Programa para ALC de Bioética de la UNESCO Oficina Regional de Ciencia de la UNESCO Montevideo, Montevideo, Uruguay
e-mail: svidal@unesco.org.uy; suvidalmonte@gmail.com

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vulnerability necessary to observe when conducting clinical research in resource-poor settings. In connection with this, it is also suggested to make use of the capabilities approach to human development and human poverty developed by Martha Nussbaum. Capabilities are here understood as the foundation of basic political principles, which are to be constitutional guarantees, and become the basis of human rights and an essential contribution to an all-out notion of justice. Consequently, capabilities are viewed as a universal pattern which applies to all individuals alike, and finding out about capabilities thus implies inquiring about what an individual or group of individuals is able *to be and to do* with their lives, and what resources are available for them to fully develop as human beings. Fifth, from this vantage point, the debate about exploitation in international clinical research is critically scrutinized, and it is claimed that those who reduce exploitation to unfair *distribution* of benefits fail at a crucial point because the analysis of the fairness of an interaction cannot be done on the basis that the reality of the community or of individuals is a fact of the world that falls outside the scope of consideration. An alternative analytical approach is suggested, that is, that in order to analyze fairness in an ethically sustainable way, one should take into account the conditions of vulnerability, including the trigger factors, the human needs of the individuals and communities implicated, the opportunities that they have had and they currently have to make decisions, and the scope of real options available to them; and finally, the opportunities that the individuals have had to develop their capabilities. Sixth, the concepts of risk, benefits, needs, and compensation in biomedical research are made the subject of a similar analysis, and the introduction of a human-rights-based and capabilities-oriented approach to biomedical research is suggested, something that would assert that some goods are nonnegotiable values and that the baseline is determined by the previous human rights prevailing condition of the individuals taking part in the research. Therefore, any intervention intended to satisfy an unsatisfied basic human need (human right) should not be referred to as benefit in research. It is a right, and fulfilling it is a legal and ethical obligation; consequently, any interaction that would take advantage of this situation should be deemed as a potential exploitation of vulnerable subjects. Finally, referring to Article 15 of the Universal Declaration on Bioethics and Human Rights on benefit sharing, the global responsibilities pertaining to multinational research in communities with low human development are briefly addressed.

The Four Stages of Biomedical Research Ethics

Even though the history of research ethics can be traced back to the onset of medicine (and there are several narratives about this; see Annas & Grodin, 1992; Gracia, 1998; Jonsen, 1998; Rothman, 1995), it is in the twentieth century that this history takes a decisive turn, in particular with regard to two aspects: first, the expression of international norms pertaining to biomedical research ethics in public policies and state regulations, and second, the emphasis on a clear link between human rights and the rights of subjects of research. Three stages have been

identified in this history, the last one dating back to 1947 and named by its author "the regulated clinical research and the new ethics of responsibility of experimenting with human beings" (Gracia, 1998). The main characteristic of this stage is precisely the establishment of a normative framework that regulates medical practices linked with research, that is, a model of responsibility that governs medicine so as to strike a balance between the intentions to obtain new knowledge and the practices carried out to achieve it by involving human beings. Consequently, research should be carried out without any kind of discrimination, with informed consent and with a rigorous benefit-risk evaluation. Three fundamental normative documents witness this history, two of which represent an accurate and clear reflection of the reaction that the Western World had against the horrors of war, and a much later third one reflecting the consensus of the World Medical Association with regard to the ethical standards that should govern the practice of physician investigators. These three documents are the Nuremberg Code (1947), the Universal Declaration on Human Rights (1948), and thirdly the Declaration of Helsinki (1964). The normative orientation characteristic of these documents is their rootedness in human rights, something which has been followed up in the Convention on Human Rights and Biomedicine of the Council of Europe (1997) and in the declarations adopted by UNESCO, in particular the most recent one, that is, the Universal Declaration on Bioethics and Human Rights (2005), UDBHR. The core assumption and commitment that links these normative documents and gives rise to what has been called a *universal ethical standard* is that all human beings are entitled to egalitarian treatment based on the respect of their dignity and personal integrity. The notion of human dignity is already present in the Preamble of the Declaration of Human Rights and in its Article 1 it is stated: "All human beings are born free and equal in dignity and rights. They are endowed with reason and conscience and should act towards one another in a spirit of brotherhood." Also, the Nuremberg Code is inspired by this notion, and the World Medical Association subsequently took respect of dignity and integrity to be the basis on which the whole normative structure of the Declaration of Helsinki was to rest: "In medical research in human beings, the concern about the well being of human beings must always be given primacy over the interests of science and society " (Article 5), thus placing respect for human beings above any other interest, even that of science and society as a whole, and leaning away from the paradigm that had marked science until then. In the late 1970s, a new normative model emerged, based on the so-called Belmont Report (The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979). The report was a reaction to one of the most infamous forms of biomedical research carried out in the United States, that is, the Tuskegee Study, an observational study conducted between 1932 and 1972 in the state of Alabama, and involving black people suffering from syphilis who were deprived of treatment even though efficient treatment to stop the disease was available (Brandt, 1978). In terms of normative orientation, the Belmont Report took distance from the human-rights-based frameworks mentioned above and proposed instead a framework inspired by the Anglo-American liberal tradition. Three basic ethical principles were suggested to deal with ethically

conflictive situations involving research with human beings: the principles of respect for persons, beneficence, and justice. In addition, the report suggested using these principles as a method to assess research, and it even moved a step further by proclaiming existing ethical codes and declarations as inefficient. Thus, a new pathway toward normative development was opened – *principlism* – deviating from the human-rights-based approach rooted in human dignity (Beauchamp & Childress, 1979). The recommendations of the Belmont Report were promptly adopted and backed by the American Medical Association and other medical organizations in the United States, and in practice, it became a much more influential normative document than the previously suggested codes and declarations. As will be shown later, the principlist framework proposed in the Belmont Report differed from the human-rights-based approach not only in terms of orientation but also with regard to margins of protection of individual research subjects.

As already mentioned, most ethical frameworks pertaining to biomedical research developed in the period of 1947–1979, including the Belmont Report, were the reactive result of unethical studies performed on citizens, especially individuals belonging to particularly vulnerable groups, such as racial minorities, prisoners, mentally ill or incapable people, and children or elderly people with serious diseases. From the 1980s, the history of biomedical research marks a difference through the implementation of a new research model named "multinational." Before this period, such studies were rare. From the 1980s onward, studies funded by high-income countries and carried out in low-income countries with participation of their populations started to flourish. In turn, this new model brought about not only different forms of research but also new and more complex ethical challenges. For this reason, it seems appropriate to add a fourth stage to the history of biomedical research, that is, the stage of "post-Helsinki and deregulation of multinational research." At least two research events have been paradigmatic with regard to the ethical challenges generated in the wake of the implementation of the multinational research model. The first event pertains to 15 clinical trials conducted in 1997, using placebo as a comparative alternative to 'standard of care' for the purpose of reducing perinatal HIV transmission, in spite of the fact that effective treatment had been available since 1994. The trials involved 17000 pregnant women and were carried out in Uganda, Haiti, the Dominican Republic, Thailand and in Sub-Saharan Africa. Three other trials conducted at the same time, two in the USA and one in Thailand, differed from the other 15 studies in two important respects: the absence of placebo-controls and the access of all patients enrolled in the studies to antiretroviral drugs. The second event was the Surfaxin Study, proposed by the Pennsylvania-based Discovery Laboratories in 2001, that is, a comparative study against placebo of a new surfactant in critically premature neonates in Latin American Neonatal ICUs. The study was suggested to be carried out in public hospitals in Peru. These trials were allegedly performed or meant to be performed with the participants' informed consent (IC), and they had a negative benefit-risk ratio for the control groups receiving placebo. Independent assessments of these studies were carried out, but the sample selection was not equitable since different ethical standards were used for the treatment of participants in the country

of origin of the protocols compared to participants from low-income countries. With the emergence of the multinational research model generated in affluent countries and used to conduct trials on groups and populations in poor and low-income countries, new forms of regulations also arose. Such is, for example, the case of the CIOMS' *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (CIOMS 1993). Its guideline number 8 pays particular attention to research involving subjects in underdeveloped communities and states:

> Before undertaking research involving subjects in underdeveloped communities, whether in developed or developing countries, the investigator must ensure that:
>
> - persons in underdeveloped communities will not ordinarily be involved in research that could be carried out reasonably well in developed communities;
> - the research is responsive to the health needs and the priorities of the community in which it is to be carried out:
> - every effort will be made to secure the ethical imperative that the consent of individual subjects be informed; and
> - the proposals for the research have been reviewed and approved by an ethical review committed that has among its members or consultants persons who are thoroughly familiar with the customs and traditions of the community.

The CIOMS guidelines from 1993 were followed by other recommendations suggested by different international governmental and nongovernmental organizations and interest groups. At the same time, existing declarations and guidelines pertaining to biomedical research, such as the Declaration of Helsinki and the CIOMS guidelines, underwent revisions so as to make it easier for researchers and companies involved in multinational research to carry out trials in resource-poor settings (for this, see below).

New Times, New Models, New Standards

The 1990s were marked by a global dissemination of a neoliberal market model following the fall of the Berlin Wall and notably as the sole model option for both high and low human development countries. This was accompanied by a new world strategy for the markets following the economic policy prescriptions established by the Washington Consensus, on basis of which Washington-based international financial institutions such as the World Bank and the International Monetary Fund instituted a new economic policy for developing countries, starting with Latin America (Washington Consensus, 2003). Alongside this, health-related companies, especially the pharmaceutical industry, developed their global market strategy in accordance with these recommendations. This new international economic order had a profound impact on clinical practice as well as on biomedical and health-related research. Three characteristics mark the new scenario of international biomedical research:

1. *A new model of biomedical research* where the financial support previously offered by international companies to the most prestigious universities and expressed in incentives for physician investigators was transformed into direct contracts with the principal researchers, notably outside academia, thus creating

a long list of conflicts of interest (Elliott, 2004; Vidal, 2006). In 1991, 80 % of the investment of the pharmaceutical industry aimed at clinical research went to researchers working in academic medical centers (under the incentive model), whereas in 1998, just 40 % of these funds went to academic institutions (Klein & Fleischman, 2002); the rest was allotted to researchers hired directly or through intermediary companies, such as Contract Research Organizations (CROs). Since 1996, it is known that most of the financial investment in biomedical research is not targeting the most demanding health needs in the world, in particular not the most prevalent diseases in poor countries impacting the global burden of disease and responsible for the major part of world mortality. It is this enormous discrepancy between prevalent health needs and research priorities that has been coined *the 10/90 gap* (World Health Organisation, WHO, 1996). This metaphor was introduced to depict the major inequity in the world with respect to whose diseases are favored in ongoing or planned research programs. In concrete terms, this means that at least 90 % of the economic resources spent annually on medical research are targeting the health needs of the richest 10 % of the world's population, which implies that the needs of 90 % of the world's population have to be met from the remaining 10 % of research funding (Solbakk & Vidal, 2012). Unfortunately, studies on the so-called globalization of clinical research indicate that this gap has not diminished, although during the past 15 years, the number of people from poor and low-income countries enrolled in clinical trials has substantially increased (Glickman et al., 2009; Matsoso et al., 2005; Petryna, 2007; Thiers, Sinskey & Berndt, 2008). On the contrary, evidence from these studies suggests that during this trial period, the relative availability of new drugs to populations in poor and low-income countries has not increased, whereas the gap between wealthy nations and poor and low-income countries with regard to who benefits from the advances of clinical research and development has continued to widen.

2. Globalization of biomedical research
   Since the 1990s, there has been an increase in research carried out by international pharmaceutical companies and research groups from affluent countries in poor and low-income countries. To illustrate this, of the 5,000 ongoing clinical trials in the world in 2007, more than 40 % were conducted in "nontraditional" research zones (Petryna, 2007). At the same time, an increasing number of phase II and III trials have been outsourced to India and countries in Latin America and sub-Saharan Africa. There are different explanations behind the steady increase of biomedical research in poor and low-income countries. First, a growing development of restrictive regulations in affluent countries, to protect the subjects of research (Moreno, 2001) combined with a highly bureaucratic regulatory system, makes the process of ethics approval more complex and slow in these countries (Glickman et al., 2009). Second, the normative standards and regulations in poor and low-income countries tend to be more flexible (or simply nonexisting), allowing researchers to use different ethical and scientific standards from those required in the countries of origin (for instance, the use of different versions of the same protocol for different countries, one including

placebo in the control group and the other, the best proven treatment). Third, the ethical assessment of research ethics committees in poor and low-income countries is less rigid, in part due to insufficient training of committee members, as well as to the pressure the committees are exposed to when they do not enjoy proper independence. A fourth explanation relates to the ease of recruiting subjects in these countries, due to the fact that big layers of the population are considered functional illiterates, and therefore sign (sometimes incomprehensible) IC forms (Lorenzo, Garrafa, Solbakk & Vidal, 2010). Fifth, no doubt, in poor and low-income countries, carrying out research is less costly and a physician and a nurse charge many times less than in a high-income country when involved in research (Glickman et al., 2009). Sixth, legal issues are less risky and insurance costs are much lower in poor and low-income countries than is the case in high-income countries. Finally, the search for new markets by pharmaceutical companies is also a factor that might help to explain the outsourcing of research to poor and low-income countries. In addition, some "noncommercial," scientific reasons for conducting research in poor and low-income countries should be kept in mind as well:

- Research into prevention and treatment of prevalent diseases in the population participating in the research
- Provision of less costly alternative treatments for the populations that have no access to existing drugs in the market
- Identification of virgin populations of treatment making evidence easier to document

3. *Normative deregulation*. The third characteristic that marks the new scenario of international biomedical research relates to the systematic attempt at relaxing the requirements embedded in international ethical declarations and guidelines pertaining to biomedical research, especially those frameworks which have enjoyed high normative credibility, such as the Declaration of Helsinki and the UNESCO Universal Declaration on Bioethics and Human Rights (UDBHR). Attempts to dilute the requirements of the Declaration of Helsinki have been oriented toward easing the ban on the use of placebo in the control group (this started with an explanatory note included in 2002 to Article 29 and became a separate article (Article 32) during the revision in Seoul in 2008); giving less importance to post-trial research obligations of researchers and sponsors to participants and communities implicated in the research; invalidating the notion of a unique standard of treatment in the case of adverse events or post-research damage; and, finally, giving less relevance to the idea that the population participating in a trial will be able to obtain benefits from the results (so clearly expressed in the former Article 19 of the Declaration (Solbakk & Vidal, 2012)). The modifications of this influential normative document have been perceived so severe by some Latin American bodies that they have declared themselves against keeping the Declaration of Helsinki as a normative frame of reference for biomedical research and have instead suggested the use of the Universal Declaration on Bioethics and Human Rights (Declaración de Córdoba, 2008). Likewise, after the UDBHR

was approved, it became the subject of harsh criticisms (ten Have, 2006), including questioning the quality of the experts involved in the process of drafting the document and the legitimacy of the UN body behind it (Landman & Schuklenk, 2005). In addition, the human-rights-based approach of the UDBHR was discredited as a kind of "ideology" (Williams, 2005), and its reference to respect for human dignity as its foundation was seriously criticized due to the alleged unusefulness of the concept of dignity for medical ethics (Macklin, 2003). In fact, the rejection has been so strong that in some papers and books on biomedical research ethics published during the last years (Emanuel et al., 2008), the UDBHR is not even mentioned, neglecting the fact that it was approved by acclamation by all Member States of the United Nations. In the same period, different "recommendations" pertaining to ethical aspects of research in developing countries have also been suggested (National Bioethics Advisory Commission, 2001; Nuffield Council on Bioethics, 2002) as well as "consensus" documents of dubious legitimacy due to the lack of representativity of its participants (Schuklenk, 2004). Characteristic of these documents is that they go even further than the revised versions of the Declaration of Helsinki and of the CIOMS guidelines in diluting post-trial obligations and the requirements pertaining to protecting the rights of research subjects. This situation has evidently led to a weakening of international norms and frameworks as protective safeguards, especially in relation to biomedical research carried out in poor and low-income countries and on vulnerable groups and populations in these countries. At the same time, it has helped to promote the principlist model of the Belmont Report, since it appears to be more flexible and adaptable to the interests and needs of researchers and their sponsors.

Some Concepts About Development, Poverty, and Resource-Poor Settings

The term "resource-poor settings" is at least ambiguous. During the last years, there have been different ways of classifying countries and regions, some of which can be traced back to the times of the Cold War naming most of the poor countries as the Third World (Sauvy, 1952). During the last years, the World Bank has suggested an economic classification for operational and analytical purposes, where the main criterion applied is the gross national product (GNP) per capita. Based on this indicator, every economy is classified as low income, middle income (subdivided into lower middle and upper middle), or high income, even though some other analytical measures based on geographic regions are also used (The World Bank http://data.worldbank.org/about/country-classifications). Finally, in recent years, new comparative measures reflecting the level of *human development* in social groups and countries have started to be used, such as the *Human Development Index* (HDI). The *Human Development Report* has defined human development as the

process of enlarging people's choices (UNDP, 2007). According to this view, human development has three components (UNDP, 2010):

- Well-being: expanding people's real freedoms so that people can flourish
- Empowerment and agency: enabling people and groups to act – to drive valuable outcomes
- Justice: expanding equity, sustaining outcomes over time, and respecting human rights and other goals of society

The measure takes into account three aspects of human development of which income level is just one:

- Life expectancy at birth, as an index of population health and longevity
- Knowledge and education, as measured by the adult literacy rate
- The combined primary, secondary, and tertiary gross enrollment ratio, and standard of living, as indicated by the natural logarithm of gross domestic product per capita at purchasing power parity

On the other hand, poverty is conceived of as both the lack of ability to produce or develop the productive potential and the impossibility to reach a minimal acceptable vital realization because of being deprived of the capabilities, the opportunities, and the basic rights to do it. Consequently, poverty is not just a financial state, since being poor affects life in many ways. For these reasons, it is here proposed to view the concept of "resource-poor settings" in light of the Human Development Index, as well as through other metrics suggested by the United Nations Development Program, UNDP, such as the Human Poverty Index, HPI. These measures provide accurate and clear reflections of the condition of human beings and of communities, while at the same time, they also permit to include in this analysis extremely poor groups living in high-income countries, that is, groups which cannot be visualized by means of employing average standards such as the GNP measure. The Human Poverty Index uses indicators that capture nonfinancial elements of poverty, such as life expectancy, adult literacy, water quality, and children suffering from underweight. Here, the term "resource-poor settings" will refer to those that can be considered of having low human development and high human poverty.

Characteristics of Health Systems in Resource-Poor Settings

The Report of the International Bioethics Committee of UNESCO on Article 14 of the UDBHR, *Social Responsibility and Health* (IBC, 2010), states what is already well known, that is, that the greatest share of health problems is attributable to the *social* conditions in which people are born, live, and work. This fact was already established several years ago by the World Health Organization (Wilkinson & Marmot, 2003), through the introduction of the notion of *social determinants of health*, SDH. Among such determinants count poverty, overpopulation, malnutrition, lack of access to health services, lifestyles, the physical environment, genetic inheritance, migration, lack of access to drinking water, and the environmental consequences of progress. From this vantage point, the main health problems in the world

are extreme poverty and hunger, high mortality rate in children under 5, lack of maternal health improvement, inadequate prevention and control of HIV/AIDS, tuberculosis and malaria, limited access to essential medicines, and restricted access to water supply and sanitation. These are all barriers seriously impeding health improvement, and they refer to neglected diseases in neglected populations. In more concrete terms, the following data indicate the main health problems situation:

- Maternal mortality: Data from 2005 show that the maternal mortality ratio was 9/100,000 per live births in developed countries, 450 in developing countries, and 900 in sub-Saharan Africa. In the year 2008, the bulk of maternal deaths occurred in developing countries, corresponding to 99 % of women who died during pregnancy or in childbirth (WHO, 2011).
- Infant mortality: Even though this indicator has notably improved during the second half of the twentieth century in some poor countries, this situation has come to a standstill over the last years. The majority of children under 5 years die from avoidable diseases, which means that an adequate sanitary intervention might improve their condition.
- Meanwhile, infant malnutrition is still frequent. 115 million children under the age of 5 suffer from ponderal stagnation with uneven progress. In Africa, for instance, this number increased from 24 million in 1990 to 30 million in 2010. In Asia, this number is estimated to be even higher, around 71 million for the same year (WHO, 2011). About 178 million children in the world have extremely low height for age, a common used measure to indicate chronic malnutrition. These children are more likely to have learning difficulties.
- Similar realities are depicted with respect to both infectious diseases, such as pneumonia and diarrheal diseases, and to neglected tropical diseases, which affect more than 100 million people primarily belonging to poor populations living in tropical and subtropical climates. In the case of HIV, there has been progress in the prevention and treatment of the disease; however, the antiretroviral rates are still low in poor and low-income and in middle-income countries (36 % overall), with significant variations at regional level (WHO, 2011).
- Essential medicines continue being scarce and costly for poor and low-income countries. As stated by WHO: "Surveys in more than 40 mainly low-income and middle-income countries indicate that the selected generic medicines were available in only 42 % of health facilities in the public sector and 64 % of such facilities in the private sector. Lack of medicines in the public sector forces patients to purchase medicines privately. In the private sector, generic medicines cost on average 630 % more than their international reference price, while originator brands are generally even more expensive" (WHO, 2011, p. 18). These figures are of great importance when discussing multinational research, because it raises a fundamental question, whether poorly developed countries and communities should be considered vulnerable and why. Thus, this situation does not only represent a description of the state of affairs, as has frequently been the case; it also suggests a *prescriptive* orientation and draws a line under which individuals and groups should be entitled to special protection.

Social Vulnerability and Social Determinants of Health

It is a fact of the world that socially disadvantaged populations have less access to health resources, get sicker, and die earlier than those in more privileged social positions. Hence, it could without doubt be said that they are highly vulnerable populations, mainly due to social, economic, and sometimes political conditions. For this reason, they could also rightly be viewed as victims of forms of vulnerability that require special protection in a given situation as is the case with biomedical research. Article 8 of the Universal Declaration on Bioethics and Human Rights states:

> In applying and advancing scientific knowledge, medical practice and associated technologies, human vulnerability should be taken into account. Individuals and groups of special vulnerability should be protected and the personal integrity of such individuals respected.

In the Report of the International Bioethics Committee on the *Principle of Respect for Human Vulnerability and Personal Integrity* (IBC, 2011), the conditions taken into account are those that more or less directly impinge upon the capacity to live as a free, autonomous individual and the right to live in a world where significant inequalities in the capacity to meet everyone's basic needs are adequately addressed. The report distinguishes between different situations of *special* vulnerability:

- Situations that are determined by personal (permanent or temporary) disability or disease
- Situations that are related to social, political, and environmental determinants, for example, culture, economy, relations of power, and natural disasters
- Situations of vulnerability in the health-care setting, in research, and in the development and application of emerging technologies in the biomedical sciences

In the report, it is clearly shown how social, economic, and political conditions can put individuals in vulnerable situations, prior to a research-oriented intervention is conducted. In such situations, the research can contribute to an improvement of the situation or, conversely, to a worsening of existing conditions. The report goes further in the definition of the field of vulnerability when it states:

> That is also why human vulnerability and personal integrity, the other essential concept evoked in Article 8, relate to each other. When a part of our body is inappropriately 'touched' (this is the meaning of the ancient Latin verb from which the noun 'integrity' stems), our life itself, or at least our health, may be threatened. When our freedom is hampered, either by adverse circumstances or by the actions of others, we experience a "wound" to our identity, to its value and dignity. Preservation of integrity implies protection against these kinds of intrusions, the capacity to "say no" to any sort of impingement upon our freedom or to any sort of exploitation of our body and our environment. We are nonetheless committed at least to seek to ameliorate the effects of harms and disadvantages imposed by circumstances. This is a prerequisite of human flourishing and self-fulfillment. (IBC, 2011, para 8, p. 3)

The different groups of vulnerable people here envisaged are people whose human development is seriously impaired and who have a high human poverty rate as well, affecting their decision-making capability that allows them to

decide what they want for themselves and the way they want and can plan their own project of happiness. It is when basic human needs are satisfied that the flourishing of those capabilities and a truly human development are enabled (UNDP, 1999).

Martha Nussbaum contends that human capabilities refer to a definition of dignity: an idea of human dignity with broad cross-cultural resonance and great intuitive power that turn it into a universal value. Capabilities are here understood as the foundation of basic political principles, which are to be constitutional guarantees, and become the basis of human rights and an essential contribution to an all-out notion of justice (Nussbaum, 2002, pp. 4–15, 70–101; Nussbaum, 2011). Capabilities constitute, then, a universal pattern which applies to all individuals alike. Finding out about capabilities thus implies inquiring about what an individual or group of individuals is able *to be and to do* with their lives, and what resources are available for them to fully develop as human beings. So far, the epistemological and normative potentials of the capability approach have not been systematically explored in relation to ethical problems surrounding human disease and health, let alone the issue of biomedical research. However, since the approach establishes a link between human development and human rights, it provides a framework making it possible to identify ethical problems in such a way that they reflect the reality in which they are created (Vidal, 2010). This refers both to the trigger factors that determine them and the way to solve them, and it draws as well attention to certain responsibilities regarding who is to take part in the resolution process. In addition, it refers to what ought to or ought not to be done in certain circumstances, and under what conditions biomedical research would be ethically appropriate. From the consideration that human development is linked to human dignity, which is the milestone of human rights, follows the conclusion that those individuals whose human development is seriously impaired (and are thus vulnerable) do not exercise their human rights in a proper manner, to the detriment of their personal dignity and integrity (Solbakk, 2011). Consequently, satisfying basic human needs essential for developing capabilities entails moral obligations not only for states but also for other public and private actors of the society who interact in a cooperative way with vulnerable people and populations. Furthermore, if one conceives of these types of vulnerability as affecting human dignity and integrity, then it will be easier to see why there exists no "possible transaction," no negotiation around them; rather fulfilling them is mandatory. Needles to say, states are responsible for satisfying people's needs and for promoting, protecting, and respecting human rights. Important in this context is, however, also to address the question to what extent and in what ways individuals, social groups, and – above all – powerful stakeholders, with a capacity to intervene, bear such obligations. Considerable progress has been made regarding the responsibility of states to cooperate with other states. In this respect, Article 24 on *International Cooperation* of the Universal Declaration on Bioethics and Human Rights provides invaluable guidance. Furthermore, even if the question about the obligation of other stakeholders than states with regard to satisfying people's needs and for promoting, protecting, and respecting human rights has not been finally settled, there is definitely no doubt

as to the justifiability of imposing a prohibition on actions seeking to obtain some benefits based, precisely, on such situations of vulnerability and their determining factors. This issue will be the subject of further exploration in the paragraph below when addressing the nature of benefit and the phenomenon of exploitation in biomedical research.

Exploitation in Biomedical Research

During the last few years, a fierce debate has emerged with regard to the phenomenon of *exploitation* in biomedical research. Two different approaches have gained a lot of attention in the international literature. One is related to a justice perspective where exploitation is considered as a form of injustice, in particular regarding distribution of goods involved in a certain interaction between two parts. The second approach takes as its frame of reference the Kantian and neo-Kantian concept of human dignity as the base from which each individual should be respected by him or herself, independent of the particular situation or the consequences of that situation.

Regarding the first perspective advocates of this approach usually prefer the term "transaction" among individuals who act out of their own free will, thus giving rise to forms of distribution of goods deemed as "fair." Most of the contributions pursuing this perspective have dismissed the Marxist theory of exploitation, even though it has been one of the most widely developed theories in political and moral philosophical literature, because it has been considered to be more closely related to the relative profit (value) in human labor (theory of the labor value), especially in connection with surplus value. Marxist or neo-Marxist currents are more closely linked to the distributions of profits in relation to the labor or resources provided by each party in the processes and their results (Carse & Little, 2008, pp. 206–245). Even though its application in biomedical research looks complex, the theory of value and surplus value should be reconsidered in this field. On the other hand, a group of libertarian bioethicists and philosophers in the USA also advocating a justice approach have suggested to focus the attention on and advocate the division of "social surplus" created in a given transaction. The theoretical underpinnings of this stance have been developed by Alan Wertheimer (Wertheimer, 2008, pp. 63–104). This author asserts that any research involves a *transaction* in which two aspects should be taken into account:

- The participants' voluntary nature, especially of the most vulnerable part of the transaction
- The way in which the "benefits" are distributed between the two parties interacting

This assertion, on which the so-called fair benefit approach is based, makes a distinction between "harmful exploitation" and "mutually advantageous exploitation":

> By mutually advantageous exploitation, I refer to those cases in which both parties (the alleged exploiter and the alleged exploited) reasonably expect to gain from the transaction

> as contrasted with the pretransaction status quo.... I shall generally presume that mutually advantageous transactions are also consensual. (Wertheimer, 2008, pp. 67–68)

Supporters of this stance have assigned strong importance not to "what" is at stake but "how much." They state that oppression, attack, deception, betrayal, coercion, or discrimination may be harmful to people, but it is not exploitation. From this vantage point, A exploits B when B receives an *unfair* level of benefits as a consequence of the interaction between A and B (Participants in the, 2001 Conference on Ethical Aspects of Research, 2004). Fairness is related to the burden to be borne by B and the amount of benefits to be received by A, something which applies to biomedical research. Some authors close to this perspective include further elements in their definition: "Exploitation occurs when wealthy or powerful individuals or agencies take advantage of the poverty, powerlessness or dependency of others by using the latter to serve their own ends without adequate compensating benefits for the less powerful or disadvantaged individuals or groups" (Macklin, 2004, 101–102).

The second approach to the question of exploitation draws on the tradition from Immanuel Kant and considers exploitation no longer as the unfair distribution of benefits, but rather as disrespect for human dignity. Exploitation then occurs when one of the parties "utilizes" the other one as a "mere means" or as an instrument to serve their own purpose (Carse & Little, 2008, pp. 206–245). For evident reasons, this approach does not consider the option of compensation, since *utilizing* the individual is the problem itself and such action cannot be compensated with goods. Within this position, there are also various perspectives. Some equate the respect for dignity with satisfying the criteria of informed consent ("consent-based criterion"); others consider that exploitation affects the subjective sense of dignity held by each individual, while a third group of authors hold that some actions inherently violate human dignity, as, for example, sexual exploitation and slavery (Carse & Little, 2008, pp. 206–245).

In addition to these two perspectives, there are other views which have been given very little attention in the literature, and which highlight the importance not of *what* or *how much* is part of the transaction but *why* (Carse & Little). In this respect, the whys and wherefores may refer to a number of aspects: Why does the transaction take place? Why do vulnerability situations exist? Why is an individual or population chosen to take part? Why do they voluntarily accept the terms and conditions? (Carse & Little). And what is more: why is that individual or community in a situation of vulnerability? Exploitation then occurs every time somebody obtains a benefit through another (by utilizing someone else) who is in a state of a special vulnerability (Carse & Little). As already alluded to in the paragraph on the concept of vulnerability, situations of special vulnerability define part of the discussion. Consequently, those who reduce exploitation to unfair *distribution* of benefits fail at a crucial point since analysis of the fairness of an interaction cannot be done on the basis that the reality of the community or of individuals is something given "per se" (status quo) that falls outside the scope of consideration. When it comes to analyzing fairness, one should take into account the conditions of

vulnerability, including the trigger factors, the human needs of the individuals and communities implicated, the opportunities that they have had and they currently have to make decisions, and the scope of real options available to them; and finally, the opportunities that the individuals have had to develop their capabilities. In Alex London's wording, to avoid falling into *moral minimalism*, it is necessary to take into account the economic, social, and political reality of the individuals and take it as the starting point to devise the conditions and requirements of any model deemed as "fair" (London, 2005). This does not only relate to local conditions of fairness but also to global conditions that may put (or have put) such individuals and communities at a disadvantage and lead (or have led) them into their current situation of vulnerability. The implications of the so-called TRIPS regime (Trade-Related Aspects of Intellectual Property Rights) pertaining to essential medicines illustrate this point in a dramatic way. Although this regime has been presented as the most efficient and cost-effective way of promoting medical innovations, it is a fact of the world that it represents a substantial infringement on the possibilities of producing cheaper versions of patented drugs, something which, in turn, reduces the access possibility of cost-saving-oriented patients in the affluent part of the world as well as of patients in poor and low-income countries to cheaper and/or affordable medicines. Finally, as observed by Thomas Pogge, for the group of stakeholders most in need, the TRIPS regime is undoubtedly "socially harmful" in a dramatic way: "Millions of deaths from AIDS and other treatable or curable diseases are due to the suppression of manufacture and trading of generic drugs" (Pogge, 2008, p. 5). Any conception of exploitation that fails to consider these aspects will be – to say the least of it – reductionist in scope and hardly without any credibility with regard to providing the ethical prescriptions pertaining to multinational research. Furthermore, such conceptions will prove insufficient with regard to installing the responsibilities necessary to modify a situation that prior to the research was undertaken had been unfair. Finally, it seems rather irrelevant to devote so much energy and time to the discussion on defining exploitation, if it is instead possible to define the basic necessary conditions that may enable individuals and communities to take part in decision-making processes and in the development of their own capabilities, and to decide what they want to be and what they wish to do with their lives. Such a baseline seems to be the one that ought to determine the feasibility of research studies in these social groups.

Benefits in Biomedical Research

For many years, medicine has held a very clear stance on how to benefit patients; in fact, well-doing or *beneficence* has been part and parcel of a physician's moral obligation for centuries. This was mainly related to the paternalistic idea of well-doing, the content of which was defined by medicine itself. In the second half of the twentieth century, informed consent suddenly became part of medical practice and the concept of benefit dramatically changed by introducing what the patients themselves understand as such. Therefore, benefit does not only mean what

medicine may understand as such; it also includes other values that form part of people's life projects and happiness.

In biomedical research, the concept of benefit is more complex because every research is conducted under uncertain conditions and the goal is, precisely, to prove the efficiency or efficacy of a new intervention. The technical notion for this kind of uncertainty is *clinical equipoise*, which coins a situation where there is "...no consensus within the expert clinical community about the comparative merits of the alternatives to be tested" (Freedman, 1987, p. 144), that is, "...whether being in the treatment arm or the placebo arm of a placebo-controlled trial is preferable" (Brody, 1997, p. 607). As observed by Weijer, the acknowledgement of such a kind of uncertainty is of crucial importance in the ethical assessment of a trial, because it "...frames the ethical preconditions of clinical research as an issue in medical epistemology" (Weijer, 2000, p. 71). Even when confronted with the uncertainty required in clinical trials, the ethical assumptions of medicine have been:

- *That the expected benefit was a kind of knowledge that could be generalized*. For this reason, benefit has never been a problem for the scientific community, because the intention is to find a new kind of knowledge that is to benefit mankind as a whole.
- *That in order to achieve this benefit, the following principles should be taken into account* (Pellegrino, 2009):
  - The researcher's prudent judgment
  - Technical competence
  - Benevolence (virtues of researchers)

Article 6 of the Nuremberg Code states that the degree of risk to be taken should never exceed the one determined by the humanitarian importance of the problem to be solved by the experiment. The Declaration of Helsinki (1964) establishes the priority of individuals to seek knowledge, thus marking a significant change of paradigms in research patterns, which had been overtly utilitarian until then. The pre-Seoul version of Article 5 of the Declaration of Helsinki states: "In medical research in human beings, the concern about the well being of human beings must always be given primacy over the interests of science and society." Also, Article 16 states that any medical research with human beings should be preceded by a careful comparison of the expected risks against the foreseeable benefits for the individual or others. This does not prevent healthy volunteers from taking part in medical research. Consequently, there is a new idea of benefit within the context of the R/B ratio, thus giving the term "benefit" a relative connotation. Benefit is what one can obtain when taking part in research studies with regard to the intervention being assessed. Risks are evaluated in terms of the likely harm that may be inflicted in the intervention. This means that the risks and benefits being assessed should be of an equal nature and, notably, *related to each other*. At the start of the twenty-first century, this concept changed radically, which became apparent in the discussions over the definition of exploitation. According to this attempt at introducing a radically new conception of benefit with no interconnection with the conception of risk, there is no exploitation if there is adequate compensation (*fair benefit*). So, what is then, according to this view, the nature or the content of benefit? Says Emanuel (2004):

"It is important to state how much each party receives in the interaction; this will determine whether there is exploitation or not" (Participants in the, 2001 Conference on Ethical Aspects of Research, 2004). This view proposes that the risk-benefit relation can be changed to represent a relation including the community at large as well. Consequently, the subjects may be exposed to high (physical) risks, and they or the community may receive some material benefit to compensate them in a "fair" manner, because under this new concept, the interaction (biomedical research) is a contractual relationship. But this allegedly new turn raises the question: who determines the benefit/compensation? Four answers seem to be possible:

- The scientific community, researchers, and sponsors. They establish the benefits that may satisfy the needs of the individuals or the community in terms of what they consider proper and which are accepted by the community.
- The individuals themselves. That is, the individual is the one who can and must determine the scope of the benefits and the risks they are ready to face.
- The Ethic Research Committee. Most of the documents establish that the ERCs should assess risks in an independent way, but they do not always refer to the benefits, at least when their nature is different from that of the risks (or maybe it is expected that they evaluate risk and benefit of different nature).
- The society and the state. That is, they set the general rules so that the research can be carried out.

Amid this confusion between benefits and compensations in a transaction, the following listed interventions are included under the title of benefits for the individuals or the communities:

- Medical assistance to be received by participants in a research study. Health care during the research development (to treat the pathological process and other pathologies occurring at the same time). This has been considered as a benefit especially where poor communities have no access to treatments or health services, or the existing ones are of low quality.
- Assistance provided to treat the harm that was inflicted as a result of the research (harm compensation). This view considers as a benefit the treatment of foreseeable harm which has been reported to the patient in the IC and which is deemed to have been accepted by them. The same goes for some reported risks which treatment is not an obligation, and it rather becomes part of the list of benefits. Some protocols consider the treatment of unforeseeable harm (unexpected adverse events), as well as the treatment of adverse events, as a "benefit" of the research.
- Post-research benefits. The availability of interventions when their results have proved to be effective has been a topic of lengthy discussions, and in many cases, this has been considered as a benefit that may "reasonably" be offered to participants in the research.

The debate has been broadened as to who should receive this "benefit": the participants (with or without the control group), all of those affected by the pathology, or the community. In many cases, this has been offered as part of the so-called compensations under the name of post-research benefit. The question that remains to be answered is whether the satisfaction of basic human needs

(not covered in the community where the research is being done because of the socioeconomic conditions and a low human development, with specific vulnerabilities) may be considered as a benefit in comparison with the physical risks to be run by the individuals taking part in the research. This question comes before the question about the obligations for necessary compensation, since it is an exchange that utilizes such vulnerability to create the necessary conditions for a *transaction* that is essentially asymmetric.

Needs, Benefits, and Compensations in Medical Research

Here, it is proposed to define as benefits such actions or interventions that may do "good." This conception excludes the compensation for harm or risk the individuals may be exposed to. The idea of *good* should be defined by those who are to receive a benefit that they need and not by those who are to provide it. The first basic idea is that the rate should be established among two situations of similar nature (e.g., physical damage, physical benefit). A good may be oriented toward satisfying a basic human need as long as it is not part of a transaction. No negotiation is possible when dignity and human integrity are involved; they cannot be negotiated, because they have a value that cannot be expressed in terms of price. Thus, people suffering from hunger are not eligible for research studies where the indirect benefit is receiving food, even though the individual may accept the risk resulting from the administration of a drug and may consider it as a reasonable option for his/her family. This example, extreme as it may seem, is not very different from those situations where research subjects are provided basic health-care services as a compensation for taking part in research or treatments that they would otherwise not be given to treat their condition. Unsatisfied human needs, the degree of vulnerability, and the deprivation of the individual and the community play a key role in this issue. From this view follows that a benefit should be defined as an intervention bearing the same nature as the risk. It should include the effective results of the drug being tested, the treatment with the best proven standard for the control group, and the post-research treatment in the case it has proved to be successful. Where it is not possible to provide a benefit of the same nature or the direct obligations have already been fulfilled, some considerations should be made about the indirect benefits:

- They should not satisfy a basic human need which is a reflection of a violation of a human right.
- They should be defined by the individuals, the communities, or the host states (prior to the IC).
- They should be approved by an independent local REC duly experienced to assess the research, where the participants directly involved are represented.
- They should have the participants' IC (competent and voluntary) given under no coercion.
- They should aim at increasing human capabilities so that the communities can satisfy their own needs regarding that problem in particular.

A human-rights-based approach in biomedical research would assert that some goods are nonnegotiable values and that the baseline is determined by the previous human rights prevailing condition of the individuals taking part in the research. Therefore, any intervention intended to satisfy an unsatisfied basic human need (human right) should not be referred to as benefit. It is a right, and fulfilling it is a legal and ethical obligation; consequently, any interaction that would take advantage of this situation should be deemed as a potential exploitation of vulnerable subjects. The assumption, then, is that the communities under extreme necessities should not take part in biomedical research, except when:

- The country offers appropriate protective measures to the individuals (REC, IC, and independent supervisions)
- The research is to be done with that specific group because their characteristics are typical of the pathology (and cannot be carried out in the same way in an invulnerable community)
- The goal is to benefit the direct research participants instead of a health priority that had been previously detected
- The individuals will be treated in the same way as in similar research in a developed country (universal standard)
- The individuals and the community will have access to the results of the research

For this to become true, the 1993 CIOMS standards should then be resumed exactly as it was originally conceived, giving place to a new step in the history of research ethics.

Global Responsibilities Pertaining to Multinational Research in Communities with Low Human Development

Article 15 of the Universal Declaration on Bioethics and Human Rights states: "Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries." This is a commitment all Member States of the UN family have adopted. However, very little research has been undertaken to explore how a normative framework for benefit sharing of this kind should look like. To indicate a way of turning such a commitment vis-à-vis impoverished countries and communities into something more than fine words the dominance of the market-driven language of the TRIPS regime should be critically scrutinized. This regime not only reduces the access possibility of existing drugs for millions of people in great need, it also hampers dramatically development of new, essential medicines targeting ailing people in the poorest parts of the world. For this reason, it has been suggested to introduce an additional patent language for drug innovation – a patent 2 regime besides the existing TRIPS regime – covering the field of new essential drugs (Pogge, 2008). Pogge discusses two possible models, the push model and the pull model. Here, the focus will be on the second model, because it resonates better with a human-rights-based approach to multinational research. The first element, which is common to both

models, is that essential medicines should no longer be considered private goods protected by the TRIPS regime but as public goods freely accessible to any drug manufacturer in the world to make use of them in terms of generic drug production. This open – and costless – access element must, however, be supplemented with an alternative incentive for research; if not, the original drug producer would lose most of its income from its innovation. For this reason, the introduction of a global burden of disease (GBD)-oriented research incentive is suggested, that is, an incentive that is directly tied to the effect a new essential drug has on the reduction of the global burden of disease. In Pogge's own words, the idea goes as follows:

> The basic idea is to institute – complementary to existing monopoly patents – a new kind of patent for essential medicines that entitles the patent holder, during the life of the patent, to be rewarded out of public funds in proportion to the impact of the invention on the GBD. (Pogge, 2008, p. 244)

From the perspective of the principle of benefit sharing of the Universal Declaration on Bioethics and Human Rights, this supplementary patent regime has several attractive assets. First, it would stimulate close collaboration between the patent holder and generic producers to mass produce the drug so as to "enhance affordability and availability of its medicines to poor patients and hence their favorable impact on the GBD" (Pogge, 2008, p. 245). Second, with such a model in place, there would be an incentive for the patent holders to ensure that all patients for whom the drugs would have an essential health impact "have real access to them" (Pogge, 2008, p. 245). Third, it would represent a powerful incentive toward developing not only new treatments for chronic patients (the most lucrative target group under the present TRIPS regime) but treatments, including vaccines, that will "reduce the GBD in the most cost-effective way" (Pogge, 2008, p. 246), something that would imply a much more intensive research focus on the ailments of the poorest of the poor in the world. Consequently, this would also provide genuine research benefits for people living in resource-poor settings. Finally, with the implementation of a patent 2 language to stimulate the development of essential medicines, the drug innovators would in addition have a powerful incentive to help poor and low-income countries to improve their health-care systems so as "to enhance the impact of their inventions there" (Pogge, 2008, p. 246). With such a supplementary patent language in place, large numbers of the poorest communities and peoples in the world would no longer be left out when strategies for medical research are made and the benefits of medical innovations are distributed. In addition, it would help to bring together stakeholders that under the present regime live apart from each other and often in sharp opposition to each other, that is, drug developers and the generic drug producers. These considerations lead finally to a point with regard to the power struggle taking place on the level of language in international research ethics necessary to tackle, that is, the lack of concerted actions and strategies among the critics of the double moral standard of international research in terms of joint publications and joint policymaking activities to counterbalance the Anglo-American dominance in international research ethics. As observed by Pogge in relation to the implementation of the TRIPS regime:

> The unjust rules we are seeking to reform exist because others have managed to coordinate in their support. The agribusiness, software, entertainment, and pharmaceutical industries have overcome their differences to throw their political clout behind a joint (TRIPS/TRIPSplus) strategy that—together—they got their governments to impose on the world. Those seeking to protect the poor have undeniably made great and often successful efforts of many kinds. But we have not managed to coordinate on a joint political strategy, and our dispersed efforts are therefore greatly hampered by the powerful and continuous impoverishing impact of unjust institutional arrangements. (Pogge, 2008, p. 257)

It is in the power of democratic states in the most affluent parts of the world to take the lead to change this horrible and undignified situation seriously impairing the lives and capabilities of millions of people living in resource-poor settings. In this way, they would also fulfill part of their commitment in relation to Article 15 of the Universal Declaration on Bioethics and Human Rights, by making multinational medical research a fair enterprise aimed at enhancing human capabilities.

Conclusion

All Member States of the UNESCO have adopted the Universal Declaration on Bioethics and Human Rights: a tremendous achievement in the normative history of mankind. It is, however, also a fact that the health and lives of millions of people in this world are at risk due to the grossly unjust way resources for health and for health research are distributed. In this chapter, the focus of attention is clinical research in resource-poor settings. The analyses here provided and the message conveyed is that it is in the power of democratic states in the most affluent parts of the world to take the necessary steps to change this situation so as to enable millions of people suffering from treatable diseases due to dire economical, environmental, social, and political conditions to freely choose their way of fulfilling their human capabilities, in accordance with the powerful vision expressed in the Universal Declaration on Bioethics and Human Rights to respect human dignity, human rights, and fundamental freedoms.

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Codes of Conduct

33

Robert Baker

Introduction

In the aftermath of the Second World War, a system of global institutions arose to facilitate international collaboration in rebuilding a war-devastated world and to construct new and better institutions of international understanding and collaboration. The United Nations (UN) and associated ancillary international organizations were created as a replacement for the failed League of Nations (LN). Among the UN's ancillary organizations dealing with biomedicine are the Council for International Organizations of Medical Sciences (CIOMS, founded 1949), which is a subcouncil of the World Health Organization (WHO, founded 1948), and the United Nations Educational, Scientific and Cultural Organization (UNESCO, founded 1946). The World Medical Association (WMA), a professional society, was founded independently of the UN in1947. All of these organizations are *international* in the sense defined by the English philosopher Jeremy Bentham (1748–1832), the term's originator: that is, they designate declarations or treaties involving two or more nations. Over the ensuing decades, these international organizations issued a series of documents asserting bioethical duties, principles, rights, and responsibilities that are *global* in the sense that they apply worldwide, without reference to nations or national boundaries. These documents are foundational for global bioethics, and this chapter examines some of the major global codes of conduct, declarations, and rights documents, focusing on the most influential. Among those analyzed are the WMA's Declarations of Geneva and Helsinki and its International Code of Medical Ethics, the CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects, and UNESCO's

R. Baker
Philosophy Department, Union College, Schenectady, NY, USA
e-mail: bakerr@union.edu

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Universal Declaration on Bioethics and Human Rights. Most of these texts are regularly revised and updated. The most recent versions are readily available on the Internet; however, earlier versions documenting pivotal changes are not readily accessible, and full texts of these versions have been provided as part of this chapter.

The Declaration of Geneva and the Hippocratic Oath: A Prototype for Global Bioethics

The biblical notion that old things that have passed away can become new again is exemplified in the foundational documents of global bioethics. The Hippocratic Oath, the earliest recorded statement of professional medical self-regulation (*circa* fifth–fourth century BCE), was the basis of the first document of global bioethics, the WMA's Declaration of Geneva (1948). For those unfamiliar with the text, in the Hippocratic Oath a physician's apprentice swears to abide by an apprenticeship contract and a code of ethical conduct. These apprentices pledge not to act unjustly toward or to harm the sick, and not to have sexual relations with them, but always to use their *techne* – the term from which "technique" and "technology" derived – in ways that make the sick better rather than worse. Apprentices, moreover, were not to use health-endangering medicines, like drug-soaked vaginal tampons, because they endangered *women's* lives and were not to attempt surgical procedures beyond their expertise, like cutting out bladder stones.

According to a literal translation by classicist Heinrich Von Staden (1996), the code states the following:

> (3. i) And I will use regimens for the benefit of the ill in accordance with my ability and my judgment, but from [what is] to their harm or injustice I will keep [them].
> (4. i) And I will not give a drug that is deadly to anyone if asked [for it],
> (4. ii) nor will I suggest the way to such a counsel. And likewise I will not give a woman a destructive pessary [i.e., a destructive vaginal suppository].
> (5. i) And in a pure and holy way(ii) I will guard my life and my *techne*.
> (6. i) I will not cut, and certainly not those suffering from stone, but I will cede [this] to men [who are] practitioners of this activity.
> (7. i) Into as many houses as I may enter, I will go for the benefit of the ill,ii.) while being far from all voluntary and destructive injustice, especially from sexual acts both upon women's bodies and upon men's, both of the free and of the slaves.
> (8. i) And about whatever I may see or hear in treatment, or even without treatment, in the life of human beings – things that should not ever be blurted out outside – I will remain silent, holding such things to be unutterable [sacred, not to be divulged].

What allowed this code to endure has less to do with these practical precepts, which do not address the issues of abortion or euthanasia, and has everything to do with later interpretations by readers and translators imbued with Stoic, Judeo-Christian, and/or Islamic morality who read into the Hippocratic text stirring affirmations of the sanctity of life and prohibitions against euthanasia and abortion. Thus, although line 4.ii reads literally as "I will not give a woman a destructive pessary," a popular translation by Victorian physician-classicist Francis Adams (1849) renders 4.ii as "I will not give to a woman a pessary to produce abortion." Historically, Adams' Victorian reading and dozens of similar translations are inconsistent with ancient Greek practices, since infanticide was commonplace, and Hippocratic texts describe techniques for performing abortions. Nonetheless, interpretations like these transformed the oath into a life-affirming ethics that became a talisman for Western medical ethics that could and did serve as a rallying point for physicians in Germany and in Nazi-occupied Europe who resisted the Nazi eugenic sterilization and infanticide initiatives.

This anti-Nazi reaffirmation of life would make the oath an ideal basis for publicly reasserting traditional medical values after the Second World War ended. As it happened, throughout the war, the basement pub of the London home of the BMA had become a gathering place for physicians attached to the allied armies of America, Australia, Canada, Latin America, New Zealand, the United Kingdom, as well as those serving with the Czech, Dutch, Free French, Norwegian, and Polish resistance movements. Striving to preserve this camaraderie in the postwar period, representatives of 27 national medical societies from Africa, Asia, Australia, Europe, the Middle East, and North American founded the WMA in 1947 to address the medical needs of a war-ravaged world by sending medical instruments, pharmaceutical supplies, and textbooks to areas in need of assistance – and to restore "the honor of medicine (Pridham, 1951)."

Medicine's honor was in disrepair because during the war, German physicians had committed "crimes against humanity. . .which shocked the whole profession. The fact that such horrors could be perpetrated by doctors underlined the need for. . .a modern version of the Hippocratic oath named. . .the Declaration of Geneva" (WMA, 1949a, p. 12). The Declaration was approved at the WMA's first annual conference in 1948 as a means of teaching medical students "to honor the traditions of Medicine and to absorb its humanitarian purposes—the succor of the bodily and mental needs of the individual irrespective of class, race or creed; the cure of disease; the relief of suffering; the prolongation of human life; and the prevention of disease" (WMA, 1949a, p. 12). As the authors of the Declaration noted, the tradition of oath swearing had been abandoned in many countries, including all of Nazi- and Fascist-occupied Europe. This new form of the Hippocratic Oath was designed "to impress on newly-qualified doctors the fundamental ethics of medicine and to raise the general standard of medical conduct" for "every age and every country" (WMA, 1949a, p. 12).

The new oath was drafted in English and translated into French and Spanish for approval by the WMA's 27 member organizations. The original text reads as follows.

Declaration of Geneva
Serment de Geneve
Declaracion en Genebra

At the moment of being admitted as a Member of the Medical Profession

Au moment d'être admis au nombre des membres de la Profession Médicale,

EN EL MOMENTO de ser admitido como Miembro de la Profesión Médica

I solemnly pledge myself to consecrate my life to the service of humanity.

Je prends l'engagement solennel de consacrer ma vie au service de l'humanitié.

Promento solèmnemente consagrar mi vida al sevicio de la humanidad.

I will give my teachers the respect and gratitude which is their due.

Je garderai à mes maîtres le respect et la reconnaissance qui leur son dûs.

Otorgar a mis maestros los respectos, gratitud y consideraciones que mercen.

I will practice my profession with conscience and dignity.

J'exercerai mon art avec conscience et dignité.

Ejercer mi profesion dignamente y a conciencia.

The health of my patient will be my first consideration.

Je considèrerai la santé de mon patient comme mon premier souci.

Velar solicitamente, y ante todo, por la salud de mi paciente.

I will respect the secrets that are confided in me.

Je respecterai le secret de celui que se sera confié à moi.

Guardar y respetar los secretos a mi confiados.

I will maintain by all means in my power, the honor and the noble traditions of the medical profession.

Je maintiendrai, dans toute la mesure de mes moyens, l'honneur et les nobles traditions de la profession médicale.

Mantendré en todo la medida de mis medios el honor y las nobles tradiciones de la profesión médica.

My colleagues will be my brothers.

Mes collègues seront mes frères.

Considerar como hermanos a mis colegas.

I will not permit considerations of religion, nationality, race, party politics or social standing to intervene between my duty and my patient.

Je ne permettrai pas que des considérations de religion, de nation, de race, de parti, ou de classe sociale, viennent s'interposer entre mon devoir et mon patient.

Hacer caso omiso de credos politicos y religiosos, nacionalidades, razazas, rangos sociales, evitando que éstos se interpongan entre mis servicios profesionales y mi paciente.

> I will maintain the utmost respect for human life, from the time of conception; even under threat, I will not use my medical knowledge contrary to the laws of humanity.
>
> Je garderai le respect absolu de la vie humaine dès la conception. Même sous la menace, je n'admettrai pas de faire usage de mes connaissances médicales contre les lois de l'humanité.
>
> Velar con sumo interés y respeto por la vida humana, desde el momento de la concepcion, y aun bajo amenaza, no emplear mis conocimientos médicos para contravenir las leyes humanas.
>
> I make these promises solemnly, freely, and upon my honor.
>
> Jes fais ces promesses solennellement, librement, sur l'honneur.
>
> Solemne y espontáneamente, bajo mi palabra de honor, prometo cumplir con lo antedicho. (World Medical Association, 1949b)

The parallels between the Declaration and the Hippocratic Oath original speak for themselves. The oath's code of conduct has been reformulated as a pledge of service to humanity, and the traditional pledge to benefit the patient was supplemented by a commitment not to "permit considerations of religion, nationality, race, party politics or social standing to intervene between my duty and my patient" and by a vow that "even under threat, I will not use my medical knowledge contrary to the laws of humanity." These refer directly to the Nuremberg War Crime Trials of Nazi doctors invoking the then new concept of "laws of humanity" – a precursor of the concept of "human rights" – that had no precedent in earlier codes, oaths, principles, or rules of national medical societies.

It is noteworthy that the powerful prohibitions against abortion read into the Hippocratic Oath and reflected in many national medical society codes, oaths, and precepts were muted in the Declaration. Thus, the English version of the Declaration only requires physicians to "maintain utmost respect for human life, from the time of conception," without specifying what is meant by "respect for human life." The French and the second Spanish versions of the oath, in contrast, tighten this provision by requiring "absolute respect for human life," that is, respect without exception for human life in any form or stage – including humans in their embryonic form. These linguistic nuances respond to a pragmatic need for compromise in fashioning documents for acceptance in many medical and national cultures. In 1948, however, the animating spirit of the Declaration was the world medical profession's shared horror and condemnation of physician participation in the Holocaust and the profession's resolve that never again would students graduate from medical school unaware of medicine's fundamental commitment to serve the patient and the health of humanity above all else.

Since it was first adopted, the Declaration has been modified five times, in 1968, 1984, 1994, 2005, and 2006. To indicate the nature of these changes, below find the most recent version of the Declaration with deletions to the original English

indicated by cross through lines, for example, ~~deletion~~, and additions by italics, for example, *addition*. These changes reflect a half century of moral reform: the words "my sisters" reflect advances toward gender equality, just as the words "age," "disease," "disability," "gender," and "sexual orientation" reflect the struggle to banish discrimination on the basis of age (ageism), disease (especially discrimination against people stricken with HIV and AIDS), disability (the biases of the able against those with disability), and a rejection of sexist and homophobic biases. Similarly, the change from "laws of humanity" to "human rights" reflects and documents the worldwide recognition of human rights as the moral basis of global bioethics. Fulfilling the ambitions of its authors, this first formulation of a global medical ethics is now the basis of the most commonly sworn medical student initiation and/or graduation oaths worldwide.

Declaration of Geneva —2006

At the time of being admitted as a member of the medical profession:

I solemnly pledge to consecrate my life to the service of humanity;

I will give to my teachers the respect and gratitude that is their due;

I will practice my profession with conscience and dignity;

The health of my patient will be my first consideration;

I will respect the secrets that are confided in me, *even after the patient has died*;

I will maintain by all the means in my power, the honor and the noble traditions of the medical profession;

My colleagues will be *my sisters and* brothers;

I will not permit considerations of *age*, *disease or disability, creed, ethnic origin, gender*, nationality, political affiliation, race, *sexual orientation*, social standing or *any other factor* to intervene between my duty and my patient;

I will maintain the utmost respect for human life ~~from the time of conception~~;

I will not use my medical knowledge ~~contrary to the laws of humanity~~ *to violate human rights and civil liberties*, even under threat;

I make these promises solemnly, freely and upon my honor.

(WMA, 2006a)

In the half century since its founding, virtually every medical society in the world has joined the WMA, from Order of Physicians of Albania and the AMA to its founding chapter, the BMA, and the Medical Association of the Bahamas, down the alphabet to the Chinese Medical Association, the Russian Medical Society, and the Vatican, Venezuelan, and Vietnamese medical associations – ending with the Zimbabwe Medical Association. A pillar of global bioethics, the WMA has become the conscience of medicine, issuing the *Declaration of Tokyo* (2006c) condemning physician participation in torture. In the same year, the WMA also issued *The Declaration of Lisbon on the Rights of the Patient* and *the Malta Declaration on Hunger Strikers* (WMA, 2006d). It later issued *The Declaration of Ottawa on Child*

Health (WMA, 2009). The WMA works closely with the UN and the World Health Organization to provide disaster aid where needed and to protect the integrity of medicine and its practitioners and the rights of sick people, patients, and research subjects. The WMA's most influential declarations, however, deal with human subjects research, and much of this brief introduction to the documentary basis of global bioethics focuses on these declarations.

The Nuremberg Code

It is an ironic twist of history that although one of the WMA's major objectives was the rehabilitation of medical ethics after the discovery of German physicians' inhumane medical experiments on unconsenting involuntary human subjects, the WMA did not issue a code of research ethics until a decade and one half after its founding. This might, at first, appear puzzling since 1947, the very year in which the WMA was founded, a US war crimes tribunal had formulated the following code of research ethics in passing judgment on the 23 German physicians accused of crimes against humanity.

Nuremberg Code – 1947

The great weight of the evidence before us is to the effect that certain types of medical experiments on human beings, when kept within reasonably well-defined bounds, conform to the ethics of the medical profession generally. The protagonists of the practice of human experimentation justify their views on the basis that such experiments yield results for the good of society that are unprocurable by other methods or means of study. All agree, however, that certain basic principles must be observed in order to satisfy moral, ethical and legal concepts.

1. The voluntary consent of the human subject is absolutely essential.
   This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

   The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the

experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.
2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
3. The experiment should be so designed and based on the results of animal experimentation, and a knowledge of the natural history of the disease or other problems under study that the anticipated results will justify the performance of the experiment.
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except perhaps, in those experiments where the experimental physicians also serve as subjects.
6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.
10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe in the exercise of the good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject. (United States of America v. Karl Brandt et al., 1949).

Despite the Nuremberg judges' claim that "all agree" that experiments on human subjects are justifiable only if "certain basic principles [are] be observed," in point of historical fact, before 1947, no national medical society and, more specifically, none of the societies that founded the WMA had a code of research ethics – except for the American Medical Association (AMA), which had hurriedly adopted some principles of research ethics immediately *after* the commencement of the Nuremberg Trials. Thus, the Nuremberg judges' prefatory statement that "all agree" upon "certain basic principles" of research ethics was profoundly mistaken: no principles

of research ethics had been formulated by any medical society or research organization prior to 1946. The judges had been mislead by "the evidence before [them]," specifically that offered by the AMA's representative at the trial Andrew Ivy (1893–1978) who had testified, quite plausibly, that the Hippocratic Oath was a universal medical ethics that prohibited killing humans in scientific experiments and who then suggested, quite misleadingly, that all medical researchers implicitly accepted common principles of research ethics.

The Nuremberg Code, however, was not without precedent. Its ten principles of research ethics had been suggested to them by Ivy and by his colleague, the Austrian-American psychiatrist Leo Alexander (1905–1985). Ironically, Alexander modeled his suggestions on the 1931 Germany Ministry of Health (*Reichgesundheitsrat*) guidelines on human experimentation with which he was familiar because he had studied medicine in Berlin (Annas & Grodin, 1992; Schmidt, 2004; Weindling, 2005). Nonetheless, except for the AMA and the Germany Ministry of Health, no medical society or governmental institution had issued formal rules for the regulation of research on human subjects before the tribunal issued the Nuremberg Code in 1947.

The International Code of Medical Ethics

The Declaration of Geneva did not directly address the primary focus of the Nuremberg Doctors' Trials, research on human subjects, and so, Jules Voncken (1887–1975), a Belgian physician familiar with continental traditions of *déontologie médicale* (i.e., medical ethics), argued the case for an international code of medical ethics to address human subjects research. Voncken was inspired by Ivy's speeches and articles (Ivy, 1946b, 1947, 1949) which summarized a report he wrote for the AMA (Ivy, 1946a) that described Nazi experiments on human subjects as a "tragedy, which surpasses all of the inhumanities of man to man record [ed] in human history" Ivy (1946a, p. 8). Ivy observed that "the experiments performed on human subjects without their consent, or by coercion, are contrary to the laws of humanity and ethical principles of the medical profession which have been in practice for 22 centuries" (Ivy, 1946a, p. 9). "By common agreement," Ivy claimed(1946a, p. 10), three basic principles should be adopted by all medical societies to protect the human rights of experimental subjects. First among these is the "consent of the subject" who has "been informed of the hazards if any"; the second principle requires that prior animal experimentation justify the likelihood that "the experiment [will] yield results for the good of society unprocurable by other means of study and must not be random and unnecessary in nature" (Ivy, 1946a, p. 10). Finally, the third principle requires that experimenters be scientifically qualified, that they "avoid all unnecessary suffering and injury," and that there be "no *a priori* reason to believe that death or disabling injury will occur, except in such experiments, as [in the Cuban-US] Yellow Fever [of 1900], where the experimenters serve as subjects along with non-scientific personnel" (Ivy, 1946a. p. 10). "The indicted Nazi physicians and scientists" on trial at Nuremberg, Ivy declared,

"ignored these ethical principles and rules, which have been well established by custom, social usage and the ethics of medical conduct, and which are necessary to insure the human rights of the individual." (Ivy, 1946a, pp. 8–11) It was time, Ivy argued, for medical societies to expressly state these time-honored principles that they implicitly accepted. Voncken followed through, proposing that the newly formed WMA develop an international code of ethics that would serve this purpose, among others.

Yet although the WMA did promulgate an international code of medical ethics in 1949, that code did not respond to the Ivy-Voncken call for fundamental statement of the human rights of people serving as research subjects. The experiments condemned at the Nuremberg Trials were so horrible that they were ascribed to the inhumane nature of the Nazism, and so, a code condemning these experiments was deemed irrelevant to normally humane researchers. Consequently, when the WMA convened its third General Assembly in 1949, it adopted a more general statement of medical ethics that contained none of the provisions recommended by Ivy, Voncken, or the Nuremberg Tribunal as essential to preventing the abuse of the human subjects of medical research. Instead, they issued a code based on provisions common to the various official oaths and/or guild-like regulations accepted by the WMA's member medical societies. These set standards of competent medical practice and rules for resolving intrapractitioner disputes. Few of these codes had anything to say about the rights of patients. Not surprisingly, therefore, the first international code of ethics states that doctors' only duties toward the sick are to provide emergency care, to maintain confidentiality, to refer patients to specialists, and to preserve human life from conception – except for the lives of pregnant women since therapeutic abortions, that is, abortions to save a pregnant woman's life or to preserve her health, are deemed permissible only if national laws allow them.

International Code of Medical Ethics
World Medical Association – 1949
Duties of Doctors in General

A doctor must always maintain the highest standards of professional conduct.

A doctor must practice his profession uninfluenced by motives of profit.

The following practices are deemed unethical:

a. Any self-advertisement except such as is expressly authorized by the national code of medical ethics;

b. Collaborate in any form of medical service in which the doctor does not have professional independence;

c. Receiving any money in connection with services rendered to a patient other than a proper professional fee, even with the knowledge of the patient.

Any act, or advice which could weaken physical or mental resistance of a human being may be used only in his interest.

A doctor is advised to use great caution in divulging discoveries or new techniques of treatment.

A doctor should certify or testify only to that which he has personally verified.

Duties of Doctors to the Sick

A doctor must always bear in mind the obligation of preserving human life from conception. Therapeutic abortion may only be performed if the conscience of the doctors and the national laws permit.

A doctor owes to his patient complete loyalty and all the resources of his science. Whenever an examination or treatment is beyond his capacity he should summon another doctor who has the necessary ability.

A doctor shall preserve absolute secrecy on all he knows about his patient because of the confidence entrusted in him.

A doctor must give emergency care as a humanitarian duty unless he is assured that others are willing and able to give such care.

Duties of Doctors to Each Other

A doctor ought to behave to his colleagues as he would have them behave to him.

A doctor must not entice patients from his colleagues.

A doctor must observe the principles of *The Declaration of Geneva* approved by The World Medical Association.

(WMA, 1949c)

The1949 International Code of Medical Ethics was a first step forward, but, as is typical of baby steps, it was hesitant and faltering: a minimalist code that was the best that could be agreed by the WMA's founding medical societies at the time. It has been revised three times since 1949 and has been supplemented by specific declarations on such complex and controversial issues as the role of physicians in treating hunger strikers. On more mundane matters, the revised code no longer contains the word "abortion," and the procedure is not singled out as morally suspect. Moreover, reflecting the influence of the worldwide bioethics movement – the current code asserts the physician's duty to "respect a competent patient's right to refuse treatment." Patients' rights were delineated further in the WMA's 2005 *Declaration of Lisbon on the Rights of the Patient* (WMA 2005). The WMA's 2006 International Code of Medical Ethics is below.

International Code of Medical Ethics
World Medical Association - 2006
Duties of physicians in general

A physician shall always exercise his/her independent professional judgment and maintain the highest standards of professional conduct.

A physician shall respect a competent patient's right to accept or refuse treatment.

A physician shall not allow his/her judgment to be influenced by personal profit or unfair discrimination.

A physician shall be dedicated to providing competent medical service in full professional and moral independence, with compassion and respect for human dignity.

A physician shall deal honestly with patients and colleagues, and report to the appropriate authorities those physicians who practice unethically or incompetently or who engage in fraud or deception.

A physician shall not receive any financial benefits or other incentives solely for referring patients or prescribing specific products.

A physician shall respect the rights and preferences of patients, colleagues, and other health professionals.

A physician shall recognize his/her important role in educating the public but should use due caution in divulging discoveries or new techniques or treatment through non-professional channels.

A physician shall certify only that which he/she has personally verified.

A physician shall strive to use health care resources in the best way to benefit patients and their community.

A physician shall seek appropriate care and attention if he/she suffers from mental or physical illness.

A physician shall respect the local and national codes of ethics.

Duties Of Physicians To Patients

A physician shall always bear in mind the obligation to respect human life.

A physician shall act in the patient's best interest when providing medical care.

A physician shall owe his/her patients complete loyalty and all the scientific resources available to him/her. Whenever an examination or treatment is beyond the physician's capacity, he/she should consult with or refer to another physician who has the necessary ability.

A physician shall respect a patient's right to confidentiality. It is ethical to disclose confidential information when the patient consents to it or when there is a real and imminent threat of harm to the patient or to others and this threat can be only removed by a breach of confidentiality.

A physician shall give emergency care as a humanitarian duty unless he/she is assured that others are willing and able to give such care.

A physician shall in situations when he/she is acting for a third party, ensure that the patient has full knowledge of that situation.

A physician shall not enter into a sexual relationship with his/her current patient or into any other abusive or exploitative relationship.

Duties Of Physicians To Colleagues

A physician shall behave towards colleagues as he/she would have them behave towards him/her.

A physician shall not undermine the patient-physician relationship of colleagues in order to attract patients.

A physician shall when medically necessary, communicate with colleagues who are involved in the care of the same patient. This communication should respect patient confidentiality and be confined to necessary information.

(WMA, 2006c)

The Declaration of Helsinki

Although the Nuremberg Code on human subjects experimentation was issued as international humanitarian law, it was indelibly tarred with the stigma of Nazism, and so, it seemed irrelevant as a precedent for regulations governing the conduct of sane and honorable researchers. The Nuremberg Code also seemed unsuitable for regulating normal medical research. For example, Article 1 required research subjects to be legally capable of consent. Since incapacitated adults, children, and patients with some psychiatric illnesses were not legally capable of consent, Article I inadvertently prohibited experiments to develop new drugs for treating conditions affecting them. The requirement of prior animal experimentation (Article 3) was also problematic since many diseases were unique to humans and could not be studied in animals. Complicating matters further, standards of competent medical research were in flux in the 1950s after British epidemiologist Sir Austin Bradford Hill (1897–1991) had established randomized controlled trials as the standard for unbiased medical experimentation (Yoshioka, 1998).

So the development of global research ethics had to start afresh. Yet since the WMA's member societies lacked any shared tradition or overlapping consensus on research ethics, it took a full decade for them to agree on common standards. By the 1960s, many member societies had developed their own research ethics policies, so some measure of overlapping consensus on ethical principles for research ethics could be agreed. In 1961–1962, the WMA issued a draft declaration on research ethics, and in 1964, a revised version was adopted as *the Declaration of Helsinki*.

DECLARATION OF HELSINKI—1964

INTRODUCTION

It is the mission of the doctor to safeguard the health of the people. His knowledge and conscience are dedicated to the fulfillment of this mission.

The Declaration of Geneva of the World Medical Association (1964) binds the doctor with the words "The health of my patient will be my first consideration"; and the International Code of Medical Ethics declares that, "Any act

or advice which could weaken physical or mental resistance of a human being may be used only in his interest."

Because it is essential that the results of laboratory experiments be applied to human beings to further scientific knowledge and to help suffering humanity, the World Medical Association has prepared the following recommendations as guide to each doctor in clinical research. It must be stressed that the standards as drafted are only a guide to physicians all over the world. Doctors are not relieved from criminal, civil and ethical responsibilities under the laws of their own countries.

In the field of clinical research a fundamental distinction must be recognized between clinical research in which the aim is essentially therapeutic for a patient, and the clinical research, the essential object of which is purely scientific and without therapeutic value to the person subjected to the research.

I. Basic principles

1. Clinical research must conform to the moral and scientific principles that justify medical research and should be based on laboratory and animal experiments or other scientifically established facts.

2. Clinical research should be conducted only by scientifically qualified persons and under the supervision of a qualified medical person.

3. Clinical research cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.

4. Every clinical research project should be preceded by careful assessment of inherent risks in comparison to foreseeable benefits to the subject or to others.

5. Special caution should be exercised by the doctor in performing clinical research in which the personality of the subject is liable to be altered by drugs or experimental procedure.

II. Clinical Research combined with professional care

1. In the treatment of the sick persons, the doctor must be free to use a new therapeutic measure, if in the doctor's judgment it offers hope of saving life, reestablishing health, or alleviating suffering.

If at all possible, consistent with patient psychology, the doctor should obtain the patient's freely given consent after the patient has been given a full explanation. In case of legal incapacity, consent should also be procured from the legal guardian; in case of physical incapacity the permission of the legal guardian replaces that of the patient.

2. The doctor can combine clinical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that clinical research is justified by its therapeutic value for the patient.

III. Nontherapeutic clinical research

1. In the purely scientific application of clinical research carried out on a human being, it is the duty of the doctor to remain the protector of the life and health of that person on whom clinical research is being carried out.

2. The nature, the purpose and the risk of clinical research must be explained to the subject by the doctor.

3a. Clinical research on a human being can not be undertaken without that person's consent after being informed; if the person is legally incompetent the consent of the legal guardian should be procured.

3b. The object of clinical research should be in such a mental, physical and legal state as to be able to exercise fully the power of choice.

3c. Consent should, as a rule, be obtained in writing. However, the responsibility for clinical research always remains with the research worker; it never falls on the subject even after consent is obtained.

4a. The investigator must respect the right of each individual to safeguard his/her personal integrity, especially if the subject is in a dependent relationship to the investigator.

4b. At any time during the course of clinical research the subject or the subject's guardian should be free to withdraw permission for research to be continued.

The investigator or the investigation team should discontinue the research if in their judgment, it may, if continued be harmful to the individual.

(WMA, 1964)

Drawing authority from the Declaration of Geneva and the International Code of Medical Ethics, the Declaration of Helsinki formulates what many consider the first global code of research ethics. Yet, although the Nuremberg Code is never referenced in the Declaration, as historian Susan Lederer has observed, its influence is evident throughout – even if, as Lederer also notes, the Declaration waters down many Nuremberg precepts to the point of fecklessness (Lederer, 2004). The reduction in authoritativeness is striking. Whereas the Nuremberg Code states "basic principles [that] must be observed in order to satisfy moral, ethical and legal" conduct of experiments on humans, the Declaration merely makes "recommendations as guide[s]." More substantively, whereas the Nuremberg Code unequivocally declares the "voluntary consent of the human subject" as "absolutely essential" to ethical experiments on human subjects, the Declaration of Helsinki considers informed voluntary consent necessary only for nontherapeutic experiments. In therapeutic contexts, "the doctor must be free to use a new therapeutic measure" irrespective of whether the subject is informed or consents (Sec. II.1) – although, "if at all possible, consistent with patient psychology, the doctor should obtain the patient's freely given consent." For the most prevalent form of clinical experimentation – experiments to discover new drugs that might prove therapeutic for patients – the first formulation of the Declaration of Helsinki had declared that the informed voluntary consent of legally competent research subjects was optional.

About a decade later, in a second Declaration of Helsinki (WMA, 1975), the WMA fashioned a radically different document which, unlike its predecessor, required signed informed consent statements from research subjects or their legal

guardians in all types of research – including experiments that benefit patients therapeutically. Moreover, prior to the commencement of research, the wording of these consent forms and of the protocols describing the research project had to be approved by independent research ethics committees (called "institutional review boards," or IRBs, in the US and research ethics committees or boards, RECs or REBs, elsewhere). Written statements of informed subject consent were no longer optional; they were a presumptive requirement of all research on human subjects – except in cases in which a physician "considers it essential not to obtain informed consent" and has received an exemption from a research ethics committee.

Strengthening the role of the research ethics committee further, Sec. I.8 stipulates that research "not in accordance with. . .this Declaration should not be accepted for publication." Thus, any research conducted without a subject's or surrogate's signed consent or without the approval of a research ethics committee was unpublishable. The International Committee of Medical Journal Editors (2011), an organization that represents every major medical journal in the world, enforces this provision. The 1975 revision of the Declaration of Helsinki II thus requires that all human subjects research be reviewed by a research ethics committee, that this committee insure that informed consent be part of the research protocol, and that subjects or their guardians sign written consent forms. Furthermore, it made formal review and approval by such research ethics committees a prerequisite of publication in a medical journal. By dint of these provisions, the second version of the Declaration of Helsinki became the first enforceable code of global research ethics – and of global bioethics.

Declaration of Helsinki II—1975

Recommendations guiding medical doctors in biomedical research involving human subjects.

Introduction

It is the mission of the medical doctor to safeguard the health of the people. His or her knowledge and conscience are dedicated to the fulfilment of this mission.

The Declaration of Geneva of the World Medical Association binds the doctor with the words: "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that "Any act or advice which could weaken physical or mental resistance of a human being may be used only in his interest."

The purpose of biomedical research involving human subjects must be to improve diagnostic, therapeutic and prophylactic procedures and the understanding of the aetiology and pathogenesis of disease.

In current medical practice most diagnostic, therapeutic or prophylactic procedures involve hazards. This applies *a fortiori* to biomedical research.

Medical progress is based on research, which ultimately must rest in part on experimentation involving human subjects. In the field of biomedical

research a fundamental distinction must be recognized between medical research in which the aim is essentially diagnostic or therapeutic for a patient, and medical research the essential object of which is purely scientific and without direct diagnostic or therapeutic value to the person subjected to the research.

Special caution must be exercised in the conduct of research which may affect the environment, and the welfare of animals used for research purposes must be respected.

Because it is essential that the results of laboratory experiments be applied to human beings to further scientific knowledge and to help suffering humanity, the World Medical Association has prepared the following recommendations as a guide to every doctor in biomedical research involving human subjects. They should be kept under review in the future. It must be stressed that the standards as drafted are only a guide to physicians all over the world. Doctors are not relieved from criminal, civil and ethical responsibilities under the laws of their own countries.

I Basic principles

1. Biomedical research involving human subjects must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal experimentation and on a thorough knowledge of the scientific tradition.
2. The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted to a specially appointed independent committee for consideration, comment and guidance.
3. Biomedical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given her consent.
4. Biomedical research involving human subjects cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.
5. Every biomedical research project involving human subjects should be preceded by careful assessment of predictable risks in comparison with foreseeable benefits to the subject or to others. Concern for the interests of the subject must always prevail over the interest of science and society.
6. The right of the research subject to safeguard his or her integrity must always be respected. Every precaution should be taken to respect the privacy of the subject and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.

7. Doctors should abstain from engaging in research projects involving human subjects unless they are satisfied that the hazards involved are believed to be predictable. Doctors should cease any investigation if the hazards are found to outweigh the potential benefits.
8. In publication of the results of his or her research, the doctor is obliged to preserve the accuracy of the results. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.
9. In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time. The doctor should then obtain the subject's freely given informed consent, preferably in writing.
10. When obtaining informed consent for the research project the doctor should be particularly cautious if the subject is in a dependent relationship to him or her or may consent under duress. In that case informed consent should be obtained by a doctor who is not engaged in the investigation and who is completely independent of this official relationship.
11. In cases of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation. Where physical or mental incapacity makes it impossible to obtain informed consent, or when the subject is a minor, permission from the responsible relative replaces that of the subject in accordance with the national legislation.
12. The research protocol should always contain a statement of ethical consideration involved and should indicate that the principles enunciated in the present Declaration are complied with.

II Medical research combined with professional care (clinical research)

1. In the treatment of the sick person, the doctor must be free to use a new diagnostic and therapeutic measure, if in his or her judgement it offers the hope of saving life, re-establishing health or alleviating suffering.
2. The potential benefits, hazards and discomfort of a new method should be weighed against the advantages of the best current diagnostic and therapeutic methods.
3. In any medical study, every patient – including those of a control group, if any – should be assured of the best proven diagnostic and therapeutic method.
4. The refusal of the patient to participate in a study must never interfere with the doctor–patient relationship.

5. If the doctor considers it essential not to obtain informed consent, the specific reasons for this proposal should be stated in the experimental protocol for transmission to the independent committee.
6. The doctor can combine medical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that medical research is justified by its potential diagnostic or therapeutic value for the patient.

III Non-therapeutic biomedical research involving human subjects (non-clinical biomedical research)

1. In the purely scientific application of medical research carried out on a human being, it is the duty of the doctor to remain the protector of the life and health of that person on whom biomedical research is carried out.
2. The subjects should be volunteers – either healthy persons or patients for whom the experimental design is not related to the patient's illness.
3. The investigator or the investigating team should discontinue the research if in his/her or their judgement it may, if continued, be harmful to the individual.

In research on man, the interest of science and society should never take precedence over considerations related to the well-being of the subject. (World Medical Association, 1975)

From this point forward, the Declaration of Helsinki underwent recurrent study, debate, and revision. These revisions often responded to controversies in the research community about such issues as the level of care appropriate for patients in a control group, especially in developing world. Some studies had used placebo controls in developing world studies, even though known effective treatments were available. In its fourth revision, the Declaration of Helsinki (WMA, 1996) prohibited this practice on the grounds that there should be no double standards in human subjects research: all research subjects should be treated alike, irrespective of whether they happened to live in the developed or the developing world. In the sedately bureaucratic prose of the Declaration, this statement on global justice reads as follows: "II.3 In any medical study, every patient – including those of a control group, if any – should be assured of the best proven diagnostic and therapeutic method. This does not exclude the use of inert placebo in studies where no proven diagnostic or therapeutic method exists." Researchers from the developed countries would later challenge this provision on the grounds that it limits the use of placebos in experiments designed to develop inexpensive alternatives to proven vaccines and therapies, of the sort that would fit the limited health-care budgets of developing world countries and nongovernmental organizations (NGOs).

Later versions of the Declaration of Helsinki shed the earlier rhetoric of recommendation, declaring the Declaration (Sec. A.1) "a statement of ethical principles to provide guidance to physicians and other participants in medical research involving

human subjects" (WMA, 2000). More substantively, Sec. II.3 (WMA, 2000) reiterates that "in any medical study, every patient – including those of a control group, if any – should be assured of the best proven diagnostic and therapeutic method." Since this provision seems to rule out experiments to establish less expensive means of addressing the HIV/AIDS epidemic, it became a subject of considerable debate. In response, the WMA reluctantly amended its position with the following addendum in 2001 that some researchers have interpreted as permitting such experiments:

> . . .a placebo-controlled trial may be ethically acceptable, even if proven therapy is available, under the following circumstances:
> 13 Where for compelling and scientifically sound methodological reasons it is necessary to determine the efficacy or safety of a prophylactic, diagnostic or therapeutic method
> . . .. All other provisions of the Declaration of Helsinki must be adhered to, especially the need for appropriate ethical and scientific review.
> (WMA, 2001)

The most recent reversion of the Declaration of Helsinki (WMA, 2008) expands the scope of the Declaration by welcoming researchers other than physicians to abide by its provisions. It also expands protections for disadvantaged or vulnerable communities stating that such research is justified in such communities only if "there is a reasonable likelihood that this community or population stands to benefit from the results of the research" (WMA, 2008, Sec. 17). Finally, it requires clinical trials to be registered in a publicly accessible database before recruitment of their first subject, and it further stipulates that research protocols address the issue of post-study benefits to participants and state provisions for participants' access to information about the results of a study.

CIOMS Guidelines

In a curious way, the second international organization issuing a global bioethical declaration about research ethics owes its origins to attempts to standardize death certificates. Jacques Bertillon (1851–1922), chief of Statistical Services of the City of Paris, convened the first International Classification of Causes of Death in 1893. A series of international conferences on standardizing international diagnostic standards followed, and in the 1920s, the League of Nations became the official convener of such conferences. In 1948, in the aftermath of World War II, the United Nations accepted this responsibility assigning this task to the newly founded WHO. The WHO, in turn, collaborated with UNESCO to established CIOMS in 1949, charging the new council with the responsibility of updating, revising, and publishing the International Classification of Diseases (ICD). It has done this on a regular basis ever since; the latest version is ICD-10.

In the 1970s, as newly independent nations in the developing world began to cope with issuing standards for ethically permissible research on their citizens, WHO tasked CIOMS with preparing guidelines that would interpret the

1975 version of the Declaration of Helsinki for special circumstances in the developing world. CIOMS' *Proposed International Ethical Guidelines for Biomedical Research Involving Human Subjects* was published in 1982. As it turned out, CIOMS not only had a mandate to view research ethics from a developing world perspective, but since it had always been an organization of public health officials, scientists, and statisticians, as well physicians, it brought a new perspective to issues in research ethics. Its membership included scientists specializing in public health and infectious disease (microbiologists, virologists) who belonged to societies whose moral traditions differed from those of physicians and who respected the moral authority of the UN and the WHO even though they were indifferent to the physician-oriented ethics of the Declaration of Geneva. CIOMS ethical guidelines are thus distinctive not only because of their mandated focus on the developing world but because they emanate from the perspective of biomedical and public health researchers who address ethical issues in epidemiological and genetic research beyond the scope of research normally conducted by physicians. Thus, in addition to its guidelines on human subjects research, CIOMS has also issued *International Guidelines for Biomedical Research Involving Animals* (CIOMS, 1985); *The Declaration of Inuyama: Human Genome Mapping, Genetic Screening and Gene Therapy* (CIOMS, 1990); and *International Guidelines for the Ethical Review of Epidemiological Studies* (CIOMS, 1991).

CIOMS first guidelines on human subjects research (CIOMS, 1982) were almost immediately obsolesced by the challenges of the worldwide HIV/AIDS epidemic (recognized in the same year, although it probably originated decades earlier). CIOMS (1993) published new guidelines focused on the developing world and the challenge of discovering new inexpensive ways of preventing and treating HIV/AIDS (CIOMS, 1993). These have since been superseded by guidelines issued in 2002 and 2009 (CIOMS, 2002, 2009). Because CIOMS research ethics guidelines originated as a commentary on the Declaration of Helsinki, over time, the commentaries evolved into a separate and in many ways distinctive document. Below is a summary of the topics dealt with in the CIOMS 2002 and 2009 guidelines and a sample of CIOMS commentary illustrating the application of abstract philosophical reflections on social justice to practical contexts in a way distinctively characteristic of the research ethics guidance offered by CIOMS.

SUMMARY OF TOPICS: CIOMS 2002, 2009: INTERNATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS (Adopted from CIOMS 2009 and Macrae 2007)

THE GUIDELINES

1. Ethical justification and scientific validity of biomedical research involvinghuman subjects

Ethical Review

2. Research ethics review committees (IRBs, REBs, RECs)
3. Ethical review of externally sponsored research

Informed Consent

4. Individual informed consent

5. Obtaining informed consent: essential information for prospective research subjects

6. Obtaining informed consent: obligations of sponsors and investigators

7. Inducement to participate

8. Benefits and risks of study participation

9. Special limitations on risk when research involves individuals who are not capable of giving informed consent.

Developing World Research and Choice of Controls

10. Research in populations and communities with limited resources

11. Choice of controls in clinical trials

Vulnerable Persons and Groups

12. Equitable distribution of burdens and benefits in the selection of groups of research subjects

13. Research involving vulnerable persons

14. Research involving children

15. Research involving individuals who by reason of mental or behavioral disordersare not capable of giving adequately informed consent

Women and Pregnant Women as Research Subjects

16. Women as research subjects

17. Pregnant women as research participants

Systemic Issues

18. Safeguarding confidentiality

19. Right of injured subjects to treatment and compensation

20. Strengthening capacity for ethical and scientific review and biomedical research

21. Ethical obligation of external sponsors to provide health care services

APPENDICES

Appendix 1. Items to be included in a protocol for biomedical research on human subjects

Appendix 2. The Declaration of Helsinki

Appendix 3. The phases of clinical trials of vaccines and drugs

The point to appreciate in reviewing the following sample commentary is that in striking contrast to the oaths and codes reproduced earlier, this commentary has the character of a philosophical treatise. Its style and construction, while not unprecedented, are nonetheless unusual in the arena of human subjects research regulation. This sample is offered to illustrate, for those unacquainted with CIOMS' statements on research ethics, how the organization develops its guidelines. The first paragraph opens with a characterization of "justice," a subject that has preoccupied philosophers at least since the publication of Plato's *Republic*. This characterization is then used to justify a series of principles of research ethics as they apply to the

developing world: such as the principle that a research project should leave a low-resource country "better off or. . .no worse off" than it was previously." In the next paragraph, this precept is invoked to justify the principle of "least vulnerability" of subjects chosen. In a later section, "Application," principles are specified in ways that single out some forms of research conducted in the developing world as "exploitive." A careful reader of CIOMS commentaries can thus follow the development of a guideline from an abstract moral concept, to a general principle, to a specific guideline, to the specification of which sorts of research conducted in the developing world are condemnable as "unethical."

Sample Commentary

(Preface CIOMS 2009, 17, 18)

Justice refers to the ethical obligation to treat each person in accordance with what is morally right and proper, to give each person what is due to him or her. In the ethics of research involving human subjects the principle refers primarily to distributive justice, which requires the equitable distribution of both the burdens and the benefits of participation in research. . ..

In general, the research project should leave low-resource countries or communities better off than previously or, at least, no worse off. It should be responsive to their health needs and priorities in that any product developed is made reasonably available to them, and as far as possible leave the population in a better position to obtain effective health care and protect its own health.

Justice requires also that the research be responsive to the health conditions or needs of vulnerable subjects. The subjects selected should be the least vulnerable necessary to accomplish the purposes of the research. Risk to vulnerable subjects is most easily justified when it arises from interventions or procedures that hold out for them the prospect of direct health-related benefit. Risk that does not hold out such prospect must be justified by the anticipated benefit to the population of which the individual research subject is representative.

APPLICATION OF REFLECTIONS ON SOCIAL JUSTICE GUIDELINE 10

(CIOMS 2009, 51–52)

This guideline is concerned with countries or communities in which resources are limited to the extent that they are, or may be, vulnerable to exploitation by sponsors and investigators from the relatively wealthy countries and communities.

Responsiveness of research to health needs and priorities. The ethical requirement that research be responsive to the health needs of the population or community in which it is carried out calls for decisions on what is needed to fulfill the requirement. It is not sufficient simply to determine that a disease

is prevalent in the population and that new or further research is needed: the ethical requirement of "responsiveness" can be fulfilled only if successful interventions or other kinds of health benefit are made available to the population. This is applicable especially to research conducted in countries where governments lack the resources to make such products or benefits widely available. Even when a product to be tested in a particular country is much cheaper than the standard treatment in some other countries, the government or individuals in that country may still be unable to afford it. If the knowledge gained from the research in such a country is used primarily for the benefit of populations that can afford the tested product, the research may rightly be characterized as exploitative and, therefore, unethical.

UNESCO's Universal Declaration on Bioethics and Human Rights (UDBHR)

In 2005 UNESCO issued an eight-page document, the *Universal Declaration on Bioethics and Human Rights*, consisting of a preamble—asserting its provenance and heritage—followed by 28 articles, divided into five sections. The section entitled Principles lays out the core of the document: 15 articles (Articles 3–17, which are reproduced below) designed to guide member nation states of the UN, international organizations, corporations, non-governmental organizations and UNESCO itself with respect to bioethical issues. The first of these principles, Human Dignity and Human Rights, states a fundamental premise of human rights theory: "(a) Human dignity, human rights and fundamental freedoms are to be fully respected. (b) The interests and welfare of the individual should have priority over the sole interest of science or society" (UNESCO, 2005, Article 3). The Declaration closes in the same vein, reasserting the preeminence of human rights, fundamental freedoms and human dignity over all other principles (UNESCO, 2005, Article 28).

The UDBHR, the most recent addition to global bioethics, consolidates six decades of progress into a single, all encompassing statement of global bioethics, grounding them in a fundamental moral concept: human rights. Thus unlike earlier statements of global bioethics that addressed only physicians, or healthcare researchers, and which confined themselves to narrow topics (research on humans, research on animals, research on the human genome, physicians treatment of hunger strikers, the rights of patients etc.) this is a broad foundational statement of bioethics generally, that lays the foundation for addressing these issues as well as the conduct of nation states and the nature of transnational agreements, emphasizing the importance of transparency and open discussion and respect for cultural diversity and human rights.

UNESCO – Universal Declaration on Bioethics and Human Rights—2005

Article 3 – Human dignity and human rights

1. Human dignity, human rights and fundamental freedoms are to be fully respected.
2. The interests and welfare of the individual should have priority over the sole interest of science or society.

Article 4 – Benefit and harm

In applying and advancing scientific knowledge, medical practice and associated technologies, direct and indirect benefits to patients, research participants and other affected individuals should be maximized and any possible harm to such individuals should be minimized.

Article 5 – Autonomy and individual responsibility

The autonomy of persons to make decisions, while taking responsibility for those decisions and respecting the autonomy of others, is to be respected. For persons who are not capable of exercising autonomy, special measures are to be taken to protect their rights and interests.

Article 6 – Consent

1. Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information. The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice.
2. Scientific research should only be carried out with the prior, free, express and informed consent of the person concerned. The information should be adequate, provided in a comprehensible form and should include modalities for withdrawal of consent. Consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage or prejudice. Exceptions to this principle should be made only in accordance with ethical and legal standards adopted by States, consistent with the principles and provisions set out in this Declaration, in particular in Article 27, and international human rights law.
3. In appropriate cases of research carried out on a group of persons or a community, additional agreement of the legal representatives of the group or community concerned may be sought. In no case should a collective community agreement or the consent of a community leader or other authority substitute for an individual's informed consent.

Article 7 – Persons without the capacity to consent

In accordance with domestic law, special protection is to be given to persons who do not have the capacity to consent:

(a) Authorization for research and medical practice should be obtained in accordance with the best interest of the person concerned and in accordance with domestic law. However, the person concerned should be

involved to the greatest extent possible in the decision-making process of consent, as well as that of withdrawing consent;

(b) Research should only be carried out for his or her direct health benefit, subject to the authorization and the protective conditions prescribed by law, and if there is no research alternative of comparable effectiveness with research participants able to consent. Research which does not have potential direct health benefit should only be undertaken by way of exception, with the utmost restraint, exposing the person only to a minimal risk and minimal burden and, if the research is expected to contribute to the health benefit of other persons in the same category, subject to the conditions prescribed by law and compatible with the protection of the individual's human rights. Refusal of such persons to take part in research should be respected.

Article 8 – Respect for human vulnerability and personal integrity

In applying and advancing scientific knowledge, medical practice and associated technologies, human vulnerability should be taken into account. Individuals and groups of special vulnerability should be protected and the personal integrity of such individuals respected.

Article 9 – Privacy and confidentiality

The privacy of the persons concerned and the confidentiality of their personal information should be respected. To the greatest extent possible, such information should not be used or disclosed for purposes other than those for which it was collected or consented to, consistent with international law, in particular international human rights law.

Article 10 – Equality, justice and equity

The fundamental equality of all human beings in dignity and rights is to be respected so that they are treated justly and equitably.

Article 11 – Non-discrimination and non-stigmatization

No individual or group should be discriminated against or stigmatized on any grounds, in violation of human dignity, human rights and fundamental freedoms.

Article 12 – Respect for cultural diversity and pluralism

The importance of cultural diversity and pluralism should be given due regard. However, such considerations are not to be invoked to infringe upon human dignity, human rights and fundamental freedoms, nor upon the principles set out in this Declaration, nor to limit their scope.

Article 13 – Solidarity and cooperation

Solidarity among human beings and international cooperation towards that end are to be encouraged.

Article 14 – Social responsibility and health

1. The promotion of health and social development for their people is a central purpose of governments that all sectors of society share.
2. Taking into account that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without

distinction of race, religion, political belief, economic or social condition, progress in science and technology should advance:

(a) Access to quality health care and essential medicines, especially for the health of women and children, because health is essential to life itself and must be considered to be a social and human good;
(b) Access to adequate nutrition and water;
(c) Improvement of living conditions and the environment;
(d) Elimination of the marginalization and the exclusion of persons on the basis of any grounds;
(e) Reduction of poverty and illiteracy.

Article 15 – Sharing of benefits

1. Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries. In giving effect to this principle, benefits may take any of the following forms:
   (a) Special and sustainable assistance to, and acknowledgement of, the persons and groups that have taken part in the research;
   (b) Access to quality health care;
   (c) Provision of new diagnostic and therapeutic modalities or products stemming from research;
   (d) Support for health services;
   (e) Access to scientific and technological knowledge;
   (f) Capacity-building facilities for research purposes;
   (g) Other forms of benefit consistent with the principles set out in this Declaration.
2. Benefits should not constitute improper inducements to participate in research.

Article 16 – Protecting future generations

The impact of life sciences on future generations, including on their genetic constitution, should be given due regard.

Article 17 – Protection of the environment, the biosphere and biodiversity

Due regard is to be given to the interconnection between human beings and other forms of life, to the importance of appropriate access and utilization of biological and genetic resources, to respect for traditional knowledge and to the role of human beings in the protection of the environment, the biosphere and biodiversity.

(UNESCO 2005).

Conclusion

The global bioethics codes, declarations, and oaths discussed in this chapter were issued by a new order of international organizations dedicated to facilitating

interstate collaboration in the aftermath of the Second World War. They have not been rigid statements carved in stone. They have been open to revision in response to changing ethical conceptions or changing circumstances. They all strive to facilitate the development of the biomedical and health-care science and medical practices for the benefit of humanity – without ever forgetting the ways in which biomedicine was at one time horribly abused.

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Commodification of Human Tissue

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Herjeet Marway, Sarah-Louise Johnson, and Heather Widdows

Introduction

Commodification is an important topic in ethics generally and in bioethics in particular. In ethics, it is prominent in debates about the self, prostitution, slavery, and labor conditions and practices in the global market (such as child labor and sweatshops). In bioethics, it is salient in the discourse on the sale of body parts, surrogacy, and genetic therapy and enhancement. In short, since commodification deals with the possible (it need not be actual, as will be discussed below) transformation of "people" into "commodities," it is relevant to all issues that threaten to encroach upon the boundaries of personhood, and in particular to those where there is a risk that the body or relationships will fall prey to such treatment. The concerns of commodification also relate to several of the provisions in the Universal Declaration on Bioethics and Human Rights, most notably on equality (Art. 10), human vulnerability (Art. 8), autonomy (Art. 5), and consent (Art. 6). The debate, for instance, is firmly rooted in the need to safeguard the bodily dignity and integrity of persons – particularly of the most vulnerable – by treating them justly and equitably. In addition, it highlights how, though autonomy and informed consent are central in bioethics, some conceptions fail to provide adequate protections for individuals, and justice requires extra precautions be put in place. Thus, commodification is a far-reaching and pressing issue in global ethics and bioethics.

H. Marway (✉)
School of Philosophy, Theology & Religion, University of Birmingham, Edgbaston, Birmingham, UK
e-mail: HXM447@bham.ac.uk

S.-L. Johnson
Department of Philosophy, University of Birmingham, Edgbaston, Birmingham, UK
e-mail: SXJ656@bham.ac.uk

H. Widdows
School of Philosophy, Theology & Religion, College of Arts and Law, University of Birmingham, Edgbaston, Birmingham, UK
e-mail: h.widdows@bham.ac.uk

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These discussions, however, have been fraught with disagreement with regard to what constitutes commodification, whether commodification occurs, and (if it does) whether it is ethically significant. In order to clarify these questions, this chapter will focus exclusively on commodification in bioethics, and in particular in the sale of body parts, though the discussion parallels the contours of the wider commodification debate.

To do this, the chapter will first explore what constitutes commodification; second show, using examples of kidney, reproductive tissue, and reproductive organ sale or "rental," that there is evidence of commodification in bioethics; and third argue that a market in these areas is ethically impermissible, because it leads to exploitation, because some things should not be for sale, and because commodification is destructive of social goods. Thus, this chapter defines commodification, highlights instances of commodification that are symptomatic of a wider trend, and concludes that commodificatory practices should be resisted.

What is Commodification?

The first section will provide a working definition of commodification. Although there are slight differences in the way the term is used in bioethical debates, this chapter regards two interconnected elements as central to any concept of "commodification": First that it transforms "persons" into "things"; and second that it changes "relationships" into "contracts." These will be considered in turn.

The first aspect of commodification is that it turns "persons" into "things." Instead of taking human beings to be ends in themselves that ought to be respected as such (a broadly Kantian position), it takes persons and their parts to be objects and commercializes them – or, as Marx puts it, it attributes a "use" and "exchange" value to them. To elaborate, a "use value" typically relates to the physical properties of an external object, whereas an "exchange value" is an expression of the worth of that object if it were traded (Marx, 1875). A commodity (or to commoditize) requires both use and exchange value, whereas an object (or to objectify) only needs use value. However, the Marxist categories do not map directly to how the term is employed in bioethics, where a commodity need not always pertain to a fully tradable *product* (such as diamonds or wheat), but rather can refer to objectifying and commercializing *processes* (as discussions on commodifying children using sex-selective technology have shown – Widdows, 2009). Thus, in this discipline, use and exchange value (separately and/or together) are regarded as indicative of moves toward commodification in some form. Drawing this all together, to commodify is to take something of intrinsic worth (such as "persons") and to objectify it by giving it a use value (so it has – or is subjected to processes that liken it to – the status of "things") and to commercialize it by giving it an exchange value, or by implying that it *could* be sold, (further degrading it to the level of tradable "things"). Thus, individuals and their parts become thought of not as "persons" but as "things."

The second feature of commodification is that it reduces bonds with other human beings to formal covenants; it moves "relationships" into the territory of "contracts," in a parallel way to which "persons" become "things" and are for sale relationships between people enter the market place. A view in which relationships are for sale runs counter to most philosophical accounts of persons, and most especially to those where individuals are intrinsically social beings, embedded in complex relations with others, as philosophers such as Aristotle (2004), Taylor (1992), and Sandel (1998) have argued. In the market, however, according to Marx (1844), workers are alienated (to maximize profits), not just from their labor, and its products, but from others, such that the market converts relationships between men to relationships between property owners. Taking this as a whole, to commodify, is to de-emphasize that individuals are, constitutively, relational beings and have interdependent ties to others and particular needs and wants, and instead is to shift toward seeing the connections between individuals as interchangeable, established and disestablished as the market requires, and valued only in extrinsic monetary terms. That is "relationships" between individuals become mere services for "contracts."

Importantly, for both elements of commodification, it need not be the case that these kinds of trades are *in fact* happening to qualify as commodificatory. What matters is *how* persons and relationships are regarded; if they are treated (through language or conception, for instance) as being objects where trade could legitimately occur, then commodification has occurred. That is, moving from "persons" to "things" and "relationships" to "contracts," "includes *not only actual buying and selling, but also market rhetoric, the practice of thinking about interactions as if they were sale transactions*" (Radin, 1987, 1859, original emphasis). Though one may not partake in buying and selling of body parts or services, for instance, engaging in the view that they could be bought and sold is itself to endorse a commodificatory shift; it is to treat something which is not a "thing" or subjectable to "contract" *as if* it were. Thus, it is not only the act but the "social practice for treating things as commodities, i.e. as properties that can be bought, sold, or rented" (Resnik, 1998, p. 388) which amounts to commodification.

This section sought to provide a working definition of commodification. It has stated that commodification is the (actual or implied) transformation of: first "persons" into "things," and second "relationships" into "contracts."

Is Commodification Evident in Bioethics?

The second section of the chapter uses this definition to explore the extent to which commodificatory practice is apparent in bioethics, paying particular attention to kidney and reproductive tissue and organ sale or rental as indicative of a general trend in this field. It does this in two subsections: First it sets out key developments in organ and reproductive technologies, and second it considers whether or not commodification is occurring in these areas by examining whether "people" are

becoming "things" and whether "relationships" are becoming "contracts." It argues that commodification is occurring in these instances, and by extension in bioethics, since new technologies encourage parts of human beings to be seen as objects, which are – or are spoken of *as if* they are – "for sale," and thus that this makes it more likely that relationships are regarded as similar to commercial transactions rather than complex human connections between people.

Advances in Kidney and Reproductive Technologies

First, this subsection briefly describes the technological and medical developments relating first to kidneys and then to reproduction. Starting with kidneys, successes in transplant technology and anti-rejection drugs have, most obviously, led to the possibility of kidney transplants and a prolonged and better quality of life, free from cumbersome dialysis. Many individuals with end-stage renal disease have benefitted from these advances. In 2010, for instance, at least 73,180 kidney transplants were performed in 95 countries across the world, with the USA, Norway, and France among those carrying out the most transplants per million of the population (Global Observatory on Donation and Transplantation [GODT], 2010a), and the USA, China, and India the top three in absolute terms (16,898; 5,540; 5,000 transplants, respectively) (GODT, 2010b). These developments have, therefore, helped numerous people. However, currently, demand for kidneys still outstrips supply in almost every country of the world; in the UK, in 2010, 6,871 (UK Transplant Support Service Authority, 2011), in the USA, in 2012, 92,749 (Organ Procurement and Transplant Network, 2012), and "globally, at least 200,000 people are on waiting lists for kidneys and many more have no access to transplantation or dialysis services" (Garwood, 2007). Undoubtedly then, there is an unmet desire for kidneys worldwide. Nonetheless, the breakthroughs in this area have led to the chance for successful transplants, with many lives extended and improved.

There has been similarly marked progress in reproductive technologies and the potentials they offer. Advances in in vitro fertilization (IVF) in particular have meant that eggs can now be fertilized externally and then implanted in a uterus for gestation. Individuals have taken advantage of these procedures. By 2009, for instance, 170,000 babies were born using IVF treatment, which accounted for around 2 % of all babies in the UK (HFEA, 2010), and between 1978 and 2010, approximately 3.75 million babies had been born through assisted reproduction methods worldwide (European Society of Human Reproduction and Embryology, 2010). Such technologies have enabled additional possibilities; for instance, while during pre-IVF, only traditional surrogacy (using the surrogate's egg) was achievable, post-IVF, gestational surrogacy (categorically not using the surrogate's egg) became realizable. Again, this has led to an uptake in gestational surrogacy globally; the Permanent Bureau of the Hague Conference on Private International Law's (PBHCPIL) *Preliminary Report* (2012), for instance, states that international arrangements are growing at a "rapid pace" (PBHCPIL, 2012, p. 5) and that across a sample of five agencies between 2006 and 2010, there was an "increase of nearly

1,000 %" (PBHCPIL, 2012, 8, original emphasis) in such agreements. Such technologies have made new procedures in reproduction viable and they are increasingly being used.

Along with these new technologies and procedures have come ever more sophisticated notions of what is possible and desirable, as well as greater expectations of entitlement: for instance, there are now assumptions with regard to both having children when infertile and with regard to the type of children one might have (Widdows, 2009); and, similarly, the fact that kidneys can be transplanted leads to the belief that individuals are entitled to these organs. Such expectations are understandable from the individual's perspective; a kidney transplant is life altering – it can provide some 50 % of the function of two healthy kidneys, compared with just 5 % by dialysis (UK National Kidney Federation, 2011) – and having a child is an urge felt by many. However, meeting the expectations of individuals is not the only factor to bear in mind; other pressing ethical issues, such as commodification, must also be considered.

Commodification Relating to Kidneys and Reproduction

This subsection will explore the claims of commodification, paying attention to examples of kidney and reproductive tissue and organ sale and rental (and it is trading in, rather than donating, body parts that commodification arguments typically object to – see Dickenson, 2007). It discusses both elements of the working definition above – first whether "persons" are made into "things," and second whether there is a move from "relationships" to "contracts" – and argues that there is indeed a commodifying trend in both these areas, and by extension in bioethics.

"Persons" to "Things"

First, then, the transition from "persons" to "things" will be explored. As discussed, two elements are identified in the commodification process – how far persons are becoming: first objects (objectified); and second for sale (commercialized). It is important to remember, as noted above, that these are connected and bioethicists are often concerned not with whether sale *actually* occurs or (to use Marxist language) with whether there is an exchange value (though often it does and there is – as will be discussed), but with when the language of the market enters the debate and persons (and their parts) come to be regarded *as if* they could be sold. With this in mind, this section will consider the extent to which "persons" are assuming the form of "things."

New technologies have permitted parts of the body to become thought of as distinct from the person from whom they come in a way that was not feasible before. Kidneys, for instance, can be removed from one body and reissued to another, and likewise, gametes can be extracted from one person, manipulated using artificial fertilization methods, and implanted in the womb of a third party in order to create a child. Only because it is possible to separate these parts from

people is it possible to consider them as "objects" and "objects of potential trade" at all. Objectification is beginning to occur then with this ability to "detach" parts and see them as disembodied.

On this characterization, objectification happens – or arguably happens – in donation as well as sale. However, in donation, even though "parts" are removed from persons, commodification does not occur because such parts are not thought of as being saleable. Moreover, because of the nature of donation, donating contradicts the assumptions of the market model and may, in fact, be something that reduces commodification (a point to which this chapter will return in the discussion on social goods). By contrast, in sale, commodification is evident in the practices of trade and in the market rhetoric that surrounds it. The discussion on body parts, for instance, is suffused with the language of the market: It *assumes* that one's (or another's) body and its parts are saleable. An Indian woman, for example, reported that she wished she had, "a third kidney, [so she had] *two* to sell" (Scheper-Hughes, 2002, p. 3), and surrogates are described as having a "womb for rent" (Armour, 2012, p. 231) with one seeing herself as ". . .strictly the hotel" (Ragone's study in Van Zyl & Van Nierkerk, 2000, p. 405) in the arrangement. These examples show both objectification and commercialization (together clearly commodification) happening, as terms such as "hotel" and the wish of having more to sell are undoubtedly market rhetoric. Thus, transplant and reproductive technology have enabled new procedures and also made it much easier for parts – kidneys and wombs (which of course cannot be "detached" from the person) – of "persons" to be conceptualized as tradable objects, as "things."

Commodification is even more conspicuous in instances where markets – which trade "things" – have been formalized or are practiced, since kidneys and the reproductive parts or services that are exchanged become, by definition, commodities with a price. For instance, in Iran, kidney sale is legal with "compensation" fixed at 10 million Rials (USD $1,090) (Bagheri, 2006), and in other jurisdictions, including some US states, the Ukraine, and India, there are open markets in reproductive parts – in the USA, for example, some agencies buy eggs for $7,000, with this fee increasing by $500 for each sale (up to six times) (Family Creations, 2008) and others literally offer male college students an on-campus mobile vehicle in which to ejaculate and sell their sperm (Sperm Mobile, 2007). In addition to such obvious markets, there are many unofficial "black" and flouting "gray" markets. For instance, despite exact figures being difficult to come by and varying, reports suggest that, on average, kidneys can fetch up to $5,000 on the "black" market, though this stoops to as low as $650 in some countries, like Kenya (Havoscope, 2012); and, to bypass laws, some infertility clinics in the Mediterranean offer "all expenses paid holidays" that also provide opportunities for egg-selling under the guise of "donation" (Cyprus IVF, 2007) on the "gray" market. Here, as in all markets and practices of sale, body parts are commodities, "things" sold at a "price." Where there are markets then, there is overt evidence of the objectification and commodification of human tissue and organs.

Thus, commodification occurs to some degree both when body parts are treated *as if* they could be traded and by *literally* trading them on a legal or illegal market.

Where body parts and the use of bodies are objectified and commercialized, "persons" are moving toward being "things"; they are deemed commodities – as simply objects to buy and sell.

"Relationships" to "Contracts"

The second element of the definition of commodification to apply to the sale of body parts is whether "relationships" are being transformed into services for "contracts." There are two aspects to consider – the extent to which relationships are becoming: first artificially fragmented, and second saleable. As with "persons" to "things" above, evidence of commodification in relationships is not limited to the existence of actual markets but extends to regarding them as though they were tradable. The possible shift from "relationships" toward "contracts" will be discussed in this light.

Developments in technology and seeing "persons" as "things" have begun to alter the form and structure of relationships. For instance, reproductive technologies and various types of surrogacy make it possible to create numerous parenting relationships (genetic, gestational, or social), but these are often crudely determined and demarcated through contracts, with the gestational relationship in particular relegated to a specific functional role with a start and finish. One surrogate, for example, reports, "it's like a contract and it severs it completely at the end because it's a job done and you're paid for it and that's the end of it" (Baslington, 2002, p. 64). The language of the market enables gestation to be considered a discrete task. Yet, it is unclear that such intimate relationships – even without a biological tie – could be so easily compartmentalized. Indian surrogate, Sonal, for instance, reports about her first child as a gestational mother, "When they took her away I cried for 3 days. I missed her so much" and of her second pregnancy, "I will feel like I am giving my child to someone else" (BBC News, 2011). Despite such feelings, and her pleas to help look after the child, the nature of the contract meant that she was expected to relinquish all bonds, and, Carolina, the Irish intended "mother," was adamant that a relationship between Sonal and her child should not be maintained: "I will always be eternally grateful to Sonal for what she has done, but I felt there has to be a cut off point" (Baslington, 2002, p. 64). The connections between the surrogate and child, which would normally continue, are artificially severed in surrogacy contracts of this kind, and it is treated as a finite nine-month "job," rather than an interaction of a different order, one which involves human relationships and feelings. Some surrogates may be different to Sonal and express a preference not to maintain ties with the child, though this in itself is not an argument for labeling surrogacy as mere paid work (and, if fact, studies indicate that mechanisms, such as "support" strategies and payment, are important in discouraging an attachment to the child – Baslington, 2002; Ragoné, 1994). Either way, the "boxing-up" of "relationships" in this manner is to start thinking of individuals as resources and as providers of "contractual" pregnancy services rather than bearers of "relationships." It is to treat parenting and the ties with the children involved as if they were not "relational," but "fixed term contracts," equivalent to other work.

In a different, but somewhat parallel, way, current "relationships" of kidney donor and recipient are being transformed too. The combination of medical advances, desires for prolonged lives, and the "person" to "thing" shift generates a want for kidneys which, when compounded by market rhetoric, makes it possible to regard acquiring a kidney as a service. For example, one Israeli man preferred to pay for a live kidney from a peasant in Georgia rather than wait for one, claiming, "I chose a better way. I was able to see my donor. . .He was young, strong, healthy. Just what I was hoping for" (Scheper-Hughes, 2002, p. 52). Having the option to buy is reflected in the language here, which is like that of a purchaser inspecting a prospective kidney provider rather than that of a receiver of a gift from another human being. At the same time, potential vendors are encouraged to sell, but left to face the consequences once the onerous operation is over (Aman, 2009; Zheng, 2011). In sale rhetoric, once the service is fulfilled and payment made, all relations are terminated, but this disregards the particular human responses that envelop this arduous procedure and treat it like any other "service." In these examples, whether a buyer or seller, the physically and psychologically demanding process of getting a kidney is reduced to an isolated act in the framework of sale, and the language of the market facilitates this by making the complex relationship of gift a delimited transactional affair. Thus, through the language of the market, the act of selling a kidney is artificially enclosed, separated from the person, and thought of as being sellable as a service in that distinct form to another. This makes it easier to begin to think of persons not as relational beings but as kidney sources, and with it comes a shift from "relationship" to a model that implies services for "contract."

This move is more apparent in practices of sale where "services" are formally priced, as they are for both commercial surrogacy and kidney sale. Where gestational surrogacy is legal, for example, costs to the intended parents to cover the entire arrangement (including fertilization, surrogate's fees and costs, legal and agency fees) can range from $70,000–150,000 in the USA (Ellis, 2012; Campbell, 2010) to $12,000–35,000 in India (Delhi IVF, 2012; Medical Tourism Corporation, 2012). That these elements, and in particular the surrogate's "job," have a formal cost associated (usually a fraction of the overall amount) is unambiguous evidence of seeing her as providing a service. Similarly, since kidneys on "black" and "gray" markets have a price attached – buyers can pay, on average, $150,000 and up to $250,000 (Havoscope, 2012), though again brokers, middlemen, gangs, and doctors receive the lion's share of the fee (Smith et al., 2011) – this indicates the exchange is a formal "contractual" service. Financial compensation at these rates moves away from thinking of the seller as giving an invaluable gift (of life) to providing a purchasable (kidney or child creation) service. Thus, the relationship of donor/recipient is changing into that of buyer/service provider by being allocated a formal monetary value and by being brought into the contractual model. "Relationships" are becoming "contracts."

This section has considered whether, and the extent to which, commodification is occurring in bioethics using the examples of kidney and reproductive tissue and organ sale or rental. There are indeed grounds for claiming that "persons" are being turned to "things" when body parts are being objectified and then turned into

objects for sale, either by being bought and sold in the market or by being treated *as if* these body parts and services become commodities. Likewise "relationships" become "contracts" in similar conditions; kidney sale and gestational surrogacy contracts diminish the relationship of "givers" of "gifts of life" to those of "sellers" of a "product" or "providers" of a "service." In presenting such interactions as transactions in the market, the complexity inherent in these human relationships is reduced. These products and services are presented as *mere* commodities – exchangeable with other products and services or with money – and assumed to be equivalent in nature. Thus, rather than seeing persons fundamentally as human beings with whom others have relationships, including ties of gift-giving, friendship, and love, with *an intrinsic value*, in the extremes of the market model "bodies of persons are regarded as resources" (Chadwick, 1989, p. 137) and nothing more (instrumental value). Therefore, there is evidence of commodification in the two senses defined earlier – turning "people" into "things" and "relationships" into "contracts" – in the sale or rental of human tissue and organs, so claims that there are commodifying practices present in bioethics seem to be well founded.

What Is Wrong with Commodification?

The previous section explored how commodification is a common phenomenon in bioethics. Implicit in this discussion was the assumption that commodification is ethically problematic – that people should not be things and that human relationships suffer if they come to resemble the exchanges of the market. However, these claims merit justification, as they are often contested. This section will, therefore, explore and respond to arguments from those who dismiss commodification as an ethical concern and instead advocate a market model. Two grounds for a pro-market approach – first valid consent, and second fair price – will be briefly outlined before the insufficiencies of such views, and the persisting ethical problems of commodification, are exposed.

First then the market model rejects misgivings about commodification in one of two ways. In one set of rebuttals, some contend that sale is unproblematic as long as people have the right to consent. If there is demand and supply, then individuals ought to be able to trade whatever they wish, including body parts and services, since this respects their autonomy. Julian Savulescu, for example, argues, "...to ban a market in organs, paradoxically, is to constrain what people can do with their own lives" (2003, pp. 138–139), and Carmel Shalev takes a similar line for paid surrogacy adding, to disallow enforceable contracts, "implies that women are not competent, by virtue of their biological sex, to act as rational, moral agents." (1989, p. 11) This view asserts that a "market approach plus consent" allows maximal respect for individual choices, and that allowing such choices is ethically important, and certainly more urgent than paternalistic worries that restrict what individuals can and cannot do with their own bodies.

Others also deny that commodification, or the sale of body parts per se, is particularly problematic. They argue that a market is permissible in principle, but

that safeguards must be in place to ensure that such a market is ethical. For instance, Erin and Harris propose that the market be a confined geopolitical area (perhaps, the European Union) in order to alleviate the worst forms of exploitation that comes from inequality. Likewise they suggest single fair price could be ensured by having a single purchaser (like the National Health Service) who would also be responsible for testing organs for disease and verifying their origins before distributing them according to medical need (Erin & Harris, 2003, p. 137). Others argue that ethics requires improvement of the current market conditions. Accordingly, they argue that rather than criminalize transactions in human tissue and organs – a practice already ongoing – it would be much better to properly regulate and to create "fair-trade" (Humbyrd, 2009, p. 116): sale which is safer and more equitable (a familiar argument in ethics, whether for drugs, prostitution, or any illegal practice). The claim is that non-sale models are patently less fair than sale as everyone but the donor benefits in donation, whereas the donor – who takes the biggest risks – is only rightly financially rewarded in the sale (Matas, 2004). On this account, regulation of the present system would be better than disallowing sale altogether and a "market plus fair price" model is one that could be ethical.

However, these pro-market arguments fail to address broader ethical concerns which arise from commodification and which cannot be tackled simply by insisting on consent, by setting a fair price or by seeking a fair-trade: First that of exploitation; second that some things should not be for sale; and third that contractual relationships destroy other social goods. The rest of the chapter will focus on bringing out these key commodificatory harms.

Exploitation

The first commodificatory concern which is not addressed by consent or fair price is that once persons can be considered resources (things or providers of services) – rather than persons deserving of respect in themselves – they are far more open to exploitation. While market proponents might claim that the risk of exploitation can be mitigated and absorbed by competent adults (the consent view) or the possibility reduced by the introduction of an equitable fee (fair price), this underestimates: first the vast global inequalities within and between countries that distort notions of consent and fair price, and second the way market rhetoric and market models make exploitation more likely precisely because they encourage the conception of persons as things and relationships as contracts.

First, exploitation is made likely simply by the fact of inequality, both globally and within societies. Such inequality is feature of the market. The market is not a "neutral" system of exchanging goods or services between free and equal agents, but inherently skewed to favor some more than others. This is so for any market but, as Anne Phillips argues, "more so, and more intrinsically than other markets, markets in bodies rely on inequality" (Phillips, 2011, p. 14). It is more likely, for instance, that those who sell kidneys or rent wombs are poor and buyers affluent, and in a global market, the gap is even greater. As Nancy Scheper-Hughes argues,

"In general, the flow of organs follows the modern routes of capital: from South to North, from Third to First World, from poor to rich, from black to white, from female to male" (Scheper-Hughes, 2000, p. 193). This is a pattern of market biases toward the global rich at the expense of the global poor, and the market in body parts and services is sustained by these disparities (for its supply of buyers and sellers), and the market model ignores this partiality (asserting that trades happen between supposedly free and equal parties).

Within this context, both the fair price and consent arguments begin to look ineffectual. For those who believe consent alone is enough, the fact that the seller has consented, and is not physically shackled or compelled, to engage in the transaction, does not equate to making a "free autonomous choice" in the usual meaning of this term. For someone who is poor, for example, the "choice" often can be "desperate" and so "inherently undesirable, chosen only when the range of possible choices is extremely limited" (Widdows, 2011, p. 89). Agreeing to a desperate choice then does not seem as if it provides the ethical protection that the doctrine of consent is intended to provide. For instance, Fatolaa F, an Iranian kidney-seller, opted to sell, but post-sale states, "like a cigarette end we have been thrown out. We are crushed by poverty and exploited by parasitic mercantile capitalism that press us to sell our only remaining belongings – our kidneys" (Zargooshi, 2001, p. 1791). In this example, the sale was agreed to but only reluctantly because of the dire economic circumstances, and thus is hard to regard as full "consent." To pin an argument for the sale of body parts and services exclusively on the agent's consent disregards factors that led to that consent (such as poverty) and exposes individuals to exploitation.

Likewise, for those who think a fair price is the way forward, just because there is a "reasonable fee," it does not mean that the arrangement is equitable or that the seller has a "good deal." Rather, once the economic disparities are taken into account, offering money at all can smack of a coercive force – an "offer that is too good to be true" – and this is especially the case for those in extreme poverty. That is, even if a "fair price" could be established, the inequalities serve to exacerbate the vulnerability of the sellers to this kind of contract in particular because, in contexts where buying basic amenities is the primary (if not sole) financial struggle, money in exchange for anything – including human tissue, organs, and services – can begin to look appealing. In this vein, the World Health Organisation (2004) acknowledged the risk of exploitation, given global inequalities, and urged Member States to "protect the poorest and vulnerable groups from transplant tourism and the sale of tissue and organs." Allowing the sale – "fairly priced" or otherwise – of body parts at all, therefore, will lead to exploitation.

To claim that a market model is unproblematic and commodificatory concerns unfounded so long as there is a sufficiently "fair price" paid to a seller or insofar as the seller "freely chooses" to do so then seems disingenuous in the context of vast global inequalities. Neither the "market plus" consent nor fair price approach will counteract the exploitation of impoverished sellers (a key commodificatory issue) under such conditions.

The second reason why the market model is inappropriate is because it encourages commodification, which in turn enables exploitation. Permitting the sale or rental of body parts facilitates a view of them as tradable "things" and as services for "contract." The inherent value of persons and relationships are degraded and, exploitation becomes easier and impoverished views of persons, including the self, are encouraged. For instance, if market rhetoric is entrenched, then it is likely that individuals might think it plausible that they can legitimately use their bodies and sell an organ or sign a paid surrogacy agreement and without this harming their personhood more broadly. Yet, by thinking of organs as "not really me" but a discrete and sellable part of oneself, it is easier to fall into subordination for that "part" without recognizing it as a domination of the whole person (Phillips, 2011, p. 8). A single kidney might be sold in a transaction, but the advantage is over the entire individual since "persons" cannot ethically be thought of as "things" with component parts to trade. Similarly, by assuming that relations with a child can be neatly "carved-up" into a separate gestational service when a "smoothly completed surrogacy contract and an unconcerned 'surrogate' mother" (Pateman, 1988, p. 215) is a fiction, make it more likely that such an arrangement falls short of adequate protections for the surrogate. It is not just services that are being bought, but relationships between people that are unethically subjected to the market and misused. Thus, it is false to adopt the view that one can consensually exploit particular parts or services, such as kidneys and wombs, and equally mistaken to think such exploitation excludes damage to the self.

The market model, therefore, is inappropriate since it cannot properly deal with ethical concerns relating to exploitation in two ways. First, it is unable to diminish a context of global inequalities that make it highly probable that persons in desperate circumstances might "consent" to do anything – including sell body parts – for money – even if set at a "fair price." Such individuals are often the most vulnerable, yet it is precisely these individuals that tend to become sellers in the market. To present the sale of body parts as a genuine and neutral economic option given this, is simply exploitative. Second, the market approach perpetuates the myth that parts of the self can be sold without this impacting the self in general. This is false picture because, in the process of commodifying discrete parts, the whole self suffers exploitation too. Thus, the market model does not overcome the problem of exploitation while arguments against commodification – with their worries about turning "persons" into "things" and "relationships" into "contracts" – are underpinned by concerns about degrading selves and taking unfair advantage of the most vulnerable, and so are better able to preempt this ethical problem.

Some Things Should Not Be for Sale

A second issue commodification raises that the pro-market approach cannot account for is that some things should not be for sale at all (Marx, 1844; Sandel, 1998; Walzer, 1983). Sometimes referred to as the "theory of 'blocked exchanges'"

(Wolff, 2011, p. 176), this view suggests that the nature of a particular good determines whether it should be put on, or kept off, the market; if selling would destroy the essential character of the good, then it ought not be for sale (Wolff, 2011, p. 176). A case in point is love or friendship; these are inherently valuable goods because of the deep bonds (of trust, affection, generosity, shared histories, and more) between individuals that they intrinsically involve, and selling love or friendship would eliminate these features (Sandel, 2012). Returning to "relationships" becoming "contracts," this can be explored by considering the expectations and entitlements of the parties in either case (Widdows, 2009). By way of example, if "friendship services" were purchasable, all the ties and connections that exist in relationship mutate into the enforceable, but relationally detached, set of expectations and entitlements of contract; checking up on a "friend's" welfare stems not from a loving bond but from what is expected by her in the arrangement, and likewise cooking a meal for a "friend" who has recently received some bad news is based not on sympathy with her plight but on what she feels entitled to by paying for this service. Thus, the very nature of "relationships" as deep bonds with others disappears in "contracts," so friendship *cannot* be put on the market.

Similarly, it seems like the market is not an appropriate way in which to govern human tissue and organs, since this is qualitatively different from objects like cars, and it does not work well with relationships, since these are different to being parties to contracts. That is, sale is an improper structure for bioethical matters because it ignores that the substance of the agreement is the body itself (Dickenson, 2007) – physically extracting organs and gametes, or implanting embryos for gestation, or carrying a child. Further the market is not the best approach for bioethics because it ignores that there are different "spheres of justice," each regulated by distinct principles (Walzer, 1983) – so organs and reproductive parts might be better dealt with by relationships of gift-giving than sale. For instance, receiving a kidney or a child after gestation is not a transactional matter that other individuals *should* expect or feel entitled to; rather, it is more appropriate to think of them as gifts they are lucky to receive and which the donators or volunteers might change their minds about giving. Thus, managing body parts and services by using the language of sale, with its concomitant expectations and entitlements, instead of (say) gift, with its relational roots, appears to be the wrong sphere for the substance of the good.

To illustrate, if the kidney one "orders" or the child one "commissions" through IVF sex-selection and gestational surrogacy turns out to be less than what was expected (say by being incompatible with the body in the case of the kidney, or a girl instead of a boy with the child) and one cannot return the "item," does one feel disappointed with the organ or child and entitled to compensation for not getting what was paid for? And, in the case of the child in particular, does it fundamentally alter how one views her as somehow less than ideal (Widdows, 2009)? Thinking about the language of "contract" rather than "relationships" in these examples highlights how expectations of fulfillment and assumptions of entitlement that are the norm for buying cars or painting houses seem inappropriate when applied to

relationships or bodies. This suggests that inanimate objects on the one hand and human tissue or relationships on the other are not comparable, and though sale might be permissible in the former, it is not the correct sphere for the latter, because market rhetoric destroys the nature of the donating and parenting relationship. Thus, such goods should not be for sale, and this is a further concern that a commodification analysis exposes but which is invisible on the market model.

Therefore, while the market fails to acknowledge that sale alters the essential makeup of a good, commodification arguments recognize how the fundamental constitution and purpose of inherently valuable human goods (like "persons" and "relationships") become distorted when sold, and it is this that commodification debate seeks to avoid.

Social Goods

The final reason why commodification is ethically problematic but which the market approach misses is that it has a detrimental effect on social goods and communal relationships (Titmuss, 1970). The position is that valuable societal attitudes which are encouraged by practices of "gift" and "donation" are eroded by sale; essentially that "financial incentives and other market mechanisms can backfire by crowding out nonmarket norms" (Sandel, 2012, pp. 113–114). Sale should, therefore, be rejected in order to preserve these broader goods.

To elaborate, the market, "creates relationships of trade, exchange and contract rather than relationships of gift, participation and shared endeavour" (Widdows, forthcoming), and this is so not only at an individual level but a communal one too. These differing approaches – contract and gift – carry with them sets of values that can lead to two distinct pictures of society, and in particular of social capital. For example, Richard Titmuss, in his research on blood sale and blood donation (1970), argued that blood that was donated led to attitudes of sharing and solidarity in contrast to blood that was sold which invoked a sense of individualism and a prevalence for the rights of ownership. Further, he contended that the blood donor's belief (that a system of collective goods would be beneficial) and the wider healthcare context (the UK's nonmarket model) were mutually reinforcing:

> The ways in which society organises and structures its social institutions – and particularly its health and welfare systems – can encourage or discourage the altruistic in man; such systems can foster integration or alienation; they can allow the "theme of gift" – of generosity towards strangers – to spread among and between social groups and generations. (Titmuss, 1970, p. 255)

In a self-fulfilling cycle, a context of gift and participation leads to equivalent attitudes in individuals, from which they are more likely to contribute to and support social goods; by contrast, a background of sale leads to feelings of social disengagement in persons, which reduces the opportunities for developing the kind of virtues that could bolster common goods. Thus, the social costs – alienation and selfishness, for instance – of a market model are too great.

Such arguments have been drawn on widely. Similar claims, for instance, have been advocated for state funding of particular goods; allowing nonmarket provision in many areas of citizen's lives (including free concerts and universal health care) can be socially beneficial by opening up the possibility of social cohesion, solidarity, and trust (Wolff, 2011). Again, the communal benefits are vastly more important than allowing a free market in these areas. Most recently, this approach was reiterated by the Nuffield Council on Bioethics in their report *Human Bodies: Donation for Medicine and Research*, where they noted, "departure from the altruistic model. . .could run the risk of irreversible damage to important communal virtues" (Nuffield Council on Bioethics, 2011, p. 147), and so payment for organs, such as kidneys, (although not gametes), should continue to be prohibited. Thus, while market rhetoric erodes social capital, the language of gift enhances it. Sharing, solidarity, and common goods, therefore, are part of a gift model whereas they are not at the forefront or even existent in contract, and donation is more likely to generate attitudes of altruism and trust than sale. These are significant social goods that ought to be protected and cultivated.

A market model then does not give weight to social goods but concerns about commodification in bioethics – how individual "contracts" for service undermine "relationships" of gift-giving in society – highlight, from the outset, how shared goods and virtues are important for persons and communities alike. It is not just the effect on individual cases of selling or renting human tissue and organs but – and importantly – to society as a whole that matters. That is, "[i]t is likely that a decline in the spirit of altruism is one sphere of human activities will be accompanied by similar changes in attitudes, motives and relationships in other spheres" (Titmuss, 1970, p. 224). It is these kinds of shifts that society should resist. These harms, which commodification arguments illuminate, are again obscured in the market model.

This section has discussed how pro-sale arguments are unable to deal with concerns about inequality and exploitation, or the intuition that some things should not be for sale, or the importance of fostering social goods. By contrast, an approach which focuses on commodification can recognize and critique the inequality of the market and the impossibility of a fair price and the pretensions of "free choice" in a context of global disparities; it can account why some things, including body parts and types of relationships, should not be for sale; and show that allowing sale is detrimental to common goods and destructive of social capital. Thus, commodification in bioethics remains a problem that needs to be combated by circumventing sale: because the market is unjust and, even if it was not; because "persons" and their parts and "relationships" should not be sold; and because common goods, if tradable, would have devastating effects on social cohesion and solidarity.

Conclusion

This chapter sought to explore the nature of commodification, to map its occurrence in bioethics and to consider its ethical significance. Commodification was defined as having two key features: first that of turning "people" to "things"; and second of

transforming "relationships" into "contracts." Using this framework, commodification in two areas of bioethics – that of kidney sale and reproductive tissue and organ sale and rental – was investigated. In both cases, "persons" were regarded as if "things" with kidneys, reproductive tissue, and wombs to rent all available as purchasable "products" on the market, and "relationships" considered "contracts" with donating and parenting relationships "carved-up" and sold as discrete services with an artificial start and end point. From here, it was argued that pro-market counterarguments about "free choices" to sell or rent or allowing a "fair-trade" in human tissue and organs were ethically unsustainable: There is, given vast global inequalities, a high risk of the most vulnerable being exploited by a market scheme; some goods, like bodies and relationships, should not be on the market at all as this destroys their intrinsically valuable nature, and the detrimental effect of sale over gift on social goods, such as solidarity and trust, is neglected in market rhetoric. Since commodification is a trend in bioethics, and since having a fair market will neither stop the worries relating to commodification itself nor its consequences, this chapter concludes that a trade in human tissue and organs is not ethically permissible, because to allow a market commodify "persons" and "relationships" is exploitative, damages their nature, and erodes common goods. Commodification and commodificatory practices should, therefore, be resisted.

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Corruption

35

Jennifer E. Miller and William English

Introduction

Problems of "corruption" pose unique challenges in many areas of concern to bioethics, including the research, development, and marketing of drugs, the delivery of foreign and disaster aid, and the allocation and quality of medical care. However, although it is tempting to think one knows corruption when one sees it, defining corruption and diagnosing its influence are easier said than done. Corruption can take many forms, and evaluating them requires understanding both their underlying logic and the prospects for change.

The purpose of this chapter is to identify and to catalog forms of corruption that pose serious challenges relevant to bioethics and to suggest avenues of reform, but a number of claims and concepts need to be clarified at the outset. This chapter begins by providing a broad outline of the reasons that biomedical fields are vulnerable to corrupting influences, before turning to a more detailed examination of different types and examples of corruption. This chapter focuses, in particular, on issues related to the pharmaceutical industry and does so for three reasons: It is useful for illustrating the intersection of different sorts of concerns, it is an area increasingly scrutinized by the bioethics literature, and it reflects the scholarly expertise of the authors. This chapter concludes with a discussion of the costs of corruption and strategies for reducing it, while emphasizing the need for continued vigilance and study.

Are Biomedical Fields Particularly Vulnerable to Corruption?

At the outset, it is important to note that corruption is a particular concern and vulnerability in biomedical fields for at least six reasons.

First, biomedical decisions often rely on expert judgment, making those without expertise dependent on the good faith of specialists. This asymmetry in knowledge

J.E. Miller (✉) • W. English
Fellow, Edmond J. Safra Center for Ethics, Harvard University, Cambridge, MA, USA
e-mail: jmiller@bioethicsinternational.org; wenglish@ethics.harvard.edu

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creates vulnerabilities that present opportunities for corruption. Lay people must trust doctors to give their honest opinion and recommend diagnostic testing or therapies based on medical evidence, trust researchers to disclose study risks, trust pharmaceutical manufacturers to produce safe and effective drugs, and so on. Likewise, doctors must trust the veracity and completeness of journal articles and the medical education they receive pertaining to the products they prescribe. Outsiders simply do not have the expertise to make these determinations on their own on a case by case basis. Thus, they must rely on the judgment of others, and the corruption of expert judgment will be a recurrent concern.

Second, even for experts, biomedical issues often involve complexities and uncertainties that present serious epistemological challenges. Getting to the truth of a matter may take years of data collection and careful analysis. Even then, experts may disagree about, say, the relative effectiveness of a treatment or the public health risks of a chemical. The complexity of such issues, multiple parties involved, and the extensive research that must inform their resolution increases the possible opportunities for corruption. For example, those concerned with the accessibility and affordability of life-saving medicines will need to become familiar with intellectual property and patent law, the TRIPS agreement, international tiered pricing systems, concerns over reimportation, drug diversion, and drug counterfeiting, nonexclusive licensing agreements, patent pools, and more philosophical questions regarding what can be reasonably expected from a for-profit company in terms of its philanthropy and charitable giving. Moreover, when there are disagreements regarding scientific questions, those interested in a particular outcome, regardless of its truth, might try to influence the funding of studies, the collection of data, the analysis, interpretation, and dissemination of results, etc. Ultimately, complexity increases opportunities for corruption, and biomedical research is full of complex issues.

Third, many commercial enterprises related to biomedical fields depend heavily on decisions made by regulatory bodies and thus have an extraordinary interest in influencing the regulatory process. For example, the business model that makes originator pharmaceutical companies viable rests on drug approvals and patent protections. Pharmaceutical companies have an extraordinary stake in decisions made by the Food and Drug Administration regarding patent life, clinical trial standards, ongoing evaluation requirements, and so on. The situation is similar for the medical device industry and hospital systems. Moreover, the dynamism of biomedical fields means that regulatory and legal regimes will often be playing "catch-up" in trying to adequately respond to new developments. Because of the disproportionate influence of regulatory decisions (compared to most industries) and the complexity of issues involved, biomedical enterprises must remain closely engaged with the regulatory environment. Although appropriate, this creates extra incentives for "gaming" and "regulatory capture" (to be explained shortly).

Fourth, the large amounts of money involved make healthcare, and the pharmaceutical sector in particular, vulnerable to corruption and unethical practices.

The global expenditures for general health services total more than $3 trillion USD annually (Poullier, Hernandez, Kawabata, & Savedoff, 2002). In some countries, medicines account for up to 65 % of total health expenditures, and, in the least developed countries, medicines are the second largest household expenditure, after food (World Health Organization [WHO], 2011). Although financial interests are not the only kinds of interest that can corrupt, the extraordinary amounts of money at stake in biomedical fields make them ripe for abuse. Self-serving interests are likely to target biomedical fields for the same reason that the outlaw Willie Sutton robbed banks: because that is where the money is.

Fifth, it is important to note that biomedicine can involve uneven distributions, not only of wealth and expertise, but also of power. Individual and smaller interests, even when they represent valid ethical claims, may have little recourse in dealing with the larger political, economic, and social forces that are operative in biomedical fields. Disparities in legal resources, human and financial capital, political clout, and media representation can exacerbate whatever forms of corruption exist and stifle reform efforts.

Finally, the challenges involved in diagnosing and dealing with corruption in biomedical fields are only compounded by the field's increasing globalization. Different countries have different regulatory regimes, political institutions, and social expectations. The standards by which one judges corruption in one country may be different than the standards appropriate for another country. For example, in the United States, pharmaceutical companies are largely prohibited or capped in their gift-giving practices to doctors and hospitals; however, in developing countries, companies are often encouraged to support local hospitals and physician practices through "capacity building" partnerships. One of the central questions when analyzing corruption from an international perspective is determining which standards have universal validity and which must be calibrated to the unique situation of a particular society.

What Is Corruption?

It is important, in the first instance, to distinguish corruption from a wider range of undesirable outcomes. If a surgeon's hand slips on the operating table, this may considerably harm a patient, but one would not call the surgeon corrupt. Likewise, the necessity of triage in emergency medical situations, although unfortunate, is not in itself an instance of corruption – although the process by which priority is assigned may become corrupt if driven by considerations one believes are illegitimate. What, then, is the basis for identifying an act or practice as corrupt?

The term "corruption" is itself rooted in a biological metaphor: the physical corruption of organisms. When normal capacities decline, organs begin to fail, decay sets in, and so on, a body becomes corrupt. Indeed, disease is a paradigmatic example of corruption, understood in contrast to a "healthy" body. Things are corrupt when they no longer work as they should. Inherent, then, in the very idea

of corruption is a notion of how things should work – a standard or ideal by which to judge deviations as genuine failings.

Such ideals must be "realistic" for the accusation of corruption to be meaningful. A world in which hands never slip or unanticipated disasters never strike would be desirable, but more than one can reasonably expect. By contrast, one can reasonably insist that scarce medical resources be rationed on the basis of need, that new drugs undergo objective trials to establish their safety, that research subjects be informed of known risks and provide their consent, and so on. When such practices (and the ends they serve) are compromised, one can say they have been corrupted. Generally, corruption involves catering to interests that are at odds with the ultimate ideals or goals believed to be legitimate.

Any discussion of corruption thus requires identifying how things ought to (and indeed can) work, and this, in turn, involves identifying the goods or outcomes that ought to be achieved or the legitimate procedures that ought to be followed. In many areas of bioethics, these standards are clear. There is broad agreement that a society should seek to achieve a patient's well-being, public health, scientific understanding, personal autonomy, human dignity, and so on. Indeed, these widespread convictions have been codified in important international frameworks, such as UNESCO's Universal Declaration on Bioethics and Human Rights. The declaration recognizes 15 ethical principles which should inform any approach to bioethical issues, including broad respect for "human dignity, human rights and fundamental freedoms" (UNESCO, 2005, Article 3). However, there are of course situations in which such principles can come into conflict. Public health may require placing an individual with a dangerous infectious disease in quarantine against their wishes. Drug trials in developing countries may benefit recipients of a drug, but involve leaving a control group without effective care. Or, as often happens, biomedical advances may present new quandaries regarding the proper tradeoffs between (and interpretations of) apparent goods: For example, is the destruction of embryos for stem cell research permissible if it promises to advance medical science?

Much of what people usually indicate when they talk about "bioethics" involves wrestling with these difficult questions about the appropriate tradeoffs between such goods. For the purpose of this chapter, however, these larger debates will be placed to the side. Rather, the focus is on elucidating types of corruption that arise most clearly once ultimate goals/procedures/standards are in place.

Given its scope, The Universal Declaration on Bioethics and Human Rights provides a particularly useful expression of such standards, and many problems of corruption can be understood as deviations from core ethical principles articulated in the document. In particular, corrupt practices often create disproportionate harms compared to benefits (Article 4), violate standards of consent (Article 6), and skew the legitimate sharing of benefits (Article 15). Frameworks such as the declaration perform a valuable service in articulating common standards that can act as criteria for diagnosing corruption. However, it is also important to note that differences found across international contexts may provide reasons to recalibrate the standards by which one assesses corruption. Ultimately, addressing corruption involves

indentifying and neutralizing influences judged to be illegitimate, and this means that questions about the appropriate ideals by which to judge corruption will always be relevant to the analysis of any particular case.

Types of Corruption

Distinguishing Formal and Substantial

The classic exemplar of corruption is bribery, which occurs when an individual entrusted with an official duty betrays that duty in exchange for a private side payment. The reason for condemning bribery is presumed in the definition itself. One should not violate one's official duty. However, this description of bribery masks an important background assumption, namely, that the duty in question is a good one. When institutions are in good order, this will indeed be the case. However, if an institution is itself dysfunctional, bribery could conceivably help achieve a better outcome overall. For example, a Nazi doctor may have violated the institutional agenda of the Nazi regime by choosing not to run dangerous experiments on prisoners if their relatives paid a bribe. Such bribes could be said to corrupt Nazi medical research. However, since such research was itself corrupt, a bribe of this sort might actually promote a (marginally) better outcome. It is for this reason that one needs to distinguish between *formal corruption* and *substantial corruption*.

Formal corruption is defined in reference to the explicit rules of a particular institution or practice. Violating "the rules" is what is considered corrupt, and as long as one follows the rules, the charge of formal corruption cannot be raised. This is how most legal perspectives treat corruption. *Substantial corruption* goes deeper and is defined in reference to the ultimate purposes that an institution or practice is supposed to serve. If those purposes are subverted by illegitimate influences, this is the basis for identifying an arrangement as substantially corrupt.

This distinction is important because, as the Nazi medical case suggests, instances of formal corruption need not be substantially corrupt. Indeed, if an institution is itself substantially corrupt, formal corruption may be the only way to improve it in the short run. A large body of literature in economics and political science is premised upon this basic observation and seeks to show how certain types of formal corruption may make poorly designed institutions function better (for example, under certain conditions, bribes paid to public officials in dysfunctional regimes may increase their responsiveness to citizens' needs). Much work in public policy is aimed at trying to address this disconnect by more closely aligning formal corruption with substantial corruption, crafting laws and putting into place procedures that guard against an institution's substantial corruption.

The flip side of this distinction is equally important: Substantial corruption need not involve formal corruption. That is to say, the simple fact that existing laws are not broken does not guarantee that an influence is not substantially corrupting. Rather, one must judge substantial corruption from the perspective of the larger

purposes that institutions and laws are meant to serve. As hinted at above, this may appear hopeless if there is widespread disagreement about what those larger purposes are. However, even when such purposes are agreed upon, diagnosing substantial corruption can be difficult – particularly because there are so many kinds of potentially subversive influences. Moreover, it is generally infeasible to develop and enforce rules that proscribe all forms of substantial corruption, and thus many kinds of corruption may fly below the radar screen of the standards that define formal corruption. Because problems involving formal corruption (bribery, etc.) are relatively straight forward, this chapter focuses on examining forms of substantial corruption that often do not map on to formal corruption, particularly "conflicts of interest," "gaming the system," and "regulatory and institutional capture."

Conflicts of Interest

Conflicts of interest are perhaps the most studied form of corruption in bioethics, and there is an expansive literature considering their nature, effects, and possible remedies. The UNESCO Universal Declaration on Bioethics and Human Rights, for example, obliges parties to declare all conflicts of interest as a means for promoting "professionalism, honesty, integrity and transparency in decision-making" (UNESCO, 2005, Article 18). Defined as "a set of circumstances or conditions in which professional judgment of a primary interest, such as the integrity and quality of research, tends to be unduly influenced by a secondary interest, such as personal financial gain," conflicts of interest are ubiquitous across the terrain of contemporary medical practice and biomedical research (Emanuel & Thompson, 2008, p. 760). However, it is important to note that not all conflicts of interest are necessarily driven by financial considerations. Prestige, publications, time constraints, etc., can provide competing secondary interests as well. To get a better sense of what conflicts of interest (COIs) look like in practice, consider two well-known cases. The first involves a financial COI, possibly rising to the level of a bribe, in which a drug maker's sponsorship practices had the potential to bias the judgment of healthcare providers. The second case involves nonfinancial competing interests common in academia.

Cases of companies attempting to influence the prescribing practices of doctors or formulary decision makers through financial benefits have been frequently documented in health policy literature. One of the more egregious of these cases involved TAP Pharmaceuticals, which offered a $20,000 "educational grant," later increased to $500,000, to a specific HMO to persuade its medical director to reverse his earlier finding that TAP's product Lupron, a hormonal drug for prostate cancer, was bioequivalent to a competitor's drug, Soladex (Brody, 2007). Since Lupron was more expensive, this finding of bioequivalence would ensure that the cheaper rival drug would be added to the Massachusetts managed care organization's formulary instead of Lupron, thereby reducing TAP's market share and profits. Having been accused of inappropriately using "educational grants" and other types of inducements such as Aspen ski trips, golf outings, and paying for doctors' bar tabs (also disguised as "educational grants") as part of their strategy of influence, TAP ultimately settled a legal case brought against it for $875 million (Angell, 2004).

It is important to note, however, that conflicts of interest need not be financial or orchestrated by business interests. The "Slutsky case," which involved a nonfinancial competing interest common in academia, illustrates this well. Driven by the professional prestige and advancement attached to publishing, Robert Slutsky, a junior research cardiologist at the University of California-San Diego (USDC), falsified data to improve the statistical significance of a number of studies, lied about performing others, and listed multiple coauthors for articles without permission. An investigating committee reviewed 137 articles published by Slutsky in a 7-year period, an atypically productive publication rate. They found 48 of the articles to be "questionable" and an additional 10–12 to be fraudulent (Jones & McLellan, 2000).

Unfortunately, cases of scientific fraud by top researchers appear more common than one would hope. Not long before the Slutsky incidence, John Darsee, a top young cardiovascular researcher and fellow at Harvard, was found to have fabricated data for an NIH-funded study (Culliton, 1983; Kochan & Budd, 1992). More recently, Marc Hauser, a professor of Psychology at Harvard, resigned after being found responsible for multiple counts of scientific misconduct, and South Korean researcher Hwang Woo-Suk, once a national champion, was found to have fabricated data on somatic-cell nuclear transfer published in the journal *Science*.

Both financial and nonfinancial conflicts of interests can be found in many forms in biomedical fields, but at what point do they become a threat to the integrity of a practice and require intervention? Consider, briefly, the range of other conflicts that can arise and the kinds of questions they provoke: Can a doctor who has a financial stake in a particular treatment center be trusted to refer only patients who really need the treatment to that center? Can a primary care physician in a developing country be trusted to act in the best interest of the patient when a clinical trial is offering thousands of dollars to enroll a patient? Can an overworked nurse eager to leave her shift on time be trusted not to overmedicate (within the allowable range) a difficult patient who keeps ringing the call bell?

Some of these conflicts might be adequately managed by self awareness and conscientious behavior. Others might call for more formal strategies of vigilance such as transparency and disclosure requirements. Or one might think it necessary to eliminate the conflicts outright by asking professionals to excuse themselves from certain engagements when the magnitude of their competing interest is large enough (in effect, leaving judgment to parties with no secondary interests at stake). Of all the COIs that recurrently surface, perhaps the most complex are those that involve relationships between medical professionals and the pharmaceutical industry.

Whether the actions of TAP Pharmaceuticals discussed above rose to the level of *quid pro quo* bribery is debatable, but there is little doubt they created a serious conflict of interest. A long history of similar strategies of influence within the pharmaceutical industry has led to increased oversight of the benefits conferred to healthcare professionals in an attempt to ensure that conflicts of interest are minimal and do not rise to the level of bribery, whether explicit or implicit. However, although the *quid pro quo* exchange of money or gifts for prescriptions may appear easy to recognize and condemn as illegitimate, the propriety of speaking and consulting fees paid to doctors raises a much more complex set of issues.

Pharmaceutical companies and patients have a compelling interest in information about new and useful drugs being disseminated to the medical community. Moreover, doctors and other medical researchers are the ones who have the medical expertise necessary for understanding and communicating the benefits of drugs. Paying them for their expert services to act as educators and advocates on behalf of a drug's benefits may, in itself, be entirely reasonable. But at what point does remuneration for such services begin to bias their expert judgment and corrupt their own and other's prescribing practices?

Many physicians perceive themselves, but not necessarily their colleagues, as above such corrupting influences (Kassirer, 2005). However, critics complain that companies would not pay consulting and speaking fees if they were not effective at influencing doctors. This begs the larger question of whether such influence is educational and based "on the merits," or whether expert judgment can be biased or bought outright. Medical associations often defend the relationships between doctors and industry as essential to advancing the development of new drugs, vaccines, and medical devices. Moreover, it is hard to find a medical authority who has not received industry funding: "Virtually all of the top speakers on medical topics are employed in some capacity by one or more of the country's pharmaceutical companies" (Kassirer, 2005, p. 19). Aristotle's concern that corruption of the best becomes the worst is perhaps worth considering on this point.

Drawing a line between fair and reasonable compensation for the educational services of experts on the one hand and payments that turn experts into shills for an inferior or more costly product is not easy to do at the level of theory or practice. There have been increasing calls by industry codes of conducts to standardize compensation of experts, in the hopes this will make it harder to buy off strategic targets and disguise the payments as consulting or speaking fees. Another remedy, enacted by a handful of states in the USA, and soon to become US federal law as part of the Sunshine Act, requires drug companies to publicly disclose all payments and other benefits given to physicians. Reformers hope that such transparency will dissuade companies and doctors from arrangements whose details are so incongruous as to raise obvious concerns of corruption or bias. Only time will tell if this strategy accomplishes the intended effects and whether it extracts a cost in terms of the quality of medical education.

In considering the larger landscape of COIs in biomedical fields, one final point of clarification is in order: One must be careful to distinguish *conflicts of interest* from *conflicts between interests*. The former presumes that the "primary interest" at stake takes clear precedence over whatever "secondary interests" there may be. For example, a doctor's primary interest clearly ought to be the promotion of her patient's health. If a doctor prescribed a drug *contrary to medical consensus* because it secured her a kickback payment from a pharmaceutical company, this would be reason to judge that this conflict of interest had corrupted her medical judgment and her patient's care.

In contrast, *conflicts between interests* describe those cases in which the appropriate primary interests are themselves contested or incommensurable. If a vaccine promised to save a large number of lives were it administered to a population but

would also produce severe disabilities in small fraction of recipients, public health officials would arguably be confronted with two primary interests – the interests of those who would perish without the vaccination and the interests of those who would be disabled by it. Such conflicts between interests raise larger questions about the proper ethical frameworks by which to adjudicate claims, which, although profoundly important, are beyond the scope of this chapter.

Gaming the System: Adhering to the Letter of the Law but Not the Spirit

"Gaming the system" is a type of substantial corruption that specifically does not entail formal corruption. Rather, gaming involves adhering to the letter of the law while acting contrary to its spirit (Salter, 2010). Laws/rules are generally underspecified and thus leave room for creative ways to evade their intended purposes. However, if these purposes are good ones, then acting contrary to them is a form of corruption. Keep in mind, however, that one might strategically respond to laws or rules in ways that do not subvert their intended purposes. Drawing the line between gaming and legitimate strategic responses can be difficult and often demands nuanced judgment.

Consider the following scenario. Suppose an international regulation requires that a certain drug not be tested on those below the age of consent because the drug is believed to cause developmental problems in young children. Countries of course differ in how they define the age of consent. In most Western countries, it is 18 years of age, while in many developing countries, it is a few years younger. A researcher who has a substantial interest in studying the efficacy of the drug in young adult populations might strategically choose to field the trial in those developing countries that place the age of consent at 14 rather than 18. The researcher would thus gain access to a younger population in a way that promises to substantially enhance the conclusions of the study. Moreover, the researcher would have accomplished this while staying within the technical bounds of the regulation. Whether this is an instance of gaming the system is up to debate, although there are reasons to believe this strategy is not only appropriate but beneficial.

If the real purpose of the regulation was to keep the drug from being administered to very young children still in early stages of development (say, under 6 years old), then, in fact, this would not be an instance of gaming. The age of consent rule was functioning as a convenient benchmark that would exclude experimentation on the very young, and the researcher's selective targeting of younger adolescents did not violate this ultimate, underlying standard. At the same time, this targeting may have enhanced the quality of medical knowledge in ways that would not have been possible if the Western criterion of 18 had been strictly enforced.

However, suppose another researcher wanted to study the drug's effect on infants and decided to field the study in Cambodia, an impoverished country that has no legally defined age of consent. Technically, this study might not violate the letter of the law which only prohibits testing on populations defined as under the age of consent within a legal regime. However, by exploiting this unanticipated loophole that is an artifact of Cambodia's underdeveloped legal code, the researcher

would clearly be violating the legitimate intent of the international regulation. This would rise to the level of substantial corruption and be a clear instance of gaming the system.

Gaming can take place on a number of levels, and researchers or corporations need not be the culprits. The problem of drug diversion is one instance of gaming that can take place at the "grassroots" level. Pharmaceutical companies have increasingly set up tiered pricing systems to maximize access to their products, paying special attention to lower income developing countries. These tiered pricing arrangements generally involve providing drugs to poorer populations for little or no cost. However, the good intentions of these programs can be twisted if the donated or significantly discounted drugs are diverted and resold at higher prices. When this happens, not only do drugs not reach poor patients in need but legitimate sales in developed markets are also crowded out. It is generally difficult to make every manifestation of this sort of arbitrage illegal, but if the practice becomes widespread, it limits access to drugs for traditionally vulnerable populations.

Practices of "gaming" the law impose two sorts of costs on society. First, there are the immediate, negative consequences of an instance of gaming itself. In the hypothetical Cambodia study, this would include the risk and harm of developmental problems to which infant research subjects are exposed, and in the tiered pricing example, decreased medical access for the poor.

The second cost imposed by gaming accrues to the system at large. If there are intensive efforts directed toward gaming the system, then those in charge of developing laws and regulations must be much more detailed and narrow in their approach. They must exhaustively specify every aspect of a law in an attempt to head off illegitimate strategic responses. However, there is a real worry that in doing so they will overreach and rule out benign or useful innovations as well. Also, extensive and detailed regulations can often be more costly and difficult to monitor and enforce. In the cost-benefit calculations that underlie any regulatory enterprise, expectations of gaming will tend to increase the costs of regulations and decrease their benefits. Additionally, belief that gaming is widespread can lead the public to lose trust in an institution or system at large, thereby decreasing its effectiveness (a concern that will be examined in greater detail below).

Gaming the System: Betraying the Integrity of Institutions

Taking a broader perspective, gaming can include not only attempts to circumvent legal rules but also strategies that betray the integrity of institutions, twisting them for illegitimate purposes. For example, suppose a scientist conducted quality research which raised questions about the safety or comparative economic value of a company's product. If that company hired a public relations firm to write and place articles attacking the character of the scientist, this could be described as gaming the institution of journalism. Even if the articles did not rise to the legal definition of defamation or libel, they would have corrupted the standards of journalistic integrity. Such gaming of the *modus operandi* of legitimate institutions is but a larger analog of the problem of legal gaming. This sort of gaming at large can be exacerbated by disparities in power and knowledge. Moreover, strategic

considerations embedded in the way that biomedical research is conducted make it particularly vulnerable to gaming. Consider the following, prominent example.

In 1987, Dr. Betty J. Dong signed a contract with Boots Pharmaceuticals, known at the time as Flint Laboratories, to conduct a comparative effectiveness study of their drug Synthroid. The study concluded in late 1990 with the surprising results that Synthroid was not superior; all four compared drugs were bioequivalent. Dong's concluding paper was accepted by the *Journal of the American Medical Association* (JAMA) and scheduled for publication on January 25, 1995. Days prior to its scheduled publication, Dong withdrew the paper because of a threatened legal action stemming from a confidentiality clause in the original research contract signed in 1987. The contract read: "... Data obtained by the investigator while carrying out this study is also considered confidential and is not to be published or otherwise released without written consent from Flint Laboratories, Inc" (Rennie, 1997, p. 1239). Dong reports that she signed the contract after being reassured by a UCSF patent officer that "no pharmaceutical company would have the gall to violate so flagrantly the norms of academic research" (Brody, 2007). However, Boots threatened to sue Dong for damage if sales of Synthroid suffered in any way as a result of the article.

According to *JAMA* deputy editor Drummond Rennie, "Boots waged an energetic campaign to discredit Dong's study and prevent publication," despite having conducted around three site visits per year of the study and Flint having approved the "detailed experimental design and analysis of the data" in its contract with Dr. Dong (Rennie, 1997, p. 1238). At one point, Boots suggested Dong had been bought off by rival drug maker Daniels Pharmaceuticals to produce the unfavorable results. When UCSF, Dong's academic home, investigated Boots' allegations, they found no major errors with the study, but that the company was indeed aiming to suppress unfavorable findings (Brody, 2007; Rennie, 1997).

Many observers suggested that Boots' aggressive data suppression efforts were driven in part by the company's pending merger with BASF AG' subsidiary Knoll Pharmaceutical. Synthroid's market power was an important factor influencing the company's purchase price, valued at $1.4 billion in March of 1995 (Brody, 2007; Rennie, 1997). However, the merged Boots/Knoll advised JAMA that they also intended to prevent publication of Dong's study. In fact, they published their own article in the *American Journal of Therapeutics* using Dong's data without consent or attribution and reaching opposite conclusions. Critics considered this an attempt to prevent other journals from publishing Dong's study because of journals' rules against duplicate publications.

Thanks to a *Wall Street Journal* expose on April 15, 1996, the FDA learned of the company's failure to submit Dong's data and the publication of a misleading article in 1992 (Berg & Mayor, 1992). Boots/Knoll eventually negotiated and allowed UCSF to publish the manuscript in *JAMA*, due in part to FDA pressure and poor public perception, according to the *JAMA* expose. Boots/Knoll was later the subject of a class action lawsuit by thyroid patients who claimed harm from the delayed publication. The company settled the suit for over a hundred million dollars.

Companies have a legitimate interest in questioning the rigor of studies that affect their bottom line. They reasonably want to ensure they are not the victims of shoddy research. However, they also have a financial interest in seeing negative studies discredited regardless of their quality. Moreover, there are many ways in which a company may legally try to influence researchers in ways that compromise the integrity of science – in particular, through the threat of expensive lawsuits and bad publicity.

Indeed, the fear of impoverishment from expensive legal fees, character defamation, or loss of sponsorship is not unfounded. Consider a case in which legal defense fees for a small organization totaled a significant amount of their annual operating budget. In the late 1990s, Bristol-Myers Squibb, maker of the statin drug Pravachol, took the Canadian Coordinating Office for Health Technology Assessment (CCOHTA) to court to reportedly delay them from publishing a report declaring that all available statin drugs were approximately bioequivalent. CCOHTA ultimately won the case, but only after spending 13 % of its annual budget, which was roughly equivalent to a single day of sales revenues for Pravachol in Canada (Brody, 2007). It is easy to understand why the threat of a lawsuit or character assignation may be sufficient to deter individuals and smaller researcher centers from acting against the interests of a large company, and this represents a prominent class of temptations for companies to game the systems of legal activism, publicity, and grant making (Brody, 2007).

Institutional Capture: Corrupting Dependencies

Along with character assignations and expensive lawsuits, the threat of withdrawing sponsorships, or the promise of funding for only certain types of projects, can corrupt the conduct of research or the integrity of advocacy groups. These are but pieces of a larger concern that well-established economies of influence operate in biomedical fields in ways that create dependences that compromise the independence and objective judgment of third parties.

On the one hand, industry donations and grants to nonprofits are highly commendable for their generosity. However, if donations are accompanied by tacit strings, they can easily rise to the level of a corrupting influence. This is of particular concern for smaller organizations for which grants can command a significant share of their annual operating budget.

Indeed, cases in which pharmaceutical sponsorships dominate medical societies' operating budgets are not uncommon. On the one hand, the financing is helpful and possibly laudable; however, it is also easy to imagine ways in which this could corrupt the integrity of such organizations. For example, in 2009, Daiichi Sankyo funded 70 % of the American Society of Hypertension's (ASH) annual budget ($3.3 million) and asked the society to create a training and accreditation program for its salesmen (Ornstein & Weber, 2011). However, critics questioned whether ASH could actually demand any reforms of the company's practices, as this could jeopardize 70 % of the society's budget. More generally, can medical societies be expected to render objective judgments and medical education regarding their major industry sponsors?

It is important to emphasize that these concerns about corrupting dependencies are not hypothetical. There are many documented cases in which companies withdrew research funding because of practices or outcomes they deemed unfavorable. For example, Apotex pharmaceutical company was reported to have abruptly canceled its contracts with Dr. Nancy Olivieri in the late 1990s after she insisted on disclosing her concerns about the safety and efficacy of Apotex's drug deferiprone to patients in her study (Healy, 2004). The merits of Olivieri's concerns continue to be debated, but the determination with which Apotex sought to defund and discredit her is not. Similar strategies have been deployed to marginalize other sorts of research as well. For example, some allege that Eli Lilly, the largest individual sponsor of the Hastings Center in 2000, discontinued supporting the center after it published a series of papers on antidepressants that collectively failed to promote Eli Lilly's blockbuster drug Prozac (Healy, 2004).

Again, there is nothing clearly illegal or perhaps even unreasonable about companies making donations with strings attached or not offering to perpetually fund projects. However, in such situations, the independence of recipient organizations cannot be taken for granted, and there are good reasons to expect that targeted donations can have a corrupting influence on the objectivity of beneficiaries.

As suggested by concerns regarding regulatory capture (to be examined shortly), economies of influence in biomedical fields interact with political institutions as well. These interactions can raise particularly difficult issues across international contexts. For example, many have questioned how effective independent ethics committees (IECs) in developing countries can be if they are underfunded, understaffed, or politically undercut by clauses that require their decisions to be approved by state officials. It is thought that clinical trial companies can command enough political power to ensure that state officials provide a sympathetic hearing. Moreover, there appears to be a tacit understanding among some IECs in developing countries that if they disapprove of too many studies submitted to them, research sponsors can and will seek out other IECs (Lemmens & Freedman, 2000). This leaves IECs on a rather short leash with regard to their real ability to stop trials that raise ethics- and safety-related red flags.

Finally, no discussion of corrupting dependencies would be complete without mentioning the fact that political influences can raise the stakes of corruption. The political process can, of course, be useful for negotiating outcomes that benefit the common good. However, it can also be a site where deals are struck that have enormous costs or implications that are difficult to defend from the standpoint of a compelling public interest. A recent byline in the *Los Angeles Times* – "A company controlled by a longtime political donor gets a no-bid contract to supply an experimental remedy for a threat that may not exist" – could perhaps be recycled to describe deals made in many countries, year in and year out, administration after administration (Willman, 2011, November 13). In this case, it was for a $433 million plan for the US government to buy a smallpox vaccine of unknown effectiveness for a disease that has been considered eradicated worldwide since 1979. Some may wish to debate whether this was a prudent public health

decision, but the larger lesson proposed here is simply that when the financial stakes are high, as they often are in biomedical fields, stakeholders have reason to seek powerful political interventions – which may prove an additional avenue for corruption.

Regulatory Capture

"Regulatory capture" refers to the phenomenon of regulators being influenced by those whom they are supposed to regulate in ways that shape regulations to the detriment of the common good. In an ideal regulatory environment, one might hope that: (1) those tasked with regulatory oversight would have a clear understanding of the industry under their purview, (2) the need for welfare-enhancing regulations and the details of how they should work would be apparent, and (3) regulators would be primarily driven by considerations of the common good rather than the private interests of industry or special interest groups. Unfortunately, the knowledge needed for (1) and (2) is very difficult to obtain and political forces make (3) difficult to achieve as well. That is to say, regulators are often highly dependent upon those they regulate for both epistemological and political reasons.

Epistemologically, regulators of complex industries generally must rely on industry insiders in order to obtain an accurate understanding of how things work, as well as an appreciation of the complexities that any proposed changes involve. Consultation processes during the development of regulations and "notice and comment" periods for proposed changes aim to facilitate this exchange of important information. However, there is an underlying asymmetry of information, and regulators face a difficult task in assembling and filtering industry feedback. Some of this feedback will be vitally important for crafting sensible rules; other feedback may aim to influence regulations in ways that benefit an industry or a group to the detriment of public welfare – granting special exemptions, lowering liability, erecting barriers to competition, and so on.

Politically, the regulatory enterprise is subject to a general problem that plagues democratic institutions when they deal with decisions that have concentrated benefits and diffused costs. In short, if regulations will impose significant costs or benefits on a small number of agents, those agents are likely to be much more motivated and successful in their lobbying efforts than a large number of people who all have a small amount to gain or lose.

For example, suppose that extending patent protection by 1 year for a commonly prescribed drug will keep its price $100 higher than it would otherwise be (with competition from generics). If a million people take the drug each year, then the total cost of the patent extension to consumers will be $100 million – not a small amount! However, any single consumer only stands to lose $100 due to the patent extension. For most consumers, it will not be worth investing considerable time calling congressional representatives, organizing publicity campaigns, drafting and submitting review comments, etc., to fight the extension. Conversely, the drug company stands to gain $100 million, and it would thus be worthwhile for them to invest a large amount of resources on lobbying efforts to preserve the patent. Ultimately, the drug company with many millions of dollars on the line is likely to

be more motivated and effective in exercising regulatory influence than dispersed, individual consumers who only stand to lose $100 each.

The phenomenon of regulatory capture means that in judging the wisdom of regulatory oversight, one must take into account not only the hypothetical benefits of optimal regulations but also ask whether regulators can garner the expertise and political support needed to implement them. However, recognizing the problems posed by regulatory capture can also enhance the practice of regulation by reminding both regulators and those with diffuse interests to remain vigilant with respect to the influences of special interests.

Finally, it is important to note that, as in the case of gaming, diagnosing regulatory capture depends on nuanced judgments, and, as in the case of conflicts of interest, it is important to distinguish between the kinds of disagreements that may arise. On some issues, the need for regulations, and the details of such regulations, may be unambiguous and the regulatory task thus straightforward. On other issues, the questions of whether and how things should be regulated will be far from certain and require thoughtful research, reflection, and debate. It is entirely appropriate for the interests and expertise of the regulated to be represented in these discussions. Ultimately, however, regulators need to adjudicate between narrow, self-serving interests and the larger public interest in order to avoid corruption of the regulatory enterprise. Often, there will be legitimate concerns on both sides of an issue, and the task is to judge whether one side is ultimately more compelling. Moreover, in cases where neither side is more compelling, it is often preferable for regulators reach a principled compromise, rather than let the regulatory process become a political battleground for incommensurable interests.

The case of drug patents illustrates the complexity of these issues. Drug patents are widely recognized to provide property rights that are essential for a sustainable and innovative pharmaceutical industry. Patents enable companies to profit from the considerable investments they make in drug research and development, and those investments in turn benefit public health. Thus, it is in the public's interest to grant and protect patents. But, how long should patent protection last? The answer admits of less precision than one might hope, and, at the margins, drug companies and consumers have conflicting short-run interests.

Extending patents will benefit drug companies at the expense of consumers in the short run. However, consumers ultimately benefit in the long run from the existence of some patent regime. If *either* consumers or drugmakers completely captured the regulatory process, the outcome would likely be detrimental to long-term pharmaceutical innovation. The details of a compromise between no patents and permanent patents may be arbitrary in some respects, but still superior to endless back and forth renegotiations in the short run. Furthermore, once a framework is firmly in place, interest groups have fewer reasons to expend resources on political influence, which may benefit both their bottom line and the health of the regulatory enterprise in the long run. Thus, one part of the challenge of preventing regulatory capture is figuring out what should be on the regulatory bargaining table in the first place. The greater challenge, however, lies in judging the quality of information and arguments that bear on the details of any regulatory proposal.

The Costs of Corruption in Healthcare and Biomedicine

The types of corruption outlined above can be found across a wide range of industries, practices, and political systems. They are meant to highlight the kinds of influence and conflicts that can generate substantial corruption at large. However, as noted at the outset, there are reasons to believe that corruption is a particular concern for the field of biomedicine. The role played by expert judgment, the complex and uncertain nature of many issues, the dependence on regulatory bodies, the large amounts of money involved, the globalization of biomedicine across different international contexts, and disparities in wealth and power in biomedical fields all combine to create heightened opportunities for corruption.

While there is some debate and ambiguity about just how costly and harmful current practices of corruption are, there is no doubt that their existence, coupled with their perceived existence, generates short-term and long-term costs. In the short term, corruption involves not living up to a realistic and legitimate standard. In this sense, substantial corruption does an immediate injury to those whose interests are aligned with the legitimate standard, although this may not be visible. However, in the long term, corruption also imposes costs that accrue to society at large. In biomedical fields, these costs can include (1) substandard medical care and research and decreased medical access and affordability and human research subject protections, (2) weakened stakeholder trust that undermines the long-term sustainability of institutions and industries, (3) overregulation, and (4) malaise about the possibility of reform and the acceptance of a culture of corruption as the way things are done.

First, corruption can decrease the affordability and accessibility of healthcare and lead to substandard medical care and inferior research. For example, if research results showing that older cheaper drugs are bioequivalent to newer more expensive drugs are suppressed, then doctors may unknowingly prescribe more expensive treatments. Or, doctors may be tempted to recommend newer, costlier, or even inferior products if the speaking or consulting fees are overly enticing. Moreover, lawsuits, over perceived or actual corrupt practices, further drive up costs and lessen the affordability of healthcare. Although each instance of corruption may have its specific winners and losers, over time corrupt practices are likely to raise medical costs for everyone.

Second, corruption is costly for institutions and industries because it weakens stakeholder trust. If people perceive an institution to be corrupt, they may restrict their engagement with it, which can undermine the effectiveness of the institution at large. For example, if someone is convinced that medical professionals or drug manufacturers are corrupt, he or she might decline helpful medical treatment. If the corruption of medicine runs deep, this could perhaps be a reasonable response. However, it would be tragic if individuals ceased to avail themselves of beneficial medical resources because the corrupt practices of a conspicuous few lead to systematic distrust in the larger institution. Similarly, perceptions of corruption in the way that foreign disaster and medical aid are handled can cause a loss of confidence that cripples goodwill donations, investments, and further aid.

The third cost imposed by corruption accrues to the system at large in the form of overregulation. Unduly burdensome regulation can impede critical collaborations, reduce innovation, and incur expenses that exceed their benefits. Calls for regulation are an understandable response to scandals involving corruption, but the costs of regulation may undermine the ultimate goals they are supposed to serve.

Finally, cynicism can result from an abundance of corruption leading to general malaise about attempting reform efforts. Likewise, individuals who would not normally engage in corruption may decide that it is the only way to get things done. If the culture or leadership of a society or institution is sufficiently warped, corrupt practices may in fact appear ok to individuals because that is "the way things are done."

Ultimately, the stakes of addressing the challenges of corruption in biomedicine could not be higher. At some level, they involve matters of life and death, as well as other important concerns about the responsible use of resources, the safety of products, and the quality of patient care and human research subject protections.

Conclusion: Prospects for Reform?

In reviewing different types of corruption, this chapter has already touched on a number of implicit strategies for reform, including transparency, independent monitoring, and incentive design. In conclusion, it is worth briefly considering the strength and weaknesses of these strategies, as well as the additional role that might be played by ethical persuasion.

The promise of transparency is straightforward and succinctly captured by Justice Louis Brandeis's famous quip that "sunlight is the best disinfectant." If a relationship or conflicting interest cannot hope to bear the scrutiny of public attention, this is a good indication that it is problematic. Moreover, if relevant parties are aware that payments, gifts, and other forms of influence and dependence will be public knowledge, this provides a powerful motive for self-restraint.

There are, however, at least two limitations of transparency requirements. First, they may be hard to enforce if there are ways to hide or to simply not report information. Second, even if the relevant information is disclosed, it may have no behavioral effects if the dependencies in question are commonly accepted as the status quo. Indeed, critics of the Sunshine Act in the United States, which requires pharmaceutical companies to disclose all payments to physicians, point out that many physicians and patients consider such payments to be a sign of a doctor's eminence and expertise. Thus, it is not clear that there is a public mandate for doctors and companies to change their current behavior.

The concept of independent monitoring builds upon the basic promise of transparency but deepens it by assigning the power of oversight to a third party and by specifying more detailed standards for compliance. Independent monitoring can, in theory, be carried out by government regulators, private organizations such as accrediting agencies, or even by sufficiently independent compliance departments within firms. Independent monitoring takes for granted certain standards, which

need not rely on the whims of public opinion, and seeks to verify compliance with them. Although there are many instances of successful monitoring efforts, it can still be a challenge for third parties to gain the knowledge needed to verify compliance. Moreover, as suggested by the examination of corrupting dependencies and regulatory capture, the independence of monitors can be undermined by the lobbying efforts of those who are monitored or subverted by a powerful industry unwilling to be subject to the risks of scrutiny. Incentive design tries to address these sorts of larger, underlying strategic problems.

The hope animating incentive design is that, by understanding the nature of the strategic interests involved, regulators can change the rules of a game so that self-interested players act in ways that promote a better outcome. Put simply, incentive design attempts to make it in people's interest to be good, and this is typically accomplished by developing rules that put those with conflicting interests in a position to monitor and challenge each other within some framework that is considered to be fair. In the political realm, this takes the form of the division of power between branches, which allows "ambition to check ambition." In biomedical fields, it can entail arrangements as diverse as whistleblower laws that reward insiders who expose illegal behavior while providing sufficient protections, tort laws that assign liability for products or actions that hurt others, or public "notice and comment" procedures that allow everyone interested in a regulatory decision to have their say. Accreditation programs that contain strong public relations components, communicating to stakeholders an institution's verified commitment to excellence in ethics, can also realign incentives in meaningful ways.

Designing good incentives is a worthwhile enterprise and is what much of the legal and regulatory process aims, in theory, to accomplish. It will continue to describe many successful approaches to reforming corruption. However, there are inherent limits to the project of incentive design that one should not lose sight of. The incentives for those in power to design better incentives are often lacking, and at a theoretical level, one can always ask who will incentivize the incentivizers. Put another way, at some level, one must hope that individuals can be motivated by more than just the immediate material incentives they face. Furthermore, there will always be limits to the scope and inclusiveness of any reform, and institutions will never be designed so well that it *always* pays to do the right thing.

Ultimately, ethical persuasion is likely to be an important component of any successful reform. At the level of motivation, if those involved in some practice can be persuaded that it is in fact corrupt, this conviction can play a role in changing behavior (which is not to suggest material incentives will not exercise influence as well). Also, ethical persuasion plays a role in diagnosing and analyzing the problems with corrupt practices in the first place. To return to a point made at the outset of this chapter, the charge of corruption always implicitly involves some judgment about why the status quo is bad and how things could be better. Attempting to persuade those involved in a corrupt practice of its vices is an important enterprise, as is trying to dialogue with and persuade the larger public (UNESCO, 2005, Article 18). This is why documents such as UNESCO's Universal Declaration on Bioethics and Human Rights are so useful. Such efforts to

dialogue, clarify, educate, and persuade help establish the standards of evaluation that enable us to judge a state of affairs as corrupt. In so doing, they also illustrate the importance of reform.

Because of the limits inherent in all strategies of reform and the ever-changing landscape of biomedical fields, there is not likely to be any permanent solution to the general problem of corruption. Moreover, meaningful reform efforts can be difficult to organize because of economic challenges and collective action problems. However, there are reasons to believe that specific problems of corruption do admit of improvement through a mixture of the strategies explored above. Indeed, the very diagnosis of corruption suggests that things could realistically be better. Developing an understanding of the nature of corruption is one important step in the process of reform and the central purpose of this chapter. Although this analysis hopes to advance the search for enduring improvements, the complexities of corruption documented here likewise demonstrate the need for continued study and vigilance.

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Disasters

36

Dónal P. O'Mathúna

Introduction

Disaster bioethics is a relatively new topic. At every stage in preparing for disasters, developing risk reduction strategies, and responding to disasters, ethical and value-based decisions are made. These have seldom been made explicit. This is beginning to change as organizations recognize the importance of ethics in disasters and put structures in place to address ethics explicitly.

The need for greater attention to disaster ethics is coming from those in the field. Research reveals that those receiving assistance identify unethical practices by well-meaning responders (O'Mathúna, 2010; Pittaway, Bartolomeim, & Hugman, 2010) and responders themselves struggle with ethical dilemmas which can haunt them when they return home (Schwartz et al., 2010). An early publication for the UN's Disaster Management Training Programme identified ethical dilemmas that permeate every aspect of disaster relief (Jensen, 1997). These range from "small" individual decisions, like a truck driver allowing looters to take some of his aid to ensure he gets the rest to survivors, to the field manager considering breaking head-office policy because his own moral compass suggests another approach is better, to government officials deciding whether to permit outside military forces to assist humanitarian aid provision. The scale of impact differs, but the ethical quandaries persist. This chapter will examine some of the more frequent ethical issues, focusing on three areas: disaster responses, disaster research, and healthcare during disasters.

The underlying premise of this chapter is that ethics is concerned both with fundamental values, rights, and dignity and with pragmatic dimensions. Trust can be built as sound ethical decisions are made and good practices flourish; trust can be destroyed by unethical behavior. Promoting a culture of ethics can increase cooperation and collaboration, while unethical practices lead to conflict and

D.P. O'Mathúna
School of Nursing and Human Sciences, Dublin City University, Dublin, Ireland
e-mail: donal.omathuna@dcu.ie

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disunity. Ethical practice contributes to an atmosphere of mutual respect, where responders benefit from the satisfaction of knowing they are promoting goods that go beyond the physical to enhancing survivors' dignity.

Disasters Defined

Disasters have been defined in various ways, but they are characterized by extensive damage and human suffering. They lead to what have been called the 6Ds: destruction, death, disease/disorders, displacement, disappearance, and disarray (Sumathipala et al., 2010). According to the Centre for Research on the Epidemiology of Disasters (CRED), a World Health Organization (WHO) collaborating center, a disaster is "an unforeseen and often sudden event that causes great damage, destruction and human suffering" and "which overwhelms local capacity, necessitating a request to national or international level for external assistance" (www.emdat.be). CRED tracks disasters globally, with an event classified as a disaster if 10 or more people are killed, 100 or more people are affected, authorities declare a state of emergency, or an appeal is issued for international assistance.

The World Medical Association (WMA) defines a disaster as "the sudden occurrence of a calamitous, usually violent, event resulting in substantial material damage, considerable displacement of people, a large number of victims and/or significant social disruption" (WMA, 2006). While disasters vary in nature, they share several common features:

- Sudden, unexpected onset requiring prompt response
- Massive damage to materials, infrastructure, and the environment
- Large numbers of human casualties, with difficulties accessing survivors
- Complications to relief efforts from weather, pollution, infection, and psychological factors
- Insecurity due to physical dangers, conflict, or violence
- Broad media attention (WMA, 2006)

Disasters are usually categorized into one of three groups: natural disasters (such as floods, earthquakes, or mudslides), technological disasters (such as industrial accidents, transport accidents), or complex emergencies, which involve natural and human causes. Disasters can also be conflict related (due to war or terrorism), which raise additional factors and complications which will not be addressed here. These classifications help to identify some of the major causes of the disasters but can be very arbitrary. However disasters are grouped, it is clear that their frequency is on the increase (see Figs. 36.1 and 36.2).

The devastating effects of disasters are well known from recent examples. These include the ongoing drought in the Horn of Africa, the 2011 great East Japan earthquake, the 2011 flooding in Australia, the 2010 earthquake in Haiti, hurricane Katrina in the USA in 2005, and the 2004 Indian Ocean tsunami. While large-scale disasters receive widespread attention, smaller disasters occur regularly, averaging one per day. For example, in 2010 winter storm Xynthia killed 65 people across

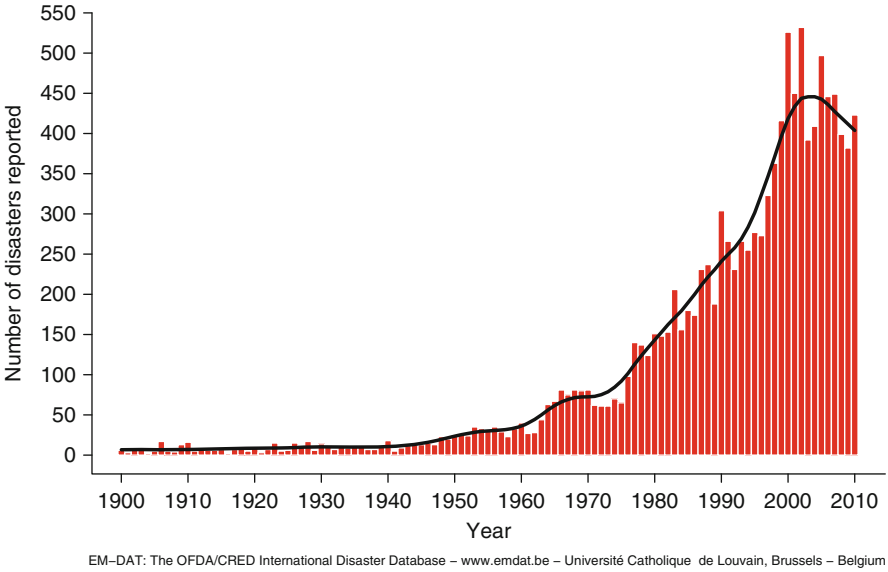

Fig. 36.1 Natural disasters reported 1900–2010

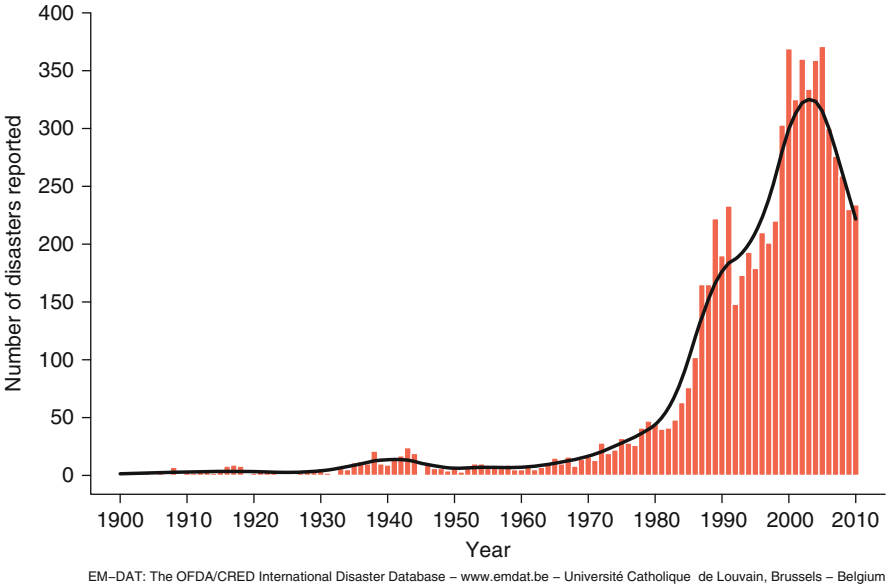

Fig. 36.2 Technological disasters reported 1900–2010

Europe, while flooding later that year killed 43 people in Portugal (www.emdat.be). According to the United Nations International Strategy for Disaster Reduction (UNISDR), the number of natural disasters is increasing steadily, with 2010 being the deadliest year in decades: 373 natural disasters killed 300,000 people, impacted 200 million more, and cost over US$100 billion (www.unisdr.org/archive/17613). Foremost among these were the Haitian earthquake that killed over 222,000 people and a heat wave in Russia that killed 56,000 people.

The frequency of disasters is projected to continue to increase. One assessment found that climate-related disasters (which make up 98 % of all disasters) will impact 375 million people annually by 2015, a 50 % increase on recent averages (Ganeshan & Diamond, 2009). Financial costs are also increasing, especially in more urbanized regions. The year 2011 was the costliest year ever for damages from disasters, estimated at between US$350 and $380 billion, largely due to the Japanese earthquake (www.unisdr.org/archive/24588). Disaster preparedness and risk reduction are top priorities for the United Nations (UN) and many other organizations.

Disaster Response Ethics

Disasters are commonly categorized as natural, technological, or complex emergencies. Such categories might help with donations, as people help more when disasters are natural. However, even these classifications have ethical dimensions. Such distinctions are based on an assumption that humans have little to do with causing natural disasters. People appear to have greater sympathy for those impacted by earthquakes or volcanic eruptions than when the disaster is caused by human error or deliberate sabotage. A natural disaster is seen as uncontrollable, while technological disasters could have been avoided. The damage and suffering caused by natural events are seen as random, while a sense of injustice or victimization exists with technological disasters. Why was the nuclear reactor built near us and not them? Why was the building code not enforced more strictly?

Such distinctions are convenient and commonplace, yet not easily sustainable under careful analysis. For example, the 2010 earthquake in Haiti was smaller in magnitude than one that occurred soon afterward off the coast of Chile. However, the number of people killed, injured, and made homeless was many times greater in Haiti than in Chile. The scale of aid needed in Haiti, and continuing to be needed, was vastly greater also. Although each disaster could be classified as natural, human factors played a large role in the scale of the disaster. Those need to be considered if lessons are to be learned so that other potential disaster victims can benefit. The destructiveness of Haiti's earthquake was influenced by the country's history and economics, where the vast majority live under the poverty line. This impacted the quality of housing and the resources available on the ground to respond to the disaster. While some of this can be traced to corruption in recent Haitian leadership, part of the problem stems from colonial days and indemnities required by France after Haiti became independent.

Understanding these factors is important for ethics because it impacts how disaster response is perceived. If some disasters are seen as completely unpredictable natural events, the response may be restricted to helping people in the immediate aftermath. Disaster preparedness may be limited to developing better defenses or early warning systems. But if the human contribution to disasters is identified, an ethical responsibility exists to make changes in those factors. This may motivate those involved to enact the necessary changes to reduce future pain and suffering.

A practical example of this is the observation that disasters increasingly impact urban settings. This is partly due to expanding urbanization of the world. When disasters hit more urbanized regions, the death toll tends to be lower, but the economic cost greater. Exceptions occur to this, such as the earthquakes in Haiti and one in Sichuan, China, in 2008. At the same time, more people are living in urban regions and individual cities are growing to unprecedented sizes. For example, in 1950 there were 75 cities in the world with a population over one million; in 2008, there were 431 such cities (IFRC, 2010).

Urbanization itself is not a bad thing. But the way urbanization is occurring is putting in place conditions for future disasters. For example, the probability of earthquakes is not increasing, but their devastation is – because of where and how building is occurring (IFRC, 2010). Currently, almost all the growth in urbanization is taking place in low- and middle-income countries, particularly in Asia. Much of this occurs as informal or illegal settlements, inadequately constructed houses, and building on sites at high risk for floods, landslides, earthquakes, or industrial accidents. These practices are allowed because of either a lack of knowledge of good planning principles, an unwillingness to act on those principles, or an inability to afford good housing. Such urbanization creates a "vulnerability gap" where those with lower incomes are being placed at higher risk of disaster (IFRC, 2010). Addressing such inequalities in disaster risk reduction is an ethical issue.

Disaster preparedness must therefore go deeper than preparing to rescue people after the disaster strikes. It must go to the core of why such social inequalities exist and are permitted to continue. Adam Smith (1790), after the Lisbon earthquake of 1755, wondered how "a man of humanity in Europe" would respond to news of a disaster in China. He speculated that he would express sorrow for the victims, reflect on the precariousness of human life, and then go back to his business or pleasure as if nothing had happened. He would be deeply disturbed at the loss of his own little finger but would sleep soundly while a hundred million people perished in some faraway land.

"Human nature startles with horror at the thought, and the world, in its greatest depravity and corruption, never produced such a villain as could be capable of entertaining it" (Smith, 1790, III.3.4). Nevertheless, today news of disasters travels the world, yet many go to bed worried about their own concerns. The human conscience, what Smith called "this judge within," should signal when people value themselves too much and others too little. It shows "the propriety of generosity and the deformity of injustice" (Smith, III.3.4). Ethics must address issues of conscience and character if it is to impact disasters. The dignity of those who look on is at stake, just as is the dignity of those directly impacted by disasters.

Encouraging others to respond generously after disasters raises other ethical issues. For years, "the starving child image" was used to raise funds for humanitarian aid (Jensen, 1997, p. 49). The ethical appropriateness of such images is now questioned because of how they impact people's perceptions of those in need. The problem is not that suffering is revealed, but that an image is conveyed of helpless victims who cannot help themselves. Even when consent was given during the disaster, people have been shocked to see themselves on public display when they later saw their photographs used to raise relief funds (Pittaway, Bartolomei, & Hugman, 2010). Such images of helplessness do not contribute to an atmosphere of mutual respect and dignity. The potential ethical implications of all fund-raising activities should be explored. "Do they convey respect for the dignity of the survivors? Have we carefully considered the effect of the images of reality we project on the psyche and inter-cultural attitudes in the constituencies from which we hope to raise funds?" (Jensen, 1997, p. 51). Other images can be dignifying, such as those showing donated animals that empower people to provide for their families and communities. The choice of image reflects concern for the ethical values projected directly or indirectly, intended or unintended.

Disaster responses must prioritize the immediate needs of disaster survivors but should also consider the long-term implications. Emergency aid should be tied into longer-term sustainable development. If not, tragic situations can arise where those seeking to do good end up causing harm in the long run. For example, after an earthquake in Guatemala, so much food was donated that the price for local crops was depressed (Jensen, 1997). As a result, crops unaffected by the earthquake were never harvested. Unless carefully monitored, disaster relief can end up promoting dependency. On the other hand, relief can lead to unsustainable economies. When relief workers purchased goods and services within the disaster region, prices can increase dramatically. While some survivors benefit greatly from this, the higher prices can leave basic necessities unaffordable for other survivors. Local organizations and businesses also lost many of their staff to international organizations who paid higher salaries.

None of these issues have simple solutions, but they are not just financial or strategic problems. Ethical values influence all the choices made. Recognition of these values is crucial to avoiding long-term negative consequences. For this reason, the International Federation of Red Cross and Red Crescent Societies (IFRC) has developed a code of conduct for those responding to disasters to which 492 humanitarian organizations have become signatories (IFRC, 1994). The voluntary code commits organizations to making decisions during disaster relief based on ten ethical principles:

1. The humanitarian imperative comes first.
2. Aid is given regardless of the race, creed or nationality of the recipients and without adverse distinction of any kind. Aid priorities are calculated on the basis of need alone.
3. Aid will not be used to further a particular political or religious standpoint.
4. We shall endeavour not to act as instruments of government foreign policy.
5. We shall respect culture and custom.

6. We shall attempt to build disaster response on local capacities.
7. Ways shall be found to involve programme beneficiaries in the management of relief aid.
8. Relief aid must strive to reduce future vulnerabilities to disaster as well as meeting basic needs.
9. We hold ourselves accountable to both those we seek to assist and those from whom we accept resources.
10. In our information, publicity and advertizing activities, we shall recognize disaster victims as dignified human beings, not hopeless objects (IFRC, 1994).

These principles provide an important starting place for organizations and individuals as they consider the ethical implications of the many decisions they make regarding disaster response and planning.

Evidence and Disasters

A compassionate response to the suffering caused by disasters is important. Those responses are always limited by availability, and aid must then be allocated on the basis of need alone (IFRC, 1994). This fundamental principle is often taken for granted, but important reasons underlie it (Milletts-King, 2006). A needs-based approach satisfies the notion that all people have the right to such items as life, safety, or food. Such rights are inherent to all individuals. A needs-based approach helps reduce discrimination and prejudice, where resources might be distributed based on race, religion, class, or gender. Being impartial can help foster trust and cooperation, facilitating the provision of need to more people. A needs-based approach also helps ensure that limited resources are used as effectively as possible for those who need them the most.

A needs-based approach to relief requires accurate knowledge of those needs. Unfortunately, precise data on needs are often limited, especially immediately after a disaster strikes (Bradt, 2009). Conducting needs assessments in disaster settings is challenging and points to the importance of identifying predisaster resources and infrastructure. For example, Sri Lanka was hit by the 2004 Indian Ocean tsunami with over 30,000 deaths and about half a million people displaced (Yamada et al., 2006). Sri Lanka received much international assistance, but inattention to needs assessments meant that some resources sent were not what were needed. Unlike other countries, Sri Lanka had a strong public health system which mobilized quickly to prevent an infectious disease epidemic. Lack of awareness of these local resources led to duplication of services by foreign nongovernmental organizations (NGOs). Some people received unnecessary cholera vaccination or malaria prophylaxis because NGOs incorrectly assumed these diseases were endemic (Yamada et al.). At the same time, needs assessments revealed that, contrary to expectations, few people were critically injured in Sri Lanka. A characteristic of this tsunami was that people either drowned or escaped with few physical injuries.

Local and international coordination is needed to identify needs accurately and ensure those needs are met with appropriate resources. This was lacking

in Sri Lanka, resulting in some camps for displaced persons receiving excess food and inappropriate clothing, while other camps were short of supplies. Sleeping mats and hygiene kits were always needed, but news reporters found that international crates arrived with "winter jackets, expired cans of salmon, stiletto shoes, winter tents, thong panties, and even Viagra" (http://msnbc.msn.com/id/6954302). Presumably sent with the best of intentions, shipping unneeded items uses resources that could have been spent more wisely. Such mistakes can hurt on a deeper level. The same news report quoted a woman displaced by the tsunami reacting to another box of unneeded clothing saying, "We're not beggars. We don't need these hand-me-downs."

Needs must be accurately assessed to avoid such situations and develop effective responses. Such an evidence-based approach has been slow to gain acceptance among humanitarian aid providers. "Without appropriate evidence, allocation is based on estimates and professional judgement, and needs assessments in practice play a minor part in determining allocations" (Milletts-King, 2006, p. 26). Currently most disaster relief operations make decisions based largely on expert opinion, authority, or nonrigorous studies (Bradt, 2009). Such approaches are problematic as this type of evidence can be of low quality. However, "the limited corpus of rigorous studies is notable" (Bradt p. 488). Rigorous studies include randomized controlled studies (RCTs) of interventions, quasi-experimental studies using matched control groups, and systematic reviews of such studies.

Overall, "much of the existing operational research related to emergencies and disasters lacks consistency, is of poor reliability and validity and is of limited use for establishing baselines, defining standards, making comparisons or tracking trends" (UNISDR, 2011, p. 46). As a result, globally accepted standards for performance and accountability during disaster relief operations do not exist. All of this points to the importance of generating evidence to guide disaster responders and policy makers. As with any research involving human subjects, conducting such research raises ethical issues.

Disaster Research Ethics

Research provides answers to various types of questions. Disasters can raise many different questions, some of which are listed in Table 36.1.

Each type of question is best addressed by a particular research method. Some research evaluates interventions, seeking to understand, for example, whether certain medications are effective and safe or which policies are most effective. Intervention studies randomize individuals or groups to receive one intervention or another, striving to be as objective as possible. Other research methods, common in the social sciences, address different research questions with interviews or focus groups. These studies raise different ethical issues, although some overlap exists. All research should respect subjects, minimize risks, and respect confidentiality. However, different types of research will raise distinctive ethical issues.

For example, "reciprocal research" seeks to transform "people from subjects of research to participants in research" and "has the potential for bringing about

Table 36.1 Possible disaster research questions (Adapted from Jesus & Michael, 2009)

General topic	Potential research questions
Mass casualty management	Which approaches to triage work best in particular types of disasters?
	Do people displaced after disasters fare better in camps or dispersed among the general population?
New technology	Are point-of-care diagnostic devices effective guides in disaster settings?
	What methods of detecting chemical, biological, or radiological exposures work best in disaster settings?
Infectious diseases	Which vaccines for specific diseases work best in disaster settings?
	What public policy strategies work best to prevent the outbreak of epidemics after disasters?
Mental health	How do disaster survivors cope with their experience of the disaster?
	What training and support best prevent burnout among disaster responders?
Resource management	What are the most urgent/prevalent health needs among disaster survivors?
	Are the needs of women, children, or other special populations addressed differently from those of men?
Education and assessment	What types of training best prepare individuals as disaster responders?
	What outcome data can be collected during disasters to improve future disaster responses?

social change" (Pittaway, Bartolomei, & Hugman, 2010, p. 247). The objectivity of intervention research, where confounding factors are controlled as much as possible, is not a factor here. For the social scientist, research in humanitarian settings seeks both to contribute knowledge to a better understanding of the world and to change policies or attitudes so that the lives of those studied are improved. Many within this research tradition hold that research into people's suffering is only justified if relieving that suffering is an explicit objective.

Intervention research is well established within medicine. The ethics of such research has been explicitly addressed in guidelines like those of the WMA Declaration of Helsinki and the Council for International Organizations of Medical Sciences (O'Mathúna, 2010). While a specific set of guidelines addressing disaster research has not been adopted internationally, the core ethical principles of these other guidelines are directly applicable (Jesus & Michael, 2009).

However, concerns have been expressed that research ethics in general has become too cumbersome and overly bureaucratic (O'Mathúna, 2011). Such critiques are generally raised concerning the research ethics review process and regulatory frameworks, which can always be improved. The underlying reason for research ethics should be the focus: to promote respect for research subjects and ensure risks of harm are minimized. Henry Beecher's highly influential 1966 article on medical research ethics began by listing numerous ways in which published research projects had violated ethical principles. Stimulated by such publications and revelations about unethical research, research ethics procedures have become well established for intervention research. Beecher saw value in research ethics review and informed consent, but he also held that the most reliable safeguard to ethical research involving humans was "the presence of an intelligent, informed,

conscientious, compassionate, responsible investigator" (Beecher, 1966, p. 1360). Developing character traits and virtues such as these in researchers remains challenging, yet is central to what research ethics should be about.

Past ethical problems and failures can stimulate interest in promoting ethical practice. Recalling and discussing such blemishes can both help to prevent similar problems in the future and instill humility in current decision-making. Intervention research has many such examples, from the Tuskegee syphilis experiments to more recent HIV drug trials in low- and middle-income countries. More recent studies are revealing ethical concerns in social science research in disaster settings. Although the research involved interviews, not experimental drugs, harm has resulted, leading to calls for closer attention to disaster research ethics. For example, a sociologist with a strong working relationship with women in refugee camps found that things changed when she proposed conducting research with the same women. The women became wary of her motives because of a "deep fear of exploitation by researchers" (Pittaway, Bartolomei, & Hugman, 2010, p. 236). When this was explored further, some of the concerns about research came from beliefs held by the women themselves, including:

- Overly high expectations of receiving humanitarian aid
- Fears of backlash from community leaders and authorities
- Mistrust of foreign, Western researchers or local researchers from a different class or ethnic group

Other concerns could be traced to ethically questionable practices in previous research:

- Names and photographs of research subjects were released without authorization, at times putting them in danger.
- Promised feedback from researchers never arrived.
- Researchers "flew in" and "flew out" causing inconvenience and more problems than benefits.
- Consultation about recommendations and proposed strategies never occurred.
- Researchers were unable to cope with the stories they were told by the women interviewed.
- Interviewees were retraumatized without being provided support.

One research subject noted that after putting previous researchers in contact with women who had been raped and were willing to have their stories recorded: "We never heard from them again – we decided then that we would never work with researchers again. They stole our stories" (as cited in Pittaway, Bartolomei, & Hugman, 2010, p. 236). A men's group in a refugee camp reported:

> You know many of the organizations came to the refugee camp and they see the refugees in many ways as the monkeys... like a monkey in a cage... and then they thought that if we show this monkey to... the big countries of power like the EU [European Union], they will have a lot of money and it will benefit us [the non government organizations]... They documented things [stories] of the women that is oppressed, then when they get money they use some for the refugees but mostly they use for themselves. (Pittaway, Bartolomei, & Hugman, 2010, p. 230)

Such researchers likely did not intend to cause harm, but in research, good intentions are not good enough. Research in disaster settings engages people in vulnerable situations and has the potential to cause good or harm. In other disaster research, people have been pressured into participating, biological samples have been smuggled out of disaster settings, and informed consent has been ignored (O'Mathúna, 2010). Researchers often get caught up in the goals of their projects and may not see other aspects or potential conflicts of interest, some of which may violate ethical principles.

Disaster research covers a wide range of practices and raises many different ethical issues. The following sections will examine some ethical principles that are particularly relevant to disaster research. Some examples will be given to illustrate how the principles apply in disaster settings. However, this section will not address all the ethical issues in disaster research and will not provide an exhaustive discussion of each topic. Some of these topics are examined in more depth elsewhere (O'Mathúna, Gordijn, & Clarke, 2012). However, much further work is needed on disaster research ethics.

Beneficence

The underlying motivation for disaster research is generally the ethical principle of beneficence: to do good for disaster survivors, both current and future. This is accomplished by generating high-quality evidence that can be used to give strong recommendations in disaster planning, prevention, or responses. In responding to disasters, the primary motivation is to do the most good for as many people as possible (Bradt, 2009). However, in many areas of disaster response, what will bring about the most good is not clearly understood. Many myths and fallacies about health risks and health needs during disasters exist in both public perceptions and views of some responders (Magone, Neuman, & Weissman, 2011). Good-quality evidence is needed to identify the best ways to help people after disasters.

For example, panic is believed to be widespread after a disaster, yet evidence shows that most survivors do not panic. Empirical research has shown that survivors remain calm and play crucial roles in helping to rescue people and treat their injuries (Magone, Neuman, & Weissman, 2011). In the immediate aftermath of the 2004 tsunami in Sri Lanka, thousands of people came from the affected regions and nearby to search for survivors, care for the injured, and provide basic needs (Yamada et al., 2006). These informal networks were mobilized before government agencies responded or international teams arrived. Empirical research in other countries has found that the vast majority of disaster survivors are rescued by other survivors (Magone, Neuman, & Weissman, 2011). These research findings have important implications for disaster preparedness training and planning, highlighting the importance of conducting research immediately after disasters.

Research can also provide evidence to prevent the provision of ineffective or harmful interventions. Because of the trauma of disasters, psychological care of different types has been offered to survivors. Thousands of well-meaning

counselors arrive in disaster settings to help survivors. However, a systematic review of research on psychological debriefing to prevent posttraumatic stress disorder (PTSD) showed that it is not generally effective (Rose, Bisson, Churchill, & Wessely, 2002). Similarly, critical incident stress debriefing (CISD) was initially used to help disaster responders process their experiences and avoid subsequent negative effects (Alexander & Klein, 2009). When empirical data became available, CISD was shown to either be ineffective or to worsen the situation. On the other hand, for those exhibiting PTSD symptoms, cognitive behavioral therapy (CBT) can be safe and effective, although many people do not respond to CBT for various reasons. The WHO and other organizations recommend against using debriefing sessions that push people to share their experiences beyond what they would naturally disclose (WHO, 2003). Other research shows that most (but not all) disaster survivors benefit more from practical help and general conversations with family and friends rather than professional counseling (O'Mathúna, 2010).

While conducting research in disaster settings is challenging practically and ethically, the results are needed to provide evidence to guide responders. Otherwise, well-meaning responders will continue to send inappropriate aid with unintended consequences. Some international disaster responses have been found to undermine local disaster relief efforts and, in places, set back local organizational infrastructural. Such outcomes were surely unintended, but "good intentions do not excuse bad outcomes" (Bradt, 2009, p. 483). High-quality research can help identify why problems resulted and how they can be avoided in the future.

Vulnerability

Disaster research should recognize the inherent vulnerability of people in disaster settings. The devastation that disaster survivors endure means that rescue and relief should take precedence over research. Vulnerability is usually raised in research as a concern either that subjects may not be able to give informed consent because of outside influences or that participating in the research may cause additional harms (O'Mathúna, 2010). On the other hand, labeling people as vulnerable and thus unable to give truly informed consent could be "inaccurate and potentially stigmatizing" (Collogan, Tuma, Dolan-Sewell, Borja, & Fleischman, 2004, p. 365). Little research has been conducted on the decision-making capacity of those affected by disasters, but the available evidence suggests that most people are able to make informed decisions, even when extremely upset by disasters. At the same time, some people are more deeply impacted by the disaster to where their decision-making capacity is impaired. The potential vulnerability of disaster survivors imposes additional duties on disaster researchers to ensure that subjects are adequately informed.

Labeling people as vulnerable can be problematic if it leads to a paternalistic attitude or to the exclusion of certain groups from research important for them (Levine, 2004). Giving people the opportunity to participate in research could be beneficial and dignifying for them. For example, a research project assessed the

hurricane-related stressors among adult patients at an outpatient psychiatric clinic 1 week after hurricane Katrina (O'Mathúna, 2010). Some staff members at the clinic were concerned that patients might feel pressured into completing the surveys. Patients were told they could refuse to be involved and could talk to the clinic staff about any concerns they had with the research. Approximately 1 % of the patients refused to participate, while those who participated reported that they appreciated that the researchers were trying to understand how the hurricane had affected them personally.

Vulnerability must be taken into account in disaster research but provides little specific guidance for research ethics. Disaster survivors should be viewed as capable of consenting or refusing to participate in research, although appropriate steps should be taken to evaluate whether individuals may have impaired decision-making capacity. As with any group of research subjects, disaster survivors will show a range of capacities that should be assessed during the informed consent process. At the same time, "the concept of vulnerability should remind us of the fragility of human life and the importance of protecting people from unnecessary harm. As such, it points to other important ethical principles that need to be taken seriously with all participants" (O'Mathúna, 2010, p. 69). How these are addressed depends on the details of each study, such as whether it is observational or interventional, its risks and benefits, how soon after the disaster it is conducted, what conflicts of interest are involved, and other factors.

Informed Consent

Informed consent is a bed-rock ethical principle in research. The most heinous ethical violations in research have occurred when informed consent has been ignored. The unethical medical research conducted in Guatemala in the 1940s by US researchers is abhorrent partly because the subjects were not given the opportunity to consent to their involvement. Research is regarded as a voluntary activity, and therefore, not seeking informed consent is disrespectful and a violation of the individual's rights. Informed consent for research is regarded by the UN a "nonderogable right" and therefore cannot be exempted if individuals have the capacity to give it.

Informed consent in disaster research raises many challenges, especially if the situation is chaotic, fraught with danger or stress, and involves translation of technical information and if research is an alien concept for participants. The urgency involved with disasters and other emergencies has raised the possibility that some research should be permitted without informed consent. Researchers in the USA can obtain a waiver for written informed consent in emergency situations if the patient is unconscious and no relative is available. When such waivers have been used in multicenter emergency medicine trials, recruitment has been faster and higher than when informed consent is required. Some claim such consent waivers will lower ethical standards in research; others reject these concerns and claim informed consent is a legalistic ritual in medical research which does not actually respect patients' autonomy (O'Mathúna, 2011).

Waiving informed consent in any research can have far-reaching consequences. Research on an experimental blood substitute was conducted on trauma patients on their way to hospitals. As the patients were unconscious, an approval to waive informed consent was obtained. However, the study was harshly criticized for this in academic and media sources. "Severe public resistance to research conducted without informed consent, even when consent is impossible to obtain due to an emergent condition, suggests that extending a waiver of informed consent to include disaster research would face similar opposition" (Jesus & Michael, 2009, p. 113).

As a way of respecting people's dignity, especially in disaster settings when they may have lost everything else, informed consent provides people some control over themselves and what happens to them. The Working Group on Disaster Research and Ethics (WGDRE) was constituted after the Indian Ocean tsunami and has been developing draft guidelines for disaster research (Sumathipala et al., 2010). These guidelines insist that informed consent always be obtained for disaster research, even with the challenges this entails. The consequences of using people as research subjects without their consent could far outweigh any potential evidence gained. When such practices would be revealed, the potential for erosion of public trust in research and public health systems could have long-term consequences and undermine future research efforts (Pittaway, Bartolomei, & Hugman, 2010).

Humanitarian Misconception

One challenge with informed consent is to ensure that people understand the risks and benefits of research. In medical research, the risks include unknown adverse effects, while the benefits might include receiving an intervention that is more effective than current standard care. However, the clearest beneficiaries are future patients who will be treated with the benefit of whatever knowledge is gained from the project. In the research, to justify randomly assigning people to one intervention or another, "clinical equipoise" should exist. This means that the researchers do not know which intervention is most effective or safest. If they did know which was best, that should be provided to the patients.

However, subjects in medical research frequently do not understand this distinction between research and therapy. Studies have found that patients often think that being a research subject ensures they get the newest and best treatments (Ahmad & Mahmud, 2010). Subjects often believe that researchers decide between interventions based on their individual needs – not the toss of a coin in random allocation. This can make it difficult to accurately weigh up the risks and benefits and has become known as the "therapeutic misconception" – the mistaken belief that being a research subject is a way to obtain the best therapy.

Something similar has been identified in humanitarian research and called the "humanitarian misconception" (Ahmad & Mahmud, 2010). Here, people may believe they are more likely to receive humanitarian aid if they agree to participate in research. In some cases, they may be correct if the only effective medical care

available is from the research team. In that case, however, they may unwittingly expose themselves to risks from experimental interventions, as has been alleged in the Trovan case during a 1996 meningitis outbreak in Nigeria (O'Mathúna, 2010).

Such concerns can be addressed in intervention studies through a detailed informed consent process. However, other types of research do not begin from a situation of clinical equipoise and do not seek to objectively assess the effectiveness of interventions. The reciprocal research method mentioned above seeks both to generate new knowledge and to help participants. People agree to be interviewed assuming this will provide benefits for them or their community, or lead to improved policies or practices. Such projects have both research and humanitarian goals and must make this clear to participants. One way this can be done is by promoting the "principle of reciprocity," whereby tangible benefits for participants are identified ahead of time through discussions with potential participants (Pittaway, Bartolomei, & Hugman, 2010). The benefits can be in the area of training or providing participants opportunities to present their concerns to others. Even in medical research, the principle of reciprocity is increasingly accepted, where patients are entitled to be informed of the outcome of the research and to share in any resulting benefits. As with overcoming any misconception, clear communication and active dialogue clarify expectations and promote respect on all sides.

Cultural Issues

Another factor complicating disaster research (and humanitarian aid in general) is the cultural difference that can exist between researchers and participants. Disasters strike all over the world, but disaster researchers frequently come from one culture to conduct projects in another. One principle in the IFRC code of conduct for disasters is that cultures and customs should be respected (IFRC, 1994). Cultural sensitivity is not the same as ethical relativism, where any practice is accepted on the basis of cultural values (Pittaway, Bartolomei, & Hugman, 2010). Hence, if a local authority insists on making all research decisions for those in his jurisdiction, a process of dialogue and negotiation should be initiated where fundamental human values and rights are promoted and protected.

Ethical Review and Oversight

Given the general chaos and infrastructural breakdown following disasters, research ethics approval and oversight may be low on survivors' priority list. Nonetheless, researchers should ensure that their studies are both ethically sound and methodologically rigorous. Research ethics committees have emerged as a way to facilitate this through peer review. Disaster research projects will usually be reviewed by researchers' home institutions, but a role for dedicated research ethics committees is increasingly being suggested. For example, Médecins Sans Frontières (MSF) is an international medical humanitarian aid organization which

developed an independent research ethics review board to approve research projects conducted by MSF researchers (Schopper et al., 2009). The board is composed of people familiar with humanitarian organizations and representative of different professions and geographical regions. Their work is carried out electronically, with face-to-face meetings every 18 months.

Many of the board's functions are similar to those of other ethics review committees. However, a distinctive feature of disaster research is the need to get projects started unexpectedly and quickly. All disaster research does not need this, but for projects investigating the earliest stages of the disaster aftermath, speed is of the essence. For this reason, the MSF board will review a "generic" research protocol and grant approval without knowing the specific location or nature of a disaster (Schopper et al., 2009). When the disaster occurs, the research team submits a finalized protocol for expedited review and can quickly deploy to the field. However, the MSF board also requires that such projects gain approval from national authorities at the disaster site.

Such a model allows for careful planning, reflection, and review away from the time pressures of the disaster, with final adjustments made once the disaster occurs. Other governmental or international relief agencies could provide such preapproval as part of disaster readiness planning and as a way to encourage research into needed topics. Preapproval would also facilitate oversight and coordination of research once a disaster strikes. Such a model was developed after the 1995 Oklahoma City bombings in the USA (Collogan, Tuma, Dolan-Sewell, Borja, & Fleischman, 2004). All bombing-related research projects had to obtain ethics approval from the University of Oklahoma Institutional Review Board. This helped both to coordinate the research enterprise and to project survivors from being burdened by numerous requests to participate in different research projects. In this way, research ethics review can both facilitate ethically sound research and fulfill its requirement to protect research participants.

Disaster Healthcare Ethics

Responders to disasters include people from a wide variety of backgrounds. Among these are many healthcare professionals who volunteer to help injured and traumatized survivors. The outpouring of well-intentioned help is often tainted by criticisms about lack of preparedness, coordination, and appropriate skills (Krin et al., 2010). Many responders return from disasters experiencing what have been called "vicarious traumatization," "compassion fatigue," and "burnout," although these terms have not been clearly delineated (Alexander & Klein, 2009, p. 88). While this section will focus on healthcare professionals, many similar issues are faced by researchers and other aid workers whose well-being also needs to be taken into account (O'Mathúna, 2010).

The negative experiences of disaster responders relate to the devastation they have seen, the human pain and suffering they have witnessed, physical fatigue, and frustration with difficult working conditions. At the same time, many responders

report positive results from their involvement in disasters, especially the development of resilience. After the 2003 outbreak of SARS (severe acute respiratory syndrome) in Hong Kong, frontline healthcare workers reported that along with some "survivor guilt," their work in the disaster had positive effects by affording them the opportunity to reassess their life values and priorities and deepen their relationships (Alexander & Klein, 2009).

Responders often have to make ethical decisions that they struggle with in the field and afterward. These ethical dilemmas are faced daily but have received relatively little attention (Sheather & Shah, 2011). Triage decisions are the most obvious: choices must be made to treat some people or not treat others. These decisions should be based on objective, medical criteria (Merin, Ash, Levy, Schwaber, & Kreiss, 2010; WMA, 2006). Rationally, it makes sense to triage people in disaster settings to expectant management (i.e., not to treat them) when they have burns covering more than half their body. However, in the field, such guidelines can be much less clear-cut, leading to ethical conflict over whether or how to follow them. Military medical units often treat civilian casualties and transfer them to local hospitals when severely injured soldiers arrive. Sometimes they know the local facilities do not have the resources to keep these patients alive. They know they will soon die but are told there is no alternative.

Such ethical dilemmas deeply impact healthcare professionals. Cases have been reported of healthcare professionals being overwhelmed with guilt over not being able to do enough to help people. A qualitative study of 20 Canadian-trained healthcare professionals who had volunteered in disaster settings identified four general types of ethical challenges experienced (Schwartz et al., 2010):

- Resource scarcity and decisions over allocating those resources
- Social injustice, arising from inequalities, exploitive industries, or violence
- Frustration with aid agency policies or agendas
- Healthcare professionals' roles and interactions

While some of these ethical challenges arise in high-income settings, they are intensified by the degree of scarcity; the extent of need; lack of familiarity with cultural, social, and professional norms; and poorly defined roles. The researchers contacted three medical organizations that send healthcare professionals to disasters (Schwartz et al., 2010). None of them had specialized ethics training for field workers but relied on them using their professionalism and standard codes of ethics.

Such professional ethics training is of value, but these researchers found that it sometimes contributed to the ethical challenges in the field. The ethical dilemmas are similar enough to lead professionals to look to their professional codes, yet in disaster settings, some ethical principles become impossible to uphold completely. One such area is where public health interests come into direct conflict with the needs of individual patients. Healthcare professionals trained in Western ethics strongly favor individual needs and patient autonomy, yet in disaster settings, public interests often take priority. This can produce feelings of isolation and distress over triage decisions (Schwartz et al., 2010).

Western ethics training usually focuses on resolving ethical dilemmas in rational ways by identifying ethically sound options. In analyzing cases and dilemmas,

ethical principles are identified and prioritized according to professional values or individual preferences. Such "ideal morality" assumes that moral goodness is always possible. Ethics is seen as a way to help people act ethically, leaving them confident that they have done the right thing. Moral dilemmas, in this approach, either do not really exist or show that further analysis is needed to identify ideal ethical solutions.

When such an approach is brought into disaster settings, its inadequacy becomes apparent quickly. Humanitarian ethical dilemmas "often entail choosing between undesirable alternatives" (Jensen, 1997, p. 7). Using a Western approach to ethics can result in frustration and guilt, as Schwartz et al. (2010) found. This leads some to question whether ethics can provide any concrete guidance in disasters. Claims have been made that "the world today is simply too complex and too diverse for prescriptive ethics" (Jensen, 1997, p. 50). Yet the outcry over certain decisions, such as questions about whether some patients were euthanized without their knowledge during hurricane Katrina, shows that the solution does not lie in ethical relativism.

Recent work on "nonidealized morality" provides a useful model for disaster ethics. In this approach, "moral dilemmas should be understood as situations of unavoidable moral wrongdoing or failure" (Tessman, 2010, p. 798). Ideal morality focuses on ideal situations and abstract principles, but these can be divorced from the realities of actual situations. Nonideal morality starts by describing the real world, including its wrongs and injustices. It acknowledges that, "Not all wrongs can be rectified, not all losses can be compensated, not everything can be repaired or replaced, and – especially given the limits of psychological resilience – not everyone can recover" (Tessman, p. 801). The failure and guilt are real, because sometimes no choice is ideal. True dilemmas exist where all options carry a bad side. When a doctor chooses to operate on one patient and leave another to die, guilt is normal. The challenge then is to develop ways to better prepare people to address such nonideal moral dilemmas, to assist them in the field as they wrestle with such decisions and their consequences, and to support them when they return home and have to process their experiences. This requires examination of the emotional dimensions of ethics, including guilt, forgiveness, grief, and anger, even though these typically are not addressed in ethics training.

Conclusion

Disasters are increasingly prevalent. In addition to complex issues of global inequalities and responsibilities to help one's fellow humans, disasters raise many challenging ethical issues. Our understanding of disasters needs to be furthered so that the multiple contributions to their causes – human and natural – can be addressed. Foremost among the ethical issues is identifying reliable strategies to prepare for future events and minimize the risk of harm. While saving lives and healing wounds are the immediate priorities, longer-term development strategies must be considered at all stages of relief. From the beginning, ethical considerations are involved and should be explicitly addressed.

In developing effective preparation and response strategies, the highest quality evidence available should be used. For many decisions, this is lacking, pointing to the need for disaster research. Many different research questions need to be addressed, each with their distinctive ethical issues. International guidelines should be developed and adopted to ensure that all disaster research, especially that carried out in low- and middle-income countries, is conducted to the highest ethical standards. International ethics review committees, like that of MSF, need to be set up to approve and monitor research occurring in regional disasters. As a way to respect the contributions made by research subjects in these projects, research findings should be incorporated into policies and practices so that disaster planning and prevention becomes increasingly evidence based and beneficial to those living in disaster-prone regions.

The ethical challenges facing disaster responders are only beginning to be addressed in detail. Few investigations have been conducted into the factors that help responders cope in the field. One factor is selection of responders to identify those most resilient, and the other is training (Alexander & Klein, 2009). Much work is needed to develop tools and training programs that will help prepare healthcare professionals (and researchers) for the ethical challenges and decisions they will face in the field. Support mechanisms are needed to help responders address the ethical challenges as they arise in the field. For example, one field hospital in Haiti developed a system of ad hoc ethics committees to deliberate on the ethical decisions being made and share their burden (Merin, Ash, Levy, Schwaber, & Kreiss, 2010). Without such supports, some survivors will not be helped effectively and may even be harmed, while some responders will return with debilitating moral distress. "If we fail to give this set of issues careful and considered attention, the consequences range from burnout and reduced ability of aid organizations to attract and retain [healthcare professionals] to do fieldwork, to avoidable suffering of all involved" (Schwartz et al., 2010, p. 53). Much further work remains to be done on this significant topic.

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Dual Use

37

Michael J. Selgelid

Introduction

While recent developments in genetics and biotechnology may have tremendous benefits regarding the advancement of medicine and improvement of human health and well-being, they could also enable causation of harm. Of particular concern is the "dual use" phenomenon, whereby the very same scientific knowledge and/or technology that can be used for good purposes can also be used for bad purposes. Discoveries that may facilitate scientific progress and/or prevention or treatment of disease, for example, may (sometimes) also facilitate production of biological weapons of mass destruction.

The dangers of dual-use life science research are illustrated by a series of controversial experiments that have been published during the twenty-first century. Australian researchers, for example, accidentally created a superstrain of mousepox. They used genetic engineering techniques to insert an interleukin gene into the mousepox virus genome. While their hope was that the altered virus would induce infertility in mice and thus provide a powerful new means of pest control, the virus they produced unexpectedly killed both mice that were naturally resistant to and mice that had been vaccinated against ordinary mousepox. They published their findings, along with description of materials and methods, in the *Journal of Virology* in 2001 (Jackson, Christensen, Beaton, Hall, & Ramshaw, 2001).

In a second study, American researchers artificially synthesized poliovirus "from scratch." Following the map of the polio (RNA) genome, which is published on the Internet, they bought and strung together corresponding strands of DNA. Addition of the synthesized genome to a solution containing cellular ingredients (but no live cells) led to the creation of a "live" virus that paralyzed and killed mice. They published their findings, along with description of materials and methods, in *Science* in 2002 (Cello, Paul, & Wimmer, 2002).

M.J. Selgelid
Centre for Human Bioethics; School of Philosophical, Historical and International Studies, Monash University, Clayton, VIC, Australia
e-mail: michael.selgelid@monash.edu

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While both of these studies revealed information that may be important to the advancement of science and/or medicine, they both have implications for biological weapons making. The technique that led to creation of vaccine resistant mousepox, for example, might also enable creation of vaccine resistant smallpox. The technique used to synthesize polio might enable artificial synthesis of smallpox (or other biological weapons agents).

Smallpox is one of the most feared biological weapons agents. Historically, smallpox has been one of humankind's worst enemies. It killed 300–500 million people during the twentieth century alone (Oldstone, 1998). The mousepox experiment is significant because there is no curative treatment for smallpox. Vaccine is our only defense against it. The polio experiment is significant because aspiring bioterrorists would not usually have easy access to smallpox – because all remaining samples of the virus are, officially anyway, supposed to be held in secure facilities (in the US and Russia). The potential ability to synthesize smallpox, therefore, might provide bioterrorists with access to an especially dangerous biological weapon agent that would otherwise have been unavailable to them.

In public controversy surrounding these two studies, critics complained that the research in question should not have been conducted and/or published (Selgelid, 2007). At the very least, according to many, the materials and methods sections of the published articles should have been omitted or altered. Publishing such studies in such detail, they claimed, provides aspiring bioterrorists with detailed "road maps," "blueprints," or "recipes" for the making of dangerous biological weapons.

Similar controversy has surrounded more recent research on influenza. In 2005, for example, American scientists synthesized the 1918 Spanish flu virus using techniques similar to those used in the polio study – and they likewise published their findings along with description of materials and methods (Tumpey et al., 2005). This study is significant because the virus in question was responsible for one of the worst epidemics in human history. The 1918 flu killed between 20 and 100 million people over the course of just a year or two (Crosby, 1989).

The most recent and, to date, most controversial dual-use experiments have involved research with the H5N1 avian influenza virus. In this case, researchers in the Netherlands and USA succeeded in creating strains of H5N1 that are "airborne transmissible" between ferrets, which provide the best model for influenza in humans. This is important because public health experts have long wondered whether H5N1 could possibly become transmissible between humans and thus potentially lead to a severe pandemic. The ferret research apparently yields an affirmative answer to this question.

Much debate has surrounded the question of whether or not detailed description of the materials and methods of this ferret flu research should be published. The researchers involved, and many others in the scientific community, have argued in favor of publication on the grounds that this may facilitate (1) development of vaccines against dangerous strains of H5N1 that may eventuate in the future and (2) surveillance and thus recognition of relevant changes occurring in H5N1 in nature (Enserink, 2011). The hope with regard to (2) is that this would provide

advanced warning if a pandemic strain is about to emerge and thus enable early implementation of preparatory public health measures.

On the other hand, these potential benefits of publication (of research details) might actually be quite limited. The idea that details regarding these particular studies need to be published in order to enable production of vaccines against naturally occurring transmissible H5N1 and/or to provide advanced warning that transmissible H5N1 is about to occur in nature seems to presuppose that when (and if) transmissible H5N1 evolves in nature, this will occur via the same genetic changes generated in the laboratory. But there are presumably any number of different ways via which transmissible H5N1 might evolve in nature (Selgelid, 2011). If this is correct, then developing vaccines against specific strains produced in the lab, or keeping an eye out for the natural emergence of strains similar to those produced in the lab, might not do much good.

With regard to the benefits of surveillance, meanwhile, an important lesson learnt from pandemic H1N1 (swine flu) is that there is not much that can be done to contain outbreaks of pandemic strains of influenza once they emerge. The point here is that even if publication of details of these studies allows somewhat earlier detection that a transmissible strain of H5N1 is emerging in nature, there might not be much that can (effectively) be done with this information to forestall or contain the epidemic/pandemic foreseen.

Appropriate vaccine production, of course, could be useful – but large-scale vaccine production takes months, while influenza spreads rapidly. The influenza virus is prone to a great deal of genetic mutation, and specific vaccines are needed to protect against specific strains of influenza. This is why different vaccines for seasonal influenza are offered each year and why it would be difficult to prepare vaccines against naturally occurring transmissible strains of influenza before such strains actually arise.

Even if benefits regarding vaccine development and/or surveillance are real, furthermore, they might be achieved without making details of these studies available to the general public. Those specifically involved in vaccine production and/or relevant surveillance, that is, could be informed about details of the ferret flu research on a need-to-know basis.

While the benefits of publishing full details about this research are thus arguably limited, the potential harms might be enormous. Though it is not transmissible between humans, ordinary H5N1 kills approximately 60 % of humans infected. While the airborne transmissible strains of H5N1 produced in the above-mentioned research were not deadly to ferrets, the ultimate worry is that the research in question could (eventually) lead to production of a strain of H5N1 that is transmissible among humans and as deadly as ordinary H5N1. Such a strain could cause enormous harm if intentionally released by bioterrorists or others bent on wreaking havoc. If such a virus were intentionally (or accidentally, for that matter) created and released, perhaps one-half of the world's population would become infected, and 60 % of those infected would die. Given the current world population of 6,800,000,000 people, roughly two billion human lives could be lost.

In December 2011, the US National Science Advisory Board for Biosecurity (NSABB) recommended that *the results* of the research in question be published, but that *detailed description of materials and methods* be omitted from the published articles. After a WHO meeting in February 2012 reached the opposite conclusion – recommending publication of the ferret flu research in full detail – the NSABB reversed its initial recommendation in March 2012. The articles in question were finally published, in full, in June 2012 (Herfst et al., 2012; Imai et al., 2012).

UNESCO Guidance?

Dual-use life science research poses ethical questions about what kinds of research should be conducted and/or published, and ethical questions about how the scientific enterprise should be governed. The following analysis considers the extent to which UNESCO's *Universal Declaration on Bioethics and Human Rights* (UDBHR) (2005) provides guidance regarding dilemmas posed by dual-use life science research.

UDBHR "Article 4 – Benefit and Harm" states that "In applying and advancing scientific knowledge, medical practice and associated technologies, direct and indirect benefits to patients, research participants and other affected individuals should be maximized and any possible harm to such individuals should be minimized." While this sounds like a sensible principle, it unfortunately provides little clear guidance about what should be done in cases where the very same research that might benefit society might also be used to cause harm. Consider the ferret flu research, for example. On the one hand, according to Article 4, it should have been conducted and published because this may be necessary to realize the potential (and arguably significant) benefits described above. On the other hand, according to Article 4, the requirement to minimize possible harms perhaps entails that it should not have been conducted and/or published. Rather than clarifying what should be done in the case of dual-use research, Article 4 highlights why it is commonly thought that dual-use research poses a dilemma in the first place. In the case of dual-use research, benefits come with risks, and so it is impossible to maximize the former and minimize the latter at the very same time.

Perhaps the point of Article 4 is that the overall benefits and risks of any given research project and/or publication should be evaluated, and that the project and/or publication should go forward if the benefits are likely to outweigh the risks, and that the project and/or publication should not go forward if the risks are likely to outweigh the benefits, all things considered. Again this sounds quite plausible. The problem, however, is that in the case of dual-use research it will often be difficult to predict what the ultimate long-term consequences of a research project and/or publication will turn out to be. The potential harms associated with dual-use research, for example, partly depend on the future actions of malevolent actors – but it will often not be easy and/or even possible to predict whether or not such

actors will actually misuse the research in question and/or what the ultimate consequences will be in the event that they do.

Application of Article 4 thus presumably requires appeal to other UDBHR principles. "Article 20 – Risk Assessment and Management" holds that "Appropriate assessment and adequate management of risk related to medicine, life sciences and associated technologies should be promoted." Determining whether or not the benefits of any given research project or publication (likely) outweigh the risks, or vice versa, thus requires good risk assessment. While this sounds correct, again, it might not get us very far. Among other things, risk assessment in the case of the ferret flu research, for example, would involve estimations of the likely motivations, abilities, intentions, and actions of potential malevolent actors (i.e., aspiring bioterrorists) and the consequences thereof. It would also involve estimations of the likelihood of naturally occurring H5N1 mutating into a pandemic strain that could be better controlled if the research in question is conducted and published and estimation of the benefits that would thereby be realized. Risk assessment, that is, should include assessment of the risks of not conducting and/or publishing the research in question as well as the risks of conducting and publishing such research. Even with the best risk assessment, however, all of these things are radically uncertain.

Even if it were possible to make good estimations of potential and/or likely risks and benefits of dual-use research and/or publication thereof, furthermore, deciding what should be done would require appeal to appropriate risk-taking strategies – but there is no general agreement about what these would/should be. UDBHR offers no guidance about this. Suppose that, on the best estimates from rigorous and well-informed risk assessment, it is determined that (1) there is a relatively good, say 10 % chance, that publication of ferret research details would end up saving 5,000,000 lives, but (2) there is a small, say 1 %, chance that publication would lead to bioterrorism that causes 500,000,000 deaths. Would Article 4 and Article 20 (together) then imply that publication should or should not occur?

While questions about the ethical acceptability of restricting or censoring especially dangerous research are paramount in debates about dual use, meanwhile, there are numerous statements in UDBHR that appear to favor scientific freedom and openness in the dissemination of scientific information. Its preamble states that "based on freedom of science and research, scientific and technological developments have been, and can be, of great benefit." Article 2 refers to "the importance of freedom of scientific research and the benefits derived from scientific and technological developments" and the aim "to promote … the greatest possible flow and the rapid sharing of knowledge concerning those developments and the sharing of benefits." Article 15 states that "Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community … In giving effect to this principle, benefits may [include] … access to scientific and technical knowledge." Article 24 states that "States should foster international dissemination of scientific information and encourage the free flow and sharing of scientific and technical knowledge."

While these statements appear to be at odds with the idea of censoring dual-use research, it is unclear if they are meant to favor complete scientific freedom and openness in the sharing of scientific information without exception. It is likewise unclear how these statements can or should be squared with Article 4 (in cases where free sharing of scientific information might, or is likely to, pose serious risks and/or do more harm than good). Reason for doubting that absolute value should be placed on the free sharing of information is, in any case, provided by "Article 27 – Limitations of the Application of the Principles" which implies that "application of the principles of this Declaration" may be limited "by law, including laws in the interest of public safety … for the protection of public health or for the protection of the rights and freedoms of others." That it may be appropriate for governments to take (e.g., legislative) actions necessary to protect against dual use dangers, furthermore, is suggested by Article 21, which holds that "States should take appropriate measures, both at the national and international levels, to combat bioterrorism."

While much debate about dual use has questioned whether there should be top-down as opposed to – and/or in addition to – bottom-up governance of dual-use research (Miller & Selgelid, 2008), therefore, UDBHR is not clearly opposed to the former. In the case of bottom-up governance measures, "Article 23 – Bioethics Education, Training and Information" states that "In order to promote the principles set out in this Declaration and to achieve a better understanding of the ethical implications of scientific and technological developments … States should endeavour to foster bioethics education and training at all levels as well as to encourage information and knowledge dissemination programmes about bioethics." This call for increased bioethics education is well aligned with at least one area where consensus has emerged in debates about dual-use life science research. Most would agree that one thing needed to address the dangers of dual-use research is increased education of scientists about (bio)ethics in general, the dual-use phenomenon, ways in which their own research might be misused by malevolent actors, and requirements of the Biological and Toxins Weapons Convention (BTWC) (Rappert, 2010). Empirical research has shown that scientists often lack awareness of the dual use problem and the BTWC in particular (Dando & Rappert, 2005).

"Article 19 – Ethics Committees" is also highly relevant to dual use. It states that "Independent, multidisciplinary and pluralistic ethics committees should be established, promoted and supported at the appropriate level in order to … assess scientific and technological developments, formulate recommendations and contribute to the preparation of guidelines on issues within the scope of this Declaration." A popular idea in debates about dual use is that the role(s) of existing (ethics) committees should be expanded – and/or that new committees should be established – to scrutinize dual-use research (Miller & Selgelid, 2008). While it is common for existing committees to review research proposals regarding (laboratory or environmental) biosafety and human (and animal) subject protection, that is, an additional role for existing – or new – committees should arguably involve evaluation of dangers associated with potential malevolent use of the research (or publication) under consideration and evaluation of whether or not potential benefits

outweigh such dangers (National Research Council, 2004; WHO, 2010). While Article 19 is not explicit about this role in particular, committee fulfillment of such a role is in line with its spirit and that of UDBHR in general.

Conclusion

This chapter has illustrated dilemmas posed by dual-use research, focusing on recent studies regarding H5N1 transmission in particular. In this and other cases of dual-use research, controversy has surrounded questions about whether or not potentially dangerous scientific information should be published. These questions are not easy to answer because achievement of the benefits that might result from publication involves significant risks of harm – i.e., because malevolent actors might use the published information for nefarious purposes, bioterrorism being of particular concern. While UDBHR "Article 4 – Harms and Benefits" is especially relevant to dual-use research, it fails to provide clear guidance about how dual-use research should be governed. Though UDBHR emphasizes the importance of the free sharing of scientific information, some statements of UDBHR (at least implicitly) suggest that censorship might be called for in exceptional circumstances to prevent harms associated with bioterrorism. "Article 23 – Bioethics Education, Training and Information" and "Article 19 – Ethics Committees" are consistent with popular ideas that have emerged from debates about dual-use research – i.e., that, among other things, increased ethics education of scientists is needed, and there is a crucial role to be played by (ethics) committees in the review of research posing dual use dangers.

Given the ethical importance of dual use life science research, more explicit international policy and/or guidelines explicitly addressing dual-use research are wanted. Because both the potential benefits and potential risks of dual-use research affect global public health, a governance framework specific to dual-use research should ideally be developed by an international body – such as WHO or UNESCO. Because UDBHR was not specifically developed to address dual-use research in particular, its failure to provide clearer guidance about the dual-use problem is perhaps forgivable. (And though UDBHR provides unclear guidance about crucial matters – such as censorship – it does not clearly provide wrong guidance). In light of the potentially catastrophic consequences of dual-use research, on the other hand, the failure of WHO, UNESCO, or some other relevant international (e.g., UN) body to develop and implement an international policy framework specific to dual-use research would be unfortunate . . . and (depending upon what unfolds in the future) possibly tragic.

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Enhancement

38

Fiachra O'Brolcháin and Bert Gordijn

Introduction

Although we now face issues that are global in scale, much of our moral thinking (as well as political action) is concerned with local issues, both temporally and geographically. This can be most clearly observed in the response to the environmental problems we face. The effects of environmental degradation and global warming are becoming apparent (United Nations Environment Programme, 2011), and will affect future generations, particularly in terms of interests such as subsistence. The effects are currently most keenly felt in the "developing world," where many struggle to gain access to sufficient food and to clean water (United Nations Development Programme, 2011). Future generations will have to cope with greater degrees of global warming, further environmental degradation, and presumably fewer resources than we now have (in order to cater for a larger population). These harms are caused by the actions of current generations, but will be felt by future generations through no fault of their own. Despite widespread awareness of these harms, it has been difficult to make the changes necessary to mitigate or prevent them. Expanding the moral circle to take into account all the people of the globe as well as future generations is proving to be a difficult task. The response to the environmental crisis illustrates current problems in addressing new dilemmas that are global in scope and that will affect the lives of future generations.

Against this background of emerging problems concerning global inequality and harms and costs for future generations, this chapter addresses the question of the ethical desirability of the further development of human enhancement technologies (HETs). HETs hold out the promise of improving the lives of those who can access them. However, their widespread adoption might have major implications beyond individual quality of life, affecting the social, economic, and demographic structure of society. They might increase existing inequalities, thus exacerbating harms associated with inequalities (such as crime and social unrest) and potentially undermining people's right to a life of dignity. Thus, the decisions we make now

F. O'Brolcháin (✉) • B. Gordijn
Institute of Ethics, Dublin City University, Dublin, Ireland
e-mail: Fiachra.OBrolchain@dcu.ie; bert.gordijn@dcu.ie

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regarding HET might affect future generations considerably. We first discuss the concepts of HET, equality of dignity, and rights and protection of future generations. Next, we briefly address the relevance of UNESCO's Universal Declaration on Bioethics and Human Rights, which we use as a normative instrument for our analysis. Then we present the cases against and in favor of HET. Finally, we will discuss both positions and explore whether there is a middle-way to be found between them.

HET, Equality of Dignity, and Rights and Protection of Future Generations

The term "HET" covers a wide variety of technologies, many of which are already in existence, ranging from brain-computer interfaces, genetic interventions,[1] cosmetic surgery to neuropharmaceuticals.[2] Many of these are medical in origin, but may have applications attractive to those with no therapeutic needs, as is the case with much cosmetic surgery. We define enhancement as "the directed use of biotechnical power to alter, by direct intervention, not disease processes but the 'normal' workings of the human body and psyche, to augment and improve their native capacities and performances" (The President's Council on Bioethics, 2003: 16). In the future, HET might perhaps prolong people's maximum life span; make them fitter, stronger, and more resistant to diseases; allow them to determine their own moods; and improve their cognitive abilities.

HETs have the potential to have an effect on inequality, although whether they are likely to increase or decrease inequality is the subject of much debate. Inequalities in health, in the global disease burden, and in the distribution of wealth are major global issues. The continuing existence of severe global poverty is one instance of inequality that is of immense moral concern. The extent of global inequality is noteworthy: according to Thomas Pogge (2008: 104–5), "high income countries" with 15.7 % of the global population possess 79 % of aggregate global income, while the bottom 15 % survives on 0.2 % of the global product. The lives of many of those living in severe poverty may, in many cases, result in a breach of the fundamental equality of all human beings in dignity, if not in rights (UNESCO, Article, 10). A person may formally have the rights to life and to work, but circumstances (such as famine or severe poverty) may result in them being unable to live a life of dignity, particularly if human dignity is considered as intertwined with a life of human flourishing as Martha Nussbaum (2006) suggests. Thus, while someone may have the right to many things, circumstances, such as severe poverty,

[1]Somatic genetic interventions have been performed on human beings in clinical trials since 1989. They only affect the individual. In contrast germ-line genetic interventions have not been performed on human beings yet. They would result in alterations that could enter the gene-pool by being passed on from one generation to the next.

[2]Neuropharmaceuticals are drugs that affect neurological functioning. As such, they might enhance mood as well as cognition.

may render this right hollow and have a negative impact on their dignity. The UNESCO declaration (adopted by 193 nations) commits nations to at least addressing issues of equality of dignity and rights.

Much philosophical interest has recently focused on future generations. Many of these questions concern the obligations current generations have towards future generations and the implications that these obligations have in terms of distributive justice. Areas of concern surround the pursuit of policies that accrue benefits for current generations but impose costs for future generations. Our current actions can result in harms for future generations through the creation of conditions that will make their lives more difficult. For instance, our ineffective efforts to cut emissions of global greenhouse gases mean that future generations will have to bear the brunt of climate change, triggering intricate questions of intergenerational justice (Gordijn and Ten Have, 2012). More generally, our use of natural resources will affect what resources will be available to future generations, and our response to poverty will affect the societies into which future generations will be born. In the case of HET specifically, certain types of HET have the capacity to radically alter the genome of future generations; thus, we might affect what sort of future generations exist along with impacting on the conditions in which they exist. Although there is an academic debate regarding whether or not we can have any obligations towards future generations, by adopting the UNESCO declaration, nations have committed themselves to protecting them.[3]

UNESCO Universal Declaration on Bioethics and Human Rights

In 2005, UNESCO adopted by general acclamation the *Universal Declaration on Bioethics and Human Rights*. Its aim is to provide a universal framework of principles and procedures to guide states in formulating their legislation and policies in the field of bioethics. This Declaration is an important global regulatory framework that commits UNESCO members to upholding its principles in relation to bioethical issues. As such, it provides a touchstone for ethical debates on HET, an agreed-upon basis, and starting point for thinking about the topics.

The UNESCO Universal Declaration on Bioethics and Human Rights aims (amongst other things) "to promote equitable access to medical, scientific and technological developments, as well as the greatest possible flow and the rapid sharing of knowledge concerning those developments and the sharing of benefits, with particular attention to the needs of developing countries" Article 2 (f); emphasizes the "fundamental equality of all human beings in dignity and rights" so that "they are treated justly and equitably" (Article 10), and stresses the importance of human dignity and human rights (Article 3). Moreover, it also

[3]There is debate regarding whether future generations can, given that they do exist yet, be the bearers of rights. Given that the UNESCO Declaration is being used a normative guide in the chapter, we accept the view that obligations to future generations exist.

acknowledges that due regard must be given both to protecting future generations (Article 16) and to protecting the environment, the biosphere, and biodiversity (Article 17). However, the commitment to respecting human dignity and rights is of central importance to the Declaration. The list of principles is bookended by statements stressing the centrality of protecting human rights, basic freedoms, and human dignity. As such, it is reasonable to interpret the Declaration as viewing the latter as preeminent.

The Case Against Enhancement

While HET seem to have many attractions, their development poses significant threats as well. We will outline three reasons for objecting to the development of HET. The first worry regarding HET is that they could be mainly available to only a small and affluent percentage of the global population. Thus, those who already control the majority of the world's wealth might gain further advantages (i.e., increased intelligence, looks, lifespan, disease-resistance) as a result of HET. Secondly, some authors advance the concern that HET might harm future generations both indirectly and directly. Thirdly, there is the argument that the project of pursuing enhancement represents a type of Promethean hyperagency, that the development of enhancement technologies is an example of a hubristic desire for mastery over nature that leads to the loss of openness to the unbidden.

Increasing Inequity and Injustice

One of the most common objections to the use of HET is that they might aggravate existing inequalities. Enhancements might confer relative advantages on the enhanced in relation to the unenhanced. HET might provide the rich with the opportunity to ensure that their children, as well as having educational and health-care advantages, will also be better looking, less prone to disease, and more intelligent. Enhancements such as neuropharmaceuticals, smart-clothes, and brain-implants might in the long term be available to everyone, but initially the cost would most likely be prohibitive. In this scenario then, people who could afford, and were willing, to use these enhancements would gain a significant advantage over those who are unable to afford the same. Certainly, someone who has constant and instant access to the online world, an enhanced memory, or a greater capacity for concentration and information-processing will have many advantages over those without. If these enhancements are expensive, the advantages offered by them will fall to the wealthy. In such societies, upward social mobility would be far more difficult as people's positions would be fixed by their access to enhancements, thus creating a greater impediment to social mobility than currently exists. When the best-paid and/or most satisfying jobs require people to be above a specific cognitive threshold or to possess certain physical and/or mental abilities and skills, those with enhancements would have the advantage. Furthermore,

the development of these technologies is likely to require great technical, scientific, and medical expertise, most likely to stem from companies operating in wealthy markets or from wealthy government-funded research and health-care systems. As such, these technologies and enhancements are unlikely to be readily available for the majority of people who live in the developing world.

When successfully using germ-line genetic interventions for enhancement purposes, it will in principle even be possible that new "posthuman" species will emerge, raising fears that an unbridgeable inequality might arise. In such a scenario, people might still have moral equality and formal equality of opportunity but enhancement inequalities would mean that these rights are hollow. The poor will, as Peter Singer (2009) notes, be stuck with the genetic lottery and will fall further and further behind. Being without enhancements, they would have little chance to gain important positions and thus little chance to escape from relative poverty. A vicious circle of poverty would then be created.

Globally, an enhancement divide would become apparent between nations. Affluent nations will have far greater access to HET than all but a very small minority in the developing world. The consequence is that the existing medical divide will become even more pronounced. Currently, the global health divide is already striking – with many affluent countries having a life-expectancy in the seventies, compared to under-forties for some countries in sub-Saharan Africa (Marmot, Friel, Bell, Houweling, and Taylor, 2008; Pogge, 2008). The development of HET has the potential to further increase divides in living standards, life-expectancy, and wealth. With enhancements, the populations of the affluent parts of the world will be better able to protect their positions should they want to. They will be better able to set the terms of trade and the distribution of resources in their favor.

Harms to Future Generations

Indirect harm: The inequalities discussed above can be considered indirect harms for future generations. Less equal societies have a greater overall burden of health and social problems. For instance, income inequality has negative societal effects: health and social problems such as violence, mental illness, and educational failure are more common amongst the poor in any given society than they are amongst the rich. Although there is a debate over whether future people can be harmed (given that their existence is dependent on us and the policies we choose), we can say that they are wronged if we choose a policy that will harm them. If we accept that inequalities cause harms, choosing policies that will exacerbate inequalities is causing harm or at least failing to prevent harm. Future people will be born into inequitable conditions not of their choosing and will suffer the harms arising from inequalities. Insofar as HET increase societal inequalities, they will be a source of indirect harm for future generations. If HETs make inequalities more difficult to overcome, they will increase societal ills. If access to newer HET is mainly the preserve of the wealthy, their use of HET such as smart-drugs, brain-computer interfaces, and mood enhancers is likely to ensure their continued dominance. In the

most extreme scenario, raised by Peter Singer (2009), germ-line engineering might see social and economic privileges become biologically embedded, as the rich genetically alter their children to ensure their benefits. Such inequalities would be even more difficult to overcome than inequalities arising from lack of education, poverty, or lack of access to technology. If HET makes future societies more unequal, future generations can be said to be harmed by our choice to adopt HET. We are either (1) causing indirect harm to future generations by using HET in the knowledge that they will increase inequalities and thus negatively affect the lives of future generations; (2) failing to prevent indirect harms to future generations by allowing the use of HET to increase inequality; or (3) failing to benefit future generations by allowing the use of HET to increase inequality.

Direct harm: There are some fears regarding direct harms to future generations arising as a result of enhancements. For instance, germ-line genetic "enhancements," like any technological development, have the potential to create unforeseen problems for future generations. Alterations to the germ-lines of future generations could, given that the human genome is a complex product of evolution, backfire in numerous ways. For instance, an enhancement that increases memory-capacity may, due to the complexity of the neuropsychological processes at work, have a negative impact on mood, or an enhancement that reduces racism by reducing the biologically encoded aversions to other races risks reducing positive moral emotions (such as aversions to morally repugnant things) on the same continuum. Moreover, genetic interventions that are currently perceived as advantages might prove disadvantageous in future contexts vastly different from contemporary ones. Similarly removing perceived genetic disadvantages might leave us (as a species) vulnerable in unanticipated ways. For instance, the removal of a trait perceived as "undesirable" might for generations appear innocuous, but may leave future people vulnerable to the emergence of new pathogens.

Loss of Openness to the Unbidden

The quest to develop HET is characterized by Michael Sandel (2007) as being a Promethean project. Not only does Sandel highlight the problems that HET will pose to individual autonomy and equality, but he also asks questions from a perspective outside the usual liberal framework, referring to the moral status of nature and the proper stance of humanity towards the given world. He argues that pursuing enhancement represents a type of hyperagency, an example of our impulse to master nature, including human nature, so that it will serve our purposes and satisfy our desires. Sandel argues that increasing our mastery over nature, including our own natures, will transform three features of the moral landscape – humility, responsibility, and solidarity (2007, 86). He contends that in a world which prizes mastery, for example, the ability to specify the sex and genetic traits of children, people's openness to the unbidden (particularly in the case of parenting), a key source of humility, would diminish. He continues that the social basis of humility would also be diminished, as people would no longer have the restraining knowledge that their talents and abilities are due in part to luck. This in turn would lead to an explosion of responsibility, as now parents would be responsible

for more choices regarding the lives of their children – they would be responsible for choosing traits and for failing to choose traits. Domains once governed by "fate" or luck would now be arenas of choice and therefore responsibility. Sandel suggests that this would reduce social solidarity, as people would be less alive to the fortuitous nature of their lot, and thus have less reason to share their fate with those less fortunate. Ultimately, he implies that the project of mastery epitomized by HET will distract humanity from reflecting critically on the world and deaden the impulse to social and political improvement (Sandel, 2007).

The Case for Enhancement

We will outline three reasons in favor of the further development of HET. The first states that individuals should have the right to use new scientific technologies to improve their lives. A second argument advanced by proponents is that HET can make people healthier, happier, longer-lived, more intelligent, and physically stronger. In addition, it is argued that moral enhancement might play a significant role in motivating societies to reduce inequality and environmental degradation.

Rights

There exists a presumptive case stating that people have a right to use enhancements to improve their own lives so long as their use of enhancements causes no harms to other people. The assumption is that people should be allowed to make certain choices (regarding reproduction or their own bodies) according to their own values irrespective of the values of society, so long as they harm no others. Emphasizing negative rights (entitlements to non-interference), proponents of HET often appeal to rights in arguing that HET should be developed. Advocates such as Nick Bostrom (2003) (Bostrom and Roache, 2007, 2009) and Julian Savulescu (2007, 2009) contend that enhancement technologies should be made widely available and that individuals should have the choice over whether and which enhancements to apply to themselves and furthermore that parents should have the right to select enhancements for their children. They argue that enhancements offer great potential for valuable and beneficial human uses, such as increased longevity, healthier lives, greater cognitive capacities, and the opportunities to control emotions. So long as there is adequate information available, public debate, and education, there is no reason to forbid people from using enhancements. Furthermore, it is held that the right to use enhancement technologies is connected with rights to bodily autonomy, reproductive freedom, and free expression. The concept of autonomy suggests that so long as a person is not harming others, they are within their rights to alter their body as they see fit, for example, to implant a brain-computer interface or to take mood enhancers. From this perspective, to ban people from using enhancements would be a violation of their autonomy, liberty, or reproductive freedom.

Improvement and Beneficence

In addition, a consequentialist reason is advanced in favor of use of HET. Proponents claim that there are many ways in which enhancements can improve people's lives. After all, it would be better if people were healthier, happier, longer-lived, more intelligent, and physically stronger. Therefore, if biomedical enhancements can achieve this, there exists a powerful incentive to develop these interventions. The widespread use of cognitive enhancements may also enable greater scientific breakthroughs, or enhance people's abilities to work and to appreciate their lives. Mood enhancements could be used to ensure that people are, invariably, happy or content. Utilitarians aim to maximally promote well-being. From this perspective, therefore, insofar as enhancements can contribute to an overall increase in well-being, they should be pursued.

This consequentialist line of reasoning has been taken further so that some proponents of HET contend that there is in fact an obligation to enhance future generations. The obligation to enhance is based on two underlying obligations: the obligation to do good (beneficence) and the obligation not to do harm (non-malfeasance). The obligation not to cause harm can be characterized in both a positive and a negative fashion. The positive obligation not to cause harm means that we must not deliberately act in a manner that will produce harms; the negative argument states that we must not stand by or fail to act if doing so will result in avoidable harms. Thus, if enhancements are available and provide the opportunity to prevent avoidable harms or to do good, there is an obligation to use them. For example, Savulescu and Kahane (2009) argue in favor of the "principle of procreative beneficence," which suggests that couples who decide to have a child have an obligation to select the child who, given her genetic endowment, can be expected to have the most well-being. Similarly, Harris (2007) argues that there is a moral obligation to use enhancements if we are concerned with human welfare.

Moral Enhancement

Despite huge technological progress, our moral progress does not seem to have kept pace. We are willing to live in a world rife with the most horrendous inequalities. Even in the face of climate changes that will affect everyone, including the wealthy, we appear unwilling to accept decreases in our standard of living for the sake of future generations. However, some advocates of HET suggest a new technology-based solution. In recent discussions of HET, the issue of moral enhancement has become prominent. The idea of "moral enhancement" connects ethics with HET by aiming to improve our moral capacities via biological alterations. The assumption is that there is a biological basis for our moral inclinations. Moral enhancements do not yet exist but, in theory, they might be possible. Tom Douglas (2008) argues that due to our increased understanding of the biological and neurological underpinnings of emotions, enhancements could be used to attenuate "counter-moral" emotions, such as aggression and racism. Douglas (2011) expresses the hope that

morally enhanced individuals would be less prejudiced, pollute less, and care more about the environment and global poverty. Moral enhancements are also said to promise to increase our motivations to act morally. For instance, Persson and Savulescu (2008) contend that our moral dispositions are biological and that their core consists of altruism and of dispositions stemming from the "tit-for-tat" patterns of reciprocal behavior. These patterns give rise to our sense of justice and fairness, to gratitude, anger, remorse, and forgiveness. They argue that moral enhancement would consist in the strengthening of our altruism and in making us more just and fair. Furthermore, Savulescu and Persson argue that in order to eliminate the risks of cognitive enhancements being used for ultimately malevolent ends, it is imperative that moral enhancements are developed.

Therefore, assuming that what is rightly and rationally desired is a just and sustainable world, which is currently some distance away, then moral enhancements might be a way to achieve these goals, if they could indeed be used to make people less greedy, less aggressive, and less competitive. Enhancements could then arguably also be developed to ensure that we have more concern for future generations. Moral enhancements might make people more concerned with the plight of the impoverished and more concerned with environmental degradation. The UNESCO Declaration emphasizes (Article 15) that solidarity amongst human beings is to be encouraged. Article 17 stresses the protection of the environment, the biosphere, and biodiversity. Much of the damage being done to the biosphere and the environment is due to the appetites of those in affluent nations, who crave entertainments, cheap travel, and cheap food. The prospect of people who cared more about global poverty and the environment and who were less prone to violence, prejudice, and racism is certainly an intriguing one.

Discussion

Review of the Case against Enhancement

Increasing Inequity and Injustice

As discussed above, HETs have the potential to increase inequalities. The advantages conferred by HET imply relative disadvantages for those who lack access. These disadvantages might be seen in employment opportunities, in education, in sport, in economic opportunities, and in general social life. If the use of HET becomes widespread, those without will be relatively impoverished. This is likely to reduce their ability to participate in their societies, and may impinge on their access to healthcare, education, and political life. Let us call this the *exclusion argument*. Such exclusion risks creating social unrest and discontent.

The necessity of competing for jobs and societal positions may result in people finding themselves forced into enhancement arms-races in order to compete. People may find themselves willing to sacrifice significant goods in order to pursue HET. Let us call this the *arms-race argument*. The existence of enhancements will increase the pressure on those at the bottom of society, who are often struggling

with bills (in the developed world) or with hunger (in many parts of the rest of the world). In many places, education and healthcare are unavailable. People make enormous sacrifices in order to feed their families or children. The widespread adoption of HET would result in yet another rung on the ladder to achieving a life of human dignity. Thus, people may feel pressurized into working longer hours in worse conditions or into taking great risks in order to gain parity.

However, those with enhancements might also come to resent the existence of these inequalities. Let us call this the *resentment argument*. From the perspective of people with enhancements, those without enhancements could be seen as imposing unfair costs the society. A refusal to select the best possible embryo, or to otherwise enhance children, or to use enhancements to improve one's performance in sports, exams, or socializing might become socially unacceptable. The claims of the unenhanced on the resources of any society might come to be resented by those with enhancements as the choice to remain unenhanced will impose costs that must be borne by the rest of the society. Questions will arise as to whether those who have chosen not to obtain enhancements are entitled to extra resources to compensate them for certain losses (i.e., loss of earnings). Those without enhancements might require more healthcare, or extra-tuition. In such a scenario, it is plausible that the enhanced might begin to question the rights of the unenhanced to remain unenhanced or to have unenhanced children. Thus, it is possible that future debate will not concern the right to use enhancements, but the right not to use them.

One might respond that enhancements will trickle down and eventually be available to everyone, as Harris (2007) has asserted. While this argument appears plausible, it does not counter fears of inequality, as those at the top would continue to have access to newer and better HET. If HET continues to develop at a great pace, and the newest developments continue to provide great benefits, inequalities will continue to exist. The trickle-down argument makes a good case against any sort of moratorium on the development of HET due to inequalities, but does not address the fundamental problem of inequalities arising from HET.

The issues of inequality arising from HET will most likely be addressed by individual states according to the principles of distribution that they consider fair and just. This still leaves the issue of inequality between states to be confronted. The UNESCO Declaration on Bioethics and Human Rights is addressed to States (Universal Declaration, Article 1.2) and so does not explicitly address the issue of inequalities between states. However, the preamble to the declaration explicitly recognizes that decisions regarding ethical issues in medicine, the life sciences, and associated technologies may have an impact on individuals and humankind as a whole and also that new approaches to social responsibility should ensure that progress in science and technology contributes to justice, equity, and the interest of humanity. As such, the potential for harmful inequalities arising from HET to exist between states and peoples ought to be an area of concern.

The threats posed by HET of exacerbating inequalities are compelling and must be addressed. Current inequalities resulting from HET are trivial in comparison with inequalities in the global disease burden, for example, but the strange and (at times) troubling futures suggested by HET force us to look afresh at the

problems of inequality. The potential of HET to exacerbate existing inequalities suggests not that we abandon the development of HET (as they are only one form of inequality) but that we have an urgent need to address both national and international inequalities.

Harms to Future Generations

Indirect harm: Future societies will face significant ethical and political debates regarding the maintenance of equality in such societies. The enhanced might resent paying taxes for health and educational goals that, due to enhancements, they and their children no longer require, while the unenhanced will most likely resent their inability to compete with the enhanced. It is even conceivable that the right to remain unenhanced will be attacked, as to remain unenhanced may be viewed as socially irresponsible. Moreover, when it comes to things such as genetic enhancements, the unenhanced cannot be held responsible for the decisions of their forebears. Widespread use of enhancements risks entrenching extant inequalities if their adoption benefits the wealthy disproportionately.

As such, we have an obligation to be extremely careful with the development and distribution of HET. Our actions will affect levels of inequality that future generations, through no fault of their own, must confront. Given that inequalities cause indirect harms, it is incumbent on current generations to ensure that new technological developments do not contribute to these indirect harms. Stringent rules and regulations will be required to safeguard people's rights and to ensure that harmony exists between the enhanced and the unenhanced. Consequently, a laissez-faire approach to the development and distribution of HET appears problematic.

Direct harm: As discussed above, one of the main objections to the use of HET is that they will result in direct harms to those who use them as well as to future generations. It could be said that, by definition, something that causes harms could not be an enhancement, but this is not the approach we will take. Firstly, some technologies may be enhancements in certain contexts and harmful in others. Secondly, some technologies might enhance mood, cognition, or physical strength (for example) but have harmful side effects or long-term effects.

These issues do not result in intractable problems. In the case of new technologies and techniques that are solely harmful, it is unlikely that they will be developed by governments or by companies as enhancements.[4] Either governments will prohibit the use of harmful enhancements or market forces will ensure that harmful enhancements will not be worth developing as people will not wish to purchase them. In the case of harmful-but-pleasurable enhancements or harmful-but-useful enhancements that have both beneficial and negative effects, regulation will be required. It is possible that a class of harmful enhancement technologies would be illegally developed and that problems of addiction similar to contemporary drug problems would arise. Various mood enhancements might develop in this

[4]These techniques are quite likely to be used in the development of weapons, but this is another matter.

problematic way. Yet the prospect of such developments does not create a fatal problem for HET as a whole. The potential for direct harms to individuals makes the case for regulation of the development of HET, not the abandonment of their development.

Loss of Openness to the Unbidden

That argument that HETs are illustrative of human hubris is intriguing. Sandel claims that in developing HET, humanity adopts a stance of mastery and dominion that fails to appreciate the gifted nature of human powers and achievements. The result of this is that enhanced humans no longer access the part of freedom that consists in a persisting negotiation with the given. Firstly, it is essential to ask whether HET would mean humanity was no longer open to the unbidden. Although people might be enhanced, they would still confront many aspects of the world beyond their control from traffic, to other animals, to the movements of the weather. Secondly, it is not clear that not being open to the unbidden, if true, is in fact as morally problematic as Sandel implies. Thirdly, even if it is the case that the stance of mastery and dominion and the loss of openness to the unbidden have undesirable social and moral consequences, it is an open question as to whether these moral problems are outweighed by the moral (and practical) benefits of the adoption of HET. It is at this point that Sandel's approach is most intriguing, as it questions the moral and political framework used to respond to deep issues such as HET. Sandel argues that in order to think about developments such as HET, a moral framework based around individual rights, autonomy, and fairness does not equip contemporary society to address questions about the moral status of nature and about the proper stance of humans towards the given world. The question of the correct moral and political stance to adopt in relation to the world and to HET is an open question, though Sandel is surely correct in pointing out that the debate currently is dominated by a liberal framework. Ultimately, while he has not illustrated that this is necessarily a fatal flaw, he has at least opened out the debate to include issues such as the correct moral stance of humanity to the unbidden and to nature, and whether HET reduces the freedom of humanity to reflect critically on these issues. At the very least, he is persuasive in that further critical reflection on these issues is required.

Review of the Case for Enhancement

Rights

That people should be permitted to improve their lives and their health appears to be a basic right. Given the likelihood of HET being introduced incrementally, it would be very difficult to find a compelling argument to deny people the right to use many of these enhancements. Realistically, a moratorium on the use and development of HET as a whole is not an option due to the widespread use of certain enhancement techniques, such as cosmetic surgery. As such, there exists a presumptive case that

people have rights to use technologies and techniques so long as they do not harm other people. The UNESCO Declaration commits nations to respecting human rights and fundamental freedoms.

That people have rights to use some enhancements does not mean that people have rights to use all enhancements. The extent of these rights is yet to be determined. HET will come in a variety of forms, our rights to use them are not necessarily total – the rights we enjoy now suggest that we ought to be able to benefit from some enhancements though other enhancements may be beyond the limits of these rights. Currently, cosmetic enhancements are permitted, but the use of certain drugs (cocaine, heroin) as mood enhancers is prohibited.

A libertarian view would accept only minimal limitations on rights to use HET. This view, stemming from the Enlightenment tradition of negative liberty, is common amongst advocates. Proponents argue that the right to use enhancement technologies is an extension of our right to reproductive freedom, cognitive liberty, and bodily autonomy. However, it is unclear whether these rights extend to include rights to use HET, despite the assertions of proponents. This outlook would have distributive consequences as rights may trump considerations of distributive justice. A libertarian perspective on justice would argue that if HETs are developed privately and are bought by people using their own (legally and justly acquired) resources, any interventions stopping this are unjustified. This libertarian perspective finds some justification in Article 3 of the Universal Declaration on Bioethics and Human Rights – emphasizing the importance of respecting human dignity, human rights, and fundamental freedoms – but may conflict somewhat with the aims of Article 15 (concerning the sharing of benefits) if libertarian principles of property prevent the sharing of benefits. Libertarians can be expected to favor the benefits of HET being distributed via the free market, which is likely to exclude many. This latter highlights the need to share the benefits resulting from scientific research and its applications. Moreover, the justness of the starting point (of those with access to enhancements) can be questioned.

However, some limitations are likely to be acceptable to libertarians. Reproductive rights, for instance, are likely to be limited by considerations of harm to the child. Certainly, any putative right to genetically alter a future human will most likely be limited by considerations of harm. Nor is it clear that reproductive freedom necessarily includes the right to use novel technologies. These prospective rights to certain HET may be limited by considerations of the effect the institutionalization of such practices will have on the society. People may be limited in how they are permitted to use HET on their own embryos. For instance, sex-selection of embryos is not currently permitted.

As mentioned, however, a broader conception of harms may be considered. The concept of harm need not only concern direct and measurable harms to identifiable individuals. We are now aware, as noted above, of the ways in which our actions might cause indirect harms to other people, by participating in inequitable trade or by negatively affecting the environments necessary for people's subsistence. These harms are not direct in the sense of one person directly harming people

(i.e., by shooting them) but contribute to an overall effect that may be harmful. Global inequality is one such harm (climate change another) in that although individuals in the developed world are not individually and directly causing poverty in the developing world, the global economic and political system in which they partake produces harmful effects. The use of HET by some people will place those without at a relative disadvantage, thus harming them. If these harms are distributed across populations as a result of inequitable historical and political processes, then the harms caused by HET might be considered unjust.

Related to this argument is a concern with human dignity and with positive rights. From the perspective of social justice, a right is not secured unless effective measures are taken to ensure that people are capable of using this right. At times, securing a right of human dignity will require affirmative institutional and material support. For instance, female children might have a right to education, but due to social conditions and historical traditions, they may never receive an education. The development of HET may leave the unenhanced incapable of enjoying rights – for instance, they may find themselves incapable of civil and political participation if these activities require enhancements. Unchosen exclusion from the life of their society would risk undermining the dignity of unenhanced individuals. This suggests that either there is an obligation to ensure that everyone has access to similar HET in order that they can live a life of human dignity or enjoy basic rights, or that the rights to use HET must be limited in situations where their use will undermine the fundamental rights of the unenhanced.

Thus, there are three outstanding problems regarding the rights argument in favor of HET. (1) It is unclear that current rights to reproductive freedom, cognitive liberty, and bodily autonomy extend to HET. (2) If it is acceptable to limit rights due to harms, there is an obligation to consider the indirect yet foreseeable harms that might result from the development of HET under current economic conditions. (3) A positive interpretation of rights might place obligations on states to ensure that all have a relatively equal access to HET when they are required for political and social participation. As noted, the unrestrained societal use of HET may pose threats to the possibility of a life with dignity of those who cannot afford to obtain enhancements or alternatively threats to the rights of those who wish to remain unenhanced.

Improvement and Beneficence

The consequentialist argument in favor of HET is less compelling. However, adopting this approach may have more far-reaching implications than initially considered by Harris and Savulescu. For instance, if there is a moral obligation to ensure that a child has the best possible life, societal biases ought to be taken into account by the parents, i.e., that the child should not be homosexual or have a skin color that a society is biased against. Furthermore, if there is an obligation to have the best possible child that they can have, there may be an obligation to use an embryo created by some other couple, if it is likely to result in a better person.

Moreover, it is not certain that we do have an obligation to be the best we can possibly be, nor is it certain that we are obligated to create the best possible future

people. Firstly, it is not clear what is meant by "best." Enhancements that provide immunities are relatively uncontroversial, but whether there is an obligation to ensure that children have specific skills and talents is debatable. There is no way of knowing whether the skills and talents chosen will count as genuine improvements. An enhancement that improves mathematical ability may be rendered obsolete by advances in computer technologies.

The assumption of an obligation to enhance also results in a number of disquieting implications, as discussed by Sparrow (2011). The obligation to enhance is based on our obligation to be concerned with the welfare (or improvement in general) of future generations. However, upon examination, the consequences of this approach are more far reaching than is immediately apparent. The suggestion is that people should be concerned with acting to promote happiness or welfare in the world and that insofar as enhancements can achieve this, there exists an obligation to pursue them. The most obvious way to guarantee this would be to use HET to manipulate the brain chemistry of everyone so that they all feel happy. There are less fanciful but more disturbing implications too. This obligation would mean that parents in a racist society would have the obligation to ensure their prospective children will fit in to that society, or that in a society in which males are treated better, there exists an obligation to ensure that a child is male. The obligation to enhance in order to increase the well-being of a child might result in a collective-action problem (Singer, 2009), where parents are obliged to ensure that their children are taller, or blonde, or have some other relatively trivial trait that improves their chances of success in life even if this creates problems for the society. Over generations, these individually rational decisions risk producing new problems, i.e., taller people might require more resources, or may have novel health problems, societies might become increasingly homogenous, and research funding might flow disproportionately to profitable but trivial projects. Nor does the line need to be drawn at aesthetic enhancements. It may be beneficial (and hence obligatory according to this reasoning) to ensure that children are patriotic, fearless, or uncurious. The desire of parents to ensure that their children thrive in their society may stymie change within a society if the children are designed to thrive in and respect the norms of the culture of their parents rather than question it. Such a society is likely to stagnate. In certain cases, it might be in the best interests of the child to ensure through pharmaceutical means that they are contented, despite living in wretched conditions. Would a parent be obliged to put their child in Nozick's "experience machine"[5] if their chances of success in life were low enough?

[5]The Experience Machine is a machine in Nozick's thought experiment that would give you any experience you desired. During the time in the machine, the person would have no memory of their previous life or of the external world. They would believe that the experiences they have in the machine are real. The purpose of the thought experiment is, supposedly, to provoke a realization of the importance of something more than just experience – of actually living and of authentic experience. (Nozick, 1974: 42–45)

Indeed this line of reasoning has the result that parents may be obliged to select the best embryo available, even if it is not carrying their own genes but of some other couple's. The consequentialist argument can be taken further to the point that prospective parents ought to be coerced (through direct or indirect means) into ensuring that their children receive enhancements. The existence of unenhanced future people will, as noted above, potentially impose costs on the rest of society. If these costs are high enough, then coercion may be considered justified. Furthermore, if there is soft coercion (due to advertising campaigns, etc.) to obtain enhancements, direct coercion becomes more plausible.

Therefore, the case for there being an obligation to enhance is far from clear. The consequentialist argument runs up against the rights of people to choose not to use enhancements. The obligation to enhance to ensure a child's welfare risks a collective-action problem, in which enhancements could lead to the pursuit of relatively unimportant positional goods that ultimately impose costs on the society as a whole. On top of this, there is a risk of stagnation of the moral and societal development, as the values of the current generation become embedded in the next generation, who would presumably wish (due to their design) to further continue the aesthetic and political trends of their forebears. Finally, there is the disquieting logical conclusion of the argument – that all people would be obliged to use the best embryo available regardless of its provenance.

Moral Enhancement

The concept of moral enhancement is an intriguing development in the discussion of HET. Intuitively, it is appealing. Firstly, we accept that our moral behavior has a biological basis. Our moral intuitions have developed over millions of years of our evolution from our ape-like ancestors to our present state. Yet, there are clearly serious moral issues that we appear incapable of adequately addressing, such as entrenched inequalities and the environmental crisis. These problems are global in scale and have a time-scale of many generations. As such, these problems do not seem to be issues that our evolutionary moral sense is designed to deal with. It is most likely that we have evolved to care for ourselves, close family members, and broader kinsfolk – for those of our genetic heritage. While our political development has meant that the moral circle has expanded, it is not certain that our political institutions are adequate for dealing with the pressing moral issues of global inequality, resource scarcity, and environmental degradation, particularly if we have to take into account the requirements of future generations. Moreover, if we accept that our moral inclinations are the product of evolution, then this lack of concern with distant peoples, future generations, and non human issues is unsurprising. There would have been little evolutionary reason in our history and prehistory for such a broad moral sense (concern with future generations, and distant peoples) to have developed.

If our morality does have a biological basis and we have the technological means and techniques of enhancing it, the initial appeal of the perspective of moral enhancement is obvious. Moral enhancement may result in people who are less greedy, less aggressive, more concerned with addressing global poverty, and more

interested in ameliorating the effects of climate change. The idea that politicians, policy makers, and the judiciary receive moral enhancements is an appealing one. If brain-computer interfaces, pills, or genetic alterations were available to ensure that those in power behaved ethically, they would obviously be of enormous benefit. The benefits to the species over the long term would be enormous if it were possible to ensure that future generations had greater empathy towards each other and towards the natural world.

The environmental crisis can be considered as both a tragedy of the commons and a prisoner's dilemma. A tragedy of the commons describes a scenario in which a common resource (in this case, the biosphere) can be used freely by everyone. Each user, in pursuing their own interests, fails to consider how their actions affect others. Ultimately, the commons becomes depleted and all suffer. However, the gains from exploiting the environment are available immediately, while the costs will be borne by future generations. Moreover, even if nations were to attempt to find some sort of solution to the problem of the commons, they find themselves in a prisoner's dilemma. All parties know that action must be taken to ameliorate the effects of climate change. If the USA (for example), agrees to cut emissions, it loses out competitively to China (for example), and vice versa. The solution to the prisoner's dilemma is, as is well known, cooperation. There are two solutions to the tragedy of the commons – one is to privatize the commons, while the other involves managing the commons and restricting its use. Privatization is not practicable for the biosphere, and, would, in any case have problematic distributive implications. In any case, either solution requires cooperation and long-term planning.

Exhortations to reduce our carbon footprint have not had any significant impact in terms of reducing our harmful impact on the environment. Moral enhancements might theoretically offer a surer method of changing peoples' ways of life. If we take seriously the aims of creating a basically equitable global system and building a political and economic system that is environmentally sustainable, moral enhancements may be a necessity.[6]

Enhancements that make us more willing to cooperate, less willing to betray others, and less materialistic might have to be considered if the biosphere is to be protected, inequalities diminished, and the interests of future generations provided for. If we as a species wish to preserve what is left of the planet's biodiversity, and maintain a climate we find comfortable, moral enhancement might perhaps provide a solution where philosophy, politics, and religion have so far failed. There are, however, a number of difficulties with moral enhancements.

First there is the problem of the indistinctness of moral enhancement. It is not clear what would count as a moral enhancement. There is of course great disagreement over what constitutes a good life or whether such a thing exists. Even within

[6]Persson and Savulescu (2008) argue that due to the perils posed by cognitive enhancement in the shape of our increased ability to do harm, we should not undertake cognitive enhancements without also undertaking moral enhancements.

a single generation, different societies possess quite different versions of the good. The values of Wall Street are very different from the values of a Buddhist monastery. Furthermore, it is not clear which virtues or vices should be enhanced or diminished. Aggression would surely be the appropriate response to witnessing a rape. John Harris (2010) has suggested that the traits that lead to wickedness or immorality are the same traits that are required for the existence of any sort of moral life. Thus, weakening negative traits, such as racism or a propensity to violence, might also weaken positive traits such as kinship ties and drive.

A second problem concerns the obstruction of long-term moral progress. There would be a significant risk that the values of the first generation to adopt moral enhancements would become entrenched in a society and moral progress would become impossible. Many of our current moral values may well appear to be barbaric to future generations just as we view the gladiatorial fights and slavery of Roman antiquity as anathema.

Moreover, there must be doubts about the incentives to take moral enhancements. Assuming that there was agreement on what constituted a moral enhancement, it is not clear why people would want to take or undergo them. The societies that would most benefit from widespread use of moral enhancements are most likely made up of people who will not be amenable to using them. In these societies, strong inclinations to act morally might leave a person vulnerable to being taken advantage of by those lacking that same moral drive. Many parents might not want to enhance children and might consider giving their children moral enhancements to be putting them at a disadvantage in a world in which deceit, self-interest, and greed predominate. Politically, such enhancements might leave policy makers and negotiators at a significant disadvantage. Any individual state could legislate that all people entering public office would be required to make use of moral enhancements, but these politicians would be at a disadvantage in international affairs unless their rivals were also using moral enhancements.

This could be offset by nations requiring that all citizens or all future citizens receive moral enhancements. Requiring that all citizens receive moral enhancements would most likely be seen as a violation of the autonomy of individuals. This would be less of a risk in relation to unborn future generations, who do not yet possess autonomy. The people that would exist after a decision to enhance was made would be entirely different people to the people who would exist after a decision not to enhance was made. Nonetheless, this scenario is still disquieting: It risks turning into an Orwellian nightmare in the hands of oppressive regimes or regimes with a perverted sense of morality (what counts as perverted, of course, depends on one's moral perspective). Once more, however, it is difficult to envisage why a nation would wish to morally enhance its entire populace – nations seem to require a certain measure of aggression in their soldiers, suspicion in their police forces (at least some of the time), and (unofficially at least) deceit in their leaders.

Thus, moral enhancement is both unsettling and appealing. The idea of being designed or pharmaceutically manipulated into doing the right thing is unpleasant. The idea of ensuring that the species as a whole was less aggressive and greedy is

very appealing. Yet, three problems of moral enhancement make its development unlikely. Firstly, there will be disagreements over what counts as a moral enhancements. Secondly, it is hard to see why people would choose to use moral enhancements. Thirdly, the practical difficulties, such as locating and altering neurophysiological processes that promote moral behavior, developing techniques to alter these processes safely, agreeing upon moral ends to promote, and persuading people to use these enhancements, mean that moral enhancements appear to be a very distant prospect.

Conclusion

Proponents of HET envision a world in which people are cleverer, more beautiful, and live longer. Opponents of HET raise significant issues regarding the emergence of greater inequalities as a result of enhancement technologies. We examined arguments for and against HET.

We argued that the threats posed by HET of exacerbating both national and international inequalities are compelling and must be addressed. Furthermore, the threats of direct harms to future generations arising from HET are small and can be dealt with via regulation and oversight. However, the indirect harms to future generations likely to emerge from exacerbated inequalities are more serious and need to be addressed at a global scale. Nonetheless, these threats did not lead us to call for a moratorium on the development of HET, as it is neither realistic nor desirable.

A negative conception of rights (entitlements to non-interference) suggests that limiting non-harmful HET is a breach of our right to improve ourselves. That we have certain rights to improve ourselves seems clear, although the suggested obligation to use enhancements is not persuasive. That our rights should be extended to *some* HET is difficult to dispute, but does not suggest that all forms of enhancement should be permitted. The extent of these rights should be considered in relation to the grave issues of inequality that beset the world. Furthermore, a more positive conception of rights, which would only consider rights as secured when people have the relevant capabilities to use them, also has implications for the development of HET. Over the past number of decades, research has shown that inequalities produce real societal harms. We are now aware that some practices (such as unfair trade agreements, or the production of pollution) or inequitable social arrangements cause real but indirect harms to people. In some cases, these harms prevent people from functioning normally (in a way characteristic of human life), as these harms might include mental distress, starvation, and death. Thus, in order to guarantee a person's rights, it is (arguably) not sufficient to merely not interfere with their pursuit of their autonomously chosen goals, but it is necessary to actively ensure that people are capable, at a minimal level, of pursuing their goals. This interpretation is not uncontroversial – libertarians would fiercely resist it. Furthermore, this understanding of rights has not been dominant (though not entirely absent) in political and economic life over the past two centuries.

Nonetheless, the evidence of real harm occurring as a result of indirect actions must be taken into account.

Concern with future generations is an even greater challenge to the dominant forms of liberal political philosophy and is the subject of much debate. Nonetheless, given that we are aware of the existence of indirect harms, and that we know that future people will be affected by our actions, including how we develop and use HET, it behooves us to consider the effects of our actions on them. This positive conception of rights, along with the argument from indirect harms, and concern for future generations, suggests that there is an obligation to ensure that HET does not exclude anyone from social or political processes.

Finally, we looked at moral enhancements. Proponents claim that moral enhancement could enable future generations to overcome problems resulting from our evolution as an ape species. Our limited rationality, limited sympathy, distrust, and greed must, in the environmental context, be seen as disabilities. They endanger not only other species, but also the environmental foundations of all modern societies. Just as propensities to heart disease, cancers, and dementia are held by those in favor of enhancement to be avoidable ills, the tendency of humans as a species to primarily care about those genetically close to us or who are members of our tribe, to use the natural environment beyond sustainable limits, to compete with each other for positional goods (and thus waste limited resources), and to fail to make long-term (multi-generational) plans can be seen as avoidable ills. Although moral enhancements carry much appeal, unfortunately, they cannot be viewed as a panacea. Their development is speculative, and while it should be pursued, moral enhancements are unlikely to be available early enough to help us confront the urgent moral issues raised both by current inequalities and by the development of HET themselves.

The development of HET has the potential to radically improve the lives of current and future generations. However, while many parts of the world suffer from the effects of environmental degradation, extreme poverty, and lack of food and water, the development of HET appears something of a luxury. The development of HET also risks entrenching existing and harmful inequalities, with negative consequences for future generations. Therefore, although the further pursuit of HET is recommended, it is necessary that this research takes into account and is shaped by an awareness of the harms caused by inequalities, and the risks that both HET and inequalities pose for future generations. Unregulated development of HET is not fit for this purpose. In short, it would be wise to heed Sandel's suggestion and critically reflect on our stance towards nature and towards the social institutions of solidarity as they currently are and as they might be improved or worsened by technological developments such as HET. Exclusive reliance on individual nations to regulate their own development of HET will most likely not adequately address issues of global inequality. Therefore, it is necessary to create a global regulatory system for the development of HET. The UNESCO Universal Declaration on Bioethics and Human Rights, signed by 193 nations, is the first step towards such a global regulatory system.

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Fair Trade

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Nicole Hassoun

Introduction

Historically, Fair Trade proposals have tried to improve the terms of trade to reduce poverty and protect the environment. What does this have to do with bioethics? Perhaps the most obvious answer is that those who are concerned about global health have reason to care about poverty and environmental quality and Fair Trade is one way of ameliorating poverty and protecting the environment. Poverty is probably the biggest public health problem, and both environmental quality and trade have a large impact on the poor. Poor people often lack adequate food, water, shelter, education, and the emotional and social resources necessary for avoiding debilitating illness (Center for Disease Control and Prevention, 2007; Doyle, 2002; Leathers & Foster, 2004; Red Cross, 2007; Woolcock, 2001; World Health Organization, 2007a). The rules of trade can have a large impact on individuals' ability to secure these things. After introducing Fair Trade certification schemas and considering some of the arguments for and against (different kinds of) trade in the literature, this chapter suggests some avenues for further research into new Fair Trade proposals that focus on health, in particular.

Fair Trade-Certified Goods

Although there are many conceptions of fairness, one way of promoting fair trade in practice is to try to improve the lives of poor producers by purchasing "Fair Trade"-certified products. To receive Fair Trade certification, organizations must pay their laborers a living wage and farmers must receive fair prices (FLO-CERT, 2009). Moreover, Fair Trade-certified goods may have to be made in an environmentally sustainable way in safe working conditions. Fair Trade products should not be

N. Hassoun
Department of Philosophy, Carnegie Mellon University, Pittsburgh, PA, USA
e-mail: kikseven@gmail.com

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made with slave or child labor, and workers must have the right to organize (FLO-CERT, 2009).

Some Fair Trade organizations also try to improve poor people's lives by investing in infrastructure (e.g., roads, schools, or hospitals), reducing the length of supply chains, providing credit and technical assistance, and implementing community development projects (FLO-CERT, 2009; World Fair Trade Organization, 2009). Other Fair Trade organizations focus on creating equitable, sustainable trading relationships, increasing market access, improving the capacity of farmers' cooperatives, and raising consumer awareness (International Fair Trade Association, 2008).

Fair Trade markets are growing (Fairtrade Labeling Organization, 2009). In 2000, European countries sold 27 million pounds, or more than 300 million dollars worth, of Fair Trade coffee, and Fair Trade coffee made up 1.2 % of the European market (EFTA, 2001, cited in Raynolds, (2002)). In the USA, Fair Trade coffee was the fastest growing segment of the coffee market (it grew by 79 % in 2000–2001) (McMahon, 2001, cited in Raynolds (2002)). More generally, sales of Fair Trade-certified goods are growing incredibly quickly and amounted to approximately €2.3 billion by 2007 (FLO-CERT, 2009). Tea, sugar, cocoa, spices, honey, bananas, cotton, fruit, handicrafts, wine, and flowers are only some of the Fair Trade goods available for sale. About 7.5 million poor people benefited from Fair Trade projects by 2008 (FLO-CERT, 2009).

The Moral Status of Fair Trade

Some argue that on both deontological and consequentialist moral theories, there is an obligation to purchase Fair Trade-certified goods. Jos Philips suggests, for instance, that Western consumers cannot reasonably reject a duty to purchase Fair Trade goods on the assumption that Fair Trade benefits, but does not harm, the global poor. Philips believes that poor peoples' basic interests are at stake and Westerners do not have to give up much to support Fair Trade. Moreover, he suggests, even if Western consumers have to give up a few luxury goods, this is justifiable, for, as Thomas Pogge argues at more length, the rich often contribute to the plight of poor people (Philips, 2008; Pogge, 2002). Philips does not think that consequentialists should only be concerned with efficiency. He thinks they should also consider individuals' basic interests. Moreover, he argues that even governments may have an obligation to reduce taxes on Fair Trade-certified goods (Philips, 2008).

Some have given arguments that might provide reason to question the traditional Fair Trade movement's desirability. Consider, for instance, Aaron James' argument for free, as opposed to, fair trade (though James is concerned with philosophical conceptions of fairness in trade and not the Fair Trade movement, in particular). James asserts that participation in markets does not, on its own, raise issues of fairness. Questions of fairness only arise within a social relationship that "embeds market relations" in the practice of free trade that "allows and regulates economic interdependence" (James, 2009, 5). When considering the distribution of gains from

trade, he says that only countries can be treated unfairly and they can only be treated unfairly if exchanges are not mutually beneficial to trading partners. (Though, James does qualify his argument a bit to allow that human rights considerations may also have some force.) He says this is because the purpose of free trade is "for countries to mutually increase national income" (James, 2009, 5). As he puts it:

> Egalitarian claims, concerned with relative gains or losses, are held by… countries. For such claims are essentially tied to the type of good the trade relation is intended to create, and the ultimate aim of international market reliance is for countries to mutually increase national income (via productivity-enhancing specialization). (James, 2009, 5)

It seems there is little room for properly fair trade on James' theory.

If, however, the primary aim of free trade should not just be to ensure that countries make mutually beneficial exchanges, James' argument will not go through. Perhaps, for instance, the gains from trade should primarily benefit the least well off globally. Perhaps, if the gains from trade do not benefit the least well off globally, those who can should try to alter or work around these rules (by, e.g., buying Fair Trade-certified goods) (Hassoun, 2009).

Or consider Kurjanska and Risse's argument against Fair Trade. They argue that the case for Fair Trade-certified goods hinges, primarily, on whether or not Fair Trade is part of the best development strategy for poor countries. They do not think Fair Trade is part of the best development strategy, and so, they believe purchasing Fair Trade-certified goods is only acceptable because it does not constitute a large share of the market in traded goods (Kurjanska & Risse, 2008).

Kurjanska and Risse do not, however, argue that the case for purchasing Fair Trade-certified goods hinges, primarily, on whether or not Fair Trade is part of the best development strategy for poor countries. (They do not even specify what kind of development they have in mind.) They just suggest that a roughly Rawlsian account of fairness would support this conclusion. So, if Fair Trade need not promote countries' development, Kurjanska and Risse's argument will not go through (Hassoun, 2011b). Perhaps purchasing Fair Trade goods is justified, or required, if it promotes poor individuals' agency or welfare. This is probably so on some cosmopolitan theories of justice (Hassoun, 2012c).

In any case, the argument Kurjanska and Risse advance for the conclusion that Fair Trade is not part of the best development strategy for poor countries is much weaker than they make out. They rely on anecdotal evidence to support some of their key claims (Hassoun, 2011b). More precisely, they think that Fair Trade may not be the best development strategy because it may induce poor people to specialize in ways that are not in their long-term interests. They try to support this point with the following case:

> In Costa Rica a focus on new exports and eco-tourism allowed for diversification away from coffee and bananas. The export share of non-traditional products rose from 38.6 % in 1982 to 87 % in 2003. Consumers who would have supported Fair Trade with regard to coffee and bananas in Costa Rica would have resisted a shift that *in the long run* turned out for the better (One may even argue that providing opportunities for farmers to transition out of farming improved the lot of those who entered a new more profitable and less volatile sector. Moreover, by decreasing production of bananas, it increased returns for those who

> retained their business. It can be asserted that by providing aid and higher than market price returns to those who can obtain its label, it simultaneously provides incentives for others to continue in or even enter an unprofitable market with hopes to gain access to the limited Fair Trade market). (Kurjanska & Risse, 2008, 28–29)

It is not clear that Costa Rican farmers would have been worse off if they had tried to produce Fair Trade coffee. Even if Kurjanska and Risse are right about Costa Rica, however, Fair Trade may, generally, be part of the best development strategy for poor countries.

Moreover, even if critics of Fair Trade are right and there are only humanitarian reasons to pursue any kind of fair trade, these may be significant. Many poor people may depend, for instance, on Fair Trade for their survival. So, purchasing Fair Trade goods may even be morally required. There is some evidence that Fair Trade is effective in alleviating poverty (Bacon, 2005; Raynolds, 2002). Impact assessments suggest that Fair Trade projects help poor people secure better prices for their products (Imhof & Lee, 2007; McMahon, 2001). There is also evidence that many Fair Trade farmers have more stable incomes, are more organized, and have greater access to credit information and training programs than many traditional farmers (Bacon, 2005; Calo & Wise, 2005; Imhof & Lee, 2007; Milford, 2004, 76; Murray, Raynolds, & Taylor, 2003; Raynolds, 2002; Ronchi, 2000; Taylor, 2002). Fair Trade can help farmers to do better than organic farmers (Bacon, 2005; Calo & Wise, 2005; Imhof & Lee, 2007; Milford, 2004; Ronchi, 2000; Taylor, 2002). Although further, more rigorous, evaluations are necessary, there is evidence that Fair Trade farmers may be less vulnerable to crises and less likely to lose their land than their traditional counterparts (Bacon, 2005, 506). There is also some evidence that Fair Trade can help farmers better educate their children and meet their basic needs for things like food, water, and housing (Bacon, 2005; Hopkins, 2000, cited in Raynolds (2002); Murray et al., 2003; Ruben, 2008). A recent study commissioned by the Center for International Development Issues in the Netherlands even found that Fair Trade can increase market prices and wages for other poor farmers in a region (Hassoun, 2011a; Ruben, 2008).

Extending the Idea of Fair Trade

If purchasing traditional Fair Trade-certified goods is ever praiseworthy, never mind morally required, there is reason for bioethicists to consider ways of extending the idea to more properly medical arenas. One possibility is to embrace a traditional Fair Trade labeling campaign for pharmaceutical products, ensuring that those involved in producing pharmaceutical products (or products made by pharmaceutical companies) can meet their basic needs (Bhutta, 2006).

There may also be reason to consider other kinds of "Fair Trade" proposals that do not focus on poor producers. While most Fair Trade proposals focus on improving the lives of poor producers and workers, others try to prevent companies from employing certain kinds of workers. "Respect: Fair Trade Sports" and "GoodWeave International" focus on eliminating child labor, for instance (GoodWeave International, 2009;

Respect Fair Trade Sports, 2008). If it is legitimate to extend the concept of Fair Trade beyond production processes, Fair Trade labeling organizations might evaluate producers' impact on those poor people they do not employ. So, Fair Trade standards might apply to more producers, even large transnational corporations that do not employ poor people. One idea is to rate pharmaceutical and biotechnology companies based on how their policies impact poor peoples' access to essential drugs and technologies. The best companies, in a given year, might then be Fair Trade certified and allowed to use a Fair Trade label on their products. Socially responsible investment companies could also include in their portfolio Fair Trade-certified companies. Having a Fair Trade certification system for pharmaceutical and biotechnology companies would open the door to all kinds of fruitful social activism including boycotts of poorly rated companies and lobbying of insurance companies to include Fair Trade products in their formularies. Because, for instance, pharmaceutical and biotechnology companies rely, to a large extent, on university research and development, universities might make it a condition of the sale of their licenses that companies agree to abide by Fair Trade standards (Hassoun, 2012a).

Another possibility is to rate competing energy or extractive resource firms. Energy companies that develop, and help poor people secure access to, renewable energy sources might be Fair Trade certified, for example (Hassoun, 2012c). One reason for including such proposals under the umbrella of "Fair Trade" is that that would explain why "antiglobalization" activists *a*nd those in "the global justice movement" argue that Fair Trade provides an alternative to the neoliberal economic policies central to globalization that they reject (Highleyman, 2002).

Whatever one thinks about how one should use the term "Fair Trade," it may be fruitful to consider new ways of incentivizing improvements in global health that are, in some ways, analogous to Fair Trade campaigns. Such *Global Health Impact* campaigns may help combat some of the world's worst health problems. One such problem is that the poor lack the resources to secure the existing drugs and technologies that they desperately need. In 2002, the top ten causes of death in low-income countries included lower respiratory infections, HIV/AIDS, perinatal conditions, diarrheal diseases, malaria, and tuberculosis (WHO, 2007b). Reliable treatments exist for many of these conditions but few poor people can afford the treatments. Less obviously, poor health-related infrastructure can make it hard for the majority of the world's population to secure essential drugs and technologies even if they are cheap or free. In many countries, there are too few clinics and many of the existing clinics are hard to access (Global Health Watch, 2005). Some clinics lack staff, equipment, resources, and personnel. Others lack basic services like consistent electricity (necessary for refrigerating vaccines and other medicines) (Barnard, 2002). Moreover, few existing drugs and technologies address the most prevalent diseases in poor countries. There is a large mismatch between the amount of research and development (R&D) done on health problems in developed countries and the global burden of disease (GBD). Though things have improved recently, only 16 of 1,393 new chemical entities on the market between 1975 and 1999 were for tuberculosis or tropical diseases (Trouiller et al., 2001). "Malaria,

pneumonia, diarrhea, and tuberculosis, which together account for 21 % of the GBD, receive 0.31 % of all public and private funds devoted to health research" (Pogge, 2007). Most of the newly approved drugs are not new molecular entities (NMEs). "In 2002, only 17 of the 78 newly approved drugs were NMEs" (Angell, 2004, 43). And there are many other problems as well.

Consider how rating pharmaceutical companies based on their efforts to extend access to essential medicines to the poor, and providing the best companies with a label (that could say, for instance, that the company is "Promoting Global Health" or "Extending Access"), might address a few of these problems. Once again, the idea is that the best companies, in a given year, will be Global Health Impact certified and be allowed to use a (say) Extending Access label on their products. Highly rated companies, then, have an incentive to use the label to garner a larger share of the market as those engaged in trade and investment often prefer to purchase ethically labeled goods. If even a small percentage of consumers or doctors would prefer products from Extending Access companies, the incentive to use this label could be substantial. Moreover, socially responsible investors could include in their portfolio Extending Access-certified companies. Finally, having an Extending Access certification system for pharmaceutical companies would open the door to all kinds of fruitful social activism including boycotts of poorly rated companies and lobbying of insurance companies to include products from Extending Access companies in their formularies. Because, for instance, pharmaceutical companies rely, to a large extent, on university research and development, universities might make it a condition of the sale of their licenses that any companies holding their technologies must abide by the standards the Global Health Impact rating organization requires companies to meet to be Extending Access certified. None of these possibilities will solve all of the world's health problems, but they might have a significant impact on some of them.

For Global Health Impact certification to be a good idea, the rating system upon which it relies must be objective and output based (Hassoun, 2012a, 2012b). Here the objective is to design a rating system that can incentivize companies to do more R&D on essential medicines in ways that promote global health. Toward this end, companies should be able to impact their rating and, if companies' scores improve, that should improve global health. This requires information on the need for different essential medicines (e.g., disability-adjusted life years – *DALYs* – lost to the diseases they treat) and drug impact (e.g., efficacy) information. The drug's score will be, roughly, Need*Impact. Suppose, for instance, 100 million DALYs are lost per annum to a disease treatable with a drug that reduces the impact of the disease by 80 %, on average. If there are no alternatives, the drug will save 80 million DALYs (100*.8 = 80). If there are alternatives, doing a similar analysis on the second-line drug (or best alternative) will provide the basis for estimating the first-line drug's marginal impact. Companies can then be rated on the basis of their drugs' aggregate contribution to alleviating the global burden of disease (Hassoun, 2012a, b, c).

Moreover, for a Global Health Impact label to be a good idea, there should be some reason to think that people would actually use it. Consider, here, just the

potential impact of an Extending Access label on consumer sales. There are two important questions to answer in considering this impact. First, what percentage of consumers will purchase Extending Access products? Second, what is the size of the market in these things? The most direct way to answer the question "What percentage of consumers will purchase different kinds of labeled products?" would be to do market research on how many people actually purchase products with the label. One way of collecting such data might be to design an appropriate web platform for the project to provide decision makers, companies, and researchers with access to the ultimate ratings of companies on the basis of their products' impact and the comprehensive database of information underlying these ratings. This platform might be made available to consumers via a phone application like Fooducate or the GoodGuide that will let consumers see information about all of the products they scan (see, for instance, http://itunes.apple.com/us/app/fooducate/id398436747?mt = 8 or http://www.goodguide.com/). Scanning the barcode will bring up a web page that provides information about the rating of the company that makes that product. Interested users can learn more about the rating system and the impact of the drugs that the company makes on the basis of which the company is evaluated. Under each drug's rating, the application will explain how the score was calculated and include a link to the database. Such an application will help in gathering market data about what percentage of consumers will base their purchasing decisions on the rating system's results.

To do market research, however, a model rating system must be developed already (though this research can help in fine-tuning the model). In the absence of all the necessary market research, however, one might attempt to determine what percentage of consumers will purchase Extending Access products by considering what percentage of people are willing to engage in other kinds of ethical consumption.

As an indication of what is possible, consider the market in a few ethically labeled products. As noted above, the percentage of the European market in coffee captured by Fair Trade coffee is over 1 % (EFTA 2001, cited in Raynolds (2002)). Though, coffee is not the best-selling Fair Trade product – at least in the UK, bananas top the list (Fair Trade Foundation, 2008):

> Fairtrade coffee now accounts for 20 % of the UK coffee market, well above the 7 % market share registered in France, Europe's second largest market for fair-trade coffee. Fairtrade coffee represents between 3 % and 5 % of the coffee market in Ireland, Luxemburg, the Netherlands, Sweden and Switzerland; between 1 % and 2 % in Austria, Belgium, Denmark, Germany and Norway; and less than 1 % in Finland, Italy and Spain. (Pay, 2009)

The market for other kinds of ethical-labeled products is much larger:

> Organic coffee is estimated to account for about 3 % of the North American coffee market in volume in 2007, while its share in value is slightly higher, since prices for organic coffee are higher than those of conventional coffee. Organic coffee ranked the highest in dollar value among all organic products shipped to North America last year, and it accounted for one-third of all U.S. organic beverage sales. (Pay, 2009)

"Utz Certified coffee accounts for 40 % of the coffee market in the Netherlands" (Pay, 2009).

Moreover, there are other labeling campaigns that have captured a significant market share. Consider, for instance, sales of ENERGY STAR products in the United States. In 2006, 11 % of all washing machines in private homes and 38 % of all of the washers sold were ENERGY STAR certified (US Department of Energy, 2008). The EPA reports that 17 % of new homes now earn the label, and many people buy ENERGY STAR appliances (EPA, 2009). In their 2009 report, the US Department of Energy noted that three out of every ten refrigerators sold are ENERGY STAR certified (US Department of Energy, 2008). This is not to say that the ENERGY STAR label is in all respects a positive model for an Extending Access label. The testing and certification standards are not rigorous enough (Consumerreports.org, 2008). This is something an Extending Access rating system should avoid. The point here is only that a significant proportion of customers are willing to buy ENERGY STAR products.

Similarly, although The Body Shop has been criticized for not doing enough to help the poor (as well as for using chemicals and animal products in their health and beauty lines), they have captured a significant share of the market in developing as well as developed countries (Franklin Research's Insight, 1994). The Body Shop now makes up 3.5 % of the market in local toiletries and cosmetics in Malaysia and aims to acquire 5 % of the market in India (about its share in Hong Kong and Singapore) (Fashion United, 2010; The Star, 2009).

One might worry that consumers will not purchase Extending Access-certified conventional pharmaceutical products because consumer demand for medical goods is very inelastic. When there is no reasonable competitor to a necessary medical item, its Extending Access status may not matter. Patients will not always prefer drugs from highly rated companies. Sometimes there will be one medicine that is best for a particular condition. So, the fact that it comes from a highly rated company may (and probably should) not matter.

This brings one to the second question: What is the size of the market in things that consumers might buy? One way of trying to estimate this is to look at what percentage of drugs is generic or available over the counter. In 2006, 63 % of all prescriptions were for generic drugs (Kesselheim, 2008, 125–39; New York Times, 1986). The market for generic medications alone is over US$20 billion – much larger than the market for almost all Fair Trade products, including coffee (Mullins, Palumbo & Stuart, 2000). Similarly, the market for over the counter medicines was quite large – US$16 billion (Hassoun, 2012a). So if, like The Body Shop, a GHI label can aim to capture 5 % of US$36 billion, this would yield US$1.8 billion worth of incentive for companies to become GHI certified.

Even if poorly rated companies come up with counterfeit labels or try to manipulate the rating system, highly rated companies should support it. If people are educated about what the Extending Access label stands for, it may be trusted and alternatives may look suspicious. If necessary, government regulation (along the lines of the USDA "Organic" standards) may help prevent abuse. Even if the standards are not quite as good as one might like, the USDA does oversee the use of the pesticides and other farming practices that motivated the organic movement in the first place (USDA, 2010).

Finally, it is important to recall the fact that a rating system has many uses beyond providing the basis for a consumer label. Insurance companies or pharmacies might support highly rated companies by including their drugs in their formularies or stores. Policy makers can use the rating system to provide (e.g., tax) incentives to companies that better promote global health. Companies might also use the rating in their public relations campaigns. There is a lot of room for further research.

More recently, a few others have taken up the idea of Global Health Impact labels and proposed a different way of arbitrating between them. Nir Eyal argues, for instance, that it would be a good idea to let consumers vote on which Global Health Impact labels they prefer (or delegate their votes to organizations that they trust). He points to the success of Wikipedia in providing good information on a broad range of topics. He also suggests giving a label to hospitals in developing countries that provide health services to needy communities as well as rich tourists (Eyal, forthcoming).

It is not clear, however, that the way Eyal suggests arbitrating between labels, or his particular proposal for rating hospitals, is a good idea. Consumers may not choose good labels or delegate their votes to those who will. They may delegate their votes to religious health organizations that care only about labels that ensure people will not be offered Plan B or condoms. Further, it is not clear that Eyal's suggested label is feasible or, if implemented, would produce good results. What reason do hospitals have to sign on to the rating system he proposes? Will tourists seeking medical care abroad choose highly rated hospitals? How will people learn of the rating? Will they even have a choice of otherwise comparable health facilities providing the services they require?

Still, there are many other possible ways of deciding which potential labeling schemas a Global Health Impact rating organization should endorse as well as possible bases for Global Health Impact-certified labels. As suggested above, it would be better if an umbrella organization used objective criteria for evaluating potential Global Health Impact labels (and then granted Global Health Impact status to organizations offering ratings systems that can plausibly promote global health). They might consider, for instance, whether (1) the rating system measures actual impact on global health, (2) the organizations being rated can increase their impact, and (3) the rating system will provide these organizations with reason to do so.

Conclusion

This chapter has argued that those who are concerned about global health have at least some reason to promote fair trade by, for example, purchasing Fair Trade-certified goods. Poverty and environmental quality impact global health, and Fair Trade is one way of ameliorating poverty and protecting the environment. Moreover, there are many avenues for further inquiry into what, if anything, fair trade requires and into extending the idea of Fair Trade certification into the medical arena itself. Objective, output-based Global Health Impact labels may be particularly promising ways of encouraging fair trade, and exploring this alternative may open the door to many other ways of improving global health.

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Genetic Modification

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Don Chalmers

Introduction

Genetic modification (GM) involves modern biotechnology techniques to change the genes of an organism, particularly those of plants or animals. Genetic modification may be referred to by the synonyms genetic manipulation and genetic engineering (GE). GM builds on traditional and long-practiced plant or animal breeding techniques, such as tissue culturing propagation, graft cuttings (referred to as "clones" from Greek: *klon*, a twig), and seed selection. In animals, traditional techniques have been selective breeding and artificial insemination. These traditional techniques aim, like modern GM, to identify and develop favorable traits in plants and animals or to restrict or breed out unwanted traits. Modern GM, using recombinant DNA techniques, not only has the capacity to accelerate the time traditionally taken to introduce or eliminate the traits into the modified plants or animals but also to introduce genes from other organisms to produce transgenic organisms or traits.

Scientific development and economic investment in the context of GM have been concentrated in developed nations, which have invested heavily in biotechnology generally and genetics research in particular, as a strategy for their future economic development. Biotechnology is a key component of what has been called the *knowledge-value revolution* (Sakaiya, 1992). Following the agrarian, industrial, and petroleum revolutions, which transformed national economies, many developed nations have invested substantially in research and development, within universities, research centers, and commercial companies. This research and development aims not only to develop new medicines, plant varieties, materials, and products but also to generate the "knowledge value" in patentable inventions or methods. GM plants and animals and biotechnology, in general, have not simply been facilitated by increases in public and private funding. National biotechnology strategies have been accompanied by development tax and financial incentives, access to research tools, security of investment, and new regulations.

D. Chalmers
Faculty of Law, University of Tasmania, Hobart, Tasmania, Australia
e-mail: don.chalmers@utas.edu.au

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Scientific developments in GM have been accompanied by vigorous ethical, legal, and social debates within communities generally. There are fundamental ethical and social values involved in the development of genetic science. Genetic modification of plants and animals has been highly controversial and led to the introduction of regulatory systems in most developed countries. Similarly in human genetics, there have been equally vigorous debates about the dignity of the human embryo, which is the source of embryonic stem cells in those countries, which permit this type of research. Also, in human genetics, the growth in genetic testing has prompted extensive debate about the potential for discrimination based on the results of genetic tests. Part of these ethical legal and social debates about GM has focused on commercialization and raised questions about the fundamental values of science itself. Much of the GM research and development and resulting intellectual property rights are in the hands of private-for-profit companies. Similarly, many public institutions have commercialization policies and plans for their science research. In this modern commercialized research environment, there are concerns that the values and norms of science, which were traditionally expressed as "universalism, collegiality, disinterestedness and organised scepticism" (Merton, 1973), have been radically altered.

Genetic Modification in Animals and Plants

Modern genetic modification (GM) breeding techniques have been refined over the last decades to accelerate the time traditionally taken to introduce or eliminate traits in plants or animals and to introduce genes from other organisms to produce transgenic organisms or traits. So GM can be achieved by modifying the genes of the organism itself or by introducing a gene from another organism. GM techniques are used to identify and introduce favorable traits or to restrict or silence unwanted traits. In traditional plant or animal breeding, a number of cycles may be required to introduce or eliminate a trait or traits. The traditionally bred plant or animal will still retain some of the traits of the original stock.

Modern GM techniques enable genes from one organism to be inserted, rather than bred, into another plant or animal. A genetically modified organism (GMO) is a plant, animal, or other organism that has been changed using GM. A GMO can be created with the following steps: identification of the gene interest; isolation of the gene of interest; amplifying the gene to produce many copies; associating the gene with an appropriate promoter and poly A sequence and insertion into plasmids; multiplying the plasmid in bacteria and recovering the cloned construct for injection; transference of the construct into the recipient tissue, usually fertilized eggs; integration of gene into recipient genome; expression of gene in recipient genome; and inheritance of gene through further generations. Apart from plants with pest or disease resistance, GM techniques aim to develop new plant varieties and animal breeds with improved yield or enhanced nutritional status (BBSRC, 2008). There are also efforts to develop plant varieties with drought resistance and salt tolerance traits. GM also includes the technique of *gene silencing* to reduce the activity of specific genes present in an

organism with the aim of altering the traits of the organism. As an example, some oilseed crops have had GM *gene silencing* for the reduction of oils, which are considered unhealthy. Finally, modern GM is also used as a laboratory research tool in gene discovery, gene interaction, and genetic structure studies.

Many common crops (e.g., soybeans, corn, cotton) have undergone GM research and development. Whereas many European Union members have been critical of and resistant to the use of GM technology and have little GM plantings, there are a number of countries that have taken up GM technology with significant proportions of crop plantings (the USA, Argentina, Brazil, Canada, India, China, Paraguay, and South Africa).

The Scientific Aims of GM

GM techniques have been developed for a variety of reasons. A key aim of GM has been to increase crop productivity to achieve higher yields. In this respect, there are claims that GM offers more reliable avenues for addressing the need to feed the expanding world population, particularly in the third world. One of the other key purposes of GM was to restrict the use of pesticides and other environment-damaging chemicals. As an example, GM cotton was developed for improved insect resistance by introducing a gene from a naturally occurring soil bacterium. The development of GM insect resistant cotton has enabled reductions in the amounts of chemical pesticide spraying required, with a claimed secondary benefit from reduced water run-off pollution from the reduced use of pesticides and other chemicals. In this respect, GM may be a technique to achieve bioremediation of degenerating land or to remediate degraded mining operations. There are claimed benefits for the environment along with pesticide cost savings for the grower. GM also aims not only to increase crop productivity and yields but also to improve crop quality and food value (BBSRC 2008). GM has been used to improve the appearance and color of foods, removal of blemishes on some crops (such as bananas and papaya), or to produce later ripening fruit. GM has been used also to extend the shelf-life display of a number of popular foods (e.g., tomatoes). Finally, there have been research efforts to investigate the GM development of crops suited to global warming and likely increased drought conditions (e.g., salt-tolerant wheat varieties).

GM and the Precautionary Approach

GM has attracted concerns and criticisms based upon claims of the risks involved (Weaver & Morris 2005). These concerns are not new. As recombinant DNA technology developed, scientists themselves recognized the safety concerns about the new technology. The National Academy of Sciences, USA, set up a Committee on Recombinant DNA to assess the biosafety of the technology, and, in 1975, at the Asilomar Conference USA, biosafety in recombinant DNA research was discussed and a precautionary approach to risk initiated scientists attending established biosafety

principles, the first of which required any potential research risks to be a component part of experimental design. The second principle required that effective risk containment measures be implemented, dependent of the level of risk. Asilomar also agreed that certain types of experimentation, particularly recombinant DNA on highly pathogenic organisms (e.g., *E. coli* bacteria), should be prohibited and that a moratorium was required, pending the development of safety standards and procedures. Significantly, Asilomar, by including lawyers and doctors, was a milestone in the public debate about and scrutiny of science and science policy and regulation and took place in the context of the USA *National Research Act* 1974, which established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and introduced greater regulation of the approval processes for human research projects. These ethics review procedures have been influential globally.

These basic principles of risk assessment and levels of risk containment remain key features of modern risk assessment and management in trailing GMOs. The precautionary approach to GMOs requires that *known* and *potential* to the environment and human health should be addressed at the outset of any experimentation or trials. The Convention on Biological Diversity (Rio Declaration, 1992) from the United Nations Conference on Environment and Development in Rio de Janeiro Principle 15 states that "in order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." Precautionary measures are required where long-term risks are unknown and scientific certainty may be achieved too late to provide effective responses to environmental threats (Peel, 2005). Some take the precautionary approach to be a *principle*, requiring that experimentation not be undertaken until and *unless* risks can be ascertained and addressed. The precautionary approach, more generally requires that proposes that GM can be undertaken *but* strict risk assessment, review and avoidance procedures must be put in place. In 2000, the *Cartagena Protocol on Biosafety*, building on Principle 15 of the Rio Declaration, required signatory countries to apply the precautionary approach to the transfer, handling, and use of living modified organisms (LMOs).

Risk Assessment and Management

GM raises issues of gene flow from GM crops affecting neighboring properties and possibly surrounding natural and vulnerable ecosystems. There are concerns that GM may create new types of weeds, transfer of gene expression from GMOs through vertical or horizontal gene transfer, possible allergenicity from GM plants and animals, and that the long-term impacts of GMOs are uncertain. For GM development, risk-assessment plans must be prepared before GM laboratory research and any field trials undertaken (Weaver & Morris 2005). The Asilomar principles were taken up by scientists and nations involved with gene technology and similar Recombinant DNA Monitoring Committees established. These *advisory*

committees were gradually replaced by formal statutory authorities. For example, in Australia, the Recombinant DNA Monitoring Committee, established in 1975, was succeeded in 1987 by a Genetic Manipulation Advisory Committee and replaced by a statutory Gene Technology Regulator (Gene Technology Act, 2000).

Schemes for the regulation of genetically modified organisms (GMO) have common features of risk assessment and risk management. The *Cartagena Protocol* aimed to ensure levels of protection for the safe transfer, handling, and use of LMOs from biotechnology, with proper account, was taken to risks to human health. An LMO generally refers to agricultural crops and so is narrower than a GMO. The *Cartagena Protocol* established the foundational principles for the regulatory systems of signatory countries. These systems essentially assess the risk involved with a GMO dealing and require that dealings are *licensed* unless the GMO dealings are an exempt or a low-risk dealing. Risk assessment of the GMO is essentially science based, without assessment of psychological or social conceptions of risk. Many GMO dealings are contained within laboratories, without any release into the environment by field trials. Experimental laboratory dealings, depending on the assessment of risk, will be licensed to be conducted within different levels of security containment standards (physical containment levels, PC1–PC4, depending on risk). The restriction of the GMO to a physical containment facility is a usual license condition. Institutions conducting GMO work must generally undergo an *accreditation* and require their laboratories to be *certified* to ensure the proper physical containment levels are maintained for the GMO work. Institutions must, as part of the accreditation process, have an institutional biosafety committee (IBC) to assess institutional biosafety issues. Where the GMO is to be released into the environment, usually in a field trial, specific licenses are required and a Risk Assessment Management Plan (RAMP) prepared to minimize impact involved with the intentional release of the GMO on human health and environmental safety to minimize the risks. RAMPs vary according to the significance of the risks to safety of people or environment. The RAMP will consider the effect of genetic modification on the original organism, the effect of the modification of toxicity or allergenicity to other organisms, the effect of modification increased weediness, the potential for gene transfer, and the potential for limiting the spread and persistence of the proposed GMO. Applications for licenses involving an intentional release of a GMO will allow opportunities for public consultation and comment, which will inform the development of the specific RAMP. In cases of an intentional release of a GMO, the license will impose RAMP conditions to minimize the risks of contamination and risks to health and safety. Common license conditions require isolation and setting up buffer zones around the trial site, destruction and removal of any plant, canopies over GMO crops to prevent pollen flow, and special harvesting, transport, and storage procedures.

Genetic Modification Ethics

The development of genetic modification of plants in agricultural biotechnology has met with considerable debate and controversy. Supporters of GMOs claim that the technology will improve crop production and yields, reduce the use of

environmentally damaging pesticides, and fulfill a duty to feed increasing third-world populations. Supporters also claim that scientific inquiry and the advancement of knowledge is itself a moral good. By contrast, opponents claim that GMO technology is inherently wrong, GMOs interfere with nature and damage ecosystems, GMOs reduce biodiversity, and GMOs are economically anticompetitive because the market for GMOs has been dominated by a small number of multinational corporations. In fact, much GMO research is conducted within government organizations or universities. Environmental ethics focus on issues of "naturalness" and whether GM technology distorts this natural order. Patenting has also been a major issue in GM plants with concerns about the domination of a small number of multinational corporations holding key patents over major crops (e.g., soybeans, cotton, corn, and canola).

Environmental ethics and the ethics of GM are inchoate and less formalized in comparison with established traditions of ethical debates in human or animal research (Sylvan & Bennett 1994). There are no GM or environment equivalents of human research ethics committees or animal ethics and welfare committees. Where GM involves animals by, for example, the introduction of human genes, animal welfare and ethics issues arise. Respect for animals recognizes animal sentience (sense pain and suffering) (Singer, 1975). This respect is reflected in animal welfare legislation prohibiting cruelty to animals and supported by guidelines regulating animal research. These guidelines generally require researchers in animal experiments to *replace* them, where possible, *reduce* the number involved, and *refine* the project. Respect for animals, specifically in GM projects, reflects concerns about consequences for the welfare of these modified animals and for their possible effects on human and animal health and the environment. These guidelines apply to laboratory animals and to GM production animals.

GM is not a science-only activity but embraces regulatory policy, economics, third-world development, and profound ethical questions. Decisions about applications of GM require scientific assessments of potential and risk to be accompanied by ethical discussion. Therefore, strict scientific analysis of risk is not sufficient for ethical decision making about gene technology (Singer, 1975). Global warming research has revived debates on environmental ethics, which is well recognized in some cultural traditions. In Australia and in New Zealand, government advisory bodies (the Gene Technology Ethics and Community Consultation Committee and Environmental Risk Management Authority, respectively) have developed ethics frameworks in respect of GM technology. These *ethics frameworks* contain general principles (respect for the environment and respect for people, including past, present, and future generations) and specific principles of concern for animal welfare, autonomy, cooperation, cultural identity and pluralism, human rights, human dignity, justice and equality, sustainability, and well-being.

Genetic Modification in Humans

Genetic modification is not a term generally used in relation to humans; however, human genetics is an area of intense research effort, aimed not only at developing

diagnoses and treatments for genetic conditions but also for many common diseases (Burley & Harris, 2004).

Before the advent of modern molecular genetics, genetic information came from family histories, physical appearance, and some chromosomal analysis (e.g., an extra copy of chromosome 21 indicating Down's syndrome). Many genetic conditions were known but not treatable. However, genetic information could inform reproductive choices. Marriage rules on consanguinity, which restricted near relations from marrying, were examples, with restrictions based to degrees of genetic separation. Darwin's *The Origin of Species* proposed that all forms of life are essentially convertible into one another and that each cell had propagating "gemmules" able to attach to other tissue. A second idea of *pangenesis* proposed that these gemmules have natural affinities to select and attach to other tissue. A cousin of Charles Darwin, Francis Galton coined the term *eugenics* in *Inquiries into Human Faculty*, 1883. In 1902, William Bateson in *Mendel's Principles of Heredity* used *genetics* for the study of heredity and its variation, followed by the Danish botanist Wilhelm Johannsen, with the terms "genotype," "phenotype," and "gene." Research work in the 1940s by Oswald Avery and collaborators identified DNA as the molecular material base for genes and chromosomes. James Watson and Francis Crick advanced the analysis of DNA with their publication in 1953 of its molecular structure (building on work by Rosalind Franklin and Maurice Wilkins). Building on chromatography and dye-based techniques (Southern blotting), sequencing techniques became easier, faster, and less expensive with PCR and became more detailed with the Sanger DNA sequencing technique (Kevles & Hood, 1992).

The modern "genome era" has been marked by considerable research activity, much of which is international and collaborative. This work has not only expanded understanding of the molecular genetic code of humans but is also informing and driving efforts to develop diagnoses and treatments of many common diseases and conditions, based on this genetic knowledge. A significant milestone was reached in 2001, with the joint announcement in the journal *Nature* and in *Science* of the publication of the human genome map. The announcement was made by the *Human Genome Project* (HGP), an international publically funded collaborative project, and the private company, Celera Genomics. Based on the mapping work, it was estimated that the total number of human genes was between 30,000 and 40,000. This was a considerable reduction on previous estimates and required a revision of the previous biology doctrine of "one gene for one protein." This announcement also showed a common thread of similarities between the DNA of humans, animals, and plants (Sulston & Ferry, 2004). This was a starting point for further sequencing work and improvements in sequencing technology and bioinformatics. Automation, chip technology, and mass parallel sequencing have exponentially accelerated sequencing toward *Whole Genome Sequencing* (WGS), enabling the systematic identification of genes and the complete sequencing of the genetic code of many plants, animals, humans, and organisms. Equally significantly, the HGP funding included consideration of the ethical, legal, and social issues (ELSI) in the HGP and the establishment of the International Human Genome Organisation (HUGO). The HGP adopted a policy of public release and open access to data after its *Bermuda Declaration* in 1996 with release within 24 h. The HGP and Celera Genomics joint announcement

spawned new disciplines of proteomics (gene identification, protein structure), functional genomics, and transcriptomics (genetic variation, gene expression monitoring) and targeted drug discovery and pharmacogenomics (for treatment of diseases with a genetic component) and new enabling technologies. The HGP has also spawned other major international collaborative projects, like the International HapMap Project and the International Cancer Genome Consortium, which involves some 14 countries each specializing in analysis of specific types of cancers and which has been described as the biggest collaborative international research project since the HGP.

The results from these projects, and others, have enabled medical science to better understand human genetics in relation to health and to translate this understanding into diagnoses and treatments for many common diseases and conditions. The genetic base for many diseases has been understood for some time. The *autosomal dominant disorders* include conditions such as polycystic renal disease, neurofibromatosis, and Huntington's disease. The *autosomal recessive disorders* include sickle cell anemia in certain populations, cystic fibrosis, and phenylketonuria. Similarly, *X-linked disorders* like hemophilia are also well known. However, there are many conditions which are not clearly genetically linked. High incidence conditions, which can also affect family groups, such as cancer, hypertension, diabetes, and heart disease, are *multifactorial* and depend on genetic as well as dietary and environmental factors.

Human Gene Therapy

Advance in development of molecular human genetic research and a better understanding of the genetic bases of some diseases, in the 1980s, encouraged early efforts to consideration of the use of DNA in gene therapy to treat disease by altering a patient's genes. Gene therapy aims to replace defective genes but also to introduce genes as a means to improving cellular function or repair genes. Gene therapy interventions *on* humans have been few. In the 1980s and 1990s, there were high expectations of the promise and potential of gene therapy to modify and treat diseases. These interventions were targeted not on the patient's germ cells but on their somatic cells. By the early 1990s, the director of the National Institutes of Health, USA, advised clinicians to return to the laboratory and improve experimental techniques before undertaking further clinical gene therapy trials (256 *Science*, 808–813), and an editorial in *The Lancet* suggested that the promise of gene therapy had been "over sold" (350 *The Lancet* 9071, 79). The Gelsinger case in the USA in 1999 raised grave ethical questions about gene therapy. A virus vector with modified genes was administered to a teenager, without his father's knowledge or consent to treat his OTC (ornithine transcarbamylase deficiency), which prevented his OTC (ornithine transcarbamylase deficiency, a rare condition, which prevented his liver from metabolizing ammonia). The teenager died, and the FDA inquiry found serious failures to disclose and research ethics breaches, including reports of competing financial interests of the research/medical team in a company with the right to market the tested gene therapies. Slow progress followed in gene therapy protocols with a focus on common diseases of cancer,

diabetes, and heart disease. Some clinical successes in the last decade have revived gene therapy treatment plans for patients with the retinal disease. There have also been animal model tests, as required ethically, with the first approved clinical gene therapy trial in the USA on the X-linked Duchenne muscular dystrophy disease and another first approved trial for adenosine deaminase (ADA) deficiency using autologous cells and Parkinson's disease.

The limited gene therapy trials have been on somatic cells. There is international consensus that gene therapy on germ cells is ethically unacceptable. The *Convention on Human Rights and Biomedicine* of the Council of Europe states that "any intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants" (Article 13). The Group of Advisors on the Ethical Implications of Biotechnology to the European Union (GAEIB) echoed this view and recommended that the germ line therapy techniques be forbidden on humans until there is greater scientific clarity and ethical reevaluation (GAEIB 1994). Internationally, the research ethics guidelines in most countries include restrictions or prohibitions on germ line therapy.

Gene therapy aims to replace defective genes but also to introduce genes as a means to improving cellular function or repairing genes. Research is also focusing on mitochondrial DNA, which is separate from the nuclear DNA of a cell. Mitochondrial DNA provides the energy for cell growth. There are efforts both to target and remove defective mitochondrial DNA, and transfer new DNA, and also to introduce supplementary mitochondrial DNA. Where this research is carried out on a female oocyte, the genetic change is in the germ line and will be passed on to offspring. This research is ethically controversial and is being developed on animal models (Burley & Harris, 2004).

There has been discussion about the possibility of gene therapy developing techniques to enhance human characteristics. Somatic cell gene therapy has proved to be difficult in clinical application, and any serious discussion of enhancement gene therapy must be hypothetical. From time to time, there has been hypothetical discussion that human genetic techniques could offer the opportunity to insert genes for non-disease-related traits, such as intelligence, height, musical ability, and looks. These traits are influenced by the environment and social interaction and are probably also polygenetic, thus extraordinarily complex to alter and, much less, enhance. It is unlikely that enhancement gene therapy will be realized; many human traits may prove to be far too complex to be modified by the introduction of a single gene or group of genes. Some bioethical literature has discussed the ethics of gene enhancement, even though this discussion is not matched by any research activity, much less any clinical application (Buchanan, 2011). Enhancement gene therapy, like germ line gene therapy, is considered ethically controversial.

Regenerative Medicine

Stem cell therapy is built on the knowledge that certain human cells, derived from, as examples, bone marrow, placental tissue, and human embryos, are capable of

replication. Stem cell technology aims to introduce these new replicating cells into damaged tissue as a therapy to treat disease or injury. For this reason, stem cell therapy is a component of the area of what is referred to as "regenerative medicine." The replacement of cells can be viewed as a method of genetic modification for therapeutic purposes. Some stem cell therapies are well established in regenerative medicine and uncontroversial and involve minimal invasive techniques. As examples, whole blood transfusions and bone marrow transplants for particular types of cancers are standard treatments. Stem cell therapy is another area of future promise, which may become a pathway for treatment in diabetes, heart disease, spinal cord injury, Parkinson's, Alzheimer's, diabetes, some cancers, and the production of synthetic blood. Stem cell technology may become a new treatment strategy and delivery method for therapeutic agents for malignant brain tumors. In 2001, the National Academies Committee on the Biological and Biomedical Application of Stem Cell Research stated that stem cell research "offers unprecedented opportunities for developing new medical therapies for debilitating diseases and a new way to explore fundamental questions of biology" (National Academies Committee on the Biological and Biomedical Application of Stem Cell Research, 2001).

Stem cell technology involves a continuing search for reliable sources of regenerative tissue for medical treatments. International public attention was attracted to stem cell research in the late 1990s with the *Dolly* announcement that a somatic cell nuclear transfer procedure (SCNT) had been undertaken at the Roslin Institute in Scotland in 1997. According to the report, a sheep egg had been enucleated and somatic cells from the same sheep (Dolly itself) inserted and a replicated "clone" of the somatic cell developed. This "cloning" procedure built on earlier research work in animal studies. The experiments showed that somatic cells could be differentiated and reset by transferring them to an enucleated oocyte. This indicated that an adult cell could be changed back to a premature pluripotent state. Later scientific work demonstrated that a human pluripotent state was present in human blastocysts (Thomson et al. 1998), and in 2001, the first "cloned" human embryo was reported. Somatic cell nuclear transfer (SCNT), also called cell nuclear replacement (CNR), has developed as an established research area of regenerative medicine for cell replacement. SCNT has a critical advantage over embryonic stem cells. SCNT cells involve the transfer of an individual's own somatic tissues, which means that the modified somatic cells are autologous cell lines, thus avoiding the problems of allogenetic transplants and immuno-rejection. These cells should be compatible with the recipient's immune system. The continuing search for reliable sources of regenerative tissue for medical treatments has moved to iPS cells. There were simultaneous publication of reports of the creation of induced pluripotent stem cells (iPS) from human fibroblasts in Japan (Takahasi & Yamanaka, 2006) and the USA (Thomson). iPS cells show many similarities to pluripotent stem cells as they proliferate indefinitely and appear to differentiate into cells across cell lineages. iPS cells can be derived equally because they can be derived from skin cell biopsies to produce autologous cells for transplant. In addition, parthenogenesis techniques aim to produce stem cell lines of compatible tissue using human oocytes. Much research work lies ahead in the characterization of the differences and similarities between embryonic, SCNT, iPS, and parthenogenic stem cells.

Clinical Applications of Regenerative Medicine

Some stem cell technologies, particularly those involving bone marrow, have been available as standard clinical care for many years. The gradual introduction of stem cell therapies to relieve serious disabilities and diseases will take a number of years of preclinical and clinical research before they are approved. The trials current in the USA can be seen at http://clinicaltrials.gov/.

Like the Asilomar conference, the scientists involved, the International Society for Stem Cell Research (ISSCR) has developed *Guidelines for the Clinical Translation of Stem Cells*, 2008, at www.isscr.org, which propose that clinical trials of stem cells should not be undertaken until there has been rigorous independent assessment of the safety of the procedure. Standards for good manufacturing practice are a necessary precondition to the use of embryonic stem cells in a clinical setting as part of "established" clinical practice. The major ethical issues surrounding stem cells relate to the novelty and safety of the proposed applications. The proposed application must be carefully assessed for risk, that risk properly communicated to the patient and the risk involved and the application properly managed and addressed. Secondly, the application should be subject to independent scientific assessment and ethical review. Thirdly, as with all human research, the risks and benefits should be properly assessed by the independent science and ethics review committees. Fourthly, the risks involved must be carefully communicated and explained to the patient involved so that they can give voluntary consent to involvement in the trial. These ethical principles, including quality control, preclinical work, ethical trials, and ethical evaluation, are consistent with the UNESCO *Declaration on the Human Genome and Human Rights* that "research, treatment and diagnosis affecting an individual's genome shall be undertaken only after rigorous and prior assessment of the potential risks and benefits" with the informed consent of the person and after the research protocols have been submitted for prior review in accordance with relevant research standards and guidelines (Article 5). In view of the innovative aspect of the application, the benefits should not be overstated. This is particularly important as some clinics, in countries with lax or dubious regulatory structures, have advertised treatments of unsubstantiated and unproven effectiveness, raising unrealistic hopes for seriously ill patients with promises of entirely novel and untested therapies.

The Ethics of Regenerative Medicine

Some stem cell technologies, such as bone marrow and whole blood transfusions, are standard clinical practice. These procedures do not arouse bioethical debate. However, like the public debates on genetic modification of plants, the *Dolly* report prompted a worldwide international discussion on the ethics of "cloning" among international organizations, regulatory bodies, and the bioethics community. This report unleashed an avalanche of press comments and academic writings about the potential application of the SCNT process to produce human "clones," sometimes with wildly exaggerated

suggestions that duplicate "clones" of dead children could be brought back. There were also reports of the use of embryonic stem cells for use in drug testing.

The *Dolly* report led to two lines of ethical debate, the first on whether research should be undertaken on human embryos and the second on the possible use of SCNT in assisted reproduction programs (ART). In the first line, human embryo research focused on the moral status of the human embryo and its likely destruction if used in research. Many countries, such as Austria, Ireland, Canada, and the Philippines, banned human embryo research, considering it contrary to human dignity. Interestingly, Germany banned embryo research but allowed stem cell lines to be imported for research. Internationally, the UNESCO *Declaration on the Human Genome and Human Rights* stated that "no research. . .concerning the human genome. . .should prevail over respect for the human rights, fundamental freedoms and human dignity of individuals or. . .groups of people" (Article 10). Arguments based on human dignity recognized that the human embryo may not have human rights but, nevertheless, deserve to be treated with dignity, because early human life represents the fundamental nature and values of a society and transcends individual rights. Human dignity also underpins human rights and places proper limits on research and to avoid its trivialization of values. However, many other countries (e.g., the UK, Finland, Greece, Israel, the Netherlands, Sweden, South Korea, some states in the USA, Australia, Singapore, China, Spain, and Japan) took a utilitarian approach and permitted the use of "surplus" human ART embryos (i.e., not to be used in ART by the parties creating the embryo). These countries weighed utilitarian benefits and harms and preferred the use of excess embryos rather than their destruction. However, these permissive countries all imposed conditions on embryo research. These conditions include strict consent requirements, requirements to explain and justify the intended research purposes, and approval by an IRB/research ethics review committee. Some states in the USA permitted embryo research, but public funds for such research were restricted until the presidential embargo was lifted. Accurately, the President's Commission on Bioethics in the USA described the regulatory landscape on human embryo research as a "patchwork, with authority divided among numerous sources of oversight" (*Reproduction and Responsibility: The Regulation of New Biotechnologies* 204 at 75). This comment applies equally in the international context. No country, however, has approved the creation of human embryos for research purposes.

The second line of debate considered whether SCNT could be used in assisted reproduction programs (ART). Two rather misleading terms developed of "reproductive cloning" and "therapeutic cloning." The former, reproductive cloning, was condemned universally. Article 11 of the UNESCO *Declaration on the Human Genome and Human Rights* stated "practices which are contrary to human dignity, such as the reproductive cloning of human beings, shall not be permitted." This was followed by similar bans on "reproductive cloning" by the WHO General Session and a resolution of the United Nations. Similarly, the Council of Europe added an *Additional Protocol* to its *Convention on Human Rights and Dignity with regard to the application of Biology in Medicine*. The *Protocol on Prohibition on Cloning of Human Beings* states that "any intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited."

There were some comments that reproductive cloning was part of the right to procreate but with little influence.

Significantly, debates about human embryo research do not arise with some stem cell technologies. iPS cells, for example, are not derived from human embryos and will produce autologous transplant cells. This procedure removes much of the moral objection to the use of excess embryos for the production of stem cells. Similarly, parthenogenic stem cells avoid using human embryos but may raise ethical questions about the procedures for women donating their oocytes for research.

Genetic Research for Future Medicines and Treatments

There are considerable efforts to develop medical treatments matched to the specific genetic characteristics of individual patients. This development has been termed "personalized medicine," although it has been long recognized that different people vary in their metabolic responses to the same medicine. Dosing variation in medicines has been standard practice since the 1950s, but what is novel is the link between genetic tests to profile an individual patient to more accurately prescribe specific drugs matched to individual patients. This process is further refining current patient stratification practices by the use of genetic tests to classify patients between those more susceptible to benefit from a particular intervention and those who are unlikely to benefit. As an example, the effectiveness of the drug Herceptin can be indicated by a test identifying the genetic pattern in some women. These have been termed "rational drugs" (Presidents' Council of Advisors of Science and Technology). Personalized medicine also aims to improve current clinical trial procedures of new drugs, especially at Phase II and Phase III stages. Genetic tests may better identify participants who should be excluded from trials as they are unlikely to benefit or may be harmed. This may reduce the number of patients to be recruited. In these ways, the time and cost for the completion of drug trials may be reduced substantially (Presidents' Council of Advisors of Science and Technology, 2008).

Ethical Issues in Human Genetics

Apart from the specific issues of embryo research discussed above, human genetics has attracted considerable bioethical debate. The issues of genetic privacy have been a prominent topic of debate and a subject of a major Australian Law Reform Commission Report (Essentially Yours Report, 96 of 2003). This report also considered genetic research, databases, employment, insurance and law enforcement in relation to human genetics. Genetic privacy was debated and legislation introduced, in the United States (*Genetic Information and Non-discrimination Act*, 2008). Secondly, there have been debates about the introduction of genetic tests and their potential discriminatory application in the workplace, insurance applications, and immigration. Genetic testing debates have also extended to discussion of growing trends for direct-to-customer (DTC) tests and their accuracy and use. Any wider

discussion of publically funded genetic testing would be dependent on evidence of cost benefit, utility, and effectiveness of these tests. Certainly, testing for late-onset conditions would require proper counseling support services to be available and screening of children limited to cases where it is clinically indicated or where some treatment regime is available. Thirdly, GM has involved, in some cases, cross transfer of human, animal, and plant genes. In heart surgery, for example, porcine and bovine tissue replacement heart valves have been used for humans with success. This form of *xenotransplantation* involves cellular and molecular transfer from one species to another and aims to provide a source of human body parts for transplantation. However, xenotransplantation is controversial, and a precautionary approach has been applied to the clinical application of these procedures. A precautionary approach has been taken to avoid risks to the individual patient through hyper-rejection of the GM transplant and to avoid risks to the population through the possibility of introducing animal viruses or new pathogens (xenozoonosis) into human beings. Efforts have been invested in relation to developing genetically modified animals as sources of parts for human transplantation. Regulation of some aspects of xenotransplantation and human genetics should be harmonized internationally. There is a possibility of "xeno-havens" developing in countries with lower standards of regulation. Fourthly, patenting is also an issue in human genetics. Patenting of the human genome attracted international attention in the early 1990s when the USA National Institutes of Health attempted patent partial gene sequences of unknown function. There were also a number of commercial companies involved in what was described as the "patent rush" to patent human gene sequences. The current view is that it is possible to patent gene sequences provided their function is known. Generally, there is a patent exemption for research, and this is generally included in legislation, including the *European Patent Convention*. As noted, there is a general practice for international consortia to release their data publically on open-access websites. Most recently, there has been international discussion on the growth of biobanks, which are essential tools for undertaking genetic research as well as the translation of research findings into clinical applications. Finally, "rights-based" approaches to bioethics have been immensely influential but may not sit comfortably with familial obligations in the context of human genetic information. Movements from rights to duties can be identified in the UNESCO *Declaration on the Human Genome and Human Rights* 2005 expressly referring to a notion of a "practice of solidarity" which states should respect and promote toward individuals, families, and population groups which are particularly vulnerable or affected by disease or disability of a genetic character.

Public Consultation, Engagement, and Trust

Genetic modification in plants, animals, and humans has been accompanied by widespread public comment and debate. Many countries conducted public consultation on GM development, and field trials are usually preceded by formal notification and opportunities for public comment. Apart from formal public consultation

on GM issues, there has been considerable academic research conducted in an attempt to identify public attitudes and opinions. The European Commission has undertaken systematic polling over nearly two decades, publishing annual reports under the title of *Europeans and Biotechnology*. These reports track the broad awareness, perceptions, and opinions in relation to biotechnology for food production (GM food and animal cloning) as well as emerging technologies of nanotechnology biofuels and synthetic technology. More recent reports have also started to track climate change. These reports also track the knowledge of and attitudes toward biobanks and their governance. These reports are rich sources of information about the EU and do not cover the Americas, India, China, or the third world, which have been more receptive, for example, to GM crop plantings. *The Europeans and Biotechnology* has generally supported biotechnology in the areas of medicine, regenerative medicine, and healthcare generally, including genetic tests to identify diseases. There has been less enthusiasm for applications to crops for human consumption. There has also been continuing support to develop GM bacteria to clean pollution. There has been widespread acceptance that the developments of biotechnology in general and GM in particular require public acceptance and trust. Public consultation and engagement enables levels of trust to be investigated.

The EU-based surveys are aligned with surveys in other parts of the world and academic research that public trust is a major component of GM and that public consultation and engagement are important processes in the development in GM, its regulation, and application. In addition, risk assessment processes require public consultation and engagement.

Conclusion

The challenges posed by GM technologies and the scientific research involved are essentially how society is to harness the promise of potential benefits of the technology or research and at the same time minimize or avoid the threat of possible risks from GM. These challenges transcend national boundaries. GM has also transcended the technical scientific aspects and has significant ethical, legal, and social issues, including safety, privacy, and accountability. It is highly desirable that these core international issues should be governed by the same or at least closely harmonized international regulations and standards, including administrative controls, enforceable and voluntary guidelines, and review structures (such as research ethics committees and national bioethics bodies) that apply principles consistent with developing international norms.

The GM horizon has benefited OECD and developed nations. Although there have been significant uptakes in GM crops in many developing nations, the financial benefits have flowed, mainly to developed nations. There is the need for a more equitable distribution of the benefits from the GM knowledge value… The gap between rich and poor nations is widening at an increasing pace. The promise of GM and human genetics "…carries with it extraordinary responsibilities. It is incumbent on both scientists and public servants to ensure that science serves humanity

always, and never the other way round" (Clinton, 1998). The costs involved in many of the developments and applications of this technology may lead inevitably to exclusion of the poor and needy from access to the products. The United Nations Economic and Social Council echoed this view and stated that ". . .[t]here is a general recognition of the need for international cooperation in order to ensure that mankind as a whole, benefits from the life sciences and to prevent them from being used for any purpose other than the good of mankind."

There is a continuing challenge in GM research and development to strike an appropriate balance between the value of scientific freedom and the protection and safety of individuals and the environment. There is also a further continuing challenge of recognizing that science is not purely technical nor value neutral but involves profound ethical, legal, and social issues.

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Human Cloning

41

Toivo Maimets and Kristi Lõuk

Introduction

The word "cloning" comes from a Greek word "κλών" (twig) and refers to the agricultural process where a new plant is generated from a twig. Through this asexual multiplication, genetically identical plants can be produced.

"Human reproductive cloning" describes the creation of a human embryo from nuclear DNA sequence of an existing human being in order to implant it into a womb, leading eventually to the birth of an identical human being. The meaning of the word "identical" here is different from that in cloning plants and is even not scientifically entirely correct: to get an identical organism, one also has to copy all the developmental processes involved, in addition to the DNA resource. The long development time of mammals in the mother organism before birth, when many micro- and macroenvironmental effects not directly caused by its own DNA sequence influence the future "outcome," creates a substantial difference between processes of cloning plants and "cloning" mammals. Even monozygous twins are not entirely identical, although they share the same DNA sequence and have passed through a very similar pre-birth developmental environment. However, the term "human reproductive cloning" has been deeply engrained in global discourse and already features in a number of national legislations and international documents and should therefore be kept in use, at least for the time being.

Several sources also use the term "human therapeutic cloning," or, synonymously, "research cloning," the definition of which is rather vague and unclear. It seems that instead of clearly defining it, the term has been used to distinguish "good" from "bad" cloning. It therefore has created a lot of confusion in ethical and legal debates, and, as has been noted by the UNESCO International Bioethics Committee (IBC) *Report on Human Cloning and International Governance* (2009):

T. Maimets (✉)
Institute of Molecular and Cell Biology, University of Tartu, Tartu, Estonia
e-mail: toivo.maimets@ut.ee

K. Lõuk
Centre for Ethics, University of Tartu, Tartu, Estonia
e-mail: kristi.louk@ut.ee

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"The terminology used in the bioethical debates is misleading and does not adequately describe the technical procedures used (or potentially to be used) today" (p. 7). More specifically, it adds that: "While 'reproductive' is a term that clearly indicates the ultimate intention of the procedure, the term 'therapeutic' fails to clearly define the purpose of the procedure. . ." (p. 6). Therefore defining and, indeed, using the term "therapeutic cloning" is avoided further in this chapter.

Since the birth of the first mammal clone – Dolly the sheep (Wilmut et al., 1997), the issue of human reproductive cloning and the appropriate international system of governance have been triggering off profound reflection and debates at national and international levels, including within the United Nations system. A number of norms have been elaborated at the international and regional levels, which address directly or indirectly the issue of human cloning. Although several attempts have been undertaken to achieve an international ban of human reproductive cloning, this result has not been achieved yet. Therefore, it is possible today to carry on this work in many countries of the world (mostly in underdeveloped countries), which have not introduced the ban. The UN Declarations are not legally binding to the member states, and achieving a consensus for a UN Convention has not been possible so far.

In this chapter, the scientific developments over the last two decades which have created new technical possibilities for human reproductive cloning and an acute need for new ethical and legal reflections on these issues are analyzed. Then the arguments for and against the use of human reproductive cloning are presented. In the last part, the national and international actions (at the level of United Nations and UNESCO) to regulate and govern the issue of human reproductive cloning are described.

Methods for Reproductive Cloning

Embryo Splitting

The first method to clone human embryos was embryo splitting, which was used for human embryos by Jerry Hall and colleagues in 1993 (Kolberg, 1993). Using micromanipulation techniques, it is possible to separate some cells from the early phase embryo, and by injecting them into "empty" natural *zona pellucida* (or an artificial one), recipients achieve normal development of an identical organism. Basically, one can split an embryo even into more than two, whereas genetically identical individuals develop from each portion in the same way that identical (monozygous) twins are formed in nature. This technique has been used to successfully clone embryos and animals.

Tetraploid Complementation

Tetraploid complementation is a technique where two mammalian embryos are combined to form a new embryo (Kaufman & Webb, 1990). Normal mammalian somatic cells are diploid: each chromosome is present in duplicate. The assay starts

with producing a tetraploid cell in which every chromosome exists fourfold. This is done by taking an embryo at the two-cell stage and fusing the two cells by applying an electrical current. The resulting tetraploid cell will continue to divide, and all daughter cells will also be tetraploid. Such a tetraploid embryo can develop normally to the blastocyst stage (an early stage embryo with about 100 cells) and will implant in the wall of the uterus. The tetraploid cells can form the extraembryonic tissue (placenta, etc.) but usually not the tissues of the fetus.

In the tetraploid complementation assay, one now combines such a tetraploid embryo with normal diploid embryonic stem cells (ES) from a different organism. This can be achieved either by direct injection of ES cells into tetraploid embryos or aggregation of ES cells with 4-cell stage tetraploid embryo. ES cells are pluripotent, meaning they are able to produce (through proliferation and differentiation) all cell types of the future organism. The embryo will then develop normally; the fetus is exclusively derived from the ES cells, while the extraembryonic tissues are derived from the tetraploid cells.

Somatic Cell Nuclear Transfer (SCNT)

Somatic cell nuclear transfer (SCNT) is a technique for creating a clonal embryo using an egg cell with a donor nucleus. The nucleus (which contains the organism's DNA, except mitochondrial DNA) of a somatic cell is removed and the rest of the cell discarded. At the same time, the nucleus of an egg cell is removed. The nucleus of the somatic cell is then injected into the enucleated egg cell. Alternatively, the entire donor cell may be fused (using electrical current or chemicals) with the enucleated egg cell. After being inserted into the egg, the somatic cell nucleus is reprogrammed by the egg cell. The egg, now containing the nucleus of a somatic cell, is stimulated to divide. After mitotic divisions in culture, this single cell forms a blastocyst with almost identical DNA to the original organism. The difference from the original organism remains in the content of mitochondrial DNA. Mitochondria are cellular organelles located in cell cytoplasm and carrying their own DNA. Hence, mitochondrial DNA in the new organism comes not from a donor of the nucleus, but from the enucleated egg cell. The technique of transferring a nucleus from a somatic cell into an egg was used to produce Dolly the sheep. The same technique has now been successfully used to clone many animals, including primates. The first SCNT clone of humans was reported recently, although it needed triploid chromosomes (two sets from donor nucleus and one from oocyte) to fully develop into blastocyst and pluripotent ES cells (Noggle et al., 2011).

Induced Pluripotent Cells (iPS): Generation of Embryonic Stem Cell-like Cells

Induced pluripotent stem cells, commonly abbreviated as iPS cells or iPSCs, are a type of pluripotent cells artificially derived from a non-pluripotent cell, typically

an adult or neonatal somatic cell, by inducing a "forced" expression of specific genes. iPSCs were first produced in 2006 from mouse cells and in 2007 from human cells. This has been cited as an important advance in stem cell research, as it may allow researchers to obtain pluripotent stem cells, which are important in research and potentially have therapeutic uses, without the controversial use of embryos. Because iPSCs are developed from the patient's own somatic cells, it was believed that treatment of iPSCs would avoid any immunogenic responses; however, recently this assumption has been challenged (Zhao et al., 2011).

In many aspects, iPS cells are similar to natural stem cells, such as ES cells, but the full extent of this similarity is still under study. Differences between iPS- and blastocyst-derived embryonic stem cells have been reported for gene expression, DNA methylation, and differentiation potential. In addition, reprogramming to iPS cells seems to compromise genomic integrity, introducing de novo mutations and copy number variations.

Since the development of iPS cells, the ethical and legal debates over human reproductive cloning have entered the "post-SCNT era." Until that, the ethical center of the issue was the moral status of human embryo. The destruction of an existing embryo, which was unavoidable for SCNT, was ethically unacceptable for those who believe that human life begins from the moment of conception. It is now possible to use tetraploid complementation and iPS techniques to create new organisms from somatic cells of existing persons turning them first back to the embryonic stem cell stage. Moreover, direct derivation of human sperm cells using iPS technology has been described recently (Yao et al., 2011), and attempts to create mammalian oocytes (Imamura et al., 2010) are in the way. Therefore, the destruction of an existing embryo may be not needed any more for human reproductive cloning. These developments have not, however, ended the ethical debates over the issue (see below).

From the description of these laboratory techniques, which have been tremendously advanced over the last decade, one can make two conclusions important in the context of ethical and legal discussion over human reproductive cloning. First, SCNT is not the only possible method for human cloning – several other techniques are existing and upcoming. Second, there are alternative methods of mammalian reproductive cloning, which do not require destruction of any existing embryos.

Arguments Supporting and Opposing Human Cloning

By using the SCNT technique, the new individual roughly copies the genome (nuclear DNA) of the donor and is not a combined product of two parental genomes, which is the case in regular sexual reproduction. It has been pointed out (Häyry, 2003) that part of the opposition to human cloning has been created by misconceptions about the procedure. The popular belief is that through this process the copies of existing human beings are created. This is not so. "Genetically speaking, it comes very close to creating a later identical twin to an already existing individual. Socially and psychologically speaking, it produces an entirely new individual,

whose biological features just happen to be quite similar to somebody else's" (Häyry, 2003, p. 449).

Sören Holm indicates that the problem is in widely believed genetic essentialism, a concept that a person's character is wholly determined by genes, and in the fact that popular media amplifies this misconception (Holm, 1998).

Following is an overview of the main arguments used in the human reproductive cloning debate.

Arguments Used in Favor of Human Cloning

Reproductive Freedom

This includes not only the familiar right to choose not to reproduce (e.g., by using contraceptives or abortion) but also the right to reproduce. The right to reproductive freedom should therefore include various artificial reproductive technologies, such as *in vitro* fertilization (IVF), surrogacy, or cloning (Brock, 2001). Brock is of the opinion that "the reproductive right relevant to human cloning is a negative right, that is, a right to use assisted reproductive technologies without interference by the government or others when made available by a willing provider" (Brock, 2001, p. 95). "The case for permitting the use of a particular means of reproduction is strongest, however, when that means is necessary for particular individuals to be able to procreate at all" (Brock, 2001, p. 96). Takala underlines that the right to start a family is one of the internationally acclaimed human rights. However, it is not always clear who possesses the right to reproduce – this notion has been interpreted in different ways (Takala, 2005). For example, due to developments in iPS technology it could soon be possible for couples of the same sex to have offspring. Takala also points out that there is no general positive right for everyone to have children, but is of the opinion that in the modern world the right to reproduce has been seen as a liberty right, and therefore it would be plausible to argue that there is no public duty to fund research on human cloning, but nobody should interfere with privately funded attempts to clone humans. Havstad has recently pointed out that commitment to autonomy simultaneously creates an obligation to limit that right appropriately (Havstad, 2010).

Norman Daniels and Dan W. Brock show that there are three main interests and values determining the moral importance of reproductive autonomy. These are self-determination, the contribution to individual good or well-being, and the principle of equality (Buchanan et al., 2001). The interest in self-determination stems from the desire to make decisions about one's life. Such decisions should be based on the values and concepts of good life that one follows and be respected by others. Daniels and Brock specify that the realization of reproductive autonomy means the creation of a new person and the possibility to choose what kind of children one wishes for.

According to Onora O'Neill, the reproductive choice, being important to people, should not be seen as a freedom of expression. She finds that ideals of personal autonomy or self-expression are not good starting points for thinking about

reproduction because the aim of reproduction is to create a dependent being and "reproductive decisions are irresponsible unless those who make them can reasonably offer adequate and lasting care and support for the hoped-for child" (O'Neill, 2002). She is also concerned about confused relationships created through reproductive cloning. No responsible parent, she argues, would want to put a lifelong additional burden of confused relationships on their child. O'Neill finds that a possible solution to this problem would be cloning from the child of the same couple or using oocytes and sperms (genetic material) from strangers. At the same time, Takala has claimed that due to changes in family life, the traditional model with two parents of opposite sexes and their own genetic offspring is outdated. She is of the opinion that "it is the socio-political atmosphere that determines how these methods, and in the future possibly cloning, are used and not the technology that determines the socio-political views" (Takala, 2005). Due to the well-known fact that moral acts are acts in the interest of others, there should be a limit for egoism and self-love in order for the society to be able to function. This means that it is difficult to condone the use of cloning when there are realizable, safer, and simpler methods for reproductive choices. Holm adds that as long as genetic determinism prevails, cloning should not be permitted (1998). There is a real threat that expectations will not be fulfilled and the result would be hard to endure. Indeed, many experiments with cloned animals have shown that the "clones" can differ considerably in both character and appearance. It is important that we set the position of the future possibly cloned human being in the center of the discussions concerning human reproductive cloning. This should help us to better understand the possible negative impacts, such as how life in shadow (Holm) and constant psychological harm (Havstad) may impact the cloned human being.

Relief to the Problem of Infertility

Cloning would allow infertile persons/couples to have biologically related offspring. This purpose of reproductive cloning has been pointed out by the President's Council on Bioethics (PCB, 2002, p. 79). Typical situations in this case would be women producing no functional ova or men producing no sperm (Brock, 2001). Recent work mentioned above provides new solutions to male infertility through the use of iPS cells (Yao et al., 2011). "While the moral right to reproductive freedom creates a presumption that individuals should be free to choose the means of reproduction that best serves their interests and desires, the benefits from human cloning to relieve infertility are greater the more persons there are who cannot overcome their infertility by any other means acceptable to them" (Brock, 2001, p. 98). Although there are other possible solutions, e.g., adoption, it is important for many to be biologically related to the child. It is possible to have a biologically related child with other forms of assisted reproduction. That said, according to Brock, cloning could be accepted only if it is the only means to overcome infertility. The counterargument would be that this is a temporary solution, as the biologically related child may also have fertility problems. Which raises the question of what should be more important – biological ties or the health and quality of the child's life?

Cloning Avoids the Transmission of Diseases

If one partner has a risk of transmitting a serious hereditary disease, cloning could be used in order to avoid the transmission. The avoidance is also possible using other methods than human cloning, but these might be not acceptable as they involve genes from a third party (Brock, 2001). Takala has pointed out the possibility of human cloning to avoid certain mitochondrial diseases (2005). The purpose of avoiding genetic disease is mentioned as one of the main purposes for reproductive cloning also by the Report of the President's Council on Bioethics (PCB, 2002, p. 79).

Cloning Provides Organs and Tissues Necessary for Transplantation

Cloning would solve the problem of finding a donor with matching tissue or acceptable organ. The purpose of obtaining "reject-proof" transplants is also mentioned by the President's Council on Bioethics (PCB, 2002, p. 79). However, if cloning takes place with the sole purpose of saving another human being, this could be criticized based on the categorical imperative by Immanuel Kant. The second formula of the categorical imperative reads: "Act in such a way that you treat humanity, whether in your own person or in the person of another, always as the same time as an end and never simply as a means" (Kant, 1994, p. 36). Brock has, however, indicated that the problem here is more complex, asking why it is considered acceptable to have children with the purpose of not being alone or receiving financial assistance from the state (Brock, 2001).

"Bringing Back" People with Special Meaning

Classical example is the case when parents have lost their child. Parents should, however, take into account that the new child will not replace the lost one, that despite the same genes, this is a new child. Cloning would help to deal with the loss and go on with their lives (Brock, 2001). To "replicate" a loved one is a purpose of human reproductive cloning mentioned by the President's Council on Bioethics (PCB, 2002, p. 80). This argument also triggers the accusation of treating people merely as means, especially when the cloned person is not treated as a person of his/her own, but as a recreation of someone else. Takala brings to our focus that if one does not believe in genetic determinism and instead thinks that a person's uniqueness is a sum of different factors, many of which are nongenetic, then the aim of bringing someone back is wrong as it cannot be done (Takala, 2005). Murray adds that even if cloning would become safe and result in a healthy embryo, the outcome would not be the same person, whose genetic material was used. Moreover, there are no technological solutions to grief: cloning a deceased loved one is not the escape, as science cannot reincarnate the dead (Murray, 2009).

"Bringing Back" People with Great Talents, Character, or Other Qualities

Once again, one should not be fooled by genetic determinism stating that only the genes determine who a person is or what he or she is capable of. Take a hypothetical case of cloning Michael Jordan or Andrew Lloyd Webber (the names of the persons

are changed compared to those used by Dan W. Brock). One should take into account that although persons with great talent may be indeed created, it is not clear how similar they would be in capacities and accomplishments to the ones they were cloned from. The hope for exceptional accomplishment due to cloning is considered to be a reasonable ground for doing so (Brock, 2001). The report of the President's Council on Bioethics also mentions the purpose "to produce individuals of great genius, talent or beauty" (PCB, 2002, p. 80). However, the cloned Michael Jordan might have no interest in playing basketball and become an accountant instead. We should not forget that what made Michael Jordan great was "not merely his physical gifts, but his competitive fire, his determination, his fierce will to win" (Murray, 2009, p. 663).

Arguments Used Against Human Cloning

Human Dignity Objection

UNESCO Universal Declaration on the Human Genome and Human Rights states in article 11 that "practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted" (UNESCO, 1997). According to the UNU-IAS Report, "the concept of dignity is inherent in foundational UN texts that were written at the end of the World War II when there was political unanimity that abuses of war were against human dignity, and it was accepted that everyone knew what was meant" (Kuppuswamy et al., 2007, p. 9). The report also stresses the need to be clear about the elements of the debate. Careful attention should be paid to understand "whether opposition to cloning stems from concern for human dignity or respect for divine dignity" (Kuppuswamy et al., 2007, p. 11). Takala points out that it is often uncertain what human dignity actually is. According to her "dignity seems to be something that is given to humans by humans" and "dignity could be interpreted to lie in God's perception of us" (Takala, 2005 p. 55). Haugen writes that "the notions of human dignity have been nurtured in the natural law tradition, and subsequently confirmed and developed through the social teaching of the Catholic Church" (Haugen, 2010, p. 207) and that when clarifying the concept, it would be natural to refer to Catholic social ethics.

The Report of the President's Council also has a human dignity objection. The Council states that "Parents beget a child who enters the world exactly as they did – as an unmade gift, not as a product. Children born of this process stand equally beside their progenitors as fellow human beings, not beneath them as made objects. In this way, the uncontrolled beginnings of human procreation endow each new generation and each new individual with the dignity and freedom enjoyed by all who came before" (PCB, 2002, p. 105–106). This has also been mentioned as the "lessening the worth of an individual and respect for human life" objection in the literature. Returning to the wording used in the PCB report, this seems to indicate that begetting creates a child, but by cloning one obtains a made object, a product. This is seen as a violation of Kant's categorical imperative never to treat others merely as means to our ends (the humanity principle). It has been questioned

whether this is a fair objection, (e.g., Steinbock, 2009, p. 659). She is of the opinion that if the technology of cloning were safe, then the cloned child would not be a thing or object but a human being with human dignity, with the same human dignity as any other. It should be noted that what makes a child a product is designing the child (e.g., parents wanting a specific genome). Steinbock finds the idea that human cloning or reproductive technologies can violate human dignity puzzling. She explains that if dignity means acting with formal, grave, and noble bearing, then this sense of dignity has not much to do with the issues of reproduction. Dignity could also be understood in the Kantian sense as a requirement for respect for persons, that people should not be tortured, humiliated, or exploited. Steinbock finds that none of these concepts have anything to do with the ways how children are brought into the world.

According to Takala, it is debatable whether cloning violates the humanity principle any more than any other act of reproduction. She finds that in philosophical literature, arguments derived from the concept of human dignity are inseparable from the idea that we should not treat people as mere means. Takala is of the opinion that if the purpose of reproductive cloning is to "bring back a lost loved one" (Takala, 2005, p. 57) and the person will be treated not as a person of his/her own, then this would constitute treating him/her as a mere means and, therefore, a violation of the humanity principle.

The usage of the notion has raised much criticism. For instance, Ruth Macklin has claimed that dignity is a useless concept and that it means no more than respect for persons or their autonomy (Macklin, 2003). Ashcroft is of the opinion that "it is not immediately obvious whether dignity is something that admits of degrees, whether it is alienable or not from its possessor, whether an assault on dignity or a bearer of dignity is something that destroys dignity or whether it is a sort of insult to dignity" (Ashcroft, 2005, p. 679). Häyry is of the opinion that one cannot settle ethical disputes by stating that something is against human dignity. He gives five interpretations of the concept of dignity and shows that each yields different moral norms. These are the dignity of God, the dignity of reason, the dignity of genes, the dignity of sentient beings, and the dignity of important beings (Häyry, 2003).

Caulfield shows that international instruments rarely provide an operational definition of human dignity, and it is rarely explained whose dignity is infringed in the context of human reproductive cloning (Caulfield, 2003). He stresses that if human dignity is used as a blanket argument against human cloning, then it is much more difficult to reflect about the real risks and benefits. Caulfield and Brownsword are of the opinion that the use of the blanket justification of human dignity marks a departure from the traditional human-rights informed view of human dignity (which is to a large degree manifested in a respect for individual autonomy and self-determination) that has dominated bioethics debates for decades and that the policy-making role of human dignity becomes more questionable when it is used as a form of general condemnation (Caulfield & Brownsword, 2006). They are of the opinion that in a pluralistic society, the possibility should exist to debate all aspects that form the content of human dignity, and that without conceptual clarity, there is a danger that the notion will turn into a rhetorical slogan.

Right to Open Future/Life in Shadow

A cloned person would know or believes he/she knows too much about him/herself. The choices that the earlier person has made would always be present. This might cause the impression that the life has already been lived and determined so that the later person does not have the opportunity to make his/her own choices that would create his/her future (Brock, 2001). Holm points out that if the parents of the clone have a definite picture of how the clone will develop based on the development of the person who was cloned, this will have an impact on how the child will be raised. Whatever the cloned person does, his/her actions will be compared to the ones of the original, so there is no possibility for self-determination and for living one's life the way one wants to live it (Holm, 1998). Takala brings out the "life in shadow" argument: as long as people see clones as shadows of the originals, there is something wrong with human cloning (Takala, 2005). She suggests that a possible way to counter these problems would be to apply the right of genetic ignorance. This is a negative right, meaning that "the right-holder has no duty to know about her own genetic makeup, and that others have a duty not to inform her (against her own wishes). A right like this does not, however, obligate others to actively protect her from the information" (Takala, 2005, p. 62).

Psychological Distress and Harm to the Later Person

Knowing the choices already made by the earlier twin will cause psychological stress and harm, because the later twin may feel that his/her autonomy and freedom are diminished. Adding to it the knowledge of lack of individual uniqueness, the burden of the later twin is even higher. However, this should not be taken as a suggestion that it would be better not to exist at all, which is the only way to avoid these stressful circumstances and psychological harms (Brock, 2001). Holm argues that this harm can be avoided if all clones were adopted anonymously, so there would be no knowledge available to the social parents about the original. He is, however, skeptical about this argument because cloning is attractive to many exactly because of the idealized belief of recreating oneself (Holm, 1998). Havstad's objection to cloning is the threat of psychological harms to clones. These harms could result if the clones were forced to live the lives of those they were cloned from, thus violating their self-determination (Havstad, 2010).

Unacceptable Health Risks to the Clone

The success rate of cloning Dolly the sheep was frustratingly low, less than 1 %, and it has not been considerably improved since then. Clearly, additional animal research should be carried out before one could approve the use of this technique on humans. It is questionable how to make sure that the process of cloning humans is safe and effective and whether the procedure will ever be safe and effective enough to meet the criteria of ethical standards (Brock, 2001). The report of the President's Council on Bioethics "Human Cloning and Human Dignity: Ethical Inquiry" elaborates on the topic of the ethics of human experimentation and details the problems of safety: for the child, the egg donor, and the birth mother (PCB, 2002, p. 87–99). The problem of safety is not a temporary ethical concern, but it is

not an objection to cloning as such (PCB, 2002, p. 96). Takala also argues that in terms of research ethics, research into human cloning cannot be justified because this technique cannot be tested on other mammals due to different reactions in practice. At the same time, no ethics committee would allow controlled trials on human cloning extending after the birth of the cloned person (Takala, 2005). The UNU-IAS Report points out that serious safety concerns apply to reproductive cloning. These are "the current immature state of cloning technology, the possibility of mutations, potential physical harm and general long term health risks" (Kuppuswamy et al., 2007, p. 13).

Human Cloning Would Divert Resources from More Important Medical Needs

The number of cases, where cloning would meet human needs, is relatively limited. Therefore, public funds should not be used to support human cloning and spent for other more pressing medical needs. After all, it is not known how expensive human cloning would be, especially in comparison with other methods to relieve infertility (Brock, 2001). Also it has been argued that funds for human cloning research could be used for more pressing issues such as infant mortality and diseases, e.g., HIV/AIDS (Kuppuswamy et al., 2007, p. 13).

Effect on the Human Gene Pool

Cloning could reduce genetic diversity and hence our capacity to adapt to new environmental conditions. Brock does not consider this to be a realistic concern because human cloning would not be used on a wide enough scale, as people would prefer sexual means of reproduction and maintaining their own biological ties (Brock, 2001). Takala is of the same opinion that cloning would not threaten the human gene pool even if it one day became an acceptable method of reproduction (Takala, 2005). If new developments make it possible to use combined genetic material from both parents, this argument loses its strength even more. This argument can also be seen as a part of the human dignity argument against cloning, as according to the Universal Declaration on Human Genome and Human Rights "human biological diversity is considered a fundamental part of human natural heritage, and diversity is recognized as part of the concept of human dignity" (Kuppuswamy et al., 2007, p. 12).

Moral Status

On the top of the arguments described above, one also has to discuss the issue of moral status. According to Warren (Warren, 2000), to have a moral status means to be morally considerable, or to have a moral standing. Moral agents have moral obligations toward such entities. This means that it is not possible to act or treat them as one pleases, but there is a moral obligation to take into account their needs, interests, and well-being as they have moral importance in their own right. Protecting these entities might benefit us or others, but this is secondary compared to the moral obligation (Warren, 2000).

Warren emphasizes that we need the concept of moral status to establish the entities, objects, and phenomena toward which we have moral obligations. She proposes the idea of many types of moral status, which come in varying degrees of strength. According to Warren, moral agents, sentient human beings who are not moral agents, sentient nonhuman animals, and non-sentient living things – all have legitimate claims to moral consideration. It is to be noted that of all these entities with which we interact, only moral agents have full moral status (based solely upon their mental and behavioral capacities). The rest have moral status, which is partially determined by their social and other relationships to moral agents (Warren, 2000).

However, the concept of moral status does not answer all the questions about the duties of human beings. Many of our duties are not dependent on the moral status of the persons toward whom we have an obligation but also on particular circumstances, e.g., earlier promises, personal connections, a new penal code, or previous wrongdoings, which imply that the harm needs to be compensated.

The concept of moral status represents only very general claims about how moral agents ought to behave toward entities of a particular sort. For example, by postulating that all human beings have a moral right to life and liberty, a claim is made that the moral status of human beings forbids harming them in certain ways if there is no good reason for it. Most interpretations also include the obligation to help in case of need and if there is no risk to oneself. An important feature of the concept of moral status is its generalness – moral status is not ascribed to specific individuals but to members of a group (Warren, 2000).

There are two main reasons why human beings need shared standards and principles of moral status that are based on arguments that most of them can understand and accept. The first is the capacity to do harm (in considerable amount and with the aid of technological advances), and the second is the capacity to care about other living beings (both human and nonhuman) (Warren, 2000).

The latter aspect shows that using merely exterior sanctions, one cannot assure moral actions. This is a notion that values interior sanctions and the inner motivation to be a moral actor. From the positive side, the concept of moral status is a tool, which allows expanding the minimum standards of acceptable behavior. Following lower standards than the minimum is not acceptable. Although one usually does not doubt the equal and full moral status of all human beings, if the focus is on embryos, embryonic stem cells, or induced pluripotent stem cells, there seems to be much less consensus.

It has been shown that if the argument remains at the level of the moral status of the embryo, there are different arguments and opinions (for instance, see the report of President's Council on Bioethics (PCB, 2002, p. 133–149)) and no room for achieving common ground and understanding. As reproductive cloning may become possible without using embryos, the focus here is on iPS cells. The technological developments that led to the production of iPS cells have been seen as an ethical breakthrough: the iPS cells enable the production of human pluripotent stem cells without the need for human oocytes. According to Chan and Harris, the anti-embryo research lobbyers have welcomed iPS cells as a source of "ethical stem

cells," in contrast to the so-called unethical human embryonic stem cells (Chan & Harris, 2008). Hyun draws our attention to the understanding that human iPS cells, if they are truly pluripotent, should be capable of generating also human sex cells. This would mean that ordinary skin cells could be transformed into human sperm and eggs, and this fact could radically alter our common sense notions of human fertility and infertility (Hyun, 2008).

Chan and Harris (2008) argue that it is incorrect to assume that derivation of stem cells without the destruction of embryos solves all the main ethical issues of stem cell research. The significance of the embryo as the starting point of human life and its status of moral relevance seem further threatened when any cell can be programmed to embryonic state. The situation, according to them, is ironic, as those who were concerned about the human embryo and its moral status, welcomed the new developments which may at the same time diminish its status. They elaborate on the status of skin cells reprogrammed to embryonic status and ask whether they are really embryos *in potentio*, just like an embryo is a person *in potentio*. The authors do not provide a direct answer to that, but they point out that those who value the embryo for its potentiality might feel obliged to value all cells that might be reprogrammable for the same reason. They suggest that this kind of thinking will lead to asking whether there is an obligation to release the potential contained in each cell by reprogramming them so that every skin cell can experience its future of value! Their own position is that human embryonic research is ethical as it takes place on embryos less than 14 days old. At that point, an embryo is not a subject of rights or interests and cannot be harmed. Based on analogy, we could draw the conclusion that reprogrammed skin cells cannot be hurt or harmed either.

According to Magill and Naeves, the scientific breakthrough of iPS cells raises a different ethical question: that of the philosophical meaning of cellular development in early human life. "The science of direct nuclear reprogramming may shed light on the ontological status of cells in the early stages of what could become a human foetus and thereby contribute to the justification of research in this controversial field" (Magill & Naeves, 2009, p. 24). Numerous cells in the human body have a biological capacity or natural potential, with appropriate help and supportive circumstances, to become a fetus and possibly be born as an individual person. "Because it is technologically possible to develop a foetus from reprogrammed human cells, the question of their ontological status arises with ensuing ethical implications for research. By ontological status we mean the assignment of either personal or potentially personal life in the sense of having full moral respect" (Magill & Naeves, 2009, p. 26).

Holm argues that no implications for the debate arise from the moral status of the embryo. He is of the opinion that nothing in these research results can affect the positions of the persons who believe they have good arguments for supporting their opinion, being it either that the embryo has no moral status at all or that it has considerable moral status. Holm draws the line between embryonic stem cells (artificially derived from an embryo) and the cells naturally inside a blastocyst. He is of the opinion that "it might mischievously be argued that the results show that every somatic cell is potentially an embryo, thereby constituting a *reductio* of

the moral status argument, because the methods allow the production of pluripotent cells from somatic cells, but the argument is fallacious" (Holm, 2008, p. 63). He stresses that it is important to understand that embryonic stem cells are cells derived from embryos, not embryo cells.

Baerschi and Mauron discuss a property called "reversed potency," i.e., the capability of somatic cells to return to a pluripotent state in a controlled way. This necessitates the reexamination of the role of the traditional concepts of potentiality and capability. Their understanding is that moral status must refer not only to intrinsic properties but also to extrinsic and relational properties (Baerschi & Mauron, 2010). If the focus is only on the intrinsic properties, then the conclusion we have to draw is that all somatic cells are potential persons. The role of relational properties is relevant because these properties affect the emergence of intrinsic properties important for moral status. Moral status of a cell emerges when a cell induced (reversed) to its pluripotency (or totipotency) is placed into uterus. Their understanding is that iPS cell does have a low moral status insofar as they are used in cell therapy in humans and not for producing humans by introducing them into human blastocysts (2010, p. 102).

In the following, the initiatives on both national and international (UN and UNESCO) levels to regulate and govern the issue of human reproductive cloning will be described.

National and Regional Regulations for Human Cloning

Numerous domestic laws and regulations that directly or indirectly prohibit practices that may lead to reproductive human cloning have been in place for many years. A detailed overview of the legislation as in 2009 is available as annex to the *Report of IBC on Human Cloning and International Governance* (IBC, 2009). These national regulations are diverse and reflect different cultural, religious, social, and political backgrounds of different countries. Together they constitute "general principles of international law" under article 38 (3) of the Statute of the International Court of Justice.

At regional level, the Council of Europe has approved *Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings* (Council of Europe, 1998). As a convention, this instrument creates binding international law obligations, but only for those State parties that have signed or ratified it. Article 1 of the Additional Protocol enunciates that "any intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited"; and that "for the purpose of this article, the term human being 'genetically identical' to another human being means a human being sharing with another the same nuclear gene set." This definition is ambiguous because the commonly used method of reproductive cloning (SCNT) does not create genetically identical organisms: the content of mitochondrial DNA is different, and there are numerous epigenetic differences and those created by individual developmental processes (see above).

The above-mentioned national and regional regulations cannot be considered as sufficient in addressing the global challenges posed by the contemporary developments related to human cloning for the following reasons:

(a) The norms contained in these instruments pose clear conceptual problems: they are often mutually inconsistent, vague, and expressed in scientifically inaccurate terminology.
(b) The declarations do not constitute international legal obligations enforceable either by states or individuals.
(c) The existing instruments may have unintended consequences of either inhibiting socially valuable medical research or encouraging prohibited practices for profit.

Internal Governance of Human Cloning

The following regulatory acts for international governance of human cloning are in existence today:

Universal Declaration on the Human Genome and Human Rights (UNESCO, 1997). Article 11 of the Declaration states that "Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted. States and competent international organizations are invited to co-operate in identifying such practices and in taking, at national or international level, the measures necessary to ensure that the principles set out in this Declaration are respected."

Universal Declaration on Bioethics and Human Rights (UNESCO, 2005). Article 16 specifies that "the impact of life sciences on future generations, including on their genetic constitution, should be given due regard."

United Nations Declaration on Cloning (2005). The Declaration, adopted by the general assembly with a narrow margin (see below), states that "Member States are called upon to prohibit all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life." On its face, this norm is broader in scope than that of the UNESCO Declaration (1997) and could cover forms of genetic research that are treated as fully legal by legislation in many domestic legal systems. Moreover, the wording of the document leaves room for very different interpretations of the text, which reflected, in part, the lines of division between different Member States on this issue. The main point of contention was the question of linking the issues of reproductive and nonreproductive cloning, which was not agreeable to many States, who abstained or voted against the Declaration.

World Health Organization Resolutions WHA50.37 (1997) and WHA51.10 (1998). These resolutions, which, again, do not create obligations under international law, call to "foster continued and informed debate and take appropriate steps, including legal and juridical measures, to prohibit cloning for the purpose of replicating human individuals."

In August 2001 in the United Nations General Assembly, the Permanent Missions of France and Germany requested the secretary-general to include

a supplementary item in the agenda of the 56th session entitled *International Convention against the Reproductive Cloning of Human Beings*. An international convention would be, after ratification, legally binding to the Member States. The German representative at the Sixth Committee (legal) of the General Assembly called for the mandate to be "focused, by narrowing down the issue to the cloning of human beings for reproductive purposes in order to win a speedy consensus that would deter irresponsible researchers."

At the same meeting, the observer from the Holy See, however, argued that action must also be taken to prohibit the production of human embryos as suppliers of specialized stem cells. He observed that in the view of the Holy See, embryos have a status equal to human beings, and therefore the destruction of innocent human beings for the purpose of collecting stem cells "constituted even more serious offences against human dignity and the right to life." The irreconcilable differences on the issue of many other forms of human embryo manipulation loosely defined as "research cloning" or "therapeutic cloning" and their linking to the issue of prohibition of human reproductive cloning accompanied all further discussions over this proposal from the French and German delegations.

Almost 4 years later, in the face of the political stalemate, members of the United Nations agreed to abandon efforts to put in place an international convention for the prohibition of human reproductive cloning. The Sixth Committee (legal) of the General Assembly was tasked with drafting a declaration rather than a convention.

The *United Nations Declaration on Human Cloning* was adopted on 8 March 2005 (A/RES/59/280). The Declaration was voted and passed with 84 countries supporting it, 34 countries voting against and 37 abstaining. The wording of the document left room for very different interpretations of the text, which reflected the lines of division between different Member States on this issue. The main point of contention was the question of linking the issues of reproductive and nonreproductive cloning, which was not agreeable to many States, who abstained and voted against the Declaration.

The journal *Nature Cell Biology*, in its editorial "Missed opportunity to ban reproductive cloning" (April 2005) wrote: "At a critical time, the UN has thus failed to send a clear message that human reproductive cloning is unacceptable. It is lamentable that this salient issue has fallen victim to a debate that is driven by political agenda and religion-infused ethics, rather than rational thinking that puts the patient's interests first" (p. 323).

In 2007, the United Nations University Institute of Advanced Studies (UNU-IAS) produced a report entitled *Is Human Reproductive Cloning Inevitable: Future Options for UN Governance*, which summarized up-to-date technical information on cloning, ethical issues accompanying it, and the state of the art of international governance of these issues, specifically analyzing the discussions during the 4 years of United Nations General Assembly debate leading to the voting on the United Nations Declaration of Human Cloning. The report expressed the view that further development of international governance would be needed and envisaged several options along this line. One of possible options to further develop international governance was identified by UNU-IAS as "UNESCO IBC takes up the issue of reproductive and

research cloning, in the context of resolution A/RES/59/280 and also in the context of the Universal Declaration on Bioethics and Human Rights, which was adopted by the General Conference of UNESCO on the 19th of October 2005."

After that, the director-general of the UNESCO expressed his wish that the examination of the UNU report be added as an agenda item for discussion by UNESCO International Bioethics Committee (IBC) at its session(s). At its meeting in January 2008, the Bureau of IBC therefore decided to include the discussion of the UNU report and the issue of human cloning and international governance to the work program of IBC for 2008–2009. The IBC Working Group chaired by professor Toivo Maimets was established, which presented their findings to the IBC. The mandate of the Working Group was ". . .to explore whether there is any scientific, social or political change that would justify a new initiative at the international level, rather than to initiate another ethical and scientific analysis of the issue of human cloning." As a result of their work, the Working Group identified several changes, which would indeed justify new initiatives in the international governance of human cloning:

1. There are new scientific developments, which make the need for international governance more urgent. On one hand, the construction of induced pluripotent stem (iPS) cells and their possible uses has created more technical possibilities for reproductive manipulation of human embryos and hence brings new problems into the debate. Since it has been demonstrated that functional germ cells may be created from embryonic stem cells, this raises the possibility of creating germ cells from somatic cells (via iPS cells) which further blurs the borders between different stages of human development and reproduction. On the other hand, it is clear to scientists that "cloning" in the sense of producing identical human beings is impossible because of differences in developmental and environmental conditions, epigenetic modifications of the DNA involved, etc. In addition, it is scientifically clear that in the current state of technology, reproductive cloning is associated with serious health risks for both women and fetuses.
2. During the last 3 years since the adoption of the United Nations Declaration on Human Cloning, the public sensitivity and awareness of the issues has increased, whereas the information and dissemination of the issues could be improved.
3. Several Member States have recently updated their national regulations of governance of human cloning and embryo research in general, and therefore there is more awareness and information among politicians in these countries.
4. The financing of human embryo research has considerably increased over recent years, whereas more and more multinational commercial private interest is being involved. This is accompanied by international traffic (both legal and illegal) of embryos, eggs, and stem cells.
5. If the argument remains at the level of the moral status of the embryo, there is no room for achieving consensus. Also, as detailed above, reproductive cloning may become possible without using embryos. So there is a clear need to move to ethics of international governance of cloning, where different countries can find agreement, e.g., a ban on reproductive cloning.

Based on these findings, the Working Group was of the position that the issues surrounding human reproductive cloning cannot be ignored, and therefore a focused international dialogue considering a binding instrument against reproductive cloning was needed.

In June 2009, the IBC approved a *Report of IBC on Human Cloning and International Governance*, which was also supported a month later by UNESCO Intergovernmental Bioethics Committee (IGBC).

The IBC agreed with most of the findings of the Working Group. In particular, the Report states that "While the technology required to give birth to a human being by cloning is not yet available, it could be developed in the near future and the existing international non-binding texts relevant to human cloning (i.e., the UNESCO Universal Declaration on the Human Genome and Human Rights of 1997 and the UN Declaration on Human Cloning of 2005) are not sufficient to prevent human reproductive cloning" (IBC, 2009, p. 7).

Proposed by the Working Group, an international ban or moratorium for human reproductive cloning did not, however, find unanimous support from the IBC, neither during the approval of this Report nor at its later 18th session in 2011. Therefore, we are still in a situation where there is no internationally binding regulation of human reproductive cloning, which leaves the doors open to different kinds of "medical tourism" and makes especially vulnerable less developed countries, which have not yet introduced their national regulations. At the same time, technical developments bringing in new possibilities for human cloning are emerging with considerable speed.

Conclusion

Scientific research and technical possibilities for human reproductive cloning have been rapidly developing over the last two decades, and the current progress is even more active. Here the analysis of the present status of these developments and the main arguments speaking for and against the use of human cloning is presented. The most common arguments used in the discussions in support of human cloning are the right to reproductive freedom and the possibility to provide organs and tissues necessary for transplantation. The most common arguments against human cloning are human dignity, psychological harm, and the "life in the shadow" argument. As the new technical developments have brought again to the debates the issue of moral status, the main positions of this topic were also outlined.

The vast majority of countries, which have regulated the issue in their legislation, have supported the arguments against of human reproductive cloning and, therefore, the ban of this activity. There are, however, many countries, especially less developed ones, who have not introduced this position in their laws, which makes them vulnerable to different types of "medical tourism." The international actions at the level of UN and UNESCO have so far been not successful and need to be continued further.

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Immigrants and Displaced Persons

42

Lindsey N. Kingston and Christopher P. Morley

Introduction

Migration, whether that entails crossing an international border or fleeing to another part of the same country, often creates vulnerabilities that limit or deny the enjoyment of the human right to health. Even temporary migration may cut a person off from social systems, both formal and informal, which supported them and kept them healthy. Crossing international borders and entering a state where one is not a citizen will often lead to dramatically decreased levels of social support. This may be even more pronounced when a person is crossing a border for the long term (emigrating) and especially when they are moving to flee from violence, oppression, economic degradation, or other negative circumstances. While this vulnerability applies to a number of dimensions, certainly health is high among them. Although a "right to health" has been codified in international law, it is almost always the case that nation-states are ultimately the arbiters of international law (Gostin & Taylor, 2008). It is this fact that leaves those who are not clearly protected as members of a given society without full – or in some cases, any – ability to access the right to health. Migrants, including both those who cross international borders as well as those who are internally displaced across internal regions within a nation-state, are the focus of this entry.

The universal right to health has been identified and described as a right to "the highest attainable standard of health" that can reasonably be afforded, which includes not only a right to healthcare but to social and environmental precursors of health, such as clean food and water, housing, and security (Gostin, 2001;

L.N. Kingston (✉)
Department of History, Politics, and International Relations, Webster University, Saint Louis, MO, USA
e-mail: lkingston54@webster.edu

C.P. Morley
Department of Family Medicine, Department of Public Health and Preventive Medicine, Department of Psychiatry and Behavioral Sciences, S.U.N.Y. Upstate Medical University, Syracuse, NY, USA
e-mail: morleycp@upstate.edu

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Kingston, Cohen, & Morley, 2010). The right to health has been codified by international law, under Article 12 of the Universal Declaration of Human Rights (General Assembly of the United Nations, 1948). In general terms, the right to health has been posed as a fundamental issue of distributive justice, which Daniels and others have recognized as "special" in that it protects normal functioning and hence the range of opportunities open to individuals within a given society (Daniels, 2001; Daniels, Kennedy, & Kawachi, 2007; Green, 1983; Moskop, 1983). The focus on justice is particularly poignant when a consideration of the social determinants of health is taken into account, since it is generally true that the less well-off one is within a given context, the poorer one's health tends to be.

Enforcing such a right, however, has been empirically thorny. Within given societies, the argument often becomes one between those who view healthcare and other goods that are associated with health as commodities and those who view these items as public goods. However, most societies tend to provide at least some level of access to healthcare and do so within the parameters established by laws within given jurisdictions that apply principally to established members of the society (i.e., the citizens or otherwise-recognized permanent residents of a nation-state or other political entity). A distinct problem arises when people move across borders.

There are several categories of migrants that warrant consideration. An individual may cross an international border for a variety of reasons, and these reasons matter. A physician or an engineer who emigrates for more lucrative opportunities is certainly not in the same category as a person running from deprivation to a situation in another nation-state that is simply less desperate. Similarly, those who emigrate via documented (i.e., "legal") pathways are often in different empirical circumstances than those who do so "illegally." Economic refugees of any stripe are in many ways different than political or conflict-driven refugees, and the internally displaced person faces different challenges than the international border crosser.

Given these categorical differences as well as the disparity between the moral underpinnings of a right to health and the empirical ability to exercise or realize it, it is necessary to consider the empirical issues that arise in each category. The entry will begin by defining each category and describing the distinct challenges faced by each. The entry will then conclude with a summary discussion of the most pressing ethical issues posed by migrant rights to health and the lack of access many face to this right.

Characteristics

Defining the Right to Health

Article 25 of the 1948 Universal Declaration of Human Rights (UDHR) asserts that "everyone has the right to a standard of living adequate for the health and well-being of himself and his family," including medical care. Article 27 bolsters this

assertion with a statement that all people should "share in scientific advancement and its benefits." This foundation has been built upon since 1948 in a number of international agreements. In 1976, Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESR) recognized the right to the "highest attainable standard" of health, including the reduction of infant mortality as well as the prevention, treatment, and control of disease. More recently, the 2005 UNESCO Universal Declaration on Bioethics and Human Rights asserted a fundamental human right to "the enjoyment of the highest attainable standard of health," and that "access to quality health care and essential medicines" is required "because health is essential to life itself and must be considered to be a social and human good." Furthermore, the UNESCO Declaration argues that "the promotion of health and social development for their people is a central purpose of governments that all sectors of society share." Approaching health through a human rights frame, then, ultimately serves to elevate healthcare from a market commodity to a basic entitlement.

A central challenge for the protection of health rights is inequality, both at the international and national levels, and this challenge implicates the medical community. As Farmer has noted, "in arguing that health care is a human right, one signs on to a lifetime of work dedicated to erasing double standards for rich and poor. . . It has taken years for the sharp critiques voiced by the poor to begin to work their way into our medical journals and ethical codes." Farmer goes on to argue that "allowing 'market forces' to sculpt the outlines of modern medicine will mean that these unwelcome trends will continue until we are forced to conclude that even the practice of medicine can constitute a human rights abuse"(Farmer, 2003). The impacts of inequality – between the rich and poor, the marginalized and empowered – have become a matter of life and death in many cases, as biomedicine offers revolutionary new therapies that were impossible even a few decades ago. In a system which views health and healthcare as a market commodity, in which healthcare is distributed to those who can afford it, some of the individuals most in need of healthcare will have diminished access. As the following discussion will highlight, vulnerabilities related to migration often limit or deny people access to their right to the health.

Defining Migrant Categories

Immigrants fall into one of three principal legal status groups: naturalized citizens, legal permanent residents, and undocumented immigrants. The term *undocumented immigrants* refers to foreign-born people who reside in a country but are not legally recognized residents. These people are sometimes referred to as *unauthorized immigrants, illegal aliens*, or *illegal immigrants*. As immigration policies within Western countries continue to restrict and delay immigrants' ability to adjust their status, it is likely that undocumented immigration will increase. Many so-called "legal" immigrants, however, either become naturalized citizens in their new country or gain permanent residency status (e.g., procuring a "green card" in the United States) to remain in-country without transferring citizenship. What is

common among these three categories is the fact that immigrants tend to make a relatively autonomous decision to migrate.

On the other hand, a displaced person is someone who has been forced to leave their home, often because of war or the fear of persecution, in what is commonly referred to as *forced migration*. Displaced persons fall into one of two key categories: refugees and internally displaced persons (IDPs). A *refugee* is someone who has fled across international borders and is at risk for persecution or has already been a victim of persecution, in their country of origin. Refugees are protected by various international legal instruments, including the 1951 Convention Relating to the Status of Refugees. The United Nations High Commissioner for Refugees (UNHCR) identified 10.4 million "refugees of concern" in early 2011, with an additional 4.7 million registered refugees living in Palestinian camps throughout the Middle East (UN High Commissioner for Refugees). IDPs are those who have been forced to relocate within the borders of a sovereign state. Although IDPs technically do not migrate, they nevertheless often are cut off from the exercise of a right to health, either because they have left a region or district which administers the right or because the state in which they are trapped is ungovernable, in the grips or a civil conflict, or is otherwise beset by internal strife. In late 2010, the Internal Displacement Monitoring Centre (IDMC) estimated that 27.5 million people had been internally displaced by armed conflict, generalized violence, and human rights violations, an increase of about 400,000 people since the end of 2009 (Internal Displacement Monitoring Centre, 2011). This group is comprised of civilians, mostly women and children, who have been forced to abandon their homes mainly due to conflict and persecution.

In many ways, IDPs are in a worse position, qua rights claimants, than refugees who have crossed an international border. Unlike refugees, who cross state borders and are protected by a strong body of international law, IDPs are often unable to access safeguards and assistance despite having fled their homes for many of the same reasons. Legally, IDPs are under the protection of the state, even though their governments may be responsible for their flight or have proven incapable of helping civilians. The UNHCR notes that governments often view IDPs as enemies during times of civil conflict, and there are no international legal instruments to assist the displaced. General agreements such as the Geneva Convention are difficult to apply, and donors are often reluctant to intervene in domestic conflicts or offer sustained assistance. The UNHCR's Guiding Principles on Internal Displacement outline the rights of IDPs and the responsibilities of governments in accordance with international law, but the nonbinding document does not provide adequate enforcement provisions to be effective. While the refugee is endowed with the right to seek asylum and access assistance, an IDP lacks those options.

Health Challenges

Immigrants

International migration control is at the forefront of Western political debates, and growing anti-immigrant political ideology has resulted in formal obstacles to

immigrant access to health insurance. Within the United States, for example, recent policy changes such as the 1996 Personal Responsibility Work Opportunity Reconciliation Act (PRWORA or "welfare reform") have restricted immigrants' eligibility for federally funded services such as Medicaid, and many state legislatures are considering a record number of anti-immigrant measures that may further restrict immigrants' access to healthcare (Derose, Bahney, Lurie & Escarce, 2009). When President Barack Obama spoke to Congress and the public about his healthcare reform proposal in September 2009, he was sure to emphasize that the proposal would exclude undocumented migrants (thereby eliciting the now-famous "You lie!" interjection). Indeed, the Patient Protection and Affordability Care Act signed months later by Obama does not cover the near 11 million undocumented migrants in the United States (Galarneau, 2011).

Lack of health insurance, whether public or private, is a formal obstacle to health found within immigrant populations in Western countries. A recent pilot project in Montreal, Canada, suggests that access to healthcare is increasingly difficult for undocumented (and often uninsured) families and that this issue has become a national problem within Canada. Both healthcare workers and community organization workers alike reported that many, if not most, patients with "precarious" immigration status presenting with acute health crises had delayed seeking care. Consequences include shortcomings in treatment and poor follow-up for chronic conditions such as hypertension and diabetes, problems of access to treatment for tuberculosis and HIV, worsening mental health problems, and serious complications related to perinatal care (Rousseau et al., 2008). Evidence from the United States supports this trend, linking immigrants' lack of medical insurance with lower quality and quantity of medical care use and with morbidity for adults and children. Noncitizens and their children are less likely to have health insurance and a regular source of care, have lower use than the US born, and be less satisfied with healthcare and more likely to face discrimination when accessing medical services.

Ultimately, immigration status – whether someone is undocumented, naturalized, or a permanent resident – strongly affects access to health insurance or other coverage, especially in public programs. Noncitizens are the least likely to have employer-sponsored insurance, followed by naturalized citizens and the US born, and immigrants tend to work for employers that do not offer health insurance benefits (Derose et al., 2009). However, it is important to note that some undocumented immigrants do receive employer-based health insurance; The Migration Policy Institute estimated that in 2007, 59 % of undocumented adults in the USA had no insurance (four times the rate of US-born adults) while 55 % of their children were uninsured (Galarneau, 2011). In Denmark, for example, a study by Jensen and colleagues examined treatment of migrants by general practitioners and described how undocumented migrants face administrative barriers when trying to access healthcare, with lack of an insurance card limiting access to medical treatment. Respondents to the study explained that undocumented immigrants would not experience the same access to care as a native-born Dane or a regular immigrant and noted that immigrants without insurance cards were usually only treated in "very special circumstances," with most told to contact the emergency

room for treatment that would ordinarily occur in an outpatient primary care setting (Jensen et al., 2011, p. 4).

Following lack of health insurance, many immigrants also lack a regular source of healthcare. In the United States, adults 55 years or older with limited English proficiency are 1.86 times more likely lack a usual source of care than their English-speaking counterparts. Among young adults aged 19–29 years, noncitizens are 1.35 times more likely to report no regular source of care than US citizens. Trends are similar among immigrant children; noncitizen children and those with non-English-speaking parents are two to five times less likely than US-born children and children with English-speaking parents to have a usual source of care outside of the emergency department (Derose et al., 2009). Many undocumented immigrants who do receive health services receive them from "safety-net providers" such as community health centers, public health clinics, emergency departments, and outpatient clinics (Galarneau, 2011). In Denmark, undocumented immigrants do not appear on the National Register of Persons and are therefore unable to formally access general practitioners in the general healthcare system. Although foreign citizens have the right to access emergency services, undocumented immigrants lack access to regular sources of healthcare and are forced to settle for less treatment compared with that of native-born Danes. They have no formal access to further diagnostic facilities and very restricted possibilities of follow-up care, and medical conditions often worsen as immigrants delay treatment until they are ill or injured enough to seek out emergency treatment. Furthermore, undocumented immigrants often cannot access prenatal care, regular supplies of medication for chronic illnesses, and mental healthcare options (Jensen et al., 2011). The experiences of migrants seeking healthcare in the USA and Denmark, as described in the studies cited above, are generally representative of migrants globally and certainly in the health systems of most of the developed world.

In addition to these formal obstacles to health, immigrants also face a variety of informal obstacles such as language barriers. Within the United States, where there are currently few financing mechanisms for implementing national standards for culturally and linguistically appropriate services (Derose et al., 2009), adults with limited English proficiency are more likely than English-proficient speakers to report difficulties getting care, such as long waits and problems getting information or advice by telephone. Language barriers are often related to a substantial reduction in the odds of receiving mental health services. Again, in Denmark, health professionals note that language barriers pose problems for themselves and undocumented immigrants. Healthcare work is complicated when patients cannot describe their symptoms, creating difficulties for the physician and stress for the immigrant. As described by a health professional responding to the study by Jensen et al., "if [the patient] showed up, one would assume that he had an acute need, that he was in real pain, or he thought that it was life threatening. Not being able to get a proper explanation or have his worries interpreted would add to his anxiety and fear" (Jensen et al., 2011).

The foreign born are also more likely to report discrimination and lower quality of healthcare, particularly those with limited language proficiency or those who are

nonnative/majority. Such perceived discrimination discourages some from seeking medical attention or delays treatment. In the USA, parents with limited English skills are more likely than parents who speak English at home to report facing discrimination while seeking care for their children. Undocumented Latinos and those with a green card are more likely to feel that they would receive better care if they were a different race or ethnicity, as well. Perceived quality of care is another factor that sometimes impacts immigrants' access to health. The foreign-born often report lower quality healthcare than the US born, and immigrant respondents in both the United States and Canada have lower odds of reporting excellent quality of care. Immigrants also report dissatisfaction with how much their physician spent time with them or involved them in their own care. Latino and Asian immigrants are also less likely to indicate that their general and mental health services were helpful, compared to their US-born counterparts (Derose et al., 2009).

Other informal barriers to immigrant health involve health practitioners themselves, who struggle with issues related to compensation, referrals and continuing care, and police involvement. Again, the qualitative study of Danish general practitioners and emergency room physicians conducted by Jensen et al. reported that challenges for healthcare professionals could translate into obstacles for immigrant patients (Jensen et al., 2011). The majority of general practitioners, for instance, were uncertain whether they would provide treatment if a patient were unable to pay. In particular, physicians noted that problems would arise if they had to involve finances outside of their own practice, such as the use of laboratory facilities or prescription drugs. One general practitioner responding to the study described that she would refrain from referring undocumented immigrants because she would not be able to assess the financial consequences of this action. Others were hesitant to prescribe medicine for undocumented immigrants, since the patient may not wish to have the prescription made out in his/her own name or may be unable to purchase the prescription at a pharmacy. Finally, some practitioners were unsure about the legal implications of treating undocumented immigrants. Despite this uncertainty, however, the Danish interviewees expressed in general that they would not involve police or authorities to report an undocumented immigrant who contacted them for treatment. It is reasonable to assume, however, that fears of police involvement could keep some undocumented immigrants from seeking medical treatment.

Unsurprisingly, formal and informal obstacles often result in lower levels of healthcare use among immigrants. Existing literature suggests that noncitizens in the United States are less likely than citizens to seek emergency care, see a physician or a nurse, use mental health services, or have a dental visit. In terms of preventative care, immigrants and non-English speakers are less likely to receive cancer screening than the US born, with immigrants at highest risk of underuse. Other types of preventative care seem to follow similar patterns. Spanish-speaking Latinos are half as likely to receive the pneumococcal vaccine and endoscopy compared to US Whites, and foreign-born children (19–35 months old) had similar odds of having adequate vaccination coverage compared to US-born children (Derose et al., 2009).

Refugees

The health-related priorities of the United Nations High Commissioner for Refugees (UNHCR) highlight the most pressing challenges faced by refugees. Currently, the UNHCR provides public health and HIV programs to more than 10 million refugees and other "people of concern," with the aim of reducing mortality and morbidity while addressing root causes of public health concerns. According to a recent report, the UNHCR focuses on three issue areas in order to protect the health rights of refugees living in both camp and urban settings: (1) HIV/AIDS and reproductive care, (2) water, sanitation, and hygiene promotion (WASH), and (3) nutrition and food security. First, the UNHCR recognizes particular concerns related to HIV/AIDS and reproductive health due to instances of gender-based violence and the prevalence of sex work within some refugee communities. Key protection concerns include the need for HIV testing and counseling, which often requires special guidance for medical professionals and patients alike in areas where stigma and discrimination against HIV patients are high. The UNHCR continues to strengthen linkages between reproductive health services and HIV prevention, including offering information to new mothers on issues such as breast feeding and HIV exposure. Health professionals are also encouraged to offer post-rape services, and the number of rape survivors having access to postexposure prophylaxis increased from 53 % in 2008 to 88 % in 2009. The number of survivors having access to emergency contraceptives within 5 days increased from 46 % to 69 %, and access to presumptive treatment for sexually transmitted infections increased from 72 % to 76 % (UN High Commissioner for Refugees, 2009).

Second, the UNHCR stresses that "access to water, sanitation, and hygiene promotion (WASH) is a fundamental human right and essential to life, health, and dignity." The overall objectives of its WASH program are to minimize mortality and morbidity among the displaced as well as to mitigate the resulting impact on local environments including fresh water (UN High Commissioner for Refugees, 2009). A recent outbreak of cholera in Haiti illustrates the importance of clean water and proper sanitation; an outbreak was confirmed in October 2010 following a massive earthquake in January. For a cholera outbreak to occur, two conditions have to be met: (1) there must be significant breaches in the water, sanitation, and hygiene infrastructure used by groups of people, permitting large-scale exposure to food or water contaminated with *Vibrio cholerae* organisms, and (2) cholera must be present in the population. Although cholera had not been documented in Haiti for decades, evidence suggests that UN peacekeepers from Nepal may have reintroduced the disease to Haiti, killing more than 5,000 people. Circumstantial evidence showed that fecal contamination by a riverside peacekeepers' camp initiated the epidemic, with dirty water from a local stream draining into the Artibonite River and reaching local populations (Farmer et al., 2011).

Third, a global economic slowdown on the heels of the 2006–2008 food crisis has negatively impacted refugee health and food security. Refugees and IDPs, who often live in remote and barren areas with limited access to fertile lands and livelihood activities, continue to face nutritional obstacles. The UNHCR, in partnership with the World Food Programme, has recently implemented programs to

improve food assistance delivery to the displaced in this context of increasing financial crisis and resource shortages. In Djibouti, for instance, a postdistribution monitoring system was developed to better understand how refugees use food aid at the household level. In Sudan, agencies worked together to combat high levels of malnutrition through a blanket feeding program for young children. In Uganda, discussions are underway regarding a possible transfer program in lieu of food to improve refugees' market purchasing power and nutritional outcomes (UN High Commissioner for Refugees, 2009).

Resettled refugees experience unique healthcare needs relative to immigrants, but unfortunately much of the existing literature does not adequately address the healthcare experiences of refugees. It is generally acknowledged, however, that the refugee experience and resettlement process partly shape health needs and experiences. In addition to concerns related to healthcare access, refugees may also require access to employment services, shelter, and specialized health services including mental health and counseling. Therefore, refugees may constitute a particularly vulnerable health population with multiple health risks. A Canadian study of healthcare providers conducted by McKeary and colleagues, for example, identified barriers to refugee health including issues of interpretation and language, cultural competency, healthcare coverage, availability of services, isolation, poverty, and transportation issues – some of which were observed regardless of refugee status. Although there is overlap between the obstacles faced by immigrants (as discussed above) and displaced persons, interview respondents consistently stressed that refugees face more and greater barriers than those who entered the country as economic or family class immigrants (McKeary & Newbold, 2010).

In particular, obstacles related to culture – including language, cultural competency, and cultural isolation – are linked to refugee health in Canada. As is often the case with immigrants, language issues often served as a barrier and prohibited patients from making clinical appointments, adequately explaining health concerns and symptoms, following medical instructions and making follow-up appointments. Lack of translation services may delay appropriate care when the need for care is acute, and the presence of interpreters in the examining room may further stress trust relationships between physicians and patients. Refugees may have greater issues with literacy than immigrants, are more likely to have limited command of the English language, or do not have sufficient vocabulary to describe their conditions. Furthermore, refugees may have difficulties finding a health provider that provides culturally competent care and understands the specifics needs of the refugee community. Refugees often need health professionals who are knowledgeable of their experiences, sometimes requiring providers to be aware of cultural difference and have trauma training, and this issue is further compounded by waiting lists and general service shortages. As McKeary and Newbold state, "the story or history of clients is vital, meaning that providers must (conceptually) travel a similar road to that of their refugee clients to understand their health needs." Yet this is highly problematic, due to cultural differences as well as frequent lack of client medical backgrounds and records. Additionally, social and cultural isolation emerges as a barrier to healthcare by restricting interaction within the community

and constraining individuals within their homes. In some cases, isolation is further complicated by transportation availability, gender, and age (McKeary & Newbold, 2010).

Internally Displaced Persons

The World Health Organization (WHO) links the impact of war to the mental health of displaced persons and argues that recognition of the mental health needs of the displaced is emerging but remains poorly addressed. WHO estimates that more than 50 % of the displaced present mental health problems ranging from chronic mental disorders to trauma and distress. In many cases, the effects of war and displacement are compounded with destroyed (or nonexistent) health and mental health infrastructures, including a lack of health professionals. In places such as Afghanistan, Rwanda, and Chechnya, prolonged human destabilization and psychological dysfunction were caused by traumatic events including killings, material losses, torture, and sexual violence. Life in overcrowded camps, deprivations, uncertainty over the future, and disruption of community and social support networks may also lead to mental health concerns among displaced persons (Porter & Haslam, 2005).

Existing (albeit limited) health data suggest that in more than half of countries affected by internal displacement – including practically all African and most Asian countries – IDPs have no access to adequate healthcare. Examples of these situations abound; most of northern Uganda's IDPs, for example, are confined to camps with extremely limited access to healthcare. IDPs in several countries – including Burma (Myanmar), Somalia, the Palestinian territories, and Serbia (Kosovo) – face discrimination in gaining access to healthcare due to ethnicity or restricted freedom of movement (Internal Displacement Monitoring Centre). Iraqi IDPs suffer from a range of health concerns, including gastrointestinal tract illnesses from drinking unclean water, dermatological disease (primarily among children), and the absence of services such as maternal care and treatment for chronic diseases. IDPs must rely on existing health facilities in Iraq, which were neglected under previous regimes and are now plagued by shortages of health professionals, medical supplies, and essential medicines (Morton & Burnham, 2008). Displaced women worldwide face high maternal mortality, unmet needs for family planning, complications following unsafe abortions, and higher vulnerabilities to sexually transmitted disease, including HIV/AIDS (Austin et al., 2008). Although negative health impacts are often found within refugee populations, as well, the availability of international humanitarian aid within refugee camps is often life saving. These options do not exist for IDPs, who must rely on government protections that are simply not offered to them.

NGOs and policy makers are quick to attribute negative health conditions to breakdowns in health services during times of war, lack of state financial resources, and the remote location of IDPs. However, this emphasis on scarce resources and logistics ignores the power dynamics underpinning the nature of displacement in the first place. To better understand this power, one must question why certain people are displaced while others are not as well as consider who are able to access existing resources during times of crisis and who are not. IDPs often represent populations that were the most vulnerable within countries during peacetime,

including members of ethnic and religious minority groups. As noted, governments themselves are often the cause of violence leading to displacement, and many IDPs are viewed as enemies of the very states responsible for their protection. National governments are often unwilling to prioritize the delivery of services to IDPs, leading some critics to call for the creation of a specific international humanitarian agency with a mandate for the provision of services such as healthcare (Salama, Spiegel & Brennan, 2001). In Burma, for example, ethnic minorities such as the Karen and Shan peoples are often targeted as national security threats by the military government (Kingston et al., 2010). People are displaced by coercive measures that drive people from their homes, such as forced labor, extortion, and land confiscation, as well as direct eviction and relocation orders issued by the state. Displacement has also occurred due to state-sponsored development initiatives, which disproportionately impact ethnic communities. In many cases, villagers are forcibly relocated to fenced settlements, or "relocation sites," and villages have been burned down or mined to prevent return. Those who refuse to leave their homes have been treated as legitimate military targets, with many threatened with violence or even shot and killed (Internal Displacement Monitoring Centre, 2009b).

The negative health impacts stemming from abuse of state power in Burma are significant. Malaria (including drug-resistant strains) is a leading cause of death among IDPs in Burma, and its spread is linked to the army's practice of forced displacement and destruction of villages. Food insecurity and malnutrition undermine resistance to chronic diseases, and researchers contend that the country's mortality rates are much higher than official state estimates. Studies within ethnic IDP communities found extremely limited maternal care, with nearly 90 % of women giving birth at home and only 5 % of births happening with the assistance of a skilled attendant. International relief organizations put the infant mortality rate at 91 deaths per every thousand IDP births, compared to a national average of 76 and an average of just 18 in neighboring Thailand. Twenty percent of children in the Karen state of Burma die before their fifth birthday, and it is estimated that one in 12 women dies during childbirth. Conditions of poverty (including lack of shelter and warm clothing, as well as food scarcity) serve to spread and perpetuate illnesses such as gastrointestinal disease and communicable infections, while a lack of healthcare providers and medicines serves to limit access to treatments (Internal Displacement Monitoring Centre, 2009b). Ultimately, the poor health status of IDPs in Burma is intricately linked to the country's human rights context and the negative consequences associated with internal displacement.

Health, Ethics, Immigrants, and Refugees

The largely empirical discussion above should illuminate the marked disparity between international law that defines a "universal" right to health and the practical application of this right. The tension between a right to obtain services and the moral or ethical duty to provide those services is a constant. In many Western countries, polarized debates about immigration and growing anti-immigrant

sentiment have created political obstacles to immigrant healthcare, including policy measures that limit access to health insurance and regular sources of care. In addition to these formal obstacles to health, immigrants also face a variety of informal obstacles which include language barriers, perceived discrimination, perceived lower quality of care, and challenges for health professionals themselves. Within displaced populations, refugees and IDPs face sometimes similar, but often exacerbated, challenges. The health-related priorities of the UNHCR highlight the need for increased HIV/AIDS and reproductive care among refugee populations as well as improved nutrition and food security as well as water, sanitation, and hygiene promotion. Resettled refugees have unique needs that are shaped by the resettlement process itself, often related to cultural differences. Limited data on IDPs suggests that these populations lack access to adequate healthcare and present mental health problems ranging from chronic mental disorders to trauma and distress. In cases such as Burma, IDPs come from already marginalized groups whose human rights are routinely violated by the government.

Unfortunately, there is a relatively weak body of ethical literature on the establishment of health or access to healthcare as an unchallengeable human right. Even within political philosophy, only in the last 20 years have mainstream thinkers in the Western world begun to systematically question the assumption that justice applies only within bounded political communities, thereby making ethical discussions of health rights for immigrants and the displaced possible. In this respect, two dominant approaches have been used to advocate for rights protection: First, pedagogies of reason stress the importance of rationality for persuading privileged groups (in this case, Western governments, medical professionals, hospital administrators, and insurance companies) to uphold universal human rights standards. For example, treating immigrants and the displaced helps to limit the spread of infectious diseases and therefore protects the mainstream, as well as these minority groups. Second, pedagogies of sentiment focus on ethical appeals to upholding human dignity and building an international, rather than national, community (Kahane, 2009). From this perspective, one must accept that all human beings matter and individuals have transnational responsibilities. Therefore, healthcare and other health rights should be provided to immigrants and the displaced simply because they are human, and privileged actors within the international community have a responsibility to protect the rights of those with fewer resources and less political power.

Debate over healthcare reform in the United States, which is often marked by immigration concerns, illustrates the ethical issues inherent to the protection of health rights. In this context, arguments for exclusion and inclusion often center on reason and sentiment. Typically, in the USA, for example, the opponents of including undocumented immigrants in healthcare reform are groups who oppose current US immigration policy and who work toward reducing the number of immigrants in the country. Economic and political arguments dominate citizen-only perspectives, including the leading economic argument that healthcare of undocumented immigrants is a financial burden on US taxpayers. Some exclusionists target healthcare costs of pregnant immigrants whose newborns may serve as

"anchor babies" to bring citizenship to their parents, while others contend that including undocumented immigrants in healthcare reform would encourage more immigration to the USA. Some argue that inclusion would violate core American principles such as individual responsibility and that healthcare is not a priority of undocumented immigrants (Galarneau, 2011).

Arguments for inclusion, on the other hand, often center on very different moral, economic, and public health claims. The moral argument is quite straightforward: Undocumented immigrants are human beings with healthcare needs and the right to health. Economic arguments for inclusion recognize that the undocumented contribute to society through labor, tax payments, and market participation, thereby contributing financially to public benefits despite being ineligible to receive them. Some contend that American free market principles are violated when people are prohibited from purchasing private health insurance, while others argue that such prohibitions will force the undocumented to rely on safety-net providers such as emergency care. Lastly, the central public health argument rests on the reality that any individual's health depends in part on the health of the people around them. Undocumented workers may continue to work when sick, since they often lack paid sick days and job security, and access to health services will limit infection risks within the general public.

The repatriation of uninsured, undocumented immigrants illustrates the ethical tensions inherent to this political debate, and it highlights how the right to health is threatened by anti-immigrant sentiment and financial concerns. In the USA, a new cost-shifting tactic – hospitals transporting uninsured, undocumented immigrants to their native countries – is being used by some medical facilities as a creative solution to ease economic pressures (Bresa, 2010). The story of Luis Alberto Jiménez, an undocumented immigrant living in Florida who suffered devastating injuries in a car crash with a drunken Floridian, highlights the health consequences of repatriation. Although Jiménez's life was initially saved by medical care from Martin Memorial Medical Center at a cost of $1.5 million over several years, the hospital eventually discharged him and transported him to his native Guatemala following a court battle with his guardianship. After being "forcibly returned to his home country," as one hospital administrator described it, Jiménez received no medical care or medication for his extensive injuries, which included a severe traumatic brain injury. His mother described his treatment as "just Alka-Seltzer and a prayer," and his condition rapidly deteriorated with routine violent seizures (Sontag, 2008).

Although federal US laws dictate hospitals' obligations to severely injured and ill patients in the emergency room, there are few provisions for the long-term care of undocumented immigrants; the universal right to health is at odds with the financial concerns of hospital administrators and healthcare providers. The Emergency Medical Treatment and Active Labor Act (EMTALA) requires emergency rooms to stabilize patients irrespective of their legal status or ability to pay, while Medicaid governs reimbursement for emergency medical care. The Medicare Conditions of Participation prohibit hospitals from discharging patients without an appropriate post-hospital-care plan. However, federal US law does not require receiving facilities, such as nursing homes, to accept patients nor does it provide

fund for the long-term care of undocumented immigrants. Corresponding funding mechanisms are inadequate to cover the cost of providing emergency treatment, as required by EMTALA, and there are no federal guidelines that clarify hospitals' obligations to provide poststabilization or long-term care. As a result, many hospital administrators see few options other than "patient dumping" to remain financial viable (Bresa, 2010).

Financial concerns also create obstacles to health among displaced populations and raise ethical dilemmas for healthcare providers. Global financial woes have limited the amount of funding available to humanitarian organizations that provide key health services, and many donors (including governments, corporations, and individuals) have decreased or cut funding to international health causes. Donor governments such as the United States, Germany, Italy, and Spain have reduced or reneged on previous funding commitments and key institutions – including the Global Fund to Fight AIDS, Tuberculosis, and Malaria – now suffer from funding gaps that limit service and programming options. In 2010, some countries were forced to implement 10 % "efficiency cuts" to funds approved in a previous round of grants to conserve funds for future projects. Doctors Without Borders/Médecins Sans Frontières (2010) contends that lack of funding undercuts opportunities to overcome global health threats, and the humanitarian organization recently called on world leaders to continue funding key health initiatives to fight concerns such as communicable diseases and child malnutrition.

For health practitioners operating in the field, the care of refugees and IDPs is further complicated by hostile governments and political volatility. Since governments control borders and may limit humanitarian activities occurring within their territory, many health providers must make the ethical decision to censor their beliefs (such as criticizing leaders who routinely violate the human rights of their citizens) in order to continue safely providing health assistance to the displaced. Several health-based human rights and humanitarian organizations have responded to this ethical dilemma in different ways. The work of the International Committee of the Red Cross (ICRC) is based on the Geneva Conventions of 1949 and emphasizes impartiality. The ICRC plays a neutral role during armed conflict and internal violence, and the organization relies on that impartiality to provide the most comprehensive humanitarian services while protecting the safety of ICRC workers. Doctors Without Borders also focuses on providing independent and impartial assistance, but the humanitarian organization also clearly asserts its right to speak out and bring attention to human rights violations. Its medical teams regularly supply information to the international community, and advocacy campaigns target rights abuses such as recent violations against Hmong refugees in Thailand. Other organizations, such as Physicians for Human Rights (PHR), choose to utilize the medical community's scientific expertise in order to investigate rights violations and raise awareness, rather than to provide health services in the field.

Political tensions often impact the ability of health practitioners to safely provide care to patients in need. For example, the health of Sudanese IDPs was compromised in 2009 when aid workers were expelled from the country in direct

response to international calls for human rights protections. At the beginning of 2009, 2.7 million people of Darfur's total population of six million were internally displaced. Already suffering from the extreme hardships associated with displacement, Darfur's IDPs experienced a significant drop in access to basic life necessities in March when the government expelled 13 international NGOs and revoked the licenses of three Sudanese relief agencies. This decision followed the issuing of an arrest warrant for Sudanese President Omar al-Bashir by the International Criminal Court on charges of crimes against humanity and war crimes. These expulsions meant the withdrawal of 40 % of aid workers and more than half of the total aid delivered to Sudan. Although health access was already difficult for IDPs prior to the expulsion of NGOs, with bureaucratic obstacles imposed by the government delaying some shipments for more than 6 months, the health sector lost significant capacity for mitigating disease outbreaks, treating diseases, and preventing loss of life to health concerns such as meningitis. The closure of health clinics, including mobile clinics in rural areas, left hundreds of thousands of IDPs without access to basic health services (Internal Displacement Monitoring Centre, 2009a).

Conclusion

The discussion above highlights the tension between ethical principles, expressed via international law, and the actual provision of care for individuals who have been displaced due to violence or economic deprivation. At the heart of the issue is the fact that immigrants and refugees are often protected in a bare-minimalist fashion, with no practical guarantor of the right to health in place. This is due to the fact that the nation-state is the main guarantor of the right as it may exist and be practiced. When refugees cross international borders, state governments or nongovernmental organizations may offer healthcare to such individuals due to an overarching moral imperative to do so, to protect their own citizenry from the dangers of unchecked health crises (such as epidemics), or some combination of these and other influences. However, such care is often bare minimum, since its provision necessarily takes away from the provision of services to the existing citizenry. In the case of IDPs, the situation is magnified by the fact that the nation-state in which the internal displacement has occurred has either been expressly unwilling or unable to guarantee the health rights of the displaced.

As noted by Daniels, Gostin, and others, the right to health has been expressed as a right that ought to receive priority given the fact that health is a de facto precursor to the ability to live a functional life and hence to enjoy other rights that might exist. Given the empirical tensions described above, the realization of a right to health is often denied to those who have no nation-state to guarantee access to it for them. The fundamental challenge posed to bioethics by this thorny issue is to balance the right to health against the normative and practical preference by many nation-states to protect the distribution of the services and goods necessary for the maintenance of health for those who are already functioning members of the state – its citizens and recognized permanent residents.

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Informed Consent

43

Michèle Stanton-Jean, Hubert Doucet, and Thérèse Leroux

Introduction

This chapter of the compendium takes into account Article 6 of the *Universal Declaration on Bioethics and Human Rights* (2005) that states:

1. Any preventive, diagnostic, and therapeutic medical intervention is only to be carried out with the prior, free, and **informed consent** of the person concerned, based on adequate information. The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice.
2. Scientific research should only be carried out with the prior, free, express, and **informed consent** of the person concerned. The information should be adequate, provided in a comprehensible form and should include modalities for withdrawal of consent. Consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage or prejudice. Exceptions to this principle should be made only in accordance with ethical and legal standards adopted by States, consistent with the principles and provisions set out in this Declaration, in particular in Article 27, and international human rights law.
3. In appropriate cases of research carried out on a group of persons or a community, additional agreement of the legal representatives of the group or community concerned may be sought. In no case should a collective community agreement or the consent of a community leader or other authority substitute for an individual's **informed consent**.

M. Stanton-Jean (✉)
Centre de Recherche en Droit Public, Université de Montréal, Montreal, QC, Canada
e-mail: michele.stanton-jean@international.gc.ca; michele.stanton.jean@sympatico.ca

H. Doucet
Faculty of Theology and Religious Studies, Université de Montréa, Montreal, QC, Canada
e-mail: hubert.doucet@umontreal.ca

T. Leroux
Centre for Research in Public Law, Université de Montréal, Montreal, QC, Canada
e-mail: therese.leroux@umontreal.ca

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The requirement for informed consent in research is relatively recent. In the area of clinical research, the obligation to obtain consent from the potential participant is now formalized. In 1947, the Nuremberg Code declared that consent shall be mandatory for research on human beings to protect the dignity and the freedom of the participants. The Helsinki Declaration of the World Medical Association specifies, since the first version in 1964, that this consent must be informed. Furthermore, in medical practice, it would seem that it is in the United States that the word "informed" appeared in 1957 in the *Salgo v. Leland Stanford Jr. University Board of Trustees* judgment in which Justice Bray wrote: "In discussing the element of risk a certain amount of discretion must be employed consistent with the full disclosure of facts necessary to an informed consent." (Salgo v. Leland Stanford Jr. University Board of Trustees, 1957, section 5, Instructions (b) Duty to Disclose, p. 568). The concept is used at the end of a very ambiguous sentence. In juxtaposing disclosure and discretion, Justice Bray opened the door to painful conflicts that are still with us (Katz, 1984, p. 63).

The relationship between "informed" and "discretion" is the basis of the majority of problems encountered today in research and clinical practice. How should the ethical requirement to correctly inform a patient that must receive care or a study participant be completely fulfilled? Up to what point can discretion be evoked to limit the disclosure of information?

Current Context of Informed Consent

It can be said that informed consent is still a crucial element of ethics, although its applications are getting more difficult in a context of globalization and technological developments. The fact that there is now an expanded process of collaborative research including many researchers in the same project and, in the clinical field, a significant growth of information technologies that allow professional associations to share their views on informed consent has given rise to many new questions related to privacy, confidentiality, secondary use, use of data and samples, use of the information for public health purposes, quality of the information provided, and even the right not to know.

By creating a conversation between human beings, specially researchers, living in different regions of the world, where religion, philosophy, physicians' power, and social traditions are different, globalization has, in the field of ethics, increased the complexity of ethical reviews. Consequently, the conclusion that will be reached by Research Ethics Boards on a multinational project can be different from one country to another. For example, the same research project, often benefitting from multiple sources of funding, can be conducted by a team coming from many countries, and carried out in clinical contexts where the ethical reviews are based on different philosophical theories or legal norms. For example, questions raised about consent (individual versus community or family consent), such as privacy, secondary uses can be different and have an impact on the fulfillment of the project. The new technologies by possibly allowing genetic profiling,

and predictive medicine are starting to offer multiple choices to patients and raising the questions of insurability and employability, themes that have an impact on the level of information that should be given and understood by a patient or a participant in research. This complex environment has prompted some lawyers, philosophers, ethicists, scientists to ask themselves if too much emphasis has been put on autonomy and individual rights without paying enough attention to countries where communities and families are the ones who have the power to decide on matters related to medicine and research (Benatar, 2002).

At first glance, giving consent seems to be fairly easy to understand and apply. It is related to a person's agreement to accept a medical intervention or to participate in a project explained by a clinician or a researcher. But the use of this simple tool has, over the years, become more complex for two reasons: On the one hand, the citizens' wish to choose themselves what is best for them and on the other hand, the development of new technologies, applied in clinics and research, has complicated the choices offered to patients or research participants, making it difficult for a person to decide what is best for him or her. For example, preimplantation genetic testing may raise some ethical questions, unpredictable before the test and difficult to explain to parents, who depending on the results, might be faced with multiple scenarios and have to choose between different options like to keep or destroy an embryo. In the research as in the clinical context, citizens do not always trust pharmaceutical companies who want to involve them in clinical trials, or physicians still using a paternalistic decision-making process not taking into consideration the patients' will. The development of new therapies and drugs and the complexification of research in a globalized and culturally diverse world contribute to this mistrust of the patients. This context has had an impact on the development of the patient's right to be fully informed of the risks of any procedures as have many examples of unethical human researches that have also strengthened the importance of informed consent For example, cases have been reported where pharmaceutical companies have offered to provide drugs to participants in clinical trials, stopping the treatments when trials are over.

This is why in the three declarations adopted by the United Nations Educational, Scientific and Cultural Organization (UNESCO) on Bioethics (Universal Declaration on the Human Genome and Human Rights in 1993, International Declaration on Human Genetic Data in 1997, and the Universal Declaration on Bioethics and Human Rights in 2005), the prior free and informed consent is presented as a key component of the respect of human dignity and autonomy of each participant in research. It is generally well accepted that universal and international declarations are helpful and useful for countries to help them achieve more coherence in the drafting of their legislations and guidelines but the devil is in the details, and the application of these universal principles raises a lot of difficult questions. For example, during the drafting process of the *Universal Declaration on Bioethics and Human Rights*, the article on consent was the subject of long and substantial discussions reflecting the willingness to reiterate the importance of free, informed,

and express consent, but also the willingness to take into consideration ethical issues raised by recent scientific developments, cultural diversity, and globalization of research.

What is the Meaning of "Informed" Consent?

What is the meaning of informed consent? What kind of information is appropriate? Is informed consent given once and for all, or should it be an ongoing process where, if needed, patients are recontacted? How does the decision-making process work? Where does the power of the physician stop when he wants to do something that the patient rejects? How should different cultural approaches related to family or community decision-making process be dealt with?

"Article 6 of the *Universal Declaration on Bioethics and Human Rights* states that 'informed consent' is to be 'based on adequate information'. As a general rule, an individual has to receive comprehensible, relevant, structured and individually tailored information that makes it possible for him to reach a decision on whether or not to accept a medical intervention or to participate in scientific research. But it is still necessary to specify what is understood by that." (UNESCO, 2009, p. 15). In the following sections, the current challenges associated with the use of the term "informed" in the consent will be examined.

What is Adequate Information?

Giving and receiving information assumes communication between at least two individuals. Communication is a process filled with pitfalls. Even in everyday life, there are frequently misunderstandings. Understanding information is therefore a complex intellectual exercise beyond simply knowing how to read and write. It requires specific cognitive abilities ranging from understanding words that do not relate to each other to the ability to analyze and synthesize. Researches have been conducted to assess the level of health literacy defined as: "the ability of individuals to access and use health information to make appropriate health decisions and maintain basic health." (Health Literacy in Canada, 2007, p. 3). Five levels have been identified in accordance with difficulty thresholds in understanding information and some examples provided for the each level. We provide here a summary of Categories of Health Activities with some tasks examples related to those categories.

1. Health Promotion (read food and product labels, purchase food, plan exercise regimen); Tasks: purchase food, plan exercise regimen.
2. Health Protection (read articles in newspapers and magazines; understanding air and water quality reports); Tasks: Decide among products options, vote.
3. Disease Prevention (understanding letters related to tests results, understanding postings for inoculations and screening); Tasks: Determine risk, engage in screening or diagnostic tests.

4. Health Care and Maintenance (understanding health history forms, discharge instructions, calculate timing for medicine); Tasks: Describe and measure symptoms, follow directions for medicine labels.
5. System Navigation (understanding application forms, statements of rights and responsibilities, understanding informed consent forms); Tasks: Applications for insurance and benefits and offer informed consent for procedures and studies (Health Literacy Health Literacy in Canada, 2007, pp. 17–19).

The System Navigation level is the most complex and is the one related to bureaucratic demands, application for insurance and other coverage plans, rights and responsibilities and **informed consent forms** for procedures and studies (Health Literacy in Canada, 2007, pp. 17–19). The level of difficulty in which the informed consent is situated posits that it is difficult, if not impossible, for large proportions of the world population to understand what they are agreeing to by giving their "informed" consent. Health literacy in relation to informed consent is a central question. It is well known that people are often shy of saying that, even though they can read, they cannot understand complicated words or long sentences. In fact, imagine the anguish of a patient or a research participant who does not understand the information provided when it is known that, in general, people are embarrassed at the idea of telling someone that they have not understood and that they require further explanation.

In clinical practice, almost everywhere in the world, doctors are not ready or available to explain at length the procedures to follow for a treatment or a surgery whereas in research, potential participants frequently receive very long and technical informed consent forms aimed at protecting research sponsors rather than participants.

Several studies on the level of comprehension of information about treatments, participation in clinical trials, or other type of research have proven that doctors rarely check the type and quantity of information that the patient would like to obtain. As Jefford and Moore wrote in 2008: "Many participants have incomplete understanding of various features of clinical trials. Issues associated with the length, format, and language of documents for written informed consent are common" (Jefford and Moore, 2008, p. 1).

It is therefore understood that people with a low level of literacy who often live in disadvantaged countries are at risk of being exploited. This is why "informed consent needs not only disclosure and a signature, but also promotion of participants' understanding of the research project and the voluntary nature of their decision to participate"(Jefford and Moore, 2008, p. 486). Sharing this point of view implies finding means to provide an information accessible through the use of detailed interviews or aids such as graphics, drawings, cartoons, pictograms, or videos. It must be added that obtaining a written consent does not always mean that an "informed" consent has been obtained.

Variations in the Application of Informed Consent

There is an abundance of literature on the consistent application of the principle of informed consent and the difficulties that it entails. In clinical practice as well as in

research, the information provided may be adequate, relevant, and complete, but the context may present particular challenges due to cultural diversity. Consequently, the decision-making process may vary from one country to another, or even within the same country from one group to another. In clinical practice, these challenges may be related to the health system model in place. If the system is not financed by public funds, a patient may refuse a procedure because it is too expensive even though he understands the benefit of that procedure. In the same vein, a possible participant in research project who understands the risks of that project might accept to participate because he or she will receive free drugs and treatments during the time of the research.

Cases that apply commonly in clinical practice and research in all contexts and cases that require different information and decision-making processes due to cultural diversity will be presented in the following sections. Finally, some questions raised by recent scientific developments and their impact on informed consent will be addressed.

Common Issues

Clinical Cases

Informed Refusal

What happens when a patient refuses treatment? How should the physician react? The following has been proposed by The Canadian Medical Protective Association: "When patients decide against recommended treatment, particularly urgent or medically necessary, discussions about their decision must be conducted with some sensitivity. While recognizing an individual's right to refuse, physicians must at the same time explain the consequences of the refusal without creating a perception of coercion in seeking consent. Refusal of the recommended treatment does not necessarily constitute refusal for all treatments. Reasonable alternatives should be explained in a comprehensible language and offered to the patient" (Canadian Medical Protective Association, 2006, p. 9).

Advanced Care Planning

How should the ideal of informed consent be respected in a context in which longevity increases and the ability to make decisions progressively decreases to nothing? This situation is encountered more and more among seniors. It is therefore possible to use Advanced Care Planning, which "is generally described as a process of planning by an individual for a time when that person does not have the mental capacity to make decisions about his/her own health care or treatment" (Wahl, 2006, p. 1).

The practice of having advanced discussions on the type of care a patient would like to receive depending on their condition and indicating this on an appropriate form occurs in several countries and is more and more encouraged. It is a way to ensure the respect of the patient (Health Canada, 2008). In May 2007, the Collège des

médecins du Québec published a guide to this effect entitled "*La pratique médicale en soins de longue durée*." (Medical practice of long term cares (translation)). For the College, upon admission of a new resident to a nursing home, the health care team must rapidly implement a comprehensive assessment of the health status of the individual and discuss the orientation of care with the latter and his or her family in view of developing a personalized plan of interventions.

Research Cases

Placebo

The use of a placebo in studies can place some participants in a vulnerable position as they will not receive the study treatment. In such a situation, informed consent rules must be followed and participants must be specifically informed of all risks and consequences associated with receiving or not receiving the therapy being tested.

Researches Involving Partial Disclosure

There are cases where, in minimal risks situation, there can be departure from the principle of informed consent. For example, some researches involving social sciences, like psychology or sociology, are designed to understand human responses to experimentally put together situations. "For example, some social science research that critically probes the inner workings of publicly accountable institutions might never be conducted without the limited use of partial disclosure. In some research that uses partial disclosure or deception, participants may not know that they are part of a research project until it is over, or they may be asked to perform a task and told about only one of several elements the researchers are observing." (TCPC, 2010, p. 38). In those cases, the Research Ethics Board has to be reassured that there are no major risks for the participants and that after the research is completed, they will be informed about the project and given an opportunity to refuse consent. These kinds of researches can only be carried out if participants do not know the purpose of the research project and therefore do not give a real informed consent.

Multicenter and International Research

When research conducted in one country includes many centers in its protocol, how should the ethical review be conducted? If many Research Ethics Boards (REBs) are included and give different advices, how should it be managed? Should the informed consent form be the same for every center in order to guarantee that patients are receiving the same information? Who should be accountable?

The difficulties related to multicenter research have been documented in many countries: burden of many ethical reviews, frustration of researchers because of delays, bureaucratic processes, lack of understanding of other's decision-making processes, not enough scientific and expertise available, institutional accountability issues, monitoring difficulties. This issue is being discussed in many countries (Australia, Canada, USA, UK) and different models have been developed, that

share responsibilities in different manners between institutions. The success is however mitigated. No simple solution exists specially in ethics. Not being a hard science, ethics must continue to have contextual flexibility in its application. This is why reaching a consensus on ethical reviews with people coming from different institutions is very difficult to achieve. The development of good governance models seems to be the way to go in the future to achieve coherence and reliability. "A critical element of the Harmonisation of Multi-centre Ethical Review (HoMER) initiative1 is the need for research governance to be understood as comprising distinct elements ranging from the consideration of budgets and insurance, to the management and conduct of scientific and ethics review" (NHMRC, 2011, p. III).

If the research is conducted in many countries, especially with developing countries, it should follow the guidance proposed by the *Universal Declaration on Bioethics and Human Rights* in its article 21 that states: When research is undertaken or otherwise pursued in one or more States (the host State(s)) and funded by a source in another State, such research should be the object of an appropriate level of ethical review in the host State(s) and the State in which the funder is located. This review should be based on ethical and legal standards that are consistent with the principles set out in this Declaration.

Some Specific Contextual Issues

Cultural Diversity

Research Context

Article 6 on consent of the *Universal Declaration on Bioethics and Human Rights* states: "In appropriate cases of research carried out on a group of persons or a community, additional agreement of the legal representatives of the group or community concerned may be sought. In no case should a collective community agreement or the consent of a community leader or other authority substitute for an individual's informed consent." What does this item practically mean?

Countries differ culturally, socially, and politically. In some countries, adequately or misinformed groups' or communities' leaders have the authority to make decisions and give consent for the entire group, completely putting aside information to individual group members, and even if the information is provided, it is difficult to assess the level of understanding of community members. Research conducted on the practice of informed consent in developing countries has revealed the difficulties of meeting the requirements of informed consent and "whether those involved would be able to fully understand and accept information" (Molyneux et al., 2005, p. 451).

There are also cases in which the group comes to agreement based on inadequate information. In Canada, in the 1980s, blood samples were collected from members of the Nuu-chah-nulth Nation for research aimed at discovering whether this population had a genetic predisposition to rheumatic disease. Dr. Richard Ward, who led the project, wrote to the Tribal Council, "We feel that if a proper study is

carried out it will identify all people who have a problem with their joints, and a physiotherapy treatment can be started as a way of helping them" (Ward quoted by Wiwchar, 2004, p. 1). The participants were never informed of the research results or ensuing publications, and the blood samples were only returned to British Columbia in 2004 (Wiwchar, 2004).

Such examples prove that obtaining a meaningful informed consent faces many challenges within certain cultural contexts. As explained, several factors must be taken into account to relay adequate information. For research, the subject must understand the risks and benefits of their participation. In a globalized world where, for example, the delocalization of clinical trials, patent races, and the search for new molecules have already had detrimental effects, it is becoming more and more necessary to be vigilant with respect to the ways in which consent is obtained from participants and patients. Research in culturally different regions, especially in poor settings, is often difficult to undertake as, again, illness conceptions, sharing of power in families and communities, and value systems require an understanding that, for example, the pharmaceutical companies and sponsors do not always have. "Reports of abuses associated with informed consent to research in resource-poor settings consent call attention to global power inequities when research is conducted by investigators sponsored by organizations or pharmaceutical companies from industrialized nations. In a clinical trial of the antibiotic trovafloxacin (Trovan) in the treatment of bacterial meningitis in Kano, Nigeria (Khabir, 2001), researchers working for Pfizer Pharmaceuticals were charged with neglecting to obtain adequate consent." (Marshall, 2007, p. 30).That said, it is important not to fall into a cultural relativism where nothing is common among developed and developing countries but rather to recognize the importance of understanding and respecting communities values and tradition which is essential to the establishment of a strong partnership between all the actors.

Clinical Context

There are several variations in the information and decision-making process in many communities across the world and they take several forms in clinical context with respect to treatment consent. As shown by Fan and Tao, family authority, direction by the physician, and the role of the patient are always present in the medical decision-making process but managed differently in different cultural settings, i.e., the role of the physician and that of the family and the patient may be adapted based on the size of the family, and religious and cultural traditions. The patient will be involved more or less in the decision-making process depending on the familial paradigm in place. For example, in some Asian countries, the family may be informed before the patient of the treatment or procedure to be followed and take the decision to proceed or not. On the contrary, in western countries, the family will be informed by the adult patient who will be the one to take the decision. Depending on the model in place, the family or the patient may decide on their own or the physician may be the one to take the decision (Fan and Tao, 2004).

Vulnerable Persons

Article 8 of the *Universal Declaration on Bioethics and Human Rights* (2005) states:

> "In applying and advancing scientific knowledge, medical practice and associated technologies, human vulnerability should be taken into account. Individuals and groups of special vulnerability should be protected and the personal integrity of such individuals respected."

In its report on this article (2011), the International Bioethics Committee (IBC) states:

> "This Report on article 8 of the Declaration will investigate the scope and content of the principle of respect for human vulnerability and integrity, focusing on special vulnerabilities and taking into account conditions that, more or less directly, impinge upon the capacity to live as a free, autonomous individual and the right to live in a world where significant inequalities in the capacity to meet everyone's basic needs are adequately addressed." For the IBC, this means that: "The principle of informed consent is at risk whenever someone claims to know what is the right thing to do, and insists that his or her decision should prevail over the self-determination of the patient, whether that person is the physician or a family member." (IBC, 2011, p. 1)

According to these definitions, there are several categories of people that may be vulnerable in a given population, more specifically, children and seniors.

Children

The assent of the child poses a certain number of questions. The term "assent" generally refers to the willingness of a child to participate in a research project. Assent is different from consent, as it addresses the limited understanding of a child based on his/her mental capacities and level of maturity and development. If a child is capable of discernment, it is just as essential for the researcher to obtain the assent of the child before including the child in pediatric research as it is to obtain informed consent from the parents.

With children, should the consent of the two parents be mandatory? Who can be defined as a minor by law? The answer to these questions varies from country to country and can be based on legislation or on an assessment of the level of comprehension. But, generally speaking, there is an agreement, among ethicists, that minors should not be excluded from participating in the consent process only based on their age because "the inclusion of children in research advances the commitment to justice in research by improving our knowledge of, and ability to respond to, the unique needs of children throughout their development" (TCPC, 2010, p. 49). But, when a child says no, it is no, and as stated in the Helsinki Declaration: "When a potential research subject who is deemed incompetent is able to give assent to decisions about participation in research, the physician must seek that assent in addition to the consent of the legally authorized representative. The potential subject's dissent should be respected." (WMA, 2008, p. 4) In the case of treatment, if treatment is not required, the opinion of the minor must be taken into consideration.

Seniors

The mental capacity of seniors can be impaired especially when they are affected by neurodegenerative diseases such as the Alzheimer disease. In the case of research on that disease, if the family does not object, should, as it is often happening, sick persons be excluded from research on the ground that they do not have a legal representative who can legally consent?

Even if a person is vulnerable, this does not necessarily mean that they cannot freely consent to participate in the study. It is the ethical framework in place that should insure that their participation is possible or not and well supervised. "Even when the requirements of free, informed and ongoing consent cannot be met, respect for persons requires involving individuals in circumstances of vulnerability in decision making where possible. This may include asking about their feelings regarding participation and/or for their assent" (TCPC, 2010, p. 9).

New Scientific Developments and Informed Consent

The spectacular developments that have arisen over the past decades in genetics, genomics, and nanotechnologies have presented new questions with respect to the application of the principle of informed consent in a globalized world. Over the past years, several authors have examined the questions raised by these new scientific developments vis-a-vis informed consent and its approach focused only on the individual whereas these developments affect families, or even entire populations. Consequently, the individual basis of the informed consent based on autonomy, confidentiality, and the individual decision of the patient is challenged. "The traditional model fails to recognize that an individual is also a social person with a particular historical and socio-cultural context giving that person certain ways of viewing things, as well as a set of values. Each person has their own understanding of who they are, how they and others should be treated as people, and what important relationships need to be honoured. Each individual also has their own views about disease and illness and will face genetic issues with their own level of fears, concerns and questions" (Kegly, 2004, p. 832). In her discussion, Kegley argues that "various perceptions of 'adequate information', that are at the heart of informed consent, are at odds with the complexity of genetic information" (Kegly, 2004, p. 832). The complexity of the new technologies is making it even more difficult to provide adequate information to patients, and sometimes even physicians and genetic counselors are not sufficiently trained in communication skills or even willing to take the time to properly inform the participants.

The Necessity to Obtain Consent in Research Involving Human Tissues and Databanks

The proliferation of databanks and databank sharing has led to an abundance of literature in bioethics to identify and analyze the ethical questions related to the start-up and use of these databanks. Several reports, notices, and statements have attempted to address these issues and propose governing methods.

In research on human tissues samples and databanks, even if the individuals are not directly affected, it is still important to obtain informed consent. If the information identifies participants, a new consent must be obtained. If the donor is deceased, the family or a research ethics board may make the decision to provide or refuse access to the data. To facilitate the use of data, it would be useful, for example, to ask donors to insert a clause to this effect in their last wishes which are often indicated in a will.

The Right to Know or Not to Know

During the last decade, the right to know has been stressed based on the ethical view that the patient has a right to be informed about the risk and benefit of a treatment or a research. Particularly, in genetics, we are now faced with the opposite right: the right not to know. Research findings, or treatments, including incidental results, can more and more reveal diseases that will impact the participants, or their biological families by having strong psychological effects (Andorno, 2004). As Ruth Chadwick explains: "It may not be justifiable to take away hope from a person by exposing them to knowledge that they do not want" (Chadwich, 1997, p. 18). In trying to balance the patient's right with, for example, the impact of different genetic disorders, on the family and on future generations, can it be said that the right not to know is absolute based on the autonomy of the participant? The fact that the participant can refuse to get the information about the results or accept to be informed and refuse to communicate the findings to his relatives raises difficult ethical dilemmas. This is why return of the results should be discussed before the beginning of a research or a treatment and a plan should be designed to manage the information to avoid incomprehension when the results will be known. This right not to know has been recognized by international organizations like The Council of Europe Convention on Human Rights and Biomedicine (1997) and by the UNESCO Universal Declaration on the Human Genome and Human Rights (1997).

In the case of incidental results, i.e., discoveries that are beyond the goals of the research, the management of the information is also a challenge. As discussed by Zawati, Van Ness, and Knoppers (2011), it is almost impossible for the researcher to identify at the outset of a research all the possible findings. International norms that address that topic have been reviewed in that paper and as to the content of the documents analyzed, the authors found that most of them call on researchers to be clear on their practices with their participants at the time of consent concerning incidental findings. The conclusion is that there is a lack of guidance and: "Greater consensus is required on the management of incidental findings in the field of genomics and for a proportionate approach to the responsibilities of all stakeholders involved in this process" (Zawati et al., 2011, p. 8).

There are cases when the right not to know can be restricted. For example, the positive result of a sexually transmitted disease should be told to a patient and discussed with him before the test is performed. Public health interests can also, in some circumstances, limit the right not to know and those circumstances should be well defined by law (Andorno, 2004, p. 437).

Data Ownership

Tissues taken from patients, information obtained in genetic research, medical records are now part of large data and tissues banking process. Biobanks are not new, but, with scientific developments, particularly in the area of genomics, they are now more and more large population and specific disease collections (Luther and Lemmens, 2012). But who owns the data? How much do patients or research participants know about what is done with their data? When a researcher has built a databank or a tissue bank, does he have the right to sell it or to obtain a patent on his discoveries just for himself? Is his institution the owner of the data? If he quits, can he leave with his bank? Does that question need to be raised when the informed consent of patients is asked? And what about conflict of interest? Those are some of the substantial questions being discussed in a global context where researchers and data are moving around the world. Ethicists agree that research centers must provide clear policies on the subject and legal systems must take an interest in this complex question. But how is it possible to do that?

On the question of ownership, it is generally accepted that institutions, not the researcher, is the owner of the data bank and is accountable for its proper management. Some institutions have created registers where they keep a list of the data bank created in their institutions. On the other side, the discoveries that come out from these databanks are the property of the researcher unless there are specific clauses in the consent form that instructs differently.

Secondary Uses

That databanks or the biobanks constitute a very rich platform for future researches. When the data is collected, it is difficult to assess all the possible uses of the data. Should it be mandatory to obtain informed consent for each new research study using the data, or should it suffice to ask a Research Ethics Board (REB) to approve that new research? Or, is it right to forbid a general consent when, for example, a participant wants, after having obtained thorough information, to give his samples as an altruistic gift for the welfare of future generations or accept not to be recontacted if his data are to be used for another research not necessarily linked to the initial research? Whether participants should be recontacted is an unresolved issue. There are two different schools of thought at play about that: individual rights and common good or solidarity. Depending on ethicists' philosophical background, they will adopt one or the other position. Several suggestions have been proposed to respond to these questions, but none of these approaches completely satisfy the ethical rule requirements with respect to informed consent and are often perceived as distortions of the original concept based on autonomy and confidentiality.

Certain avenues aimed at maintaining the information have been explored in order to avoid the difficulties presented by the secondary use of data. For example, in a paper published in 2003, Caulfield, Upshur, and Daar recognized the impossible task of predicting all the possible uses of donated samples. They suggest an authorization model "whereby participants in genetic data banks are able to exercise a certain amount of control over future uses of genetic data. We argue this preserves the autonomy of individuals at the same time as allowing them to give

permission and discretion to researchers for certain types of research" (Caulfield, Upshur and Daar, 2003, p. 1). In that model, informed consent would be required for initial collection and future uses would be done "under a mode of preauthorization." Participants would have to say what uses they agree or do not agree with and this process would be monitored by some sort of overarching governing body.

In 2006, Knoppers and Chadwick wrote, in an important article titled *Human Genetic Research: Emerging Trends in Ethics*, that "the increase in interest in population-based genetic research has led to calls for rethinking the paramount position of the individual in ethics" (Knoppers & Chadwick, 2006, p. 416). They argue that the discoveries in genetics have been accompanied by a shift in emphasis toward new trends in ethics as reciprocity, mutuality, solidarity, citizenry, and universality (Knoppers and Chadwick, 2006). These new trends feed the debate on ethics in different ways either it be on the right to know or not to know, insurance, choices, management of data base, and autonomy versus common good. Those issues can all be related to informed consent and the need to give a clear and comprehensible information to the public.

Relation of This Chapter with the Scope and Article 26 of the Declaration

In this chapter, the challenges faced with using the term "informed" in the process of getting consent from patients and participants in research projects have been examined. Some examples of varied situation where difficulties arise in various clinical or research settings have been provided. The writers of the *Universal Declaration on Bioethics and Human Rights* (UDBHR) were aware of these challenges, most of them having been highlighted during the consultation process. This is why they made sure to specify in Article 26 entitled Interrelation and Complementarity of the principles that: "This Declaration is to be understood as a whole and the principles are to be understood as complementary and interrelated. Each principle is to be considered in the context of the other principles, as appropriate and relevant in the circumstances" (UNESCO 2005).

The Declaration having been drafted to provide "guidance to decisions or practices of individuals, groups, communities, institutions and corporations, public and private" (UNESCO, 2005, Scope) needed to be grounded in a set of principles that can take into account a diversity of international contexts. The role of religion, families, and governments is not the same everywhere and this is why a certain level of flexibility, provided by article 26 of the UDBHR, is important.

Conclusion: Informed Consent Revisited

Informed consent has arisen from the desire to respect the autonomy of the patient and protect them from harm. It is not only a form to be signed. It should be a process

through which health professionals must inform the patient adequately about all the impacts of the procedure or the research project. This is why exchanges between all partners should support the process. Schachter and Fins properly proposed in a paper published in 2008 "a reinvigoration of the doctrine of informed consent in which the physician engages in meaningful and ongoing dialogue with the patient. Ultimately, both the clinician and the patient–physician relationship will benefit as respect for this doctrine serves to facilitate compliance with the doctor's legal obligations, ethical duties, and clinical responsibilities, and, as importantly, enhances the collaborative treatment enterprise" (Schachter and Fins, 2008, p. 1113).

Without denying the value of the actual ethical foundation of the individual informed consent, the collective and globalized dimensions implied by many of the actual researches lead one to think that other principles like solidarity, responsibility, and common good should carry the same weight as autonomy and individual decision.

The questions and the applications that have been discussed in this chapter are only the tip of the iceberg. Indeed, on top of the developments in genetics (genetic testing, population genetic, and prenatal genetic testing), the scientific developments in nanosciences, neurosciences, proteomics, and regenerative medicine will continue to challenge the limits of informed consent. As explained in this chapter, new scientific developments and the globalization of research demand the capacity to innovate. Methods of keeping alive informed consent in every treatment and research should be found and tested. To benefit from science progress and at the same time to protect individuals and especially future generations is a duty for the scientific community.

It is also important to have a clear view of the differences in the application of informed consent theory between clinical and research settings. As explained by Agich in 1998, informed consent in clinical practice can be challenged and analyzed retrospectively in court following a complaint while, in research, the informed consent can be reviewed and discussed during the project (Agich, 1998).

In a globalized world where governing models and the application of laws and guidelines vary from one country to another, some scientists may be tempted to move to countries where the ethical laws and regulations are minimal or not developed at all instead of trying to improve guidelines and norms everywhere. Informed consent must continue to be applied and studied by multidisciplinary and multicultural teams involving health professionals and social scientist. Finally, to obtain a real informed consent, awareness-raising and education strategies as well as public debates should be given much more attention in the elaboration of guidelines and policies at the international and regional levels. New governance models that involve the public in meaningful consultations must be developed. Physicians and scientists must be trained to communicate in plain language with their patients. Most importantly, cultural diversity and pluralism should always be taken into consideration.

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Migration of Health Personnel and Brain Drain

44

Jeremy Snyder

Introduction

Within global bioethics, global inequities in terms of life expectancy, morbidity, and the distribution of health resources have been identified as areas of serious ethical concern. These inequities are caused and compounded by a grossly unequal global distribution of health workers, both between and within countries. In many communities, there are insufficient health human resources to provide primary and preventative care, to distribute new interventions provided by external donors such as antiretroviral drugs to combat the spread of HIV, and, most pressingly, to train future generations of health workers. Thus, these inequities in human welfare are likely to persist or even worsen if the problem of health human resource levels in these areas is not addressed.

This problem is compounded by an ongoing pattern of migration of health workers from relatively low- to high-income countries and from countries with severe health human resource shortfalls to those countries with relatively many health workers. Increasingly, bioethicists have identified this pattern of migration as an ethical concern and have accused a range of players of engaging in serious moral wrongdoing in failing to prevent or even encouraging this pattern of migration to take place (e.g., Eyal & Hurst, 2008; Dwyer, 2007; Benatar, 2007; Eckenwiler, 2009). This chapter begins with a brief background on the effects and causes of health worker migration. While there is wide agreement that this phenomenon is ethically worrisome, there is considerable disagreement as to the nature of the wrongdoing taking place and which parties are engaging in this wrongdoing. Therefore, the next section of this chapter consists of a survey of the range of arguments on the ethical terrain of health worker migration, noting that multiple forms of unethical behavior are likely taking place. In the final section, the chapter surveys policy responses to the problem of health worker migration with discussion of their chances of success and implementation and therefore their ability to address

J. Snyder
Faculty of Health Sciences, Simon Fraser University, Burnaby, BC, Canada
e-mail: jeremycsnyder@sfu.ca

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global inequities in health human resources. As with many cases in global bioethics, the international migration of health workers raises many, serious ethical concerns, but because of its global nature, it is a problem that resists easy solutions.

Background

The numbers of trained health workers are widely disparate between countries and often mirror more general disparities in resources between nations. For example, Africa has an average density of 2.3 health workers per 1,000 population, compared to 4.3 workers for Southeast Asia and 24.8 for the Americas. Perversely, countries with lower health worker density tend to be faced with a disproportionate share of the global disease burden and therefore have a greater need for these health workers (WHO, 2006). This inequality is a source of great ethical concern given that in many countries shortages of trained health workers have resulted in difficulties meeting the basic health needs of their citizens (Snyder, 2010). While more health workers can be trained given adequate facilities and resources, these resources are now lacking in many countries and the training of new health workers can be a time-consuming process (WHO, 2006).

This ethical concern is particularly acute given that shortages of health workers in some regions are exacerbated by a pattern of migration of health workers from relatively disadvantaged to advantaged areas. Health worker migration of this kind increases inequalities in levels of health workers globally and can reduce numbers of these workers in some countries in absolute terms (Anand & Bärnighausen, 2004). In India, for example, trained health worker migration has been an increasing problem, exacerbating already existing shortages of health human resources (Rao, Rao, Kumar, Chatterjee, & Sundararaman, 2011). While these countries often already suffer from limited access to medications, the ability to distribute these resources even when available is further compromised by health worker shortages. Health worker migration can contribute to a vicious cycle of health worker shortages when the best-trained and most experienced workers – who are often those most desirable to potential employers – choose to migrate. These workers serve as mentors and trainers for more inexperienced workers and students, thus undermining the capacity of these countries to replace workers who have migrated (Eyal & Hurst, 2008).

The motivations behind migration is disparate, but some pull factors (drawing workers to certain destinations) and push factors (motivating movement from worker home countries) are frequently cited as behind more recent, problematic worker flows. Push factors for migrants in the public sector in low-income countries include low wage levels at home when compared to the private sector and more economically developed destinations. These workers may also face comparably heavy workloads and more limited workplace support, which can lead to lower job satisfaction over time (Eyal & Hurst, 2008). Pull factors include better wages and working conditions in destination countries and often mirror push factors in source countries (Snyder, 2010).

The decision of any individual health worker whether and where to migrate will be a complex interplay between these push and pull factors and will involve many individualistic considerations. In many cases, it is the knowledge of an opportunity to migrate that factors into the decision to move abroad. Simply allowing the immigration of skilled health workers or even having an immigration system that favors these workers can be considered a passive form of recruitment and raises ethical issues for the destination countries that accept these workers from disadvantaged source countries. In other cases, national health systems or private employers will actively recruit these workers through job fairs, advertisements, or the use of head-hunting firms. These forms of active recruitment may make it more likely that a health worker will migrate abroad, raising distinct ethical concerns. That said, in a globalized setting where networks of health workers are able to easily communicate information about migrating to destination countries through formal and informal networks, the distinction between active and passive recruitment is becoming more blurred, while the harmful effects of health worker migration remain much similar in both cases.

Ethical Issues Raised by Health Worker Migration

The movement of health workers from relatively low- to high-income countries has been associated with a range of ethical concerns, some complimentary and some conflicting. This section surveys the most prominent of these concerns.

Nonbeneficence and Maleficence

The ethical concern with current patterns of health worker migration can be framed in terms of a failure to discharge a duty of beneficence or violation of a duty of nonmaleficence. In the first case, privileged members of wealthy destination countries can be said to have a duty of beneficence to help to reduce the needs and suffering of others throughout the world. As was discussed earlier, lack of adequate numbers of health workers in many source countries leads to considerable preventable suffering and lower levels of welfare than would be the case if there were greater support for and retention of health workers in these countries. By not doing more to rectify this problem, privileged destination and source country members alike fail in this duty of beneficence.

This understanding of the concern with health worker migration is less than satisfying, however. A duty of beneficence is commonly considered to offer some leeway in terms of how it is discharged. Given the many forms of unaddressed need worldwide, it may not be clear why the particular failing to address global health human resource levels should be seen as a failure of a duty of beneficence. Some individuals will have taken other charitable actions to address global poverty, giving them grounds for saying that they have acted beneficently in other cases and discharged the relevant duty. For those who have taken no charitable action

toward addressing others' needs, the failure to act on the need for better access to health human resources is just part of a general failing to act; that is, there is nothing special about access to health workers that could be identified as a failure of beneficence in the face of great, unaddressed global suffering.

Instead, global health worker flows can be framed as a failure of a duty of nonmaleficence on the part of certain members of both source and destination countries. This is because these worker flows should be seen as resulting in not only a failure to benefit the members of these source countries. Rather, they actively make some individuals worse off in absolute terms. As such, the migration of workers, and the encouragement and enablement of such migration, can be considered an act of maleficence. One advantage of this understanding of the moral terrain of health worker migration is that it assigns responsibility to certain actors for the repercussions of their actions – namely, those actors with a causal role in promoting harmful patterns of health worker migration. Whereas a failure of a duty of beneficence is difficult to pinpoint due to actors' discretion in discharging this responsibility, a maleficent act is identified by the specific harm caused by the actions of individuals.

It should be stressed, however, that causally tracing harms to specific actors in these cases may be difficult or impossible. Should a specific health worker migrate from an underserved population, it may be difficult to pinpoint specific persons over the long term who will suffer from this choice, even if it is known that this decision will have negative repercussions at the population level. This problem becomes more difficult as actors are further removed from the decision of the health worker and its impact on individuals in the source country. For example, it will be very difficult at best to quantify the harms caused by the action of a specific recruiter or health system administrator who encourages migration to a source country. And again, this problem is magnified at the level of immigration policy makers, citizens urging their political leaders to increase health human resource levels, and negotiators of global health services trade treaties. This observation is not to deny the negative impact of the choices of these actors but to question whether either a duty of beneficence or nonmaleficence is helpfully illuminating of the forms of wrongdoing for a systemic pattern of harms.

Equity and Justice

A general concern with global health worker migration from low- and middle- to high-income countries can be framed as an issue of health equity. This concern can be explained in terms of a redistribution of wealth from relatively poor countries to relatively wealthy countries. As health human resources have a direct impact on health, these movements can make countries already relatively well prepared to meet the health needs of their citizens better off, directly at the expense of countries that are failing to meet their citizens' basic health needs.

If low- and middle-income countries lack the resources to meet their basic health needs, then it seems perverse for relatively wealthy countries to meet their needs at

the expense of less well-off countries. That is, the actions of wealthy countries would seem to exacerbate already existing inequities in access to health care. Not only would the size of the resource gap increase, but health worker migration can make other countries less well off in absolute terms, undermining goals of providing sufficient global access to health human resources. This concern is triggered whether or not high-income countries actively recruit health workers. Even if there is no structure in place to encourage or facilitate migration by workers from low- and middle-income countries, the pattern of migration is seen as ethically problematic.

These concerns will be heightened when high-income countries have other means available to meet their health human resource needs, for example, by increasing domestic training opportunities. That is, a set of background institutions can be held to be unjust if they leave certain groups without access to a decent minimum of resources when an alternative set of background institutions could have been put into place. Neoliberal structural adjustment policies can be blamed for reducing investment in the health sector, leading to a dearth of training opportunities in high-income countries and poor working conditions in low- and middle-income countries (Benatar, 2007). Low- and middle-income countries find it difficult to resist these structural adjustment programs as they are tied to development loans and development aid in many cases. Therefore, a set of institutions imposed on these countries can be said to lead to unjust distributions of health human resources globally.

Identifying the agents responsible for causing and rectifying these global injustices can be difficult. If single responsible agents are being sought, a few can be identified. These agents would include very high-level government officials responsible for negotiating, passing, and enforcing the neoliberal trade policies that have enabled and encouraged health worker migration. As these individuals have influence on the international socioeconomic structures shaping health worker migration, they can be held causally responsible for creating and maintaining unjust social structures.

But assigning responsibility for global injustices according to the agents who cause these injustices becomes more problematic when we depart from the higher level, systemic causes of health worker migration. Individual recruiters, administrators, and health workers make their decisions against the structural backdrop that creates a set of incentives and options for these individuals. While unjust social structures do not eliminate individual responsibility, it makes it less clear how to assess responsibility for the effects of these individuals' actions. Focus can instead turn to assigning responsibility for altering the global structures that lead to a redistribution of health workers from low- to high-income countries (Eckenwiler, 2009). On this view, a range of actors who are connected to and benefit from these structures can be held responsible for pushing for more just structures and ameliorating some of the negative effects of these structures. This responsibility will vary from actor to actor but will capture a wider range of responsible parties. Thus, not only individuals and workers directly responsible for health human resource distributions are responsible for reforming the global system of trade in health services,

but so too are citizens of destination countries who benefit from these injustices and citizens of source countries who are deeply connected to and implicated by these structures.

Stealing and Exploitation

Health worker migration can also be criticized as a case of stealing or theft by destination countries from source countries for health workers. Substantial resources must be devoted to the training of health workers, including their education, infrastructure to provide practical training opportunities, certification of these workers, and payments to students during periods of training. This investment can be repaid to source countries if health workers remain in the source country for a sufficient period to provide valuable services to the wider community. However, if destination countries allow or promote the relocation of these health workers before their training costs have been recouped, the movement of health human resources is a net loss of resources for the source country. The charge in these cases is that the health human resources do not merely move from one country to another but that they are stolen. This charge is most likely to be placed in circumstances where members of the destination country take steps to actively promote or accommodate workers' migration. In these cases, where the destination country does not act to meet its own needs through local training, appropriation of other countries' health human resources appears to be a deliberate policy (Heath, 2007).

If the charge of theft is to be taken literally, the source country must be understood to lose, without its permission, a resource or property to which it is entitled. Certainly, many source countries actively resist the migration of their trained health workers and see active recruitment by source countries to be unwelcome and inappropriate. It is less clear that these countries have an entitlement to these resources if they have not already contracted with the workers for periods of service to the source country in order to repay the training costs. One concern is that the language of theft in this case tends to obscure the perspective of the worker, who may have a right to migrate and responsibilities to the source country as well (Snyder, 2009).

Similarly, charges of exploitation rest on the idea that destination countries systematically seize resources from low-income-source countries for their own purposes. An analogy can be drawn to other forms of economic exploitation where poorly paid workers create resources of value far beyond what they receive in wages or where low-income countries sell their natural resources while receiving disproportionately little in exchange. Unfair exchanges of this kind will be common against a background of pervasive, global economic injustice (Heath, 2007). This charge similarly can fail to include the perspective of health workers but does have the virtue of depicting health workers from low-income-source countries as a disadvantaged class whose options are limited and controlled by the global economic system. Typically, however, the charge of exploitation is made very loosely in the context of health worker migration and would benefit from more careful development.

Individual Rights

Individual health workers who choose to migrate – or even face overwhelming pressure to do so – tend to emigrate in order to seek better opportunities for themselves and, often, their families. Health workers who migrate can experience higher wage levels, more satisfying working conditions, improved personal safety, and more opportunities for training and advancement (Martínez & Martineau, 1998). Family members who join the health worker abroad can share in many of these advantages, and health workers can provide significant benefits to family in their country of origin through remittances. These remittances can benefit not only those persons to whom they are sent but also have wider positive economic impacts by boosting capital flows into the country. However, these remittances are not directly reinvested into the local health system and cannot be seen as directly making up for the loss of the migrant's skills (Stilwell et al., 2003). While health worker migration creates many negative effects at a population level for members of the worker's country of origin, the benefits for individuals may be significant.

Restrictions on the movement of health workers out of an interest in restricting the loss of these workers may run afoul of freedoms of movement or rights to migrate. Conceptions of these rights vary and not all restrictions on movement should be understood as potentially infringing on the rights of workers. But at the very least, many interventions aimed at dissuading health workers from leaving their countries of origin in order to seek better opportunities for themselves and their families must balance the benefits to the populations of their home countries against the losses and potential rights violations for individual workers.

While the right of health workers to migrate can be pinned to a right to free movement, the selective immigration policies of many destination countries bring into question whether this right is relevant to the implementation of their policies. As many countries tie immigration status to the skills and qualifications of the migrant or the needs of an employer, it is likely that the interests of the source country motivate these policies rather than an interest in protecting a general right to free movement (Benatar, 2007). This is not to say that such a right does not exist; rather, its relevance to the policies of destination countries is unclear, and therefore, it is not clear that a change in these policies would be relevant to the exercise of this right.

Violations of Worker Rights

Health workers stand to personally benefit by migrating to another country and seek employment abroad. However, these workers are also vulnerable to coercion, manipulation, deceit, and other forms of abuse by recruiters and their employers. In some cases, the opportunities abroad, including the existence of a job or terms of employment, may be misrepresented to workers by recruiters. As these recruiters may be paid per individual they recruit – either by the potential employer or the workers themselves – they have an incentive to encourage these workers to migrate and some may exaggerate the opportunities available to workers to do so.

Moreover, workers may be bound to their employers through the terms of their visas, work permits, or licensure in their new home. These arrangements make workers particularly vulnerable to employers who may offer wages and working conditions inferior to those received by local workers. In these cases, questions of equity for migrant workers are raised. Employers can also use the lack of mobility by migrant workers to offer wages and working conditions below what is legally required as workers may find themselves unwilling to challenge their employers out of a fear of being forced to return home. These workers may also be ill-prepared to press their rights if they are unfamiliar with the legal system or dominant language of their new home. Finally, unclear terms of migration may leave migrants unable to find work because of restrictive licensure that leaves them unqualified to work in a position for which they were qualified in their home country. These cases of what is sometimes called "brain waste" can leave workers in a new country with few or no applicable skills, far away from family and social networks, and faced with a much higher cost of living than that back home.

Workers who face these abuses may in the worst cases be made worse off than they would have been had they not migrated abroad in search of work. Other workers may be better off when compared to a baseline of their welfare prior to migrating but worse off than they were promised they would be or would be under more equitable working conditions. In these cases, workers can make the case that they have been exploited by recruiters, employers, or the immigration and employment policies of their new country, despite being better off overall. While exploitation and outright harms of these kinds may be the exception rather than the rule for migrant workers, the choice to migrate creates new vulnerabilities for workers that did not exist previously (Snyder, 2010).

Worker Responsibilities

Workers can be held morally responsible for the negative effects of their decision to migrate. This responsibility will be clearest in cases where the local community has subsidized the worker's education through tuition subsidies, development of the medical infrastructure used in training, and training and employment of medical professionals who serve as teachers and mentors to the worker. In these cases, the worker can be said to owe a debt to the community in light of these resources; the worker who simply migrates without making up this debt transfers resources to another country to which the worker is not entitled (Benatar, 2007).

Even if the worker did not receive considerable public subsidies during training or if these debts have been paid, a worker can be said to have a special responsibility to the local community in light of the worker's connection to this community, the need of the community, or the worker's special ability to aid the community (Snyder, 2009). While there are many people worldwide in need of the services of trained health workers, including in the destination countries to which health workers often migrate, these links to the worker's home community may create

a special responsibility to meet the needs of the members of the worker's home community first. Migration on this view is not a failure to repay a debt but rather a failure to discharge this special responsibility to the worker's home community.

Importantly, however, enforcing a responsibility to workers to remain in their home countries may be unfair to these individuals. As has been discussed, these workers can face a range of challenging working conditions, including low levels of pay, dangerous working conditions, and limited opportunities for advancement. As these workers begin from a disadvantaged position compared to their colleagues in wealthier countries, it may be unfair to demand that they take on particularly stringent responsibilities to address the needs of their own communities when they have alleviated rather than caused this poverty and more advantaged individuals in wealthier parts of the world do comparably little to alleviate global poverty and likely benefit more from global injustices. At the very least, a special responsibility by health workers to care for their local communities must be balanced against the demands faced by and dangers to these workers and placed in a context where all health workers and all individuals have responsibilities to meet the needs of others (Crozier, 2009).

Slowing Destination Country Reforms

As has been observed, a policy of promoting health worker migration can be used by source countries to address perceived shortfalls in health human resource levels, especially in rural and underserved areas. These shortfalls may have been caused by a failure by the destination country to devote adequate resources to training health workers, the loss of health workers to other countries, or a loss of skilled health workers to other employment if health work is perceived as insufficiently rewarding or working condition are too onerous. While the resort to immigrant health workers to meet local staffing shortages has implications for the source country, this policy also can have negative effects on members of the source country. In particular, addressing health human resource levels through migrant workers can act to reduce demands for increased funding for local, sustainable training of health workers and slow reforms that would make working in the health sector more rewarding, especially the caring professions that are historically underpaid relative to other health work. For members of the source country, this slowing of policy changes can deny them the opportunity to enter into training for the health professions. Those already in the health field may find that the influx of migrant workers undercuts their ability to advocate for better working conditions. More generally, the failure to develop sustainable mechanisms for training and retaining health workers can have severe long-term consequences if the destination country later finds itself to be less able to attract migrant workers, a less appealing destination for these workers, or in greater competition with other destination countries for a finite supply of health workers globally (Snyder, 2010).

Policy Responses

Many policy responses have been proposed to attempt to reduce the flow of health workers from low- to high-income countries and to reduce the ill effects of this migration. Given the global scope of this phenomenon, source and destination countries can choose to act unilaterally or engage in multilateral policy responses.

Unilateral Source Country Responses

Source countries for migrants may take a number of steps aimed at forcing students and other workers to remain in their country of origin for a set period of time. A bonding scheme, for example, would require that students complete a period of service to the sponsor of their training before they are allowed to emigrate. Those workers violating the terms of this agreement would be required to pay a significant fee as a means of ensuring that the period of service is completed. Importantly, a bonding scheme of this kind is only likely to be successful if the penalty to the worker is sufficiently high and there are effective mechanisms in place to enforce payment. Moreover, the penalty must be sufficiently high to ensure that potential employers may not simply pay the penalty for the worker (Martineau, Decker, & Bundred, 2004). One weakness of bonding proposals is that they may run contrary to individuals' right to emigrate, though this concern might be overcome if entering into training as a health worker were fully voluntary and any bonding conditions were clear and fully consented to. Even so, restrictions on the movements of health workers may prove counterproductive over the long run if they serve to create friction with workers and worsen working conditions, thus encouraging migration over the long term (Eyal & Hurst, 2008).

Source countries can also improve the working conditions for their citizens, thus reducing the pull of emigration to more economically developed countries. These improvements might include increased wage levels, competitive with those in richer countries when adjusted for cost of living, better equipment and staff to patient ratios in the workplace, and new opportunities for training and research. Of course, the difficulty with these proposals is that low-income-source countries will typically not have the resources to institute these changes – in fact, providing basic health services to their citizens is often challenging. In some cases, donor countries, including those that serve as destination countries for these migrants, have provided funds for salary top-ups for workers and other workplace improvements and training opportunities. However, to reduce the pull of migration, these donations must be sizable and sustained. Given the increased domestic demands of many high-income countries, sustained support of others' health systems is doubtful over the near future.

Source countries can choose to train at least some of their health workers in ways that are locally relevant to the needs of their own citizens, deviating from training foci and standards used in many high-income countries (Eyal & Hurst, 2008). Examples of such training could include a narrower focus on diseases endemic in

the source country and the health needs of its citizens, prescription of less expensive and generic medications available in the source country, and the use of less expensive diagnostic methods including stethoscopes and manual diagnosis. This training would be relevant to the needs of the source country in that it would target the health needs of its citizens and provide training that is responsive to the resource levels of that country's health sector, especially in rural areas. Because this training focus is not directed at the needs and medical resources of high-income countries, these workers would likely not be desirable for recruitment by high-income countries and their certification may not be of the type that allows for easier migration (Eyal & Hurst, 2008). Thus, this solution aims at both meeting the health needs of the source country while reducing the desirability of these workers for destination countries.

One concern that this solution generates is that it endorses a permanent second, lower quality tier of care for low-income countries. That is, the use these workers might imply that low-income countries should settle for levels of training and quality of care that would be unacceptable in higher-income countries. However, this proposal is a pragmatic response to a problem that is undermining the health of many people and a realistic response to the actual resource levels available in low-income countries. Moreover, it can be coupled with continued training of health workers to Western standards for use in district hospitals, while other responses aim to retain these other workers (Eyal & Hurst, 2008).

Unilateral Destination Country Responses

Destination countries can reduce the demand for migrant health workers by increasing the domestic supply of these workers. Critics charge that the health worker "crisis" facing some high-income countries is a product of decisions to fill health worker positions by an active process of recruitment rather than directing the necessary resources toward training new health workers domestically to meet local needs sustainably. Thus, greater levels of local training in high-income countries would both reduce demand for health workers from abroad while arguably addressing an injustice by these countries (Benatar, 2007). While this solution is ethically satisfying and straightforward in its application, it unfortunately may require higher levels of spending on health by these countries or cuts from other sectors, which may be politically unpalatable in some countries.

Similarly, destination countries might make reparations to the source countries from which they recruit health workers. These payments would be targeted at repaying the costs of health worker migration, including the loss of health human resources in these countries (possibly including replacement costs) and the costs of training for these workers. These proposals are hampered by the reality that training new workers takes not only financial resources but also considerable time, meaning that cash remunerations may not fully address the source country's loss. Moreover, as has already been observed, the loss of health workers in some countries has hit particularly hard in those workers who would normally train future generations of

workers, including university and teaching hospital staff. Therefore, source countries may lack more than the financial means of training new health workers. Encouraging destination country workers to train their colleagues abroad can help to address this problem.

Destination countries can also choose to regulate the recruitment of workers within their own borders and to enforce these regulations on private employers and recruiters and public employers such as national health systems. Recruitment policies can take many forms, but requirements could include banning active recruitment of workers through advertisements, attendance at job fairs, or source country visits, limiting active recruitment to countries that have expressed a willingness to have their workers migrate abroad, or requiring employers to limit the migration period of these workers, provide them with additional training, pay some form of compensation to the source country, or exchange workers with the source country. Similarly, the source country could modify its immigration policy so that only workers meeting the above kinds of conditions would be allowed to migrate and, possibly, only as temporary, guest workers. These interventions would all have the aim of placing legal restrictions on health worker migration such that the worst negative effects of this practice, at least, are reduced (Martineau et al., 2004).

Destination countries can also unilaterally create policies meant to guide the hiring of migrant health workers within their own countries. These policies can be crafted by both government agencies and nongovernmental stakeholder groups. For example, the Canadian Nurses Association (2000) has released a position statement on international health worker migration that focuses on licensure and professional development, which are among the key interests of this stakeholder group. These policies tend to set recommendations for members of the stakeholder group but will not typically be binding.

Policies issued by destination country governments are more likely to have the force of law, though these guidelines can be merely advisory as well. One particularly influential unilateral recruitment guideline is the United Kingdom's (UK) *Code of Practice for the International Recruitment of Healthcare Professionals* (Department of Health, 2004). While the code notes the potential benefits of international health worker recruitment, it requires that health workers in economically developing countries not be targeted unless an explicit government-to-government agreement with the UK has been negotiated to guide and set conditions on this recruitment. These workers are to be extended equal protections under the law as local workers and should receive opportunities for training and development. This code is intended to apply to hiring practices within the National Health Service (NHS) and to recruiters supplying employees to the NHS. While the document encourages adoption of the code by all employers, it is not binding on private employers outside of the NHS. Moreover, the code aims only to limit active recruitment of health workers. Passive migration, where migrants travel without the explicit encouragement of recruiters or employers, would not be affected by this code: "Individual healthcare professionals from developing countries, who volunteer themselves by individual, personal application, may be considered for

employment" (Department of Health, 2004, p. 7). As the line between active and passive recruitment can be blurry and knowledge of the UK as a destination for health workers is likely to be widely disseminated among the workforces of developing countries, the efficacy of the code is uncertain.

Multilateral Responses

Health worker migration raises ethical concerns that have been addressed in multilateral policy documents, including the UNESCO *Universal Declaration on Bioethics and Human Rights*. This document includes requirements of solidarity between states in promoting the health and social development of their people, presents health as a fundamental human right, and stresses the equal rights and dignity of all human beings. These requirements could seemingly be met by promoting greater cooperation to reduce the negative effects of health worker migration and overall levels of migration. However, the document also states that the interests of the individual should have priority over the sole interest of society, potentially forbidding attempts at addressing health worker migration by limiting the freedom of workers to migrate (UNESCO, 2005). This tension underscores the difficulty of finding solutions to the problem of health worker migration without violating the rights of affected parties.

Several policy documents have been created aiming at directing a global response to the problem of health worker migration. The World Medical Association (WMA) in 2005 produced a *Resolution on the Healthcare Skills Drain* that affirmed and expanded a 2003 declaration by this same group. The resolution describes the need of high-income destination countries to become self-sufficient in health human resources and for all countries to support and retain their health workers as well as possible given their resources (WMA, 2005). A more recent and potentially influential policy response to the international migration of health workers is the World Health Organization's (WHO) *Global Code of Practice on the International Recruitment of Health Personnel* (WHO, 2010). This code encourages nations to develop sustainable planning for their workforce needs in order not to rely on the migration of health workers in the future. In order to prevent exploitation of workers, the code encourages transparency around working conditions and equal treatment of migrant and domestically trained workers. Opportunities for migrant workers to receive training are also encouraged. In terms of the effects of health worker migration on source countries, the code encourages cooperative steps to ensure that both countries benefit from migration, including skills transfers, development of training facilities in source countries, and promotion of return migration. On this basis, the code discourages recruitment from countries with health worker shortages. Similar guidelines are included in the multilateral and voluntary *Commonwealth Code of Practice for the International Recruitment of Health Workers* (Commonwealth Secretariat, 2003).

As opposed to the UK's *Code of Practice for the International Recruitment of Healthcare Professionals*, the WHO code aims to be applicable across stakeholder

groups, including government agencies, recruiters, and private employers. In this way, active recruitment of health workers within the private sector would be limited as well as in the public sector. However, the WHO code can be criticized as being unlikely to be effective given its voluntary nature. That is, the code encourages member states to adopt it but explicitly states that it is voluntary in nature. Without binding international limitations on health worker migration, especially from low- to high-income countries, there is good reason to question whether even multilateral codes of this kind will influence health worker migration trends (Buchan, 2010). Moreover, as with the UK code, the WHO code reaffirms the right of health workers to freedom of movement and thus focuses on limiting the active recruitment of health workers. Given the extensive number of health workers from low-income countries already overseas, migration will remain highly visible and attractive if push factors for these workers are not addressed.

Conclusion

International health worker migration is associated with a wide range of ethical concerns. While many of these overlapping concerns simply serve to underscore the deeply unethical pattern of migration allowed and promoted by many destination countries, these concerns in some cases would benefit from clearer formulation and may conflict with one another. For example, the rights of health workers to migrate can conflict with the social responsibility of these workers to their source countries. Similarly, a right to adequate health human resource levels in rural areas of wealthy destination countries can conflict with similar needs in source countries. Policy responses to the problem of health worker migration are difficult to implement due to practical challenges. Doing so in ways that help to relieve rather than exacerbate these ethical problems is challenging as well. Continued discussion of the ethical landscape of health worker migration will be helpful to better expand and assess the range of policy responses to this phenomenon and to help reduce the conflict among the many parties seeking better access to health care. Given increased demand for health human resources globally and an aging population in many source and destination countries for health workers, this problem is likely to increase rather than decrease over the short term.

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Organ Trafficking and Transplant Tourism

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Nikola Biller-Andorno and Zümrüt Alpinar

Introduction

Organ trafficking is at the same time a widely known and an elusive subject. Many stories are circulating – some are dismissed as being of little credibility, others have been corroborated by legal investigations. In 2004, the New York Times ran the story of Alberty José da Silva, who lived in a Brazilian slum and sold a kidney for $ 6,000 to a woman from New York. The deal was arranged by Israeli brokers, the operation carried out in South Africa. In 2007, the UK newspaper Daily Mail reported on a British father-of-two who went as a "medical tourist" to the Philippines in the hope of receiving a kidney, after having turned down an offer from a Chinese hospital.

How are such arrangements to be judged morally? Is there a globally shared common moral ground that such judgments can be based on? The past years have witnessed a rather polarized debate on the ethical permissibility of organ sales. The prevailing international prohibition was challenged, mainly from two perspectives: a clinical view invoking the suffering of patients with organ failure, and a philosophical position claiming the vendors' right to an autonomous choice and to a fair deal. Although international policy was reassessed, the prohibition of organ selling was confirmed.

The terminology used to describe cases when people are selling, brokering, or buying kidneys is varied and sometimes confusing or euphemistic. Recently, some definitions have been offered that help clarify what is at stake. *Medical tourism* is a general term signifying a person traveling abroad to receive medical care – in the case of *transplant tourism* an organ for transplantation. *Organ trafficking* has been defined as "the recruitment, transport, transfer, harbouring or receipt of living or deceased person or their organs by means of the threat or use of force or other forms

N. Biller-Andorno (✉)
Institute of Biomedical Ethics, University of Zurich, Zurich, Switzerland
e-mail: biller-andorno@ethik.uzh.ch

Z. Alpinar
Centre for Ethics/Institute of Biomedical Ethics, University of Zurich, Zurich, Switzerland
e-mail: zumrut.alpinar@ethik.uzh.ch

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of coercion, of abduction, of fraud, of deception, of the abuse of power or of a position of vulnerability, or of the giving to, or the receiving by, a third party of payments or benefits to achieve the transfer of control over the potential donor, for the purpose of exploitation by the removal of organs for transplantation" (The Declaration of Istanbul on Organ Trafficking and Transplant Tourism, 2008). Whereas the da Silva case would quite clearly constitute organ trafficking, a medical tourist receiving services at a foreign hospital might also become involved – knowingly or unknowingly – in an organ trafficking arrangement. According to the definition, selling and trading organs are forms of organ trafficking. Sometimes, these are disguised with labels such as "rewarded gifting," "compensation," or "gratuities."

This chapter will proceed with an overview of the ethical debate on organ selling. In a next step, a review of empirical data illuminating the reality of organ trafficking in different contexts will be presented. The final part will describe policy developments in recent years and summarize the current international norms on organ trafficking.

Selling Human Organs: A Controversial Issue in Bioethics

Whereas there is a broad consensus on the ethical unacceptability of exploitative practices, the question if selling organs is morally wrong has prompted different responses. In the following, the major arguments for and against organ selling will be presented (Biller-Andorno & Capron, 2011). Transplant tourism will only be dealt with insofar as it constitutes a form of organ trafficking. Other forms, not involving abusive procurement of organs, trigger rather different questions related to medical tourism in general – such as the effects of the development of luxurious medical tourism sites for the health care of the country's population – and will not be included in this chapter. It will also not address payment for organs from deceased donors, which again leads to a different set of ethical issues, such as the potential for conflicts of interests for relatives.

The debate on whether payment for organs is blameworthy or morally required has been going on at least since the 1990s. A large number of articles have appeared, not only in bioethics publications but also in medical journals. The arguments put forward revolve around central principles of biomedical ethics, the respect for autonomy, human dignity, justice, nonmaleficence, and beneficence.

The Autonomy of the Vendor

Autonomy in decision-making depends on various factors. The person taking the decision must have been appropriately informed about what is involved. Beyond that, the person must be in a position – in terms of education, health status, mental capacity, etc. – to process this information in making a competent choice. This also presumes that the person perceives herself as a moral agent who can take decisions

on her own responsibility. This precondition to autonomy is frequently taken for granted, leading to a misinterpretation of ethical questions. It is misplaced, for instance, to consider wearing a burka an expression of autonomy, if the woman concerned does not perceive herself as someone who has moral rights and is entitled to make choices, including the choice not to comply with a religious rule. In addition to the self-understanding as a moral agent whose views matter, the situation needs to be such that genuine choices are possible; for instance, it does not make sense to talk about an autonomous decision to live in a slum if there is no alternative within reach.

When organ selling is being discussed in abstract terms, these crucial factors become invisible. But there is an enormous moral difference if a well-off professor from an Ivy League university considers the amount of money he would be willing to sell her – somewhat aged – kidney for, or if a desperate woman who gets frequent visits from a debt collector sees herself forced to this step. Organ selling under these circumstances cannot be considered an expression of autonomy but rather an "autonomy-constraining option" (Kerstein, 2009).

It could be argued that in real life many decisions are not ideally autonomous. In the case of donating a liver segment to a loved one, for instance, voluntariness is restricted, too, even if the potential donor is not threatened, forced, or manipulated. It is the simple fact that the alternative would be to watch the beloved person get worse and possibly die before he or she received an organ that is difficult to reconcile with the role as a caring relative and creates a certain pressure. This is why procedural safeguards have been called for that maximize the potential donor's degree of freedom to decline this option (Biller-Andorno, 2011). Such safeguards might be sufficient in the context of altruistic living donation, but they would be insufficient in a context marked by severe poverty, dependency, and violence.

Some have spoken out against restricting poor people's range of options, which is already limited. It was claimed that this was unfair, particularly with a view to all the risks that rich people were allowed to take just for pleasure, such as dangerous sports (Radcliffe-Richards et al., 1998). However, a prohibition of selling in fact does not curtail potential vendors' autonomy – as the decision to sell would likely not have been an autonomous one – but rather aims to protect their choice not to part with an organ in order to cover the basic necessities for themselves and their families.

Human Dignity and Instrumentalization

The prohibition of organ selling in Western countries traditionally rested on a broad consensus that organ selling was obviously and categorically wrong, as it would diminish human dignity (Cohen, 2002). More recently, the use of the concept of human dignity in bioethics has been criticized, so that its role in the organ selling debate merits a closer look.

Interestingly, human dignity can be invoked on both sides of the organ selling debate: It has been argued that organ selling enhances autonomy and therefore human dignity. Paying for organs, it has been stipulated, avoids an abusive

instrumentalization of the organ donor, and offers him or her a fair deal instead. On the other hand, organ selling has been claimed to constrain rather than enhance autonomy, and therefore to use a person who cannot decide otherwise as a means toward the end of obtaining his or her organ for somebody else.

This ambiguity underscores the point that human dignity does not help much to resolve moral questions if it is used as an unspecific, vague notion of mainly rhetorical value. It would allow speaking out against obvious abuse in the form of degrading, fraudulent, or violent treatment – however, there is consensus on the moral unacceptability of such practices anyway. For a stance that argues against organ selling as long as the major moral premise – the autonomy of the vendor's decision – is not realized and insofar as consequences are detrimental to vendors (no sustained benefits, physical harm, etc.), human dignity is not needed as an argument; it does not add anything beyond a reference to the principles of autonomy, beneficence, nonmaleficence, and justice.

Human dignity is also used in a more specific way, frequently referring to Kantian ethics. From this perspective, human beings are considered to have an unconditional and incomparable value by virtue of their rationality. By selling a part of their bodies (which is part of their selves), human beings would turn themselves into things, into their own property. This would be self-contradictory, as one cannot be a person and a thing at the same time. Putting a price on a part of persons (even if it is done by themselves or with their consent) would therefore conflict with their dignity, lowering their status to that of things that come with a price. This, according to Kantian ethics, is nothing one could rationally will. There are also religious interpretations of the concept of human dignity that refer to humans as being created in the image of God. These notions, however, are not universally accepted. There are, for instance, other positions that see nothing wrong with the self-ownership of the human body. Others question the absolute moral status of humans as rational beings. Accordingly, human dignity can be charged with being a vehicle for metaphysical premises that are not shared by everyone.

The role of human dignity in the organ selling debate can be summarized in the following way: If used as an unspecific notion, human dignity has an appellative character, evoking shared concerns about lacking respect for individual autonomy and abusive relationships. Human dignity as a specific, metaphysically rich *terminus technicus* is an essential element for positions, arguing that organ selling is intrinsically wrong. In bioethics, these two different notions are not always clearly distinguished. This can lead to misunderstandings as to the normative content and justification of positions and should be avoided. The current minimal consensus – organ selling is wrong insofar as it is coercive or exploitative – does not necessarily require a reference to human dignity.

Justice and Solidarity

Simplistic arguments in favor of organ selling point to the fact that almost everyone profits from organ transplantation – the recipient, the transplant surgeon,

the hospital, and the pharmaceutical industry that sells immunosuppressive drugs – only the donor is refused to join in the deal. This argument is assuming that donation is bound to a profit motive, which does not capture at least part of living donations. In addition, a market approach to organ donation would raise serious social justice concerns: Encouraging individuals to sell an organ in the case of economic need would remove an incentive to shape social policy such that all can sustain their existence without having resort to such options (Kerstein, 2009). Disguising the exploitation of the poor as an antipaternalistic stance that is concerned with promoting their right to autonomous choices would seem a rather cynical approach. As financial incentives would be of differential interest according to socioeconomic status, the world would be divided into organ buyers and organ sellers (Scheper-Hughes, 2003), with severe consequences regarding social cohesion and solidarity. With organs a commodity available for sale, altruistic donation would likely be further diminished – who would bother a family member if a high-quality organ can be purchased somewhere else?

There is widespread consensus that such a development would not be desirable (UNESCO, 2005, Art. 13). As a response, regulated market models have been suggested that aim to take care of negative social consequences while maintaining the possibility of organ selling in an attempt to increase the number of available organs. As features of a regulated markets, the following have been suggested: confinement to a self-governing geopolitical area; limitation of sellers to residents of that area, who are at the same time eligible to receive organs; a public health agency as the only purchaser, which would also be responsible for fair allocation according to medical criteria; and prices that are attractive to potential vendors (Erin & Harris, 2003).

A regulated market is perceived by some as the superior alternative to black markets which are presumed to prevail anyway (Daar, 2006). Others consider the idea of regionally contained, fair markets illusory, arguing that legitimizing such practices anywhere in the world will lead to exploitation of the underprivileged (Jha & Chugh, 2006), either because such models are copied but implemented in an ethically less exigent way, or because regionally contained markets in a globalized world might quickly resort to outsourcing, which – once the moral qualms about recruiting people through payment are overcome – will provide yet more organs at a cheaper price.

The question if making an organ available to a patient in need should be the subject of a business deal, and if organs are to be considered commodities that one owns and trades at will are fundamental decisions that deeply impact on one's self-understanding and on the social fabric of a society.

Risks and Benefit

Two facts are frequently cited when organ selling is discussed: One is the increasing gap between demand and supply of organs, due to a growing circle of recipients. With the advance of transplantation medicine, patients are now transplanted that

would not have been considered eligible previously, due to their condition, their health status, or other factors. In addition, the number of people needing an organ is increasing, notably in developing countries, for instance, due a rising incidence of renal failure caused by diabetes that comes with a change in diet. The other facts are the low mortality and morbidity risks of kidney donation, if carried out at excellent facilities, as well as the outcome for recipients, which usually experience an improvement in the life expectancy and quality of life as compared to dialysis. Mortality and complication rates are higher for liver segment donors, the other main organ procured through living donation.

In a market setting, quality might suffer if organs come from poor vendors. Depending on the transplantation setting, there might be an additional risk of infections and other complications. As far as the vendor is concerned, those promoting market schemes usually do not doubt that the vendor would benefit through the payment. This is, however, a hypothesis that needs to be scrutinized in the light of empirical data. Another hypothesis that frequently goes unquestioned is the assumption – in fact the major justificatory premise – that paying vendors would result in a net gain of organs. This is certainly true if an unregulated global market is considered. Many people are desperate enough worldwide to willingly part with an organ. However, it is much less certain if a significant number of individuals would be willing to sell an organ in a regulated market in a country with a well-developed social security system. For instance, an exploratory study among Swiss medical students showed that – although many found the idea of being allowed to sell an organ interesting at first sight – almost none of them would have volunteered to vend an organ other than in a situation of financial duress (Rid, Bachmann, Wettstein, & Biller-Andorno, 2009).

Selling Human Organs Under Real-World Conditions

In order to judge the validity of the ethical arguments for and against organ selling, a look at the available empirical data is indispensible. Over the past years, a number of studies have been published, describing the effects of organ selling in different settings (Goyal, Mehta, Schneiderman & Sehgal, 2002; Moazam, Zaman, & Jafarey, 2009; Zargooshi, 2001a, b).

Consequences for Vendors

It could be assumed that those who vend an organ and receive a certain amount of money in exchange would be better off after the sale. The short-time and long-term risks of nephrectomy have been found to be very small in studies published in well-known journals. The psychological effects of vending could be thought to be positive too; after all, the vendor has performed a courageous act that has helped another person survive or to enjoy a better quality of life. Regarding social status, such a person might be considered if not a hero, at least a respectable person, and

acknowledged by his or her loved ones for the sacrifice to ensure better living conditions for the family. The sum received might help to lift a family out of poverty, allowing them to move to another quarter or to start up a small business, leading to long-term, sustainable benefits. This is the utopia that is guiding some voices that speak up in favor of organ markets.

The picture emerging from social science studies is quite different. A cross-sectional study carried out among kidney vendors from Chennai, India, on average 6 years after the sale, found no long-term economic benefit and possibly a deterioration of health (Goyal et al., 2002). Once India implemented a legal prohibition of organ selling, Pakistan emerged as a center for organ trafficking, in particular the cities of Punjab. Quantitative and qualitative studies describe the impact of the sale on vendors' lives (Moazam et al., 2009; Naqvi, Ali, Mazhar, Zafar, & Rizvi, 2007).

The core findings of these studies are similar and reveal that sellers are frequently poor, illiterate, and in a relationship of dependency, such as bonded labor. Their main motivation for the sale was to pay off debts. The amount of money they received was modest (around 1,000 dollars) and frequently less than they had expected. The money was usually used to pay debts or items of daily living such as food or clothing. In many cases, the family income declined after the nephrectomy. The vendors reported a deterioration of health status and ability to work. There was no follow-up care. Most vendors would not recommend selling a kidney to others in a similar situation; many regretted their decision. The scar was perceived as a stigma.

Regulated Markets

Those who argue in favor of organ selling are quick to point out that problematic consequences might be seen in unregulated markets, with vendors being at the mercy of obscure middle men or recipients of higher social status. Iran is to date the only country that has extensive experience with a regulated system, although other countries such as Singapore or the Philippines are experimenting with various forms of incentives as well. In Iran, kidney vendors are recruited by a nongovernmental organization and receive a fixed rate from the state, plus an additional sum that can be negotiated privately between vendor and recipient. This second payment can cause conflict if promises are not kept or if there were misunderstandings about the amount to be paid. Vendors reportedly receive free health care for one year, but there is neither long-term follow-up nor a registry (Zargooshi, 2001a; Rizvi, Naqvi, Zafar, & Ahmed, 2009a). A qualitative study with interviews of kidney vendors confirms the findings reported from India and Pakistan and illustrates poverty as the main cause for the organ sales, and they describe massive anger and frustration with the vendors' dire situation before and after the nephrectomy (Zargooshi, 2001b). The picture that emerges from this study is certainly not one of autonomy, options and choice, but of poverty and despair.

The empirical studies in both unregulated and regulated settings reveal several mistaken assumptions of the organ market proponents: The assessment of risks and benefits unjustifiably extrapolated results from ideal conditions in rich countries. Under less than ideal conditions, risks – in terms of health, psychological effects, and socioeconomic status – are significant and benefits questionable. Second, the idea that financial gain would not take over regarding the motivation for organ selling has not been corroborated. There is no indication that an altruistic motivation is maintained, and the payment seen as an additional nice-to-have. It might not be possible to have it both ways – the motivation will be either mainly altruistic (if no payment is offered) or driven by the financial reward. Finally, the idea that all social strata would act as vendors and recipients has not materialized, at least not in the societies that were studied. Rather, it is the poor who sell, forced by circumstances or in the hope to improve their situation, and they are usually worse off afterward. The problems that have appeared in a regulated system are very similar to those in an unregulated one; regulation thus cannot be considered a quick fix for the problems emerging with paying for organs.

Transplant Tourism

With long waiting lists for organs in many countries, and the easy accessibility of other sites, transplant tourism is an increasing phenomenon. Yet, transplant tourism is not well characterized (Merion et al., 2008). It frequently and in some cases rather openly involves organ trafficking. In any case, transplant tourism undermines a country's ability to provide transplant services for its own population, as resources – in the form of organs, health professionals, or transplant centers – are devoted to patients from other countries (Council of Europe/United Nations, 2009). Packages are offered through websites on the Internet, including the kidney, liver, lung, heart, or pancreas. Organs come either from deceased donors (in China the use of executed prisoners has been a frequently raised issue) or from live vendors. It is difficult to assess the magnitude of transplant tourism. A conservative estimation of around 5% of all recipients in 2005 was offered as number of recipients who underwent commercial organ transplants overseas (Shimazono, 2007).

The label "transplant tourism" focuses the attention on the "tourist" and its well-being. The term has been criticized for its positive, harmless association that glosses over ethical issues. A number of studies have turned to the medical results for recipients. Many times, though not always, medical outcomes were reported to be worse (a higher percentage of transplant failures, postoperative complications, infections, etc.) than the average outcomes in the recipient's country (Cohen, 2009; Rizvi, Naqvi, Zafar, Mazhar et al., 2009b). There has been some controversy as to who would take care of, and in particular pay for, the follow-up care for organ obtained abroad. Although positions differ on this, most would agree that patients should not be penalized by leaving them without appropriate medical care (Schiano & Rhodes, 2010).

A related form of transplant tourism consists in bringing vendors or their organs to the recipient's country or a third country. Some countries, such as China, Pakistan, and the Philippines, have been recognized as "organ-exporting," whereas others are "organ-importing countries," such as Australia, Canada, Israel, Japan, Oman, Saudi Arabia, and the USA (Shimazono, 2007).

The web of international interactions that has unfolded in the context of transplant tourism shows that in a globalized world, a regionally contained market is likely to remain an illusion. Legitimizing profit motives in the procurement of organs will foster different forms of international trading and is likely to exacerbate exploitative practices at a global scale (Budiani-Saberi & Delmonico, 2008).

International Policy on Organ Trafficking

The policy issued by international bodies has always taken a prohibitive stance on organ selling. The prohibition was frequently formulated as a brief, matter-of-fact statement, without any further qualification. The Council of Europe Convention on Human Rights and Biomedicine (1997), for instance, in Chapter VII, Art. 21 stated: "*The human body and its parts shall not, as such, give rise to financial gain.*"

In more recent times, however, this prevailing consensus on the obvious moral wrongness of organ selling was challenged from two sides. One form of criticism came from those who did not question the prohibition of organ selling as prudent policy but were unhappy with its justification. A categorical prohibition of organ selling based on Kantian arguments, it was argued, could not claim to be universally accepted, particularly not in a pluralist global context. Others considered the policy in itself flawed and lobbied for liberalization, allowing the possibility of regulated markets.

In reaction to these charges, policies were revisited, leading in some cases to a more refined justification, yet the prohibition of organ selling remained untouched. In the following, an overview of current international policy will be provided.

Current International Policy

In May 2010, the 63rd World Health Assembly endorsed the *WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation*. At the same time, it urged Member States "to promote the development of systems for the altruistic voluntary non-remunerated donation of cells, tissues and organs" and "to oppose the seeking of financial gain or comparable advantage in transactions involving human body parts, organ trafficking and transplant tourism" (WHO, 63rd World Health Assembly WHA63.22, 2010).

The Guiding Principles address a number of ethical issues of transplantation, among them consent requirements, donation from minors and legally incompetent persons, and the allocation of organs, cells, and tissues. Guiding Principle 5 deals

with organ selling: "*Cells, tissues and organs should only be donated freely, without any monetary payment or other reward of monetary value. Purchasing, or offering to purchase, cells, tissues or organs for transplantation, or their sale by living persons or by the next of kin for deceased persons, should be banned.*" Further, it specifies: "*The prohibition on sale or purchase of cells, tissues and organs does not preclude reimbursing reasonable and verifiable expenses incurred by the donor, including loss of income, or paying the costs of recovering, processing, preserving and supplying human cells, tissues or organs for transplantation.*" (WHO, 2010, Guiding Principle 5).

The Commentary on Guiding Principle 5 explains the rationale for the prohibition: "Payment for cells, tissues and organs is likely to take unfair advantage of the poorest and most vulnerable groups, undermines altruistic donation, and leads to profiteering and human trafficking. Such payment conveys the idea that some persons lack dignity, that they are mere objects to be used by others." The justification thus moves away from categorical claims but refers to the (likely) possibility of exploitation that payment schemes would undeniably bring with them. It also questions the coexistence of altruistic and paid donation and points to the mutual recognition as individuals of equal moral status as a basis of modern societies, which might be put at risk if organ selling was a widely accepted legal option.

In a similar vein, the *Medical Association Statement on Human Organ Donation and Transplantation* (WMA, 2000, 2006) states: "*Financial incentives for providing or obtaining organs for transplantation can be coercive and should be prohibited.*" Again, there is no claim that payment for organs has to be coercive under all circumstances, but the probability of this occurring, especially in a globalized world, suffices to justify a cautious policy.

Implementation

Although clear international guidance provides valuable orientation on normative issues, implementation is frequently a challenge. Like the World Health Organization, UNESCO encourages states in its *Declaration on Bioethics and Human Rights* to "*take appropriate measures, both at the national and international levels, to combat (. . .) illicit traffic in organs*" (UNESCO, 2005, Art 21(5)).

Beyond the commitment of states, professional societies play a crucial role in the promulgation and implementation of the prohibition of organ trafficking. The *Declaration of Istanbul on Organ Trafficking and Transplant Tourism* plays a particularly important role in this regard. Initiated by the Transplantation Society and the International Society of Nephrology, more than 150 representatives of scientific and medical bodies from 78 countries around the world, including government officials, social scientists, and ethicists, gathered in 2008 in Istanbul to jointly draft the document. Explicitly referring to the WHO Guiding Principles, the Declaration states: *Organ trafficking and transplant tourism violate the principles of equity, justice and respect for human dignity and should be prohibited. Because transplant commercialism targets impoverished and otherwise vulnerable donors, it leads*

inexorably to inequity and injustice and should be prohibited. (Principle 6, The Transplantation Society/International Society of Nephrology 2008).

Beyond principles, the Declaration contains concrete proposals and recommendations to deal with the scarcity of organs while combating transplant commercialism. They call for legal and professional frameworks on organ transplantation as well as regulatory oversight systems in every country. Professional societies are encouraged to exclude members who violate the Declaration, and funding sources are required to affirm the Declaration when involved in research or clinical activities in transplantation (Delmonico, 2009). Furthermore, a custodian group has been established that continuously promotes the aims of the Declaration. With their forward-looking approach, those initiating and promoting the Declaration of Istanbul have set up an exemplary collaboration of professionals, international organizations, and governments that can have a significant impact on transplantation practices worldwide.

Conclusion

Payment for organs used to be an unquestioned taboo in international policy. The controversial debate on the justification of such a prohibition has helped to articulate the current consensus on ethically acceptable practices in transplantation. Although there is clearly no support for coercive or exploitative practices, opinions differ on the consequences a regulated market would have. As a scrutiny of the pro-market arguments in the light of empirical data has shown, however, there is no plausibility for the claim that markets, regulated or not, might lead to a win-win situation. Existing evidence suggests vendors would be likely to come from the poor segment of a given society and to experience a further deterioration of their health and socioeconomic status. Altruistic donation could be expected to decline, and any attempt to regionally contain markets might not withstand the dynamics of globalized market forces. The current prohibitive stance is therefore well justified.

Policies today do not necessarily claim that payment for organs needs to be unfair and have negative consequences in each and every case. This does not mean, however, that a market approach would be prudent policy. A micro-fairness approach that focuses on individual transactions is insufficient to address this question. Rather, a perspective is needed that takes real-world conditions – such as asymmetries of power and structural injustice – into account.

A lot has been achieved over the past years: There is a set of clear, up-to-date international rules and a dynamic collaboration of the transplantation community, public health authorities, and governments. Next steps might include the development of a monitoring system that would contribute to a more nuanced understanding of the different forms organ trafficking might take, as well as of locations, quantities, and specific enabling conditions. Encouraging nations to strive for self-sufficiency regarding the procurement of organs might help to counter transplant tourism. Finally, alternatives to an increased reliance on live donation might have to be explored, such as presumed consent for deceased donation, combined with an increased focus on prevention of end-stage organ failure.

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Poverty

46

Juha Räikkä

Introduction

Every year, millions of people die prematurely from poverty-related causes such as malaria, lack of clean water, and malnutrition. This makes tens of thousands of deaths per day. Many of those who die are children under the age of five. From an ethical point of view, there is little doubt that extreme poverty is a bad thing and should be eradicated. This view can be defended by various ways, for instance, by referring to the utilitarian doctrine that suffering is a bad thing, or by referring to the golden rule or categorical imperative, or by referring to the view that we all have natural rights against poverty, or by referring to virtue ethics (as virtuous persons try to help those who suffer), or by referring to the UNESCO Universal Declaration on Bioethics and Human Rights. The view that extreme poverty should be eradicated is compatible with the claim that not all people in the planet should enjoy equal living standards. Global egalitarianism is not the issue here, and the view that extreme poverty is a bad thing is a very weak claim that almost everyone can accept. Those who deny it may have environmental concerns in mind and think that extreme poverty is a welcome phenomenon as it kills a lot of people and hence decreases the number of consumers of natural resources. However, it is not clear whether this argument is a *moral* argument at all, and in any case, this chapter is based on the normative assumption that extreme poverty should be eradicated. The real problem is that there is no agreement about what should be done. Not all actions are feasible and productive, and those that are can be ethically doubtful. Extreme poverty raises difficult ethical and philosophical questions. This chapter deals with the following ones. How to define poverty? What is the point of the Millennium Declaration? What is the value of development aid? Can poor countries help themselves? Is poverty possibly based on a self-fulfilling prophecy? How poverty and population growth are related to each other? What should be the role of genetically modified food in the war against extreme poverty? Let us start with the problem of a definition.

J. Räikkä
Behavioural Sciences and Philosophy, University of Turku, Turku, Finland
e-mail: jraikka@utu.fi

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Absolute and Relative Poverty

It is customary to distinguish between absolute and relative poverty. Absolute poverty refers to a criterion that is universal and makes international comparisons possible. Relative poverty views poverty as context dependent and is closely related to the assessments of social inequalities. Poverty is related to issues such as health, education, violence, a sense of security, housing conditions, political power, population growth, and hunger. Extreme poverty is seldom voluntary, and people who suffer from extreme poverty cannot always satisfy their basic wants such as a need for food, water, shelter, basic education, minimal medical care, and self-respect.

There is no agreement about the proper definition of poverty in either sense. In the *Encyclopedia of Global Justice* 2011a, b, Teppo Eskelinen writes both about absolute and relative poverty. He points out that definitions of absolute poverty often rely on a certain understanding of basic needs and that this is problematic as we do not know, exactly, what our "basic needs" are. (Eskelinen, 2011a). It is doubtful whether they are *only* biological needs (cf. Gasper, 2004). In practice, the attempts to measure the number of people living in absolute poverty have been based on financial measurements. A poverty line is defined, and persons falling under this line are classified as poor. The most used poverty lines are expressed in US dollars (for instance, $1.08 per day for extreme poverty), and these lines have been defined by the World Bank. As Eskelinen (2011a) points out, the figures do not refer to actual dollars but to purchasing power. Typically, the purpose of poverty reduction is to raise poor people above a poverty line, not to make income distribution more equal or to increase the overall living standards in poor countries. Eskelinen (2011a) argues that this policy is often defended by the ethical argument that absolute poverty generates duties for affluent countries to alleviate poverty, while less severe forms of poverty do not generate similar obligations.

Relative poverty is a context-dependent concept, and a person can be poor in a relative sense while not being poor in an absolute sense. Eskelinen (2011b) argues that relative poverty is seen as a matter of failure of distributive justice, while absolute poverty is seen as a failure of meeting the requirements of basic dignity of human beings or human rights. Both relative poverty and absolute poverty relate to the issues of global justice, but in different ways. Relative poverty can be understood mainly as a psychological concept that refers to people's expectations and desires. When certain goods become common in a society and people are expected to have these goods, then not having them may lead to a feeling of being poor, whether or not the goods in question are, in any meaningful sense, "necessary." Eskelinen (2011b) points out that it is possible that some things become necessities for living in a society and that the inability to acquire such goods is not merely a matter of unmet wants. For example, transportation can be possible by only specific technological solutions, and the failure to access these can lead to relative poverty in a sense which refers to more than mere wants or expectations. Relative property is not merely a psychological concept (Eskelinen, 2011b).

Millennium Declaration

There is no doubt that people are familiar with the fact of extreme poverty. The main purpose of the United Nations' *Millennium Declaration* is to eradicate extreme poverty and hunger (cf. Hutchings, 2010). According to the Declaration, accepted by General Assembly, the goal is "[t]o halve, by the year 2015, the proportion of the world's people whose income is less than one dollar a day and the proportion of people who suffer from hunger and, by the same date, to halve the proportion of people who are unable to reach or to afford safe drinking water."

How can this be done? The Declaration lists, *inter alia*, the following means. The industrialized countries should (1) adopt a policy of duty- and quota-free access for essentially all exports from the least developed countries, (2) implement the enhanced program of debt relief for the heavily indebted poor countries without further delay and agree to cancel all official bilateral debts of those countries in return for their making demonstrable commitments to poverty reduction, and (3) grant more generous development assistance, especially to countries that are genuinely making an effort to apply their resources to poverty reduction.

Critics have argued that the goal of the Declaration is modest. Why is the purpose only to *halve* the number (or the percentage) of people who live in extreme poverty? And why is the time period fifteen years? (The Declaration was made in 2000.) The defenders have replied that more demanding goals would be unrealistic and unfeasible, and perhaps the view is justified, judging from the fact that even the realization of this "modest" goal has turned out to be difficult. It is important to note that the above-mentioned means of eradicating poverty – i.e., (1) fair trade, (2) debt relief, and (3) more intensive development assistance – do not *oblige* any country to carry them out. They are based on every country's voluntary efforts. Fair trade, debt relief, and development assistance are very complex tools, and one can use them counterproductively as the history of development assistance shows. For instance, when a rich country gives grain for a poor country for free it may cause permanent damage to local farmers, agriculture, and food production.

The Value of Development Aid

It is relatively widespread to doubt the value of development assistance. This doubt is often expressed not only in daily debates concerning development aid, but also in academic writing. In his *Despite Good Intentions – Why Development Assistance to the Third World Has Failed* (2003), Thomas W. Dichter argues that it is impossible to eradicate global poverty, because development assistance does not and cannot work properly. Dichter (2003, p. ix) writes that he has "doubts about the value of development assistance" and that he knows of no organization that really accomplishes much in the way of sustained alleviation of poverty or promotes real development or does exactly what it told the public it would do. According to Dichter (2003, p. xi), his "concern is to show not so much *why* development

assistance does not work (. . .) but *how* it does not work" (although the subtitle of the book is the former question). He does, however, have an explanation for the mystery why it does not work – and why it cannot work. The explanation has two, closely linked, parts.

The first part of the explanation is based on the idea that institutions are "slow" – they do not change easily – and that the *development industry* is an institution which changes very slowly, if at all. Dichter (2003, p. 2) asks "[w]hy has an industry that since 1960 has spent over $1.7 trillion on development assistance, by any commonsense cost-benefit calculus, produced negligible results (if not made things worse)?" and points out that "[n]o other large-scale publicly funded effort on such duration could have got away with such poor performance, certainly not in the private sector or even in the ranks of government" (Dichter, 2003, p. 2). Dichter's answer is that aid has become a business whose main stake is its own survival. But this is not to say that organizations or people who work in them have bad intentions. Dichter (2003, p. xiii) writes:

> Most development professionals I have met possess very high ideals about the work they do. But because no one has to date been funded to do development work outside the structure of an organization, those good intentions and ideals get twisted, bent and reshaped. Development professionals have, almost all of us, become caught in the evolution of a set of increasingly self-serving structures whose imperatives, stakes, and incentives have snuck up on us, sometimes so quietly that we have not noticed. If we haven't seen how much those structures limit and compromise development, it's partly because we are in fact so sincere and partly because it is not in our interests to do so.

The second part of the explanation consists of the claim that it is impossible to do anything good by becoming involved in a strange culture and a foreign political system. Development industry denies the validity of this claim or ignores it. One cannot control historical processes. Dichter (2003, p. 7, 9) explains:

> The keys to development increasingly lie in the realm of the policies, laws, and institutions of a society, and to change these requires indirect kinds of approaches – stimulating, fostering, convincing – rather than doing things directly. Why is it, then, that the majority of development assistance organizations continue to "do" things? And why do more and more come into existence every day with funding to do still more things? (. . .) The problems of development are far too complex for any organized and deliberate effort to solve in any lasting way. Development is not a set of obstinate problems the way cancer is but a historical process that cannot really be engineered or controlled.

Dichter's (2003, p. 19) conclusion is pessimistic. According to him, a formally organized, publicly paid for, outsider-driven industry can accomplish "very little." Whatever "few things it may make sense for 'us' to do for 'them', must be done with a light hand. These things, moreover, will have few easily measurable effects, will surely take far *less* money than is presently being applied, and will involve far fewer and much smaller organizations to manage them" (Dichter, 2003, p. 19).

One might argue, however, that Dichter's pessimism is based on an exaggeration. Although it is easy to agree that the development business is growing and that it is often difficult to influence historical processes from outside, it seems clear that even if institutions are "slow," this does not imply that they are unchangeable.

History provides a number of examples of stable institutions which have radically changed structurally – either because of a catastrophe, such as war, or because of intentional external pressure or a radical change in the financial situation. Development industry may well change. It is worth noting that development organizations do *not* get as much money as they are supposed to get. The claim that it is impossible to influence the cultural and political life of a given society from the outside is familiar from the debate on humanitarian interventions, and it seems that the acceptability of the claim should be assessed on case-by-case basis.

It is important to note that no country lives quite separately from others and that influencing the affairs of other countries from outside is something which happens all the time. To say that a development industry intervenes in the political processes of developing countries with no chance of success is to suggest that otherwise those countries are not influenced by the industrialized world and are left untouched. Indeed, Dichter's account seems to be based on the explanation of global poverty that is perhaps the most popular one, namely, the claim that the eradication of severe poverty in the Third World depends largely on their local governments and that wrong decisions explain why the countries are poor. This assumption can be and has been challenged.

Can Poor Countries Help Themselves?

In his article on global order and democracy, published in 2001, Thomas Pogge (2001, p. 333) argues that "our global order plays an important part in sustaining oppression and corruption in the poorer countries." Oppression and corruption, in turn, "cause not only poverty in the developing world, but also moral detachment among the affluent." Pogge is especially concerned about the so-called *international borrowing privilege*, i.e., a right of any Third World government to negotiate loans from international financial markets. He (2001, p. 335) suggests that the "international borrowing privilege has three important negative side effects on the corruption and poverty problems in the developing world." They are as follows: (1) The privilege facilitates borrowing by destructive governments and helps such governments to maintain themselves in power even against near universal popular discontent and opposition. (2) The international borrowing privilege often imposes huge debts accumulated by earlier corrupt regimes upon their democratic successors. It thereby saps the capacity of such democratic governments to implement structural reforms and other political programs. (3) The international borrowing privilege further strengthens the incentives at attempting a coup: whoever succeeds in bringing a preponderance of the means of coercion under his control obtains the borrowing privilege as an additional reward.

How we should try to eradicate poverty? Pogge's main idea is the Global Resource Dividend which, in some respects, resembles the proposal called the Tobin Tax (i.e., a tax for currency transactions in order to collect money for poor countries). According to the Global Resource Dividend, states and their governments shall not have full libertarian property rights with respect to the natural

resources in their territory, but can be required to share a small part of the value of any resources they decide to use or sell. However, Pogge also stresses that the democratic governments of poor countries can do something *themselves*, without complex global redistribution systems such as a Tobin Tax or a Global Resource Dividend. The governments can support democratic development, oppose corruption, and possibly stop the borrowing privilege by local efforts. What is needed is a *constitutional amendment* which says that loans that are borrowed by authoritarian rulers need not be paid back to international banks. In his *World Poverty and Human Rights* (2002, pp. 153–154) Pogge writes that

> There are (. . .) ways of affecting the dispositions of foreign states in ways that would, without violence, reduce the rewards of, and would thereby tend to discourage, an undemocratic takeover. One such measure is a constitutional amendment requiring that debts incurred by future unconstitutional governments – by rulers who will acquire or exercise power in violation of our democratic constitution – must not be serviced at public expense. The idea behind this amendment is to bring it about that successful predators will be able to borrow less, and this at higher rates. If it can achieve this purpose, the amendment would stabilize our fledging democratic order by reducing the payoff associated with a successful coup d'état and thereby weakening the incentives for attempting such a coup in the first place.

Of course, after a successful coup authoritarian rulers can simply declare the amendment suspended, but should they eventually lose power, the democratic government that succeeds them can nonetheless refuse repayment of their debts on the grounds that the coup was illegal (cf. Räikkä, 2006).

Would international banks grant loans to the future authoritarian governments in this situation? According to Pogge (2002, p. 154), they would not. The banks could not be sure that the governments of their home countries would support them in case they did not regain their money. They would know that their governments (i.e., governments of rich democracies) might refuse to help them exactly because of the amendment made by democratic rulers. "Serious public-relations problems, both home and abroad, could arise" if the governments of rich democracies openly supported authoritarian laws above democratic constitution of a poor country. Therefore, if the constitutional amendment were in place, international banks would grant loans only to democratic governments, not to authoritarian rulers. The borrowing privilege – the main cause of corruption and poverty – would be eliminated.

Pogge does not explain why banks of *undemocratic* rich countries would not grant loans to the future authoritarian governments. However, he provides a rather detailed analysis of the constitutional amendment, and he answers other difficult questions such as how to distinguish between democratic and authoritarian governments ("the criterial problem"), and what should be done if the possible authoritarian successors refuse to pay debts of democratic governments ("the tit-for-tat problem"). Pogge (2002, pp. 156–161) argues that we should have (1) a *Democracy Panel* that identifies democratic governments and (2) a *Democracy Fund* that guarantees that debts of democratic governments will always be repaid to international banks. These claims suggest that the functioning of the constitutional amendment is *not* really in the hands of an individual government. Rather, it depends on international support as would be the case with the Tobin Tax or the Global Resource Dividend.

This raises the question whether it is likely that the governments of the powerful rich democracies would readily agree to establish the Democracy Panel and support financially the Democracy Fund. After all, the Democracy Fund would cost much, and rich countries have no incentive to oppose dictators who sell at giveaway prices the natural resources of their land (and keep the money). Pogge admits that some of the governments of the rich democracies would probably object to the constitutional amendment, claiming that it would cause too much instability to international financial systems. In Pogge's (2002, p.160) view, however, this claim is plainly false. The constitutional amendment would engender instability only if rich countries refused to support the necessary institutions related to it, and anyone defending the opposite claim would be seen in a bad light "in the arena of world public opinion." This would reduce pressure by the rich countries against the constitutional amendment.

Pogge's argument seems to rely on the same assumptions as the whole idea of the constitutional amendment, namely, (1) that "public relations" and "public opinion" can have significant effects on the decisions of the governments of rich democracies and (2) that public opinion would condemn actions that contradict democratic development in the poor countries. Pogge argues further that, in fact, the support of the most powerful democratic countries is unnecessary. The Democracy Fund can be financed in another way. He (2002, p.161) writes that the "capital facility needed for the Democracy Fund can be financed through contributions by democratic developing countries, by the more progressive developed democracies, by international organizations, and by contributions from banks and multinational corporations."

Pogge's critics (Räikkä, 2006; Jaggar, 2010) have pointed out that the credibility of this argument depends on how much money is needed to finance the Democracy Fund. If a group of other powerful rich countries oppose the constitutional amendment and the institutions related to it, the Democracy Fund will probably be a very weak and poor organization. It can be argued that international organizations (such as the United Nations and WTO) or banks (such as the IMF and the World Bank) will not give any money to the Democracy Fund, if powerful countries so decide. It is likely that multinational corporations (such as Nokia and Shell) will not endanger their position by opposing world leading countries, and the same is true of "more progressive developed democracies." It is hard to imagine that countries such as Sweden or Norway would strongly support an institution which is explicitly criticized by their powerful allies.

Pogge has recently defended his position for instance in *Politics as Usual* (2010).

Poverty as a Self-Fulfilling Prophecy

There has been a tendency to explain global poverty by referring to the selfishness of the citizens of affluent countries. For instance, in *One World: The Ethics of Globalization* (2002, pp. 152–153), Peter Singer argues that "for many people,

the circle of concern for others stops at the boundaries of their own nation" and that the popular view is that we may, or even should, favor those "of our own kind." An alternative to this view is the idea that the question is about an unfortunate *self-fulfilling prophecy*. The theory states that most people in the affluent countries *believe* that for one reason or another it is practically *impossible* to eradicate poverty, and that this shared belief *itself* may be a cause for why it is practically impossible to eradicate it in the near future. The only cause for global poverty need not be the alleged selfishness of people. It is possible that the main cause is a commonly shared belief that it is impossible to eradicate poverty from the Third World, which influences people's behavior. Behavior that may seem selfish need not be selfish, if it is based on the pessimism regarding the possibilities of success.

There are several reasons why people think that it is practically impossible to get rid of global extreme poverty. Academic literature and daily newspapers are both full of arguments that aim to show that a fight against poverty would be a politically unfeasible project. A person who believes in one or other of these arguments needs not be selfish in any way. The familiar arguments include the following claims:

1. *The Argument Based on Population Growth*. It is impossible to reduce poverty effectively, because increased well-being would cause overpopulation, which in turn would decrease well-being. Famine, diseases, and a high infant mortality rate prevent population growth. There would not be enough food to feed a larger population. Genetically modified organisms that can be used in agriculture will never save people from starving.
2. *The Environmental Argument*. Global equality would cause huge environmental problems. Not everyone in the world can have a car. In the long run, pollution and other environmental problems would make living for human beings impossible, at least in most areas. Therefore, it is practically impossible to eradicate poverty in any meaningful sense.
3. *The Blame Approach*. It is impossible for Western countries to save people in the Third World from starving, because famine and suffering are their own fault. Foreign aid does not work, because the money is used, not for schools, but for dictators' Cadillacs and castles. There is no way of solving military conflicts between local groups and clans, and these conflicts are one of the main reasons for poverty. The idea of exporting democracy from the outside is a joke.
4. *The Not Enough Money Approach*. It is an unfeasible idea that people in the West could really eradicate poverty. This would be impossible because it would be far too expensive, not only in the sense that people would not be happy to give away what they have but in a concrete sense that there simply would not be enough resources to do so. To feed every single person in the world requires not only food – which is not expensive – but also roads, schools, and dozens of local uncorrupted organizations that simply do not exist.
5. *The Argument from Political Realism*. It is impossible to reduce poverty, because nation-states are selfish actors – even if their individual citizens are not. Nation-states would never create international organizations that have

power to really do something for the Third World. Nation-states act on the basis of *political realism*, and they are happy with organizations such as the United Nations, which will never have sufficient power to reduce poverty.

6. *The Technical Argument*. The idea of eradicating poverty from the world is technically unfeasible, at least in the near future. Even if there were enough money and enough political willingness to fight for global equality, it would not work. This is because there are no redistributive structures. To dream of systems such as the Tobin tax is to ignore the fact that redistribution requires not only complex civil servant machinery but also an effective system of sanctions and courts to solve cases. At the moment, we do not have them.
7. *The Argument from Multinational Corporations*. Multinational corporations, by their nature, are largely independent of the political decisions of the nation-states in which they operate, and also of their home countries. Multinational corporations are not interested in reducing poverty. On the contrary, in a sense they are interested in increasing it, because they try to benefit from the poverty in the countries in which they operate. Currently, there is no political way of controlling multinational corporations, and this is why it is practically impossible to reduce poverty or to prevent inequality from increasing.
8. *The Argument from Value Pluralism*. Suppose that rich countries would decide to fight for moderate global equality and redistribute resources. How should those resources be distributed? Should we use Scandinavian standards, or North American, or maybe Saudi Arabian? There are no globally shared standards of (re)distribution, and therefore, there is no chance of distributing them in any way.

The list of arguments for the claim that it is practically impossible to eradicate global poverty is much longer than the list above. What seems common to all these arguments, however, is that they are controversial. (Indeed, one might claim that most of them are plainly false). Even so, it seems clear that they are very popular – judging from the frequency of these arguments.

A self-fulfilling prophecy is a description of the situation that becomes true because of the actions performed as a result of the public acceptance of the prophecy. When an economist presumes that prices will go up in the housing market in the near future and reveals his opinions in public, the result may be that prices will indeed go up – and just because people try to buy a house before the prices do go up. The public announcement and the common acceptance of the prophecy make it come true. The discussion on self-fulfilling prophecies has centered on the difficulty of making predictions in the social sciences. It is hard to make predictions of social life and *test* theories, because predictions influence the data that are supposed to confirm or disprove those theories. Social predictions may possess a reflexive force. They may make themselves true (or untrue).

What could be the route from the widely shared belief that poverty in the Third World is a necessity to the possible fact that it *is* a necessity? There are several possible reasons why the claim that global inequality is unavoidable could be a typical self-fulfilling prophecy. (Cf. Räikkä, 2004). When people believe that it is practically impossible to get rid of global inequality, they might be politically passive in issues related to foreign aid. Perhaps they do not vote for politicians that

are interested in global justice. Perhaps they do not participate in the actions of different nongovernmental organizations that pursue a better world. They could give more donations or join the one percent movement. They could do voluntary work in the poor states. They could take part in an action such as "Sponsor a Child." They could start new organizations that fight against poverty in the Third World. But why should they if such actions are futile? When people believe that poverty is unavoidable, there is little pressure on national governments. And why should governments try to do something which is impossible?

Of course, not all people believe that poverty is a necessity, and there are many active citizens who really try to do *something*. Indeed, the belief that it is practically impossible to get rid of poverty is compatible with the idea that there is much that we can do. Thus, even the majority who seem to accept the *impossibility thesis* may be willing to do something, because they realize that something is better than nothing. But still it may be the case that eradicating poverty from the Third World is extremely difficult mainly because of people's pessimism.

The claim that global inequality can – at least partly – be explained by referring to the unfortunate self-fulfilling prophecy should be distinguished from the claim that people (and states) hesitate to fight against poverty because they are afraid that others will not. The so-called compliance problem, as the latter claim is often called, is important, but it is not directly related to the self-fulfilling prophecies. Rather, the compliance problem provides an alternative way of explaining why people do not do good things even if they would like to.

Poverty and Population Growth

Extreme poverty and population growth are closely related as poverty tends to enlarge family size. The growth of world population raises two kinds of normative questions. First, there are questions of intergenerational justice. How should welfare be distributed across generations? What kind of theoretical framework should we construct to deal with future generations? Second, there are ethical questions of population policy. Since determining the number of people in the world is partly a matter of individual and social choice, it is subject to moral evaluation. What are desirable goals of population policies? Which means are morally acceptable when striving for these goals? How should the burden of achieving a demographic goal be distributed? Questions of intergenerational justice and the ethics of population policies are interrelated in various ways, but it is important to note that intergenerational justice concerns current and *future people*, i.e., people who will live in the future, while the ethics of population policies concern *potential people*, i.e., entities that have the potential to become a person, and *possible people*, i.e., people who will live in the future if we so decide.

Certain population policies have caused serious social and moral problems. Eugenics and sterilization were widely used both in Europe and North America in the twentieth century. Contraceptives have had unknown side effects, and women have not been fully informed of their health risks. Especially in the Third World

countries coercion of women has been a general feature of many population policies. Control-oriented policies have been much more common than service-oriented policies. Compensation payments have linked sterilization and abortion to poverty, highlighting, and increasing social inequality. Certain policies have led to sex selection and to the killing of female newborns. These kinds of problems may suggest that active population policies are morally problematic *per se*, but a *laissez faire* population policy – a policy of nonaction – may cause serious problems too.

In general, there is a relatively good understanding of what should be done to reduce family size in areas of rapid population growth. We may, *inter alia*, try to increase social approval of small families, to cut down the opportunities for children to be productively employed, to make social security available for the elderly, to reduce the costs of contraception, to increase knowledge of contraceptive techniques, to improve social standards involved in the raising of children, to increase the cost of products used by children, to educate young women, to create well-paid jobs for young women, to speed up urbanization, and to impose mandatory education for children where the cost of this education is partly paid by parents. The most effective means to reduce family size would be to eradicate extreme poverty, since poverty causes population growth.

Are coercive population policies ever morally justified? A received view is that ethically acceptable population policies let individuals freely decide the number of their children and that we are permitted to strive for demographic goals only by policies that are noncoercive. However, an argument has been made that if there is no way to slow down the population growth other than using *directly coercive* laws, such laws may be morally justified (Attfield, 1999, p. 128). Those who sympathize with this view emphasize that population growth is inconsistent with the ideals of sustainable development and contributes significantly to environmental, ecological, and social problems in certain areas.

It is not clear whether we should prefer *indirectly coercive* population policies to directly coercive ones if we wished to respect procreative rights. Much depends on the *content* of such indirectly coercive policies. Suppose that there is a law (direct policy) that prohibits having more than two children, but that nothing really happens if one has more than two children. Compare this law to an economic deterrent (indirect policy) that in practice makes it inadvisable to have more than two children. In this case the direct policy seems less problematic than the indirect policy. Consider another example. Suppose there is a law (direct policy) that prohibits having more than three children, and that acting against this law implies heavy penalties. Compare this policy to an economic incentive (indirect policy) that in practice makes it impossible to have more than one child. Again, the direct policy is less problematic than the indirect policy. Compare now a law that restricts the number of children in families (direct policy), and an economic incentive that makes it impossible for poor people to have children and encourages rich people to have them (indirect policy). At least from the point of view of equality, once again the direct policy seems less problematic (cf. Räikkä, 2001).

Population theory has generated a number of philosophical paradoxes and puzzles. A famous puzzle is Derek Parfit's reasoning that classical utilitarianism (i.e., the

"total theory") implies the "Repugnant Conclusion." As formulated by Parfit, the repugnant conclusion is the claim that for "any possible population of at least ten billion people, all with a very high quality of life, there must be some much larger imaginable population whose existence, if other things are equal, would be better, even though its members have lives that are barely worth living." According to (the hedonistic version of) classical utilitarianism, it is a good thing to maximize happiness as long as persons' happiness exceeds their misery and adds to the total sum of happiness on Earth. As long as average happiness declines slowly enough, numbers under classical utilitarianism are encouraged to increase indefinitely no matter how low the average has fallen. But most of us think that this kind of overcrowded world is not the ideal world. There are many ways to react to Parfit's argument. One can simply reject classical utilitarianism, or one may try to show that classical utilitarianism does not lead to the repugnant conclusion or, biting the bullet, one may claim that the repugnant conclusion is not so repugnant. However, it is important to keep in mind that poverty-related overpopulation (and birth control that has followed it) have caused much pain and trouble to individual persons, in particular women. Perhaps philosophers have not always taken seriously the suffering of people.

Extreme Poverty and Genetically Modified Food

A suggestion has been made that we could reduce poverty and the number of unnecessary deaths by the use of genetically modified organisms (GMOs). This view has been supported for instance by the multinational agricultural biotechnology corporation The Monsanto. According to the argument, GM agriculture may (1) produce bigger harvests, (2) make food more nourishing, and (3) make food cheaper in the developing countries. There is no doubt that the problem of poverty should be resolved by political means, but it seems that at the moment there is no feasible political solution. The ethical acceptability of GM agriculture should be evaluated in this context. The defenders of GM agriculture argue that we should try to use *all* possible means to reduce the number of unnecessary deaths. However, there are well-known objections against this proposal (Altieri & Rosset, 2002). Let us list and consider four typical arguments against using GM agriculture in helping the poor.

The first argument is the claim that the major cause of poverty and hunger in the world is not lack of food but unfair distribution. The distribution of the means to acquire food and the actual distribution of what is already available in terms of food is poor. There is, therefore, no need to use GM agriculture. The first argument does not tell whether GM agriculture will be useful in the future. Even if there is enough food now, GM agriculture may be necessary in the future. It is also important to notice that the first objection does not prove that GM agriculture is useless: *if* GM agriculture results in bigger harvests or makes food more nourishing or cheaper, then it may be very helpful.

The second argument claims that gene-altered plants will induce allergies, or rock the delicate balance of nature. Gene-manipulated grain and other species are

living pollutants, the effects of which are beyond anyone's grasp to comprehend. Therefore, GM agriculture should not be used. This objection is based on the assumption that GM food has harmful effects on health or environment. Perhaps this is true, as the European Union stresses the risks of GM agriculture. However, the reasons behind the EU claims may be economic rather than environmental or social. The second objection raises the question whether it is more important to avoid health and environmental risks than to try to save people's lives: if GM agriculture saves five percent of people who would otherwise die, it would save a considerable number of people every day.

The third objection says that genetic engineering means that the poor in rural areas may well become more dependent on the multinational companies who provide seeds to local farmers. Local farmers will lose their own seeds. That is social injustice. Therefore, GM agriculture should be rejected. The third argument reveals one problem that is related to GM agriculture, although one should remember that *all* agriculture have similar consequences in poor countries, at least potentially. (The problem of dependence is related not only to GM agriculture.) A critic might point out that the third objection is based on the suspect ethical assumption that it is more important to oppose social injustice than try to save people's lives. Social injustice is a bad thing, but it need not *kill* anyone.

According to the fourth argument, even if gene technology were to yield bigger harvests, it would not help solve the hunger problem. The causes of underlying hunger are political and economic, they are not technical. Therefore, GM agriculture is futile. This objection shows that, at best, GM technology provides incomplete solutions to hunger and poverty: clean drinking water and cheaper medicines are, *inter alia*, also needed. However, the objection assumes wrongly that political problems cannot have technical solutions. Indeed, it is relatively common in politics that difficult questions are solved by technical means. (For example, new train connections make a change of work place more accessible and so on.) Another point is that the fourth argument is based on a dubious claim that nothing need be done if not everything can be accomplished. Of course, one must try to save one person even if it is impossible to save ten.

It is difficult to say how helpful GM technology in agriculture could be; the future may show that it is not very helpful, at least in eradicating poverty in terms of preventing unnecessary deaths.

Conclusion

Extreme poverty raises many ethical and philosophical questions, even if one agrees that poverty is a bad thing and should be eradicated. As the discussion above shows, many problems are related to the question what kinds of solutions are *feasible*. The notion of feasibility, however, is anything but clear. The evaluation of the feasibility of a certain goal seems to refer to means and processes. One can criticize a political proposal from the point of view of both desirability and feasibility, but quite often the desirability of a goal (such as reduction of poverty)

is taken *for granted* when its feasibility is evaluated. When we estimate the feasibility of the goal, we ask whether we should strive for the goal – now that we know it *is* desirable. There are at least two different attributions based on a lack of feasibility, i.e., judgments that conclude that a certain social ideal is "not realizable." First, it can be said that the realization of a social ideal is strictly and literally impossible and just cannot be implemented in practice. Second, it can be said that there are weak constraints such as economic or cultural facts that make an ideal less feasible than other goals in that their existence makes the achievement of the ideal very difficult and decreases the likelihood of success.

Notice, however, that it can also be said that a social ideal cannot be realized because its realization process would (more or less necessarily) require unjustified (moral) sacrifices. The point of these kinds of judgments is not to say that one cannot realize a given goal or that its realization would be very difficult. Rather, the point is to argue that one *should not* realize the goal, given the moral costs that its realization process would necessarily create. These kinds of judgments may require *moral defense*, but too often they are presented as if they were factual claims that need not be defended normatively. Those who make normative claims should make their reasoning explicit so that their arguments could be evaluated. People who present new proposals have a right to know exactly what are the allegedly unavoidable moral costs that make the ideals unrealizable. If someone argues that eradicating global poverty is unrealistic, then he or she has the burden of proof to show why this is so.

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Scientific Misconduct and Research Integrity

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David B. Resnik

Introduction

In the last two decades, scientists, scholars, policymakers, and members of the public have become increasingly concerned about threats to scientific integrity, such as fraudulent academic research, plagiarism, manipulation, and suppression of data by pharmaceutical companies, academic-industry collaborations, exploitative mentoring of students, abuses of animal and human research subjects, misuse of funds, and lax institutional oversight. Scandals involving unethical research have frequently drawn the attention of the press and politicians. To promote integrity in research in the USA, the National Institutes of Health (NIH) and the National Science Foundation (NSF) have promulgated ethics policies, such as conflict of interest and misconduct rules, and have required graduate and postdoctoral students funded by grants to receive education in responsible conduct of research. Scientific journals, professional associations, and research institutions have also developed ethics guidelines (Shamoo & Resnik, 2009; Steneck, 2007). This entry presents an overview of research ethics, examining the foundations of research ethics, principles for ethical research, common ethical dilemmas in research, research misconduct, famous cases of misconduct or alleged misconduct, and international ethics standards.

Research Ethics and Integrity

General ethics (or morality) consists of the standards of conduct that apply to all people in society, such as the duties to not harm others, to help others, to not steal, to tell the truth, and to keep one's promises (Gert, 2007). Individuals also have special ethical obligations based on their social roles in addition to their general

D.B. Resnik
Bioethics, National Institute of Environmental Health Sciences, National Institutes of Health, Research Triangle Park, NC, USA
e-mail: resnikd@niehs.nih.gov

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obligations. For example, parents have an obligation to care for their children. Physicians have an obligation to protect their patients' confidentiality. Scientists also have special obligations based on their social roles. Scientists perform several important social functions, including developing and applying knowledge, educating students, and providing expertise and advice for policymakers and the public. Research ethics is thus a type of applied or professional ethics akin to medical, business, or legal ethics. To act with integrity in research is to act in accordance with ethical principles (Shamoo & Resnik, 2009).

Foundations of Research Ethics

A foundation provides support (or justification) for a larger conceptual structure, such as a theory, political system, or worldview. Research integrity has two distinct foundations. First, research integrity is part of good scientific practice because it is essential for achieving the goals of science and for promoting cooperation and trust among scientists. Data fabrication, falsification, and manipulation lead to falsehoods, errors, and biases that impede the quest for truth, explanatory knowledge, and other goals of research. Refusing to share data, results, and methods or keeping inadequate records can also hinder the advancement of science. Cooperation and trust among scientists is essential to many different aspects of research methodology and practice including collaboration, peer review, publication, and the replication of results. For example, scientists who submit papers for publication must be able to trust that reviewers will not steal their ideas or use data, methods, or results. Second, research integrity makes science accountable to the public by ensuring that scientists adhere to ethical standards and produce socially beneficial results. Scientists who violate ethical standards or produce harmful results betray the public's trust and undermine support for research. Abuses of human or animal research subjects, mismanagement of funds, fraud in academic or industry research, violations of laws and regulations, and other ethical transgressions can weaken the public's trust in science and produce detrimental results that harm individuals, society, or the environment (National Academy of Sciences, 2005; Shamoo & Resnik, 2009; Shrader-Frechette, 1994; Resnik, 1998).

Principles of Research Ethics

Nearly 40 years ago, the prominent sociologist of science Robert Merton (1973) described four norms that govern scientific research: communalism (scientists should share data and results), universalism (all scientists should be able to contribute regardless of race, gender, nationality, or culture), disinterestedness (scientists should not allow their personal or political biases to affect their work), and organized skepticism (scientific claims should be exposed to rigorous criticism). Science historian and philosopher Thomas Kuhn (1977) argued that several values influence scientific judgment and theory-choice, including accuracy, consistency,

generality, simplicity, and fruitfulness. Other philosophers (e.g., Longino, 1990) have argued that slightly different sets of values influence scientific reasoning. Although Merton's and Kuhn's ideas still have considerable influence over the sociology, history, and philosophy or science, they do not provide a clear statement of the ethical principles of science, because they focus mostly on the epistemological aspects of science, such as methodology and theory-choice. Ethical principles of research apply not only to scientific evidence and belief but also to scientific behavior and conduct (Resnik, 1998). Ethical principles are implicit in our understanding of what constitutes good scientific practice and are embodied in professional codes and guidelines, institutional and journal policies, and government rules and regulations (Resnik, 1998). These principles are as follows (Macrina, 2005; National Academy of Sciences, 2005; Shamoo & Resnik, 2009; Steneck, 2007):

- Honesty: Scientists should communicate honestly with each other, research sponsors and institutions, government agencies, and the public.
- Due care: Scientists should avoid careless errors and strive to reduce or control biases in research.
- Openness: Scientists should share data, results, methods, and tools.
- Fair credit: Scientists should allocate credit fairly.
- Respect for peers and students: Scientists should treat their students and colleagues with respect.
- Respect for property: Scientists should respect physical and intellectual property.
- Respect for research subjects: Scientists should show appropriate respect toward human and animal research subjects.
- Respect for the law: Scientists should obey institutional policies and legal rules that apply to their work and promote compliance with policies and rules.
- Nondiscrimination: Scientists should not unfairly discriminate against peers or students.
- Stewardship of resources: Scientists should make effective use of physical, financial, and other resources.
- Social responsibility: Scientists should maximize benefits and minimize harms to society, public health, and the environment.
- Freedom: Scientists should respect the right to freedom of inquiry and debate.

These principles provide general guidance for the conduct of research and imply numerous subsidiary rules and obligations that apply to particular situations. For example, the principle of honesty implies prohibitions against data fabrication and falsification. Due care implies rules for managing conflicts of interest and keeping research records. Fair credit implies rules for assigning authorship on papers and prohibitions against plagiarism. Respect for research subjects implies rules for research with humans, such as standards for obtaining informed consent, protecting subjects from risks, and safeguarding confidentiality. Nondiscrimination implies prohibitions against discrimination in admissions to graduate programs, hiring, or promotion. Respect for the law implies obligations to obey the institutional policies and legal rules pertaining to one's research and to report people who violate policies

or rules. Social responsibility implies duties to educate the public about research, to communicate with the media, and to provide policymakers with expertise and advice (Shamoo & Resnik, 2009).

The principles also imply institutional obligations and responsibilities. Institutions should share data, results, methods, and tools; respect intellectual property; not discriminate; respect freedom; respect research human and animal subjects; obey and enforce the law; practice social responsibility; and make effective use of resources. Research institutions can help to ensure that ethical standards are upheld by developing, promulgating, and enforcing policies that reinforce these standards; by sponsoring education and training in research ethics; by promoting ethical management and leadership; and by auditing and overseeing research (National Academy of Sciences, 2002).

Ethical Dilemmas in Research

Sometimes ethical principles conflict with each other or with other rules or values. When this occurs, researchers face ethical dilemmas, and they must determine the best course of action to take. Some common ethical dilemmas in research are as follows:

- Analyzing data: When researchers analyze data, they often face issues relating to data analysis, such as how to deal with data outliers and missing data, editing data, using statistical methods to draw conclusions from the data, or using digital manipulation programs to represent data. Tensions can occur between honestly presenting all the data in an unbiased fashion and presenting convincing and clear results (Shamoo & Resnik, 2009; Steneck, 2007).
- Sharing data: The obligation to share data sometimes conflicts with other obligations and interests, such as protecting the privacy and confidentiality of human subjects, safeguarding propriety business information and intellectual property rights, following rules concerning classified research, and protecting scientific priority and credit for one's accomplishments. Scientists may use a variety of strategies, such as data sharing and confidentiality agreements, to balance the obligations to share data and protect confidentiality (Shamoo & Resnik, 2009).
- Assigning authorship: Determining who should be an author on a scientific publication can be a difficult decision, because individuals may have different understandings of what counts as a significant contribution. Though journal guidelines can help to resolve some of these questions, it is also helpful to discuss authorship issues at the beginning of a scientific collaboration (Steneck, 2007).
- Conflicts of interest: A conflict of interest in research is a situation in which an investigator has a professional, personal, or financial interest that is likely to affect his or her judgment or conduct. Difficult questions can arise when deciding which types interests should be disclosed and whether some types of conflicts should be prohibited (Macrina, 2005).

- Peer review: Peer review helps to ensure the quality of published research. The most qualified reviewers in a particular field often have vested interests in promoting their own theories or suppressing competing research groups. Ethical dilemmas can arise when deciding how to develop procedures that promote fair and effective review that minimizes bias (Shamoo & Resnik, 2009).
- Intellectual property: Patenting helps to foster scientific and technical innovation, but some argue that some types of biological systems, including organisms, DNA, human and cell lines, should not be patented. Others are concerned that pharmaceutical and biotechnology patents undermine access to affordable medicines (Shamoo & Resnik, 2009).
- Reporting misconduct: The obligation to report suspected misconduct (discussed below) often conflicts with self-interest, since the person who makes an accusation may face professional or personal repercussions, as well as the expenditure of considerable time and effort. Although institutions have rules to protect whistle-blowers against direct retaliation, these rules do not guarantee that those who report misconduct will face no adverse personal consequences, and individuals still face difficult choices when deciding whether to report illegal or unethical activity (Macrina, 2005).
- Human subjects research: Many different ethical dilemmas arise in human subjects research. Most of these dilemmas revolve around the basic tension between advancing scientific research and protecting human rights and well-being. For example, dilemmas can arise when deciding whether placebos should be used in clinical trials. Placebo control groups are often needed to ensure scientific rigor. However, subjects who receive placebos will not receive an effective therapy. Failing to offer an effective treatment to a subject participating in a clinical trial may violate the physician/investigator's duty to benefit his patients (Emanuel et al., 2008).
- Animal research: The most basic ethical question related to animal research is whether it should be conducted at all. Some animal rights activists argue that all animal research is unethical and should be stopped, while proponents of animal research argue that the knowledge generated from animal experiments provides important benefits for human health. Even proponents of animal research acknowledge that difficult issues may arise when experiments that advance biomedical science cause significant pain or suffering to animals (Nuffield Council on Bioethics, 2005).
- Social responsibility: Ethical dilemmas can arise when scientists participate in political debates. Though scientists have a right and an obligation to provide expertise and advice to the public, taking a strong stand on an issue can compromise their objectivity. Dilemmas can also arise when scientists decide whether – and how – to communicate with the media, because journalists may misrepresent research results. Scientists may be tempted to oversimplify their findings in order to ensure that the public receives the proper message (Resnik, 1998).
- Scientific freedom: Some types of scientific research can threaten national security, public health, or society. Ethical dilemmas can arise when deciding whether to restrict the publication or funding of potentially dangerous research (Shamoo & Resnik, 2009).

Dealing with Research Misconduct

Investigators sometimes violate widely accepted ethical standards. Severe violations are classified as research misconduct. Because misconduct can significantly undermine the integrity of research, legal or other penalties may be imposed on individuals who commit misconduct. For example, the Public Health Service (PHS), which funds NIH research, may bar a researcher who commits misconduct under a grant or contract from receiving federal funding. Other federal agencies have similar policies. Institutions may demote, suspend, or fire individuals who commit misconduct. Professional associations may revoke the membership or privileges of individuals who commit misconduct, and journals may require authors to withdraw papers impacted by misconduct. In some cases, researchers who have committed misconduct have also been convicted of criminal charges, such as fraud or misuse of funds (Shamoo & Resnik, 2009).

Because misconduct allegations can lead to serious ramifications for an individual's career, misconduct investigations are legal proceedings in which the accused parties have rights to due process. For example, the PHS' misconduct policies allow the defendant to seek legal counsel, have access to all the evidence presented against him or her, and appeal a finding of misconduct. PHS policies also set specific deadlines for different stages of misconduct proceedings and require all those involved in misconduct proceedings to maintain confidentiality. If an investigator's reputation is harmed as a result of a false allegation of misconduct investigated by an institution, the institution is obligated to compensate the investigator for the damages. NIH policies – and federal and states laws – also protect individuals who make good faith allegations from retaliation (Shamoo & Resnik, 2009).

Under NIH policy, an individual may bring a misconduct allegation to his or her supervisor or institutional official. The allegation will be forwarded to the person who is designated as the research integrity officer (RIO) at the institution, usually a dean, director, or vice president for research. If the RIO determines that misconduct allegation has been made in good faith and it fits the definition of misconduct, then he or she will sequester evidence (such as research records) and appoint an inquiry committee. If the inquiry committee determines there is enough evidence to conduct an investigation, the RIO will appoint an investigation committee. The investigation committee will consider all the evidence and make a formal finding. If the investigation committee finds that the individual has committed misconduct, then it will forward its recommendation to the RIO, who will decide whether to impose any penalties, such as academic demotion or suspension. The institution will also report its findings to the Office of Research Integrity (ORI), which oversees PHS-funded research. The ORI will review the misconduct proceedings and decide whether to impose penalties on the investigator, such as denial of funding. The ORI usually allows institutions to conduct their own investigations, but it may become involved in an investigation at any time if the circumstances warrant. The defendant also has the right to appeal the ORI's findings to an administrative law court (Shamoo & Resnik, 2009).

One of the key policy debates related to misconduct is the definition of misconduct. During the 1980s and 1990s, the PHS defined misconduct as fabrication, falsification, or plagiarism (FFP), or other serious deviations from accepted research practices. For several years, investigators and federal agency officials debated about whether "other serious deviations" should be included in the definition of misconduct, because this category is inherently vague and limitless. Institutions might be required to investigate sexual harassment, property theft, abuse of animal or human subjects, exploitation of students, and many other unethical behaviors if this category were included in the definition. In 2000, the US federal government adopted a definition of misconduct that eliminates the "serious deviations" category and defines misconduct as FFP. Misconduct does not include honest errors or differences of opinion about research methods. Fabrication is defined as making up data or results and recording or reporting them; falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record; and plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit (Office of Science and Technology Policy, 2000).

Other countries and private funding agencies have also adopted definitions of misconduct and procedures for investigating and adjudicating misconduct. Though most definitions include FFP, some also include interfering with a misconduct investigation, lying on a résumé or job application, or significantly violating human or animal research regulations (Resnik, 2003).

The incidence of misconduct is thought to be low, though it is difficult to obtain an accurate estimate, due to problems with underreporting or overreporting. Martinson, Anderson, and de Vries (2005) surveyed over 3,000 NIH-funded researchers about various misbehaviors in science; 0.3% (3 out of 1,000) admitted to falsifying or "cooking up" data in the past 3 years. However, this number may be too low, because respondents may not have wanted to admit on an anonymous survey that they have engaged in unethical or illegal behaviors. Swazey, Anderson, and Louis (1993) found that as many as 9% of students and faculty reported direct knowledge of fabrication, falsification, or plagiarism. However, this number may be too high because respondents may not have had sufficient evidence to determine that the behavior they observed was misconduct. Even if the incidence of misconduct is low, it is still a significant problem for the integrity of research, because misconduct can have wide-ranging effects on the accuracy of the research record, trust among scientists, and the public's support for science (National Academy of Sciences, 1995, 2002).

Some investigators subscribe to the "bad apples" theory of research misconduct, which holds that misconduct is committed by a few people who are morally corrupt or psychologically disturbed. However, there is considerable evidence that misconduct is a complex phenomenon caused by a variety of psychological and social factors, such as the pressure to produce results, career ambitions, competition for funding, and poor communication and oversight (National Academy of Sciences, 2002). Misconduct is often committed by people who are not inherently unethical or disturbed but who decide to bend or break the rules of science when faced with stresses and burdens.

Famous Cases of Research Misconduct or Alleged Misconduct

Scientists have recognized that misconduct is a problem in research since at least the nineteenth century. In 1830, the British mathematician and scientist Charles Babbage published an essay titled *The Decline of Science in England* in which he chided his colleagues for fabricating, falsifying, and manipulating data. In 1849, the newly formed American Medical Association formed a committee to investigate fraudulent medical claims (Resnik, 2008).

The first major scandal involving allegations of misconduct took place over several decades in the early twentieth century when Charles Dawson and Arthur Woodward claimed to have found pieces of a skull in the Piltdown gravel bed near Surrey, England, in 1912, which they said was a "missing link" between humans and apes. The skull was controversial from the beginning, however, and many claimed that it was a fabrication which was inconsistent with other hominid fossils. In 1953, physical and chemical tests proved that the skull was not genuine. The upper part of the skull was human, the jaw came from an orangutan, and the teeth were from a chimpanzee. The pieces of the skull had been treated with chemicals to make them appear to be fossils. It is not known who committed the Piltdown forgery, though Dawson is a leading suspect (Resnik, 2008).

A bizarre case of fabrication took place at the prestigious Sloan Kettering Institute in New York in 1974. William Summerlin, a well-known immunologist, had been conducting experiments to prove that tissue rejection can be prevented by culturing tissue prior to transplantation. Summerlin transplanted skin patches from black-haired mice to white-haired mice to prove his hypothesis. While cleaning the animals' cages, a laboratory assistant discovered that the black patches of hair could be washed off by treating them with alcohol. The assistant reported his findings to Summerlin's supervisor, Robert Goode, and Summerlin admitted that he had used a black felt tip pen to produce patches of black hair on the white-haired mice. Summerlin was granted a medical leave of absence and required to retract papers related to his work. The incident had a negative impact on Goode's career as well, even though he was not implicated in the fabrication (Resnik, 2008).

In 1981, a misconduct committee found that John Darsee, a postdoctoral fellow at Harvard Medical School, had fabricated or falsified data on 17 papers and 53 abstracts coauthored with faculty at Harvard, Emory University, and Notre Dame University. Although the committee did not find that any of Darsee's coauthors had committed misconduct, it raised serious questions about their responsibilities, since much of Darsee's fraudulent work would be obvious to a trained expert. All of the papers and abstracts were retracted. Though his career as a researcher was finished, Darsee went on to practice medicine (Resnik, 2008).

A scandal known as the "Baltimore Affair" took place at the Whitehead Institute, a laboratory associated with the Massachusetts Institute of Technology (MIT) and Tufts University, from 1986 to 1996. The scandal involved allegations of fabrication and falsification in a paper reporting the results of NIH-funded research published in the journal *Cell* in 1986. The paper had six coauthors, including Thereza Imanishi-Kari and Nobel Prize–winning molecular biologist

David Baltimore. The authors claimed that they were able to insert genes into laboratory mice zygotes to induce the production of specific antibodies in the offspring. Margot O'Toole, who was a postdoctoral student working under the direction of Imanishi-Kari, had trouble repeating some of the experiments reported in the paper. She asked to look at Imanishi-Kari's laboratory notebooks and found that the data recorded in the notebooks differed significantly from the data in the paper. She reported her suspicions to officials at MIT and Tufts, who launched an investigation. The committees investigating the alleged misconduct found errors in the paper but not misconduct. The paper was retracted in 1991. The Office of Scientific Integrity (which later became the ORI) reviewed the committee's findings and conducted its own investigation. In April 1988, the House Oversight and Investigations Committee also investigated the case during its hearings on fraud in government-funded research. Baltimore testified before the committee and labeled the investigations a "witch hunt" (Resnik, 2008).

The Baltimore Affair, which was splashed all over the front pages of the *New York Times*, continued to make headlines during the 1990s. In 1992, Baltimore resigned his position as President of Rockefeller University as a result of his involvement in the scandal, even though he was never implicated in any research misconduct. In 1994, the ORI determined that Imanishi-Kari had fabricated and falsified data reported in the paper, and Tufts required her to take a leave of absence. However, Imanishi-Kari never admitted to any misconduct, and she appealed the case. In 1996, an appeals panel at the Department of Health and Human Services determined that there was not enough evidence to prove that Imanishi-Kari committed misconduct, and the panel overturned the ORI's findings against her. To this day, Imanishi-Kari maintains that she was guilty of only poor record-keeping (Resnik, 2008).

In 1993, a scandal emerged involving a high-profile clinical trial, the National Surgical Adjuvant Breast and Bowel Project (NSABP). The ORI concluded that Canadian surgeon Roger Poisson had falsified data on 117 patients enrolled in the NSABP. Poisson admitted that he changed data pertaining to inclusion criteria for the study in order to help his patients qualify for advanced medical treatment. The misconduct was discovered by University of Pittsburgh statistician Bernard Fischer, who had published several papers containing the falsified data. Fisher, who was never implicated in any misconduct, reanalyzed the corrected data and found that Poisson's fraudulent work had no effect on the overall results. The NSABP represented an important advance in the treatment of breast cancer because it showed that lumpectomies are effective at treating tumors less than 4 cm in diameter. Fisher sued the NIH for damaging his reputation, because the National Cancer Institute, a branch of the NIH which funded the NSABP, had labeled 148 of Fisher's papers posted on its website with a "scientific misconduct" warning (Resnik, 2008).

In 2002, a scandal rocked the physics community when a misconduct committee determined that Jan Hendrik Schön had faked data on at least 17 publications. The committee found that experimental data sets had been reused in various publications and that graphs had been generated from mathematical functions, not from

data. None of Schön's collaborators were implicated in misconduct, although their responsibility was questioned. Schön lost his position and was required to withdraw the fraudulent papers. The 32-year-old Schön won prizes for being a bright, young investigator and for his work in condensed matter physics and nanotechnology. He worked at the world-renowned Bell Laboratories and was publishing at an astounding rate of a paper every 8 days. His publications appeared in *Science*, *Nature*, *Physical Review Letters*, and other prestigious journals (Resnik, 2003).

In 2005, an investigation by the University of Vermont and ORI found that Eric Poehlman had fabricated and falsified data on 15 grant applications submitted to the NIH between 1992 and 2000 and 17 publications. During this time, Poehlman received $2.9 million in federal funding. Poehlman was a tenured professor at the University of Vermont during the period when the misconduct occurred, but took a position at the University of Montreal while the investigation was under way. Poehlman conducted influential research on women's health. In a highly cited paper on menopause published in the *Annals of Internal Medicine*, most of the experimental subjects did not exist. Poehlman's research assistant, Walter DeNino, brought misconduct allegations against him after discovering inconsistencies in a longitudinal study on aging. During the investigation, Poehlman destroyed evidence, falsified documents, and gave false testimony. After the ORI made its findings against Poehlman, it turned the case over to federal prosecutors, who charged Poehlman with criminal and civil fraud and misuse of funds. In 2006, Poehlman accepted a settlement in which he agreed to serve 1 year and 1 day in jail, pay $180,000 in restitution to the government and $16,000 to DeNino's attorney, retract 10 papers from the literature, and be barred for life from receiving federal funding (Shamoo & Resnik, 2009).

Also in 2005, a high-profile scandal involving stem cell research occurred. Woo Suk Wang and colleagues from Seoul University in South Korea published two papers in *Science* in 2004 and 2005 purporting to show how they produced human embryonic stem cells from an embryo created by transferring a nucleus from a patient's somatic cells into a fertilized egg, which has had its nucleus removed. Tissues grown from stem cells taken from the embryo are less likely to be rejected by the patient because they will have the same genome as the patient. If this finding had been correct, it would have been an important development in stem cell research. Wang was hailed as a hero in South Korea and gained international acclaim. However, problems began to emerge in June 2005, when an informant told *PD Notebook*, a South Korean news show, that the 2005 paper had been faked. *PD Notebook* began investigating Wang. In December 2005, another informant made a posting on a website claiming that images of 9 of the 11 cell lines in the 2005 paper had been duplicated from two other images. A university investigation ensued, which found that all of the data in both papers had been faked. Both papers were retracted and Wang lost his position at Seoul University. In 2009, Wang received a 2-year suspended sentence for embezzlement and bioethics law violations. One of Wang's collaborators on the 2005 paper, Gerald Schatten, a prominent stem cell researcher at the University of Pittsburgh, had received $300,000 in consulting fees for his work on the project. Though Schatten was never implicated in misconduct, many have argued that he neglected his duties as a coauthor because

he was only remotely involved in the research (Shamoo & Resnik, 2009). Newspaper, television, and Internet media outlets provided extensive coverage of the scandal as it unfolded.

International Ethics Standards

As one can see from the Wang case, research integrity is also an international concern. International research collaborations raise a variety of ethical problems and concerns, because investigators from different nations may have different understandings of the standards of conduct and different interpretations of ethical concepts. As noted above, research misconduct may be defined differently in different countries. Other concepts, such as authorship, plagiarism, and conflict of interest, may also have different definitions. Countries may have different understandings of the proper treatment of human and animal research subjects. Because ethical standards may vary, scientists involved in international research should work toward a mutual understanding of the ethical standards that will apply to the collaboration.

Following World War II, countries around the world adopted the first international standard for human research ethics, the Nuremberg Code (1947). Since then, other international codes for research with human subjects have been developed, including the Helsinki Declaration (World Medical Association, 2008) and the Council for International Organizations of Medical Sciences (CIOMS) guidelines (CIOMS, 2002). International standards that address ethical issues beyond research with human subjects were not developed until 2010, when the Second World Conference on Research Integrity drafted the Singapore Statement on Research Integrity. The Singapore Statement addresses all of the major areas of research ethics, including data integrity, data sharing, record keeping, authorship, publication, peer review, conflict of interest, reporting misconduct, communicating with the public, complying with regulations, and social responsibilities. The Singapore Statement also includes four ethical principles: honesty, accountability, professional courtesy and fairness, and good stewardship of scientific resources (World Conference on Research Integrity, 2010).

Conclusion

Integrity is vital to good scientific practice and publicly accountable research. There are a dozen or so well-accepted ethical principles in science, including honesty; openness; due care; fair credit; respect for peers and students, research subjects, and the law; and social responsibility. Scientists and research institutions have obligations to follow ethical principles and to promote integrity in research through education, training, policy development, leadership, and oversight.

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Synthetic Biology

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Gregory E. Kaebnick

Introduction

Synthetic biology is a collection of lines of biological research linked by the common goal of engineering novel biological systems, designing and building them to human specification. The basic idea of altering biological systems has been part of genetic research for several decades, and it has been an explicit part of traditional breeding programs for much longer than that; indeed, the very phrase "synthetic biology" was coined a century ago (Campos, 2009). Contemporary synthetic biology seeks to bring this goal to fruition through the application of new technologies – especially technologies for reading and producing genetic sequences – ideally in a structured way that allows design inputs to be well understood and standardized so that design outcomes can be predictable and efficiently achieved. It has potentially transformative benefits, but it also poses a variety of questions that will be a challenge to evaluate fully and to address in public policies. What is the right balance between risks and potential benefits? How can the risks be managed in light of the complexity of microorganisms and ecosystems? Can a society ensure that the changes wrought by the field are just and environmentally beneficial? Is the idea of engineering living organisms intrinsically troubling? And how are these questions most usefully discussed – how do we ensure that deliberation reflects the global import of synthetic biology, for example? This chapter provides an overview of synthetic biology and then delves into four broad ethical concerns that encompass the questions above.

Overview of the Technology

The overall goal of synthetic biology is to make possible the engineering of novel biological systems that can be used like machines or miniature factories to make products or provide services. Such industrial analogies are inescapable when

G.E. Kaebnick
The Hastings Center, Garrison, NY, USA
e-mail: kaebnickg@thehastingscenter.org

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talking about synthetic biology, and while they may deflect attention from the fact that synthetic biology is about *living* systems, they capture several key aspects of synthetic biology, including the focus on engineering those systems and on altering them in ways that making engineering easier – standardizing and simplifying them.

Since synthetic biology is fundamentally about bringing the principles of engineering to bear on biology, it is, in principle, not defined in terms of and not limited to any particular kind of biological research or category of organism. In practice, however, the main lines of work in synthetic biology are on microorganisms and have to do with the synthesis and alteration of their genomes.

Types of Synthetic Biology

Exactly what the term "synthetic biology" refers to is contested (Brent, 2004), and various taxonomies can be found to explain the term (Presidential Commission for the Study of Bioethical Issues, 2010), but one or more of three broad lines of work are usually in mind when it is used.

One line, and arguably the line that aims most directly at the goal of integrating biology and engineering, is what Maureen O'Malley et al. have called "DNA-based device construction" (O'Malley, Powell, Davies, & Calvert, 2008). It is exemplified by the construction of "biobricks," made from DNA and other molecules, that can function as standardized and interchangeable parts or tools to perform very specific functions – turning gene production on or off, say, or measuring the concentration of a particular gene product (BioBricks Foundation, 2011). Assembled in sequences and installed in "platform" organisms, these parts would, as proponents describe it, turn that organism into a very specialized tool of sorts. Some proponents would add that the parts should also be well characterized and available to the public. Some other synthetic biologists have expressed doubts, however, about whether standardized genetic sequences are achievable (Kwok, 2010).

In a second line of research, Craig Venter and colleagues at the J. Craig Venter Institute are engaged in what O'Malley et al. have called genome-driven cell engineering. For example, they hope to use synthetic DNA to build a "minimal genome" that contains only the genetic material needed to sustain bacterial life (Gibson et al., 2008). Such a minimal genome might provide a standardized platform that could then be equipped with DNA-based devices. In May 2010, researchers at the J. Craig Venter Institute announced that they had taken a step toward creating a minimal genome by successfully synthesizing the entire genome of the bacterium *Mycoplasma mycoides* (Gibson et al., 2010 To prove that the synthesis was successful, they inserted the genome into a cell of a closely related species, *Mycoplasma capricolum*, resulting in a fully functioning *M. mycoides*.

The development of interchangeable biological parts and of general purpose platform organisms into which the parts could be installed are ideal goals. They are certainly not yet realized, and in practice, they tail off into what is sometimes called "metabolic engineering" – the study and alteration of metabolic processes within existing organisms (Nielsen & Kiesling, 2011). Metabolic engineering frequently

resembles a more advanced form of older lines of gene transfer research, differing in that it can be done faster, on a larger scale, potentially combining genetic sequences from three or more organisms, and with more information about the genetic sequences and the organism into which they are put, and therefore with greater ability to design the resulting organism. Given the links and differences with gene transfer, critics sometimes refer to synthetic biology simply as "extreme genetic engineering" (ETC Group, 2007).

A third line might be cobbled together from what are really distinct lines of research, but are united in that they seek to reinvent the basic mechanisms and materials found in living things. For example, in what is known as minimal cell creation or protocell creation (also the creation of "chemical cells," or "chells"), the goal is to design and build organisms from the ground up, first identifying the basic functions necessary for the simplest forms of life (for example, mechanisms for metabolism, for control, for replication, for organization) and then constructing them from basic parts (Presidential Commission, 2010). The new cells might use chemicals not found in naturally occurring organisms. In principle, the development of protocells could lead to an entirely new biochemistry – a biochemistry that was nonorganic, in that it would not be carbon-based. Additionally, mechanisms for control and replication need not depend on DNA.

Two particularly high-profile examples of new products to which synthetic biology might lead are worth describing in greater detail. The examples both illustrate the science and help ground a discussion of the ethical issues synthetic biology raises.

The Case of Artemisinin

What is sometimes considered the flagship example of synthetic biology is the production of artemisinin, a highly effective but to date comparatively expensive treatment for malaria. Up until now, artemisinin has been extracted from the wormwood plant (*Artemisia annua*), which can be grown in plantations but according to some commentators is not easily grown in the quantities necessary to make artemisinin affordable for widespread treatment. An alternative strategy, developed by a partnership formed between Amyris Biotechnologies, the Institute for One World Health, and the University of California, Berkeley, is to construct a new metabolic pathway, comprised of genes from bacteria, yeast, and wormwood, that allows microorganisms equipped with the pathway to synthesize artemisinic acid, an artemisinin precursor, through a fermentation process (Hale et al., 2007). The pathway was first developed in *Escherichia coli* and then in baker's yeast (*Saccharomyces cerevisiae*). The artemisinic acid produced by the organism can then be processed in the laboratory into artemisinin. (This final step in the production of artemisinin is performed by the wormwood plant, but it has not been recreated in microorganisms.)

As malaria affects hundreds of millions of people globally each year and kills up to one million, the potential health benefits of this application are considerable. The work was initially funded by the Bill and Melinda Gates Foundation, and it has now

been licensed to and further developed by the pharmaceutical company Sanofi-Aventis. Synthetically produced artemisinin is expected to be available in 2012 (Specter, 2009).

The Case of Fuel Production

Research is under way on several fronts to develop organisms that would produce fuel. One line of research is aimed at the development of organisms that can more efficiently process biomass, typically crops such as corn, into biofuels such as ethanol. The organisms considered candidates for ethanol production include *S. cerevisiae* and *Zymomonas mobilis*, which naturally produce ethanol out of glucose, and *E. coli*, which naturally produces a small amount of ethanol but can process a broad variety of substrates (Jang et al., 2012). The research aims to eliminate metabolic pathways that compete with ethanol production, allow the organisms to tolerate higher levels of ethanol, and broaden the range of substrates that the organisms can process. An organism that processed cellulose, which is abundant and cheap, would be especially desirable. Butanol production is also desirable, because butanol has a higher energy density than ethanol, allowing for better gas mileage, and because it has properties similar to gasoline, so that it can replace gasoline in existing engines and in the existing systems for fuel storage and transport. Research on butanol production is under way with *Clostridium*, which produces butanol naturally, and *E. coli* modified with clostridial genes (Jang et al.).

Research is also under way on the development of organisms that produce alkanes (which, depending on the number of carbon atoms, can be used either as gasoline or as diesel or aviation fuel), isoprenoids, and hydrogen (which has an extremely high energy density and produces only water when it burns) (Jang et al.).

Another line of research is on organisms such as algae and cyanobacteria that could produce some of these same kinds of fuel photosynthetically. Biomass from feedstocks would be unnecessary; the inputs might only be carbon dioxide, water, and sunlight. In principle, then, this method of producing fuel could avoid or limit the environmental harms of drilling and transporting oil and of growing feedstocks to produce biomass and also serve as a carbon-fixing process, thereby helping to offset the environmental costs of burning fuel. However, some methods of producing fuels photosynthetically would require a significant investment in equipment (such as greenhouses), land, and water.

Some of these methods are expected to be commercially viable in the next few years; others are longer-term propositions (Presidential Commission, 2010).

Where Synthetic Biology Occurs

The research described above is undertaken primarily by laboratories in major research universities and private industry. As noted, research on the production of

artemisinic acid is a collaborative effort involving a major research university, nonprofit funders, and private companies. Research on biofuels is conducted by the Joint BioEnergy Institute (a public-private research partnership that brings together Lawrence Berkeley, Sandia, and Lawrence Livermore national laboratories along with the University of California campuses of Berkeley and Davis and the Carnegie Institution for Science), the J. Craig Venter Institute (with $600 million in funding from ExxonMobil Corporation), Amyris Biotechnologies (with funding from Crystalsev, a large Brazilian ethanol distributor), and an assortment of start-ups and smaller biotechnology companies.

Some synthetic biologists believe, however, that the *spirit* of synthetic biology is in the research and development that occurs *outside* established academic and commercial facilities – in so-called "garage biology," "outlaw biology," "bio-hacking," or "DIY bio." These terms embrace more than synthetic biology, but synthetic biology is in some ways the most striking example of what can be accomplished in a garage setting, and if synthetic biology is defined as the application to biology of engineering principles, then the goals of synthetic biology are closely affiliated with DIY bio: both aim at the democratization of skills.

Research in DIY bio could veer off in unpredictable and entrepreneurial ways, following the inclinations of the practitioner. Although DIY biologists often aim to develop serious, marketable products–in recent years, projects at the International Genetically Engineered Machines competition, which is structured to imitate and advance amateur biology, have included bacteria that could break down plastic waste in landfills and a form of *E. coli* that could function as a drug delivery system (iGEM, 2010) – they can also experiment with toys, gadgets, and lifestyle products. Amateur biology will be greatly facilitated if extensive catalogs of well-characterized, standard "biobricks" become available, allowing people to order off-the-shelf parts.

Overview of the Ethical Issues

The ethical issues raised by synthetic biology will be familiar, in outline form, to those who have thought about the ethical implications of earlier waves of technology. As with any emerging technology, the ethical issues can be crudely divided into several general categories, having to do, respectively, with the tangible benefits and harms of the technology, with the implications for equality and justice (i.e., the distribution of benefits and harms), with the intrinsic value of limiting human intrusion into nature (aside from any questions about benefits and harms), and with deliberation about the science and its ethical issues. While these issues are already familiar in broad outline, however, they sometimes take particularly interesting and challenging forms with synthetic biology. The potential benefits and harms are uncommonly great, for example, and the issue of human intrusion into nature amounts, with synthetic biology, to concerns about the very idea of synthesizing living organisms.

Benefits and Harms

One tangible benefit of synthetic biology is nonetheless not immediately obvious, as the benefit may be indirect and deferred: synthetic biology provides further insight into the nature of cells and their genetic machinery, which may prove useful years later, and perhaps in ways that cannot be anticipated at the time the research is performed. The work at JCVI on the minimal genome, for example, which is aimed at determining which genes are essential to the cell, also provides insight into what different genes do. Other lines of research in synthetic biology provide insight into the mechanism of basic metabolic processes. Synthetic biology is a way of testing hypotheses: scientists can find out about organisms by designing and actually building systems that are capable of testing those hypotheses.

More obvious tangible benefits have to do with products and services that synthetic organisms could provide. The two examples above give a concrete sense of these benefits, but most in the field believe they are only a beginning and that the practical benefits will be very heterogeneous. Other possible applications include solvents and other industrial materials, high-yield or disease-resistant crops, new kinds of insecticides, food additives, sensors to detect food spoilage, more efficient vaccine production, and environmental remediation.

The primary concerns about synthetic biology are about the risks of deliberate misuse – bioterrorism, that is – and accidental threats to public health and the environment – dubbed "bioerrorism" by some commentators (Caruso, 2008). The risks of deliberate misuse center on the possibility that the technology used to synthesize and engineer useful microorganisms could be used instead to produce pathogens (Garfinkel et al., 2007). Some virus pathogens have already been synthesized. The 1918 Spanish flu virus has been briefly recreated in the laboratory, and in 2002, polio (an RNA virus) was created from a string of DNA that had been produced in a lab (Cello, Paul, & Wimmer, 2002; Tumpey et al., 2005). Eventually, as the synthesis of *M. mycoides* makes clear, it should also be possible to create bacterial pathogens in the laboratory. Further, it should be possible not merely to recreate pathogens but to augment them – not just to bring smallpox back from extinction, for example, but to make it even more virulent. In theory, at least, entirely new pathogens could also be created. Also, in addition to human targets, pathogens could be created to target a nation's crops, livestock, or natural resources.

Merely creating a pathogen is not the only technical hurdle that would have to be overcome to misuse synthetic biology (Mukunda, Oye, & Mohr, 2009). It would also be necessary to grow the pathogen in quantity and then to "weaponize" it. To use a human pathogen against a target, for example, one would need to develop ways of disseminating it so that it is capable of infecting targets in large enough numbers to overcome public health systems. Proponents of the technology argue that terrorists have much better ways of attacking their enemies than with bioweapons, which are still comparatively hard to make and are very hard to control. Once released, they might be expected to hurt those who have released them, and their allies and countries, just as much as or even more than the intended targets. But of course

terrorists are not always rational. For some pathogens, such as flu, the weaponization challenge could be overcome merely by sending infected people–suicide bombers of sorts–into crowded public places.

Public health concerns might be raised by some applications that do not initially appear to have any implications for human health. In principle, for example, modified *E. coli* might escape the environment for which they are intended, display unexpected properties in the new environment, or mutate to acquire them, or either acquire new properties or impart new properties to other microorganisms by means of lateral gene transfer between organisms, developing eventually into an organism that poses a health risk.

Another source of public health concerns is that microorganisms created for use in the human body could turn out to have unintended effects. For example, synthetic biology could be used to engineer the human "microbiome" – the ecosystem of microbes residing in and on the human body. These applications range from medical treatments – transgenic probiotics to treat Crohn's disease and bacteria modified to serve as vaccines, for example – to early examples of human enhancement – bacteria that eliminate body odor, allow people to take up nutrients more efficiently, or maybe even promote good mental health (exploiting the recently discovered connection between mental health and intestinal function), for example (Sachs, 2007). These applications raise questions not only about risks to the particular recipient but also, because bacteria in the microbiome can be passed from one person to another, about public health.

Concerns about possible harms to the environment follow a similar pattern. In principle, just as public health concerns could be raised by applications not intended for use in humans, environmental hazards might be posed by applications that are not intended for release into the environment. Applications that involve algae engineered to produce fuel, for example, might be designed so that the algae were contained inside sealed equipment. Nonetheless, the risk that some would eventually escape into the environment is very high, and then the question is whether they would display unexpected properties or somehow acquire them and pose a threat to other organisms in the environment.

There are some reasons to think that the threat might not be severe. The modified organisms would be designed to spend their energy on something, such as producing excess quantities of hydrocarbons, that would likely put them at an evolutionary disadvantage if they escaped into the field. Moreover, some of their protective mechanisms could be removed, and the genetic complexity that makes for adaptability might be reduced. Deliberately designed fail-safe mechanisms could also be implemented to hamper their survival in the field. Indeed, keeping the organisms separated from the environment may be more important for protecting the organisms than for protecting the environment.

Applications that involve deliberate environmental exposure might pose significantly greater environmental hazards, since the organism would be designed to survive and perhaps reproduce in the field, and once released could never be fully removed from the field. Examples of these applications include organisms

designed for contained but unprotected settings, such as fuel-producing algae grown in open ponds, and organisms intended for uncontained release into the environment. Examples of the latter include bioremediation, such as an engineered form of *Pseudomonas putida* (a soil bacterium) that degrades an organophosphate compound (commonly used as a pesticide) and *E. coli* engineered to degrade the herbicide atrazine (Presidential Commission, 2010).

All of these possible harms are hard to assess. For many of these applications, the likelihood of harm may be very low, but the severity of harm could be very great. Moreover, it may be difficult to gauge either likelihood or severity with great confidence. Because of the complexity of living organisms and because of the possibility of evolution, which for microbes can occur very rapidly and can be facilitated by lateral exchange of genes across species, synthetic biology inherently involves a high level of unpredictability. Also, once organisms invade new environments, they can be extremely difficult to eradicate, and invasive microorganisms would likely be ineradicable. Environmental contamination by living organisms would be very different in this respect from contamination by a chemical spill (Snow, 2011).

At the outset, then, extremely careful analyses are needed of the organisms proposed for commercial application. In testimony to the Presidential Commission for the Study of Bioethical Issues, ecologist Allison Snow offered the following recommendations for thinking about the risks posed by synthetic algae designed to produce fuel: "a good start for micro algae would be to publish professional monographs dealing with the biology and ecology of each species and its close relatives including information about how they reproduce, how they spread, whether they exchange genes with other strains, whether they have been bred to be suicidal, whether they could become more abundant or might die out, and whether they produce any kinds of toxins or other side effects" (Snow, 2011).

DIY biology raises special concerns about benefit and harm. If a DIY form of synthetic biology becomes feasible, then DIY synthetic biology could be practiced by people who are not affiliated with major laboratories and could prove to be hard to monitor and regulate. Also, the people who practice DIY bio often view themselves as a countercultural force, challenging boundaries and resisting control. Amateur biologists maintain that "outlaw" biology need not be "criminal" biology, but they display a certain edginess in their approach to biology and develop applications reflecting that attitude. The DIY mindset encourages trying unheard of things, which might have a multiplier effect on the inherent unpredictability of the living systems they are manipulating.

Different views about the acceptability of synthetic biology may well depend as much on different views about the weight to be given to remote risks as about different views of the likelihood of the risks. Some thought should therefore be given to the underlying philosophical and psychological questions about the perception and weighing of risk. Evaluating a technology involves both factual claims and value claims – claims both about potential outcomes and their likelihood and magnitude and claims about the significance of those scenarios. Bringing out these values is what "evaluating" outcomes means. Among these value considerations are questions about what *counts* as a risk, a cost, or a benefit, how heavily to weigh it,

how much to discount a risk or potential benefit that is low probability or would occur only many years later, and how much more heavily to weigh a potentially catastrophic impact.

The tools used to evaluate outcomes, such as risk assessment and cost-benefit analysis, make assumptions about these issues. Unfortunately, though, the assumptions are often buried and unexamined. Also, risk assessments and economic evaluations frequently focus on outcomes that can be measured easily, which may not adequately reflect what people actually care about most. In short, evaluating outcomes requires value assumptions that often go unexamined. One result is that people may feel that important values have been ignored or suppressed. Public discourse and public policy could therefore benefit from a thorough interdisciplinary inquiry into the role of values in evaluating the potential outcomes of synthetic biology and other emerging technologies.

Equality and Justice

Another kind of concern about synthetic biology has to do with the social distribution of the benefits and harms. In a nutshell, the worry is that the benefits of synthetic biology will accrue to wealthy nations and especially to those who have secured patents on the relevant technological developments, while those in poorer, undeveloped nations are either excluded from the benefits or are actively exploited and harmed, in terms both of the economic effects of synthetic biology and of damage to the environment or public health.

The production of biofuel with synthetic organisms illustrates these concerns sharply. Methods that rely on the processing of substrates collected from biomass would require the cultivation of vast acreage of feedstock crops, possibly with harmful effects in places where these crops might be grown. The feedstocks might replace crops that produce food for humans, for example. "The most productive and accessible biomass," writes a civil society organization called the ETC Group, "is in the global South–exactly where, by 2050, there may be another two billion mouths to feed on lands that (thanks to climate chaos) may yield 20–50 % less" (ETC Group, 2010, p. iii). Industrial-scale production of the feedstocks might also have ramifications for land ownership, water use, and soil quality, all of which are already often under pressure in undeveloped countries (ETC Group, 2007). Giving land over to production of feedstocks might also have bad environmental consequences.

Finally, there is a debate about the environmental benefits of producing fuel from raw materials harvested from plants, since growing the plants itself requires a lot of energy. Synthetic biology aims to make this way of producing fuel much more efficient, notably by turning to more common raw materials and more easily grown feedstocks, but the outcome of this work is still in doubt. Reliance on photosynthetic techniques would obviate the need for feedstocks, but they would still be resource-intensive; in particular, they would probably require a huge supply of water. If the production of fuel through photosynthesis were conducted in arid

locations (which would be attractive because of their plentiful sunlight and because the land might not be considered valuable for other uses), then providing water might worsen water supply problems.

The US Presidential Commission has suggested that synthetic biology might turn out not to exacerbate social disparities. Indeed, it declared, "Much of the optimism surrounding synthetic biology stems directly from its potential to address some of the longstanding, significant problems associated with these disparities. Synthetic biology offers potential applications that may be particularly beneficial to less advantaged populations, including improved quality and access to vaccines against infectious diseases, medications, and fuel sources" (Presidential Commission, 2010, p. 165). Progress on solving long-term environmental harms such as climate change – on the assumption that synthetic biology can be part of a solution – would clearly benefit less advantaged populations, since it is likely that those populations will be disproportionately harmed by those problems.

The concern about justice is also difficult to assess. Partly this is because of uncertainties about the possible outcomes, which include not only the benefits and harms mentioned above but also the long-range and international social and economic consequences of synthetic biology (should the field be as successful as its proponents believe it will be). Additionally, there are questions of values to complicate the assessment. Unsurprisingly, there are starkly different visions of justice at play in synthetic biology. For example, the goal of promoting welfare equally must be traded off to some degree against the value of protecting individual liberty. Some would hold that justice grants the liberty to experiment with emerging technologies in whatever direction one likes, at least to the extent permitted by public safety. Some would also hold that in any adequate understanding of justice, those who have worked to advance the field should benefit disproportionately. Finally, some would also hold that if the financial rewards are curtailed, none of the benefits will be realized.

A second general value question that complicates the assessment of justice is the question of responsibility for ensuring just outcomes. Possible answers range from governments, acting on behalf of citizens, through various categories of private agents. The US Presidential Commission has suggested a broader rendering: "Manufacturers and others seeking to use synthetic biology for commercial activities should ensure that risks and potential benefits to communities and the environment are assessed and managed so that the most serious risks, including long-term impacts, are not unfairly or unnecessarily borne by certain individuals, subgroups, or populations. These efforts should also aim to ensure that the important advances that may result from this research reach those individuals and populations who could most benefit from them" (Presidential Commission, 2010, p. 164).

The very idea that the development of a new technology should be influenced in order to maximize just outcomes is arguably somewhat novel. Technology development has historically not been constrained with this expectation. Thus, another question arises: Is the goal of achieving just outcomes feasible? Or is it better simply to let innovation proceed and to try to address social injustices through other measures? And what sorts of policy mechanisms might appropriately be employed

to advance this goal? Two much-discussed kinds of options include funding decisions, which can influence the directions in which the field advances and therefore the kinds of commercial enterprises it makes possible, and intellectual property policy, which determines control over and access to new developments in the field, and may therefore influence the direction in which the field advances both by affecting the incentive structure for conducting research in the field and by affecting access to the fruits of others' research.

Attitudes Toward "Synthesizing" Living Organisms

A third broad category of concern about synthetic biology is whether the idea of synthesizing organisms raises any intrinsic moral issues. This concern is a recurrent topic for synthetic biology and is probably the most controversial and philosophically difficult of the ethical issues of synthetic biology. Such concerns might tilt in different directions. On the one hand, some will find the idea of synthesizing and engineering organisms, at least in the way done in synthetic biology, intrinsically attractive. They might try to articulate this position by arguing that knowledge and creativity are intrinsically good; synthetic biology, somewhat like astronomy and basic physics, embodies the human drive to understand the world and put one's intelligence to work in it – activities that are good in themselves, apart from the physical benefits they may make possible. Many also feel, however, that the alteration of nature should have limits of some sort; opposition to genetically modified organisms is connected to this feeling, and more than a little of the concern about the environment is rooted in it; the question for them is whether the engineering of living organisms, at least as done in synthetic biology, is morally troubling.

There are several subtly varying ways of articulating this concern in the context of synthetic biology. Perhaps, the most prominent form of the intrinsic concerns about synthetic biology is that the technology reflects and promotes a troubling attitude toward life. In particular, one might object that synthetic biology undermines the specialness of life by showing that life is a purely material phenomenon – a complex combination of ingredients. In the first scholarly article on the ethical issues of synthetic biology, Mildred Cho and coauthors weighed the possibility that, by defining life in terms of DNA, synthetic biology reduces life to a single biological feature and therefore "may threaten the view that life is special" (Cho, Magnus, Caplan, McGee, & The Ethics of Genomics Group, 1999). More recently, Joachim Boldt and Oliver Müller have argued that synthetic biology represents organisms as machine-like artifacts and thereby challenges "the connection between 'life' and 'value'" (Boldt & Müller, 2008). When scientists synthesized the genome of *M. mycoides*, the achievement was heralded by Arthur Caplan as debunking the idea that living things are "endowed with some sort of special power, force or property" (Caplan, 2010).

Conversely, some have worried that synthetic biology represents a troubling attitude about human agency. Boldt and Müller suggest, for example, that with the

advent of synthetic biology, humans no longer merely *manipulate* nature; they become creators or reinventors of nature. The creation of nature might, they continue, lead to overconfidence: it "might lead to an overestimation of how well we understand nature's processes and our own needs and interests and of how best to achieve them" (Boldt & Müller, 2008, p. 388). This kind of worry harks back to a reaction sometimes evoked by earlier forms of genetic engineering, that human beings were "playing God."

Some ways of formulating these concerns – about the denigration of life or the exaltation of human agency – rely on metaphysical claims that are particular to specific traditions and open to various objections. If so, then one problem with them is that they may depend on acceptance of the underlying religious or metaphysical account within which they make sense, and the more robust this account, the less likely it is to be widely shared, and the less traction it will have in public debate.

Alternatively, these concerns can be formulated as merely moral points – as resting on claims about attitudes toward life and human agency and the role that those attitudes play in moral thinking. Still, they face some significant objections. One is that they treat "life" as a very general moral category, bringing together under one heading a variety of different kinds of living things – complex animals (such as mammals), microorganisms, plants, and fungi. But arguably, people tend not to aggregate all living things together when they think about their moral status. Instead, moral distinctions between different kinds are common. Sacredness might be attributed to some but not to all living things. It is worth noting that religious organizations themselves have by and large not voiced objections to synthetic biology per se. The Catholic Church was moderately enthusiastic about the announcement that JVCI had synthesized the genome of *M. mycoides* and successfully transplanted it into another cell: the achievement was, said the church, "a further mark of man's great intelligence, which is God's gift enabling man to better know the created world and therefore to better order it" (BBC Monitoring Europe, 2010).

Moreover, whether synthetic biology is actually tantamount to the creation or synthesis of life, rather than being merely another form of manipulation, is debatable. Most of the actual applications, as described above, amount to something less than the synthesis of living organisms. JCVI described the *M. mycoides* cell it created through genome synthesis as a "synthetic cell," and it also claimed that, because it was slightly altered from wild-type variants, it represented a new species, which they dubbed *M. mycoides JCVI-syn1.0*, but most commentators regard the JCVI achievement as considerably less than a synthetic cell. They argue that JCVI's accomplishment was synthesis of a genome, but that because the genome was inserted into a naturally occurring cell body and because the genome itself also occurs in nature (minus the slight alterations), thinking of the product as a "synthetic cell" is overblown.

Research on protocells and chells, which in some cases aims to devise novel mechanisms and use novel materials for basic cellular functions, would come closer to creating life. Successful creation of a protocell that employs novel and entirely synthesized ingredients would prove that a living thing does not acquire a "special

power, force, or property" only from a previous generation of living things. It would still not prove, however, that living things have no special, nonphysical property. If one believes that living things have such a property, nothing stops one from believing that the property was acquired in the course of the laboratory synthesis; the property might be said, for example, to have been imbued in it directly by God, who sanctioned the synthesis because He saw it as following naturally from the capacity He has given humans "to better know the created world and therefore to better order it."

Another way of articulating intrinsic concerns about synthetic biology would be to argue that the alteration of nature is in general morally troubling. One might hold, for example, that there are competing moral ideals for the relationship between humans and nature: an ideal characterized by a discourse of "altering nature to meet human demands" and an ideal of "adjusting human demands to accommodate nature" (Jennings, 2010, p. 78). The former holds that nature is no more than stuff to be put to human use, while the latter calls on a person to cherish the natural world and limit the harm that humans wreak on it.

Which of these discourses synthetic biology best fits is contestable, however. On the one hand, to the extent that synthetic biology is the "creation of life" or "extreme" genetic engineering, it might be said to fit the discourse of altering nature to meet human demands. To the extent that it is used to resolve environmental problems and perhaps to replace environmentally damaging industrial systems, however, it might be said to fit the discourse of adjusting human demands to accommodate nature. Moreover, given the moral distinctions often drawn between different kinds of living things – humans, other mammals, other vertebrates, invertebrates, plants, fungi, and microorganisms – the fact that synthetic biology is, to date, primarily about the alteration of microorganisms might be reassuring. On the other hand, if synthetic biology turns out to be harmful for the environment, then concerns about the alteration of nature would be strengthened; synthetic biology might then be morally troubling *even if* it appears to be beneficial for human well-being.

Yet, another kind of intrinsic concern that could be associated with synthetic biology is focused on the prospect of human enhancement – that is, on the possibility that some synthetic biology applications might be used to raise human cognition, mood, physical performance, or life span significantly above current species-typical norms. Applications involving human cells could someday raise this kind of concern. As noted above, applications involving the human microbiome could also have an enhancing effect. The objections to these uses would be objections to human enhancement, however, rather than to the genetic manipulation of microorganisms.

Public Deliberation

In addition to substantive questions about benefits and harms, justice, and the intrinsic values connected to synthetic biology are procedural questions about who and how the substantive questions should be addressed. One interesting feature of synthetic biology is that those engaged in the work have also sought to advance –

and perhaps influence – the discussion of the ethical, legal, and social issues that their work raises. One of the first and most salient articles about synthetic biology was written by a group of bioethics scholars brought together in the late 1990s at the request of JCVI to consider the ethics of creating a minimal genome organism. Many other organizations and commentators internationally have also weighed in on the ethical, legal, and social issues of synthetic biology.

Still, there is a widespread sense among these commentators that the discussion about synthetic biology should if anything be still broader. Recently, the US Presidential Commission has argued that policy on synthetic biology (and other emerging biotechnologies) should be guided by "a principle of democratic deliberation" – that is, by "an ongoing, public exchange of ideas, particularly regarding the many topics – in science and elsewhere – in which competing views are advocated" (Presidential Commission, 2010, p. 151). Such an approach is held to foster better decisions – "outcomes that are inclusive, thoughtfully considered, and respectful of competing views," as the Presidential Commission put it. It is also held to be intrinsically attractive – itself a mark of a just society.

Questions remain, however, about how democratic deliberation is best carried out. These include questions about how to ensure that the scientific and economic information that is fed into the deliberative process is accurate and how to ensure that the public's values are adequately represented and respected. The deliberative process could be hijacked either by corporate interests or by "civil society" organizations whose mission is to advocate for public interests; neither may adequately represent the range of public interests, and both might misrepresent the factual claims at stake and unduly influence the deliberative process.

Part of the problem in adequately representing the public's values is that the relevant "public" for most deliberative processes is restricted to the nation that conducted the deliberation, but the relevant "public" for thinking about the ethics of synthetic biology is international. Since synthetic organisms that have been released or escaped into the environment cannot be expected to observe national boundaries, the risks are international. The implications for justice are also clearly international since questions about the distribution of potential benefits and harms are rooted in the first place in concerns that the benefits will accrue to wealthy nations while developing nations are either excluded from those benefits or are actively harmed. And questions about the very idea of synthesizing organisms are also international in flavor, in the same way that questions about human enhancement are international: if one nation permits this step, then in some sense, the human relationship to nature is changed for everybody around the globe. Moreover, if one nation permits it, other nations may find it increasingly difficult to ban it, given economic competition among nations.

Conclusion

Synthetic biology is still in its infancy, leading some in the field to wonder whether ethical questions about it are being raised prematurely. Perhaps society should

await further technical development, this line of reasoning holds, so that the ethical debate can be grounded on more and better information about the field's risks and potential benefits.

Some of the ethical issues outlined above do not depend on better knowledge of the field, however. The intrinsic values connected to the science are a threshold question – an issue that, in principle, should be raised and resolved before the field progresses. To go ahead with the research is to assume that the intrinsic values generate no insuperable objections.

Questions about the benefits and harms of synthetic biology could certainly be handled more confidently if more information were in hand about actual applications. Yet, it is precisely because of the lack of confidence about outcomes that the effort to think about risks and potential benefits should start early. Perhaps the likelihood of harm is indeed as low as some proponents argue, but the severity of harm could be great, and given the complexity and adaptability of living systems, gauging either likelihood or severity with great confidence is very difficult. It is therefore important to make sure that the processes for identifying and evaluating risks and potential benefits in synthetic biology are reliable and then that the mechanisms for oversight are trustworthy.

Questions of equality and justice also require early attention. The goal should be, not just to correct distributive mistakes after they have occurred, but to correct existing distributive mistakes and avoid exacerbating them with new mistakes, and this requires trying to anticipate outcomes and, if possible, encourage lines of work that will produce good outcomes.

Synthetic biology is heralded by some of its proponents as the beginning of a new industrial revolution. If that turns out to be correct, then it will inevitably generate harms, benefits, new economic and social patterns, and perhaps new ways of understanding how humans are related to the natural world. It is therefore imperative to think about it now.

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Section VI

Future Perspectives

Future Perspectives

49

Bert Gordijn and Henk A. M. J. ten Have

Introduction

If you wish to think about the future, it is generally worthwhile to look at the past first. The growth of global bioethics – roughly understood as the establishment, analysis, and application of global ethical norms for medicine, healthcare, and the life sciences – seems to have been largely driven by globalization. Leaving out of consideration yet unknown historical contingencies, it does look as if there are currently no compelling reasons to suppose that globalization is likely to collapse any time soon. Rather, it seems more likely that different parts of the world will see yet more integration, interconnectedness, and interdependence as a result of technological developments in general, progress in transportation and telecommunications in particular, the actions of large multinational companies, and the like. As a result, global bioethics is likely to further gain significance. Looking at the steadily increasing number of publications on global bioethics over the last couple of decades (Table 49.1), it seems reasonable to reckon with a further growth of the debate in the near future.

Table 49.1 shows a similar rise since the early 1970s in the number of publications with "global bioethics" and those with the expression "global ethics" in the title. The parallel development of these two categories of publications indicates that the rise of global bioethics is not an isolated development but rather in line with a similar ascent of a global perspective in other areas of ethics (such as business, environmental, and ICT ethics). This, of course, is to be expected supposing the expansion of these fields is similarly and mainly driven by globalization. While it seems therefore reasonable to expect a further buildup of global bioethics, it goes without saying that it is much more difficult to predict any additional future particulars of the field.

B. Gordijn (✉)
Institute of Ethics, Dublin City University, Dublin, Ireland
e-mail: bert.gordijn@dcu.ie

H.A.M.J. ten Have
Center for Health Care Ethics, Duquesne University, Pittsburgh, PA, USA
e-mail: tenhaveh@duq.edu

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Table 49.1 Hits in Google scholar

Year	Publications with "global bioethics" in the title	Publications with "global ethics" in the title
2011–2012	27	77
2006–2010	55	173
2001–2005	43	133
1996–2000	22	75
1991–1995	9	16
1986–1990	7	4
1981–1985	0	2
1976–1980	0	3
1971–1975	1	1

The specific form of global bioethics advanced in this volume is centered on the UNESCO *Universal Declaration on Bioethics and Human Rights*. As a result, it has a principal orientation on human rights discourse. After all, the *Universal Declaration* involves an expansion of international human rights law into the arena of medicine, life sciences, and healthcare (Andorno, 2009). Consequently, the future perspectives of global bioethics, thus framed, are closely connected with the prospects of the human rights tradition itself. Therefore, as this volume's chosen type of global bioethics has thrown in its lot with human rights, this chapter first briefly reviews the history of the human rights tradition. It then takes a more systematic approach as it looks at the relationship between bioethics and human rights in the *Universal Declaration*. In addition, it examines the key pros and cons of global bioethics' close relationship with human rights. Based on these brief historic and systematic surveys, it finally focuses on the path ahead and endeavors to distinguish global bioethics' main challenges in the years to come.

History of Human Rights

Lynn Hunt (2007) argues that epistolary novels, such as Samuel Richardson's *Pamela*; *or*, *Virtue Rewarded* (1740) and *Clarissa*, *or*, *the History of a Young Lady* (1747–1748), and Jean-Jacques Rousseau's *Julie ou la Nouvelle Héloïse* (1761), "the three greatest novels of psychological identification of the eighteenth century" (Hunt, 2007, 39), played an important role in creating a broader acceptance of the idea of natural rights. The form of these novels, with their imaginary letters, added a dimension of immersion to the readers' experience. The latter felt they could directly sympathize with the troubles of the female heroines. Since the protagonists expressed their inner feelings in their letters, the readers could almost directly look into their soul. Hunt argues that these books and other similar eighteenth-century novels helped readers psychologically identify across social divides and appreciate that all humans were basically the same, that is, had a similar "inner core" of emotions, aspirations, and problems (Hunt, 48).

Consequently, people grew more accustomed to thinking of other human beings as equal to themselves. This again facilitated the development and acceptance of the conviction that all humans possess certain unalienable rights (Hunt, 58). "New kinds of reading (and viewing and listening) created new individual experiences (empathy), which in turn made possible new social and political concepts (human rights)" (Hunt, 33–34).

Somewhat later in the eighteenth century, Thomas Jefferson helped shape two key events in the history of human rights (Hunt, 2007, 15–16). Not only was he the main author of the *Declaration of Independence*, adopted by the Continental Congress on July 4, 1776. Subsequently, in 1789, Jefferson helped the Marquis de Lafayette compose a first draft of a document that would later be known as the *Déclaration des droits de l'homme et du citoyen* (Hunt, 16). The following famous sentences of the American Declaration can be seen as anticipating modern human rights (Hunt, 16): "We hold these truths to be self-evident, that all men are created equal, that they are endowed by their Creator with certain unalienable Rights, that among these are Life, Liberty and the pursuit of Happiness" (DoI, 1776). Similarly pivotal passages can be found in the French Declaration (DDC, 1789, Art. 1–2).

However, according to many scholars, the beginning of the human rights tradition lies much farther back in time than the eighteenth century. It is not uncommon to seek the historical roots of human rights either in antiquity or early Christianity (see, e.g., Gordon (2012, 284) who starts his historic sketch with the Code of Hammurabi). From this point of view, the development of human rights or their precursors then proceeds through medieval "natural law," seventeenth- and eighteenth-century "natural and/or unalienable rights" and "rights of man" onto twentieth-century "human rights." Thus from this long-term historical perspective, the eighteenth century is seen not as the enlightened beginning but rather as an age where the human rights tradition galvanizes and gains momentum. After the Enlightenment, the tradition is further pursued in movements such as humanitarianism, feminism, and abolitionism until it finally culminates in the *Universal Declaration of Human Rights* adopted by the United Nations General Assembly on December 10, 1948. The articles of this decisive document are then subsequently elaborated in various international treaties, national constitutions, and the like, thus establishing the current human rights practice.

A recent revisionist historiography challenges this traditional account of the historical development of human rights (Moyn, 2010). In this view, the modern tradition of human rights only starts in the 1970s when it emerges "seemingly from nowhere" (Moyn, 3). The annus mirabilis of the human rights tradition is the year 1977, "a year of shocking and altogether unpredictable prominence of human rights" (Moyn, 121). In January of that year, Charter 77 is published in Czechoslovakia. Next, in that very same month, the American President Jimmy Carter most firmly commits to human rights in his inaugural speech. Subsequently, in May 1977, he gives a key talk on human rights as a pillar of US foreign policy. In fall, finally, the Nobel Peace Prize is awarded to Amnesty International (Moyn, 239). As a result of these and similarly important events, the discourse of human rights surges. This is evidenced by the suddenly enhanced frequency, with which the term

occurs in important media such as the New York Times and the London Times. In 1977, the phrase "human rights" appeared "nearly five times as often as in any prior year in that publication's history. The moral world had changed" (Moyn, 4).

Furthermore, Moyn argues that this change was accidental and unforeseeable (Moyn, 2010, 7). The huge gain in momentum that the international human rights movement experiences in the late 1970s is a response to disenchantment with other grand political ideologies. So human rights pop up by default as the only remaining viable ideological alternative (Moyn, 120–122). Against this backdrop, Moyn criticizes more conventional historians of human rights who approach their subjects "much as church historians treated the Christian religion" (Moyn, 6). Their work respectfully treats the unfolding of the human rights tradition as a long and necessary historical progression of moral improvement. In contrast with this form of "hagiography," Moyn sketches human rights as emerging coincidentally "as the last utopia – one that became powerful and prominent because other visions imploded" (Moyn, 4).

However, Cooper (2010) claims that Moyn, in depicting modern human rights as popping up the 1970s, fails to see a link with earlier nineteenth-century phenomena such as abolitionism and the progress in the laws of war. Though these developments were not focused on human rights discourse, their ambit was truly universal and internationalist. Moyn's account also lacks an explanation of the difference between the Red Cross and modern human rights movements. Most importantly perhaps, Cooper argues that, if pushed to find a recent beginning for human rights, the 1990s, which saw the start of international criminal tribunals and a real boom of human rights organizations, might be even more appropriate than the 1970s. The rather effortless construction of an alternative modern historical trajectory demonstrates the weakness of Moyn's claims (Cooper, 2010). Be that as it may, it is clear that the court is still out on the most appropriate interpretation of the history of human rights.

The Universal Declaration and Human Rights

After World War II, a number of intergovernmental and international organizations, such as the European Council, UNESCO, the WHO, the Council for International Organizations of Medical Sciences, and the World Medical Association, established quite a number of international ethical standards in various areas of bioethics. To varying degrees, these documents are embedded in the human rights tradition and have helped shape the field of global bioethics. The most important ones are the *Declaration of Helsinki* (1964); the *Proposed International Guidelines for Biomedical Research involving Human Subjects* (1982); the *Declaration on the Human Genome and Human Rights* (1997); the *European Convention on Human Rights and Biomedicine* (1997); and the *Universal Declaration on Bioethics and Human Rights* (2005).

The *Universal Declaration on Bioethics and Human Rights* is the first global instrument that endeavors to cover the entire field of bioethics (cf. Andorno, 2007).

It can therefore be regarded as epitomizing global bioethics' recourse to the human rights tradition. It is also, of course, the central set of normative standards referred to in this volume. Within the text of the Declaration, three types of relationships between human rights and bioethics are to be distinguished: (a) human rights as starting point and context of bioethics, (b) human rights as a basic principle of bioethics itself, and (c) human rights as constraint and final authority for bioethics (Ten Have, 2013).

Human Rights as Starting Point and Context

As the title of the *Universal Declaration on Bioethics and Human Rights* suggests, its principles are closely interlocked with human rights. The Preamble of the *Declaration* unambiguously refers to human rights as the context within which ethical issues should be analyzed: "Recognizing that ethical issues [. . .] should be examined with due respect to the dignity of the human person and universal respect for, and observance of human rights and fundamental freedoms" (UNESCO, 2005). The Preamble equally refers to human rights instruments. The context of international human rights law is furthermore emphasized in Article 2.c., which states that one of the aims of the Declaration is: "to promote respect for human dignity and protect human rights, by ensuring respect for the life of human beings, and fundamental freedoms, consistent with international human rights law" (UNESCO).

Human Rights as a Basic Principle

Although an explicit hierarchy of bioethical principles is lacking in the UNESCO Declaration, the very first of its 15 principles refers directly to human dignity and human rights. This might be understood as suggesting a fundamental role of human dignity and human rights in bioethics (Byk, 2007; Nys, 2006).

Human Rights as Constraint and Final Authority

Several times, the Declaration states that its bioethical principles should be interpreted and applied in accordance with international human rights law. The Preamble refers to these constraints in a general way: "Recognizing that this Declaration is to be understood in a manner consistent with domestic and international law in conformity with human rights law" (UNESCO, 2005). The importance of consistency with human rights is repeated more specifically in the following principles: Article 6 (Consent) states that exceptions to the principle of consent can only be made, if they are in line with international human rights law. Article 7 (Persons without the capacity to consent), 9 (Privacy and confidentiality), and 11 (Non-discrimination and non-stigmatization) equally stress compliance with human

rights. In addition, the Declaration advances a few principles that are relatively new in the global bioethics discourse. An example is the principle of respect for cultural diversity and pluralism (Article 12). This is the only principle, for which a constraint is formulated within the text of the principle: Neither cultural diversity nor pluralism should not be invoked to infringe upon human rights or upon any of the other principles. Due to this limitation, this principle can be seen as the weakest one in the Declaration. Another example is the principle of social responsibility and health (Article 14), although it can be regarded as based on the human right to enjoy the highest attainable standard of health (International Bioethics Committee [IBC], 2010). Finally, the last two articles of the Declaration advance further stipulations regarding limitations to both the application and the interpretation of the principles of the document. Article 27 declares that the application of the principles can only be limited subject to three conditions: (1) it must be by law, (2) for specific reasons (public safety, criminal offences, protection of public health, or protection of the rights and freedoms of others), and (3) when the law is consistent with international human rights law. Article 28, finally, states that nothing in the document may be understood as justifying any activity contrary to "human rights, fundamental freedoms and human dignity" (UNESCO, 2005).

Arguments in Favor of a Close Connection of Bioethics and Human Rights

This section and the next one focus on the assessment of the close connection with human rights, as reinforced by the Declaration, from the point of view of global bioethics. The sketches of pros and cons below owe much to earlier analyses and surveys by Andorno (2007, 2008, 2009), Ashcroft (2008, 2010), as well as Gordon (2012). The view in favor of a close link points out that the connection is advantageous for global bioethics in order to tackle important challenges on a worldwide scale. The general argument goes as follows. Due to the global village character of the modern world, much of what goes on in any specific country is thoroughly interwoven with developments in a variety of other countries, sometimes at the other side of the globe. This goes for politics, culture, energy, environmental degradation, entertainment, science, technology, and so forth. As a result, numerous bioethical issues have emerged that are difficult to address adequately by single nation-states. Examples are pandemics, international drug trials, brain drain of healthcare workers and researchers, access to pharmaceuticals, property rights, environmental pollution, and biopiracy. Clearly, as these issues inherently cross national borders, they demand international solutions. Against this backdrop, the appeal to human rights makes a lot of practical sense in order to seek avenues for a more effective global governance of these issues. More specifically, the main advantages of human rights advanced in the literature are the following.

Familiarity and Reputability: Everybody knows human rights. In contrast, other important ethical theories, such as utilitarianism, deontology, and virtue ethics, are usually only known to academic insiders. This broad familiarity gives human rights

an instant edge when it comes to looking for instruments for the establishment, analysis, and application of global ethical norms for medicine, healthcare, and life sciences – the aim of global bioethics (see above). As human rights are firmly embedded in international human rights law, the authority of which is accepted by almost every country on earth, human rights present a commanding discourse that is broadly acknowledged around the world (Andorno, 2009; Baker, 2001; Gordon, 2012). Hence, ". . . casting a debate into human rights terms allows a well-tested and long-established common language, rhetoric and institutional practice to be applied in order to achieve consensus both on the nature of the problem and, ideally, on the form of possible solutions to it" (Ashcroft, 2010, 644).

In addition, human rights generally enjoy a good reputation. Human rights discourse is "the ubiquitous mode of expressing social criticism" (Fenton & Arras, 2010, 128). Human rights are perceived as important, almost self-evidently accepted international normative standards. Accordingly, infringements of human rights are usually condemned as grave and urgent events that demand instant intervention (Gordon, 2012).

Affinity Between Bioethics and Human Rights: Several scholars have observed that there is a certain kinship between bioethics and human rights (Andorno, 2009; Ashcroft, 2008; Gordon, 2012). More particularly, it seems that human rights and public health have important shared concerns focused on improving basic conditions, such as the availability of sufficient drinking water and food, appropriate shelter, and access to rudimentary healthcare. These circumstances are pivotal for health and, more generally, physical, mental, and social well-being (Fenton & Arras, 2010). Therefore, promoting human rights may very well amount to furthering public health (Mann, 1996). In addition, Ashcroft (2010) stresses further commonalities between bioethics and human rights. He regards them as "two alternative forms of governance for the life sciences and medicine" (Ashcroft, 640). They are an answer to "the same social and historical forces and events" (Ashcroft, 642). Annas sees bioethics and human rights as intimately interlocked in the global arena, a situation that will eventually develop into a synthesis between the two (Annas, 2003). Additionally, bioethics and international human rights are held to have similar historical roots: World War II, the Nazi concentration camps, and their follow-up events triggered the establishment of both (Annas, 2004, 2010; Baker, 2001). In addition, Baker sees further significant parallels between the historical development of bioethics and human rights. Both lost influence during the Cold War and regained sway again in the mid-1970s. Both became prominent and broadly known as a result of abandoning their earlier more esoteric philosophical foundations. Both gain support from a variety of organizations, both governmental and nongovernmental (see Baker for more similarities). Finally, many important regulatory frameworks and bioethics policy documents that have been developed in the last few decades do already employ rights terminology (Andorno, 2007, 2009).

Universalism: Human rights can be regarded as entitlements that all human beings are held to have exclusively on the basis of their species membership (Andorno, 2009; Gordon, 2012). Thus when it comes to determining whether an

entity has human rights, being human is the only thing that matters. All other traits, such as geographic location, ethnicity, gender, political outlook, and the like, are indifferent (Andorno, 2008, 2009). In this sense, human rights also rise above cultural diversity. Due to their universality, human rights enable the creation of an appeal to minimal normative standards (Andorno, 2008). Global bioethics needs certain transcultural principles that are universally valid regardless of the differences between sociocultural, philosophical, and religious traditions (Andorno, 2008, 2009; Gordon, 2012).

Flexibility: Human rights, as they occur in the *Universal Declaration on Bioethics and Human Rights*, are to a certain degree compatible with regard to cultural diversity. In other words, although human rights norms claim universality, there might still be local differences in the way in which specific rights or articles are interpreted and implemented (cf. Andorno, 2007, 2008, 2009). In its Preamble, the *Universal Declaration on Bioethics and Human Rights* clearly states that cultural diversity "...as a source of exchange, innovation and creativity, is necessary to humankind and, in this sense, is the common heritage of humanity" (UNESCO, 2005). At the same time, however, it states that cultural diversity may not be called upon "at the expense of human rights and fundamental freedoms" (UNESCO). Accordingly, Article 12 (respect for cultural diversity and pluralism) later points out that the "...importance of cultural diversity and pluralism should be given due regard. However, such considerations are not to be invoked to infringe upon human dignity, human rights and fundamental freedoms, nor upon the principles set out in this Declaration, nor to limit their scope" (UNESCO, Art. 12). Thus cultural diversity is important when it comes to interpreting and implementing the other principles in specific contexts. Nevertheless, as remarked above, respect for cultural diversity and pluralism is the only principle in the Declaration that can never overrule any of the other principles.

Effectiveness and Enforceability: The biographies of people like Václav Havel, Alexander Solzhenitsyn, Aung San Suu Kyi, and Chen Guangcheng demonstrate that violence and cruelty can meet their match. Human rights discourse can effectively transform moral bravery into political clout. In the current stage of the globalization process, it does not seem to be primarily nation-states but rather the activism of a global civil society movement that is effectively enforcing human rights. Something similar seems true in global bioethics, which is a movement of healthcare professionals, scientists, and citizens in general rather than predominantly governments. For bioethicists interested in improving global governance of important ethical issues, in order to become more effective, it is advantageous to link up with the human rights movement, which enjoys substantial support of a global network of powerful international organizations and NGOs. Thus with the help of the human rights movement, bioethics might be able to more effectively influence real-world policies on important issues (Arras & Fenton, 2009; Fenton & Arras, 2010).

In addition, human rights reinforce a link to lawmaking. Bioethics nowadays has expanded over and beyond the confines of the exclusively academic arena. In this regard, Ashcroft makes a useful distinction between "academic bioethics" and

"policy bioethics" (Ashcroft, 2010, 643). Through its focus on and link with policy, bioethics is intimately related to lawmaking, both domestically and internationally. There is also a shift from the domestic realm to the global arena as bioethics is increasingly focused on creating an international legal framework beyond merely domestic concerns. In addition, bioethics is currently more and more regarded as a form of advocacy. Rather than only providing analytical discourse and sophisticated arguments, it is also concerned with the implementation of argumentative strategies in daily practices and the application of policies in concrete circumstances. Recourse to human rights can enforce these forms of advocacy.

An example of the impact of the association of bioethics and human rights is the Trovan case in Nigeria. Following the unjustified experiment of Pfizer in the city of Kano, Nigerian families brought the pharmaceutical company to court in the USA. After an initial dismissal, the judiciary decided in 2009 that Pfizer should be condemned since informed consent is a universal ethical norm, so that not applying this norm is in fact a crime against humanity (Ten Have, 2011).

Arguments Against a Close Connection of Bioethics and Human Rights

Equally, there is also criticism of a close link between bioethics and human rights. According to this view, it is neither necessary nor desirable for bioethics to link up with human rights in theory or practice. On this view, bioethicists would better do without resorting too much to human rights discourse. The main arguments supporting this critical view are the following.

Problems of Human Rights Theory: It may come as no surprise that currently a *communis opinio* concerning the justification of human rights is lacking. Back in the seventeenth and eighteenth centuries, religious approaches were prominent in foundational discussions about "natural rights," "unalienable rights," and the "rights of man." It was usually claimed and fairly broadly accepted that these rights were God-given. In contemporary debates, however, this strategy has lost its self-evidence due to secularization and the truly worldwide scope that modern international human rights are currently meant to cover. Obviously, any successful substantiation of international human rights must aim at convincing not only those people who believe in a God who stipulates rights for human beings. Above and beyond, it must endeavor to include people with other religions or no particular religion whatsoever (cf. Baker, 2001). At present, therefore, it is critical to develop a discourse on the justification of human rights that starts from premises acceptable to everybody. As this has turned out to be a difficult task, current scholarly discussions are dominated by wide ranging and various secular attempts to justify human rights (see Gordon (2012, 285) for references).

However, all these attempts have been criticized resulting in a lack of agreement on the foundation of human rights within the scholarly community. Human dignity, for example, is rejected as a solid foundation of human rights by Schroeder (2012) on the following three grounds. First, with secularization the concept of human

dignity has lost its self-evidence, which it still possessed when it was widely perceived and accepted as an important religious concept. Nowadays referring to dignity as such does not suffice. Instead, it demands further justification. Second, the secular understanding of human dignity by Kant, whereby dignity is the ability of normative self-legislation, excludes many human beings whom we wish to be covered by universal human rights, for instance, incompetent people who have lost their rational capacities. Third, the concept of human dignity seems to provoke more intellectual criticism than the idea of human rights itself, which disqualifies it as an appropriate justification (Schroeder, 2012, 333–334).

Besides the basic problem of the justification of human rights, there are various other more specific theoretical problems such as the anthropocentrism involved in the exclusiveness of human beings as the sole bearers of human rights excluding basic and universal rights for other natural entities (Sakamoto, 1999) and the inability of human rights theory to capture the full complexity of morality and adequately deal with phenomena such as virtue, supererogation, and the good (Benatar, 2006).

Indeed, there is substantial theoretical criticism of human rights within the bioethics community. Ashcroft (2008) argues this is partly due to the fact that most bioethics scholars tend not to have human rights as their fundamental moral theory. Most of them, instead, work either with the dominant four-principle theory, a version of consequentialism or deontology or an eclectic approach. When bioethicists operate with human rights, these are often understood as derivative and not foundational concepts (Ashcroft, 2008).

Impotence: Schroeder (2005) argues that human rights discourse has two important weaknesses. First, the Western idea of human rights itself is feeble and unfamiliar in large parts of the world. Second, the human rights system focuses on rights without substantially considering the corresponding obligations. This might render those rights meaningless. The right to healthcare, for example, lacks meaning "…if nobody exists who can discharge the equivalent obligation" (Schroeder, 222). Against this backdrop, Schroeder argues that non-Western moral frameworks could help out in stressing substantive obligations "not only with reference to other human beings, but also to other living entities" (Schroeder, 222).

Activism's Deleterious Effects on Academic Work: Benatar (2006) argues human rights activism in bioethics may actually undermine the scholarly quality of the field. He argues that while bioethics is essentially an academic endeavor, the human rights movement is focused on social change. Importing human rights discourse into bioethics runs the risk of introducing activism in the field as well. If social activism increasingly drives scholarly activities, merely advancing rights claims may replace or marginalize subtle moral analysis. There is a danger that the activist agenda might instrumentalize scholarship in order to further its goals. Obviously, this would harm bioethics as a sophisticated academic undertaking (Benatar).

Western Imperialism: Sakamoto (1999) argues that Eastern and Western bioethics are substantially different. While in Western bioethics human rights are very important, the appreciation of human rights is "very weak and foreign" in Asia

(Sakamoto, 194). What is more, the very idea of human rights has triggered "moral, ethical and political conflicts among Asian societies" (Sakamoto, 194). Sakamoto identifies further differences between Eastern and Western thinking regarding the role of nature and individualism. Given these differences, a new global bioethics is needed that is more appreciative of the different cultures and moral outlooks. It should not be based on the alleged universality of human rights. Instead, the new global bioethics should harmonize and "bridge over all kinds of ethoses, East and West, South and North" (Sakamoto, 197).

Although Sakamoto states that he advocates a form of "value relativism" (Sakamoto, 1999, 196), his argument does not seem to be explicitly based on relativist premises. From a harsh relativist point of view, the observation that there are countless distinctive moral traditions, lifestyles, and cultures does not only seriously challenge the universality claim of our current set of human rights. Rather it might challenge any global bioethics with universal normative aspirations. If ethical norms are regarded as valid only in specific linguistic, historical, and cultural contexts, it might be difficult to establish universal standards that transgress different cultures, unless some moral common denominator can be found that happens to be valid everywhere as a matter of historic and cultural contingency.

So while proponents of human rights regard them as universally binding basic rights, relativists tend to disagree, even though all governments or members of the UN have adopted international human rights law as a guiding framework for policy-making. The latter circumstance can be explained as the result of Western domination and instrumentalization of the UN system, according to the opponents of human rights. From this point of view, the current human rights system can be regarded as an attempt of the West to impose human rights on non-Western cultures where they might be experienced as foreign.

Future Challenges

This chapter does not aim to systematically assess the merits of the different scholarly positions sketched above in the brief accounts of human rights historiography and the debate about the role of human rights in bioethics. Instead, it attempts to use the above accounts as a background against which to formulate global bioethics' most important challenges in the coming years ahead.

Combining Practical Engagement and Theoretical Commitment

The brief systematic survey shows that the pros and cons of using human rights within global bioethics are still very much subject to debate. Reviewing the arguments, it is difficult to avoid the impression of the ambivalent character of global bioethics. On the one hand, there seems to be a gap between the rather philosophically inclined academic bioethics scene and the more activist human rights movement. While the latter seems focused on social change, the former

sometimes gives the impression of mainly seeking intellectual elucidation of moral quandaries. On the other hand, through globalization the bioethical discourse seems to have expanded out of the esoteric academic arena as well. Even at a local level, bioethicists are often concerned with policy-making in healthcare institutions and consultation in clinical settings. This connection to policy-making is yet stronger at national and international levels where bioethicists are involved in a wide range of activities that go beyond the exclusive domain of academic enquiry.

As this *Handbook of Global Bioethics* evolves around the UNESCO *Universal Declaration on Bioethics and Human Rights*, it clearly engages with the human rights tradition as a pivotal means of communicating and implementing ethical standards on a global scale. The consideration that human rights represent a well-known, reputable, and effective framework is decisive in picking this moral framework to feature prominently within global bioethics. Admittedly, on the view that global bioethics should merely stick to reflecting about the world, without any attempt at improving it, the utility argument in favor of invoking human rights fails to make a dent. However, the editors of this volume believe global bioethics should attempt to be more ambitious and aim for social change next to elucidating and establishing moral truths.

This handbook looks at the way bioethics has developed in a variety of countries worldwide and explores the main ethical challenges through the prism of the UNESCO *Universal Declaration on Bioethics and Human Rights*. In the years ahead, it will be pivotal to further develop a global bioethics that aims at improving social conditions and combining an activist agenda with scholarly research and moral reflection. This stance implies that further serious scholarly work should be done in order to adequately answer claims about flaws in human rights theory. Additional high quality work is needed, which should be focused not only on the philosophical foundations and justifications of human rights but also on more specific "downstream features" of the theoretical human rights framework. That being said, it should not be forgotten, of course, that the other main ethical theories and traditions such as utilitarianism, virtue theory, and deontology are not free either of alleged flaws or of controversial disputes about their philosophical justification. International human rights theory, however, as the youngest contender among these ethical traditions, has some catching up to do in terms of philosophical solidification and analysis of its main theoretical features and concepts. Activists might sometimes seem hesitant toward philosophical explorations of the foundations and basic concepts of human rights, perhaps fearing that too many critical reflections might shed uncomfortable doubts on the normative standards themselves and lessen their impact in practical settings. In the long run, however, serious attempts to get human rights theory on par with its main theoretical competitors will likely solidify the human rights tradition (cf. Arras & Fenton, 2009). Raising the bar in the scholarly arena might, for example, fence off harms and damage from all too easy attacks. On the other hand, scholarly disputes should not be an excuse for abstaining from practical interventions. One cannot argue that practical action is impossible as long as there is no comprehensive consensus on foundations and all the pivotal concepts. In numerous countries, there are important ethical issues

"on the ground" that require decisions in conditions of uncertainty. As long as bioethicists are pondering and analyzing, others – for example, pharmaceutical companies and governments – will simply continue with their current policies or lack thereof as usual.

Promoting Education, Capacity Building, and Protection

Despite the fact that in some countries bioethics has achieved a strong institutional base and a high level of sophistication, in many other countries it has clearly not yet reached a full-fledged state of development. This is demonstrated in this work's survey of the state of bioethics in a large variety of different countries. Indeed, it should here be noted that the list of countries featuring in this volume involves a positive selection bias, since – for obvious reasons – countries without any noteworthy bioethics infrastructure could not be included. In the years ahead, the editors hope to enlarge the number of countries listed in future editions of the *Handbook of Global Bioethics*.

Be that as it may, efforts are needed to strengthen the state of bioethics in most countries worldwide, so that global ethical standards might be more effectively communicated and implemented. As said, human rights and their institutional mechanisms do currently seem to be the strongest implement for social change available to global bioethics. Yet the above-mentioned argument about the "impotence" of human rights should be a reminder that human rights' impact can and should indeed still be reinforced. In the area of medicine, healthcare, and the life sciences, this can be done by promotion of bioethics education and capacity building.

Thus it is important to improve bioethics education worldwide. Also, it is essential to remain critical toward existing methods of bioethics education, promote the development of alternative approaches, and develop more sophisticated ways of assessing the effectiveness of different teaching methods. Finally, there should be a better-organized exchange of teaching experiences in various educational settings. Sometimes bioethics teachers tend to be too secretive about their teaching programs. However, openness and mutual exchange are important so that academics who wish to set up new bioethics programs or improve existing ones do not have to reinvent the wheel continually. NGOs, universities, and intergovernmental organization such as UNESCO are already constructively involved in a range of international activities focused on bioethics curriculum development, designing teaching materials, and the training of bioethics teachers (Ten Have, 2008). These are exciting new initiatives that must be further expanded.

In addition, as set out in Article 19, the *Universal Declaration on Bioethics and Human Rights* advocates the establishment, promotion, and support of "independent, multidisciplinary and pluralist ethics committees." These are crucial platforms for bioethical debate, education, and policy advice (Article 19). The majority of countries worldwide still lack any noteworthy experience with these committees or have not yet established them in the first place. Consequently, it is

pivotal that the establishment and operations of these future bioethics committees in countries with an underdeveloped bioethics infrastructure be promoted and supported (Article 19).

Finally, the implementation of global bioethics requires the development of various levels of protection, especially in developing countries where individuals and populations are increasingly vulnerable due to globalization and appropriate guidelines and effective legislation are often absent. In order to protect defenseless and weak people, serious efforts should be undertaken to develop and apply appropriate legal frameworks in the area of bioethics.

Exploring Alternative Theoretical and Practical Approaches

The concise historical survey above features a mainstream account, according to which human rights have roots rather far away in the past. On this view, the development of the human rights tradition is a long process of moral improvement, whereby moral truths have gradually become clearer until they begin to really trickle through in the Age of Enlightenment. Progress then continues until, after World War II, humanity finally learns its lesson. Human rights are now set up in a serious way and crystallized into a solid foundation for modern international relations. Alternatively, according to a revisionist historical account, the international human rights tradition only really starts off in any significant way in the 1970s. International human rights begin to flourish by accident after dominant other ideologies had collapsed (Moyn, 2010, 7). On this view, development of human rights is a far cry from any necessary unfolding of moral truth. Instead, it is affected by historical twists of fate. Extrapolating from the traditional historical account it might seem reasonably safe to assume that human rights will further expand, as different people around the earth will more broadly accept their moral truth. On the alternative account, however, it is less self-evident to expect that the human rights tradition will survive the vagaries of world history in the twenty-first century. "Human rights were born as the last utopia – but one day another may appear" (Moyn, 2010, 10).

As the court is still out on the appropriate historical view as well as the likely future development of the human rights tradition, it is prudent for global bioethics not to put all its eggs in one basket. Instead, it should explore a variety of alternative theoretical and practical approaches to further its cause. The fact that the human rights framework currently seems the strongest vehicle for social change might hinge on precarious historical contingencies. Thus global bioethicists should not feel too self-confident and self-congratulatory when linking up with the human rights tradition in order to avoid that their endeavors might be swept away together with the latter, once the next ideology takes over as the new foundation of international relations. Fortunately, as this volume shows, a wider theoretical focus is available, for example, through the perspective of communitarianism, the link with environmental ethics, and the international law concept of the common heritage of humankind.

Conclusion

The goals for future global bioethics are ambitious. It goes without saying that it should focus on excellent intellectual scrutiny. However, academic reflection should not be an end in itself. Global bioethics should also aim to have a positive effect on the world. For this reason, this volume endorses human rights as the strongest vehicle for social change currently available to global bioethics. Combining a theoretical commitment with practical engagement implies the following: On the intellectual front, global bioethics should focus on further philosophical solidification and analysis of the foundations and basic concepts of human rights theory. On the practical front, it should promote ethics education, capacity building, and protection. In following this two-thronged approach, however, global bioethics should also avoid dogmatism and keep an eye open for exploration of alternative theoretical and practical approaches that are not integral to the international human rights system.

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Section VII

Countries and Regions

Argentina

50

Susana María Vidal

The author is responsible for the selection, interpretation and presentation of the facts contained in this publication and for the opinions expressed herein, which are not necessarily those of the organization she works for and do not commit it in any way.

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S.M. Vidal
Latin American and Caribbean Bioethics Programme. SHS. UNESCO Montevideo Office, Especialista de Programa. Programa para ALC de Bioética de la UNESCO Oficina Regional de Ciencia de la UNESCO Montevideo, Montevideo, Uruguay
e-mail: svidal@unesco.org.uy

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Introduction

The history of bioethics as it has been known was more an account of the events giving rise to this discipline in the Anglo-Saxon world, particularly in the United States, and later, of the attempts at establishing stages in the historic development of bioethics in Latin America, which described the reactions to the arrival of the bioethical paradigm – basically born and developed in the United States – in the region (Rodriguez del Pozo & Mainetti, 2009; Lolas, 2002). These have been accounts geared to deconstructing what appears to be a linear history.

It is well known that ethical problems related to human life and health are generated within a specific historical and cultural context, and it is essential to relate to this particular environment to understand the way in which these problems are apprehended, discussed, or decided on. For its part, institutional development has also accompanied the arrival and expansion of a "discourse" that is establishing itself in a specific milieu. For example, a fact to be taken into account is that, at the time when minority movements started to appear in North American society demanding the right to recognition of their differences (which for many has been an inflection point in the birth of bioethics), one of the darkest periods of its history was beginning in Argentina. The interruption of democratic processes in many countries of the region coincided with the explosion of the autonomist movement in the United States, something that should not be overlooked when considering the history of the ethics of life and human health.

These accounts of the ways in which Anglo-American bioethical discourse was understood in the region are of great interest. However, it is essential to consider at least three aspects when discussing the history of bioethics in Latin America and in Argentina in particular.

In the first place, the socio-political context in which the discipline started to be developed should be considered, in particular, the right to freedom, to life, to health, and the freedom of conscience, expression and movement. Secondly, the economic, social, and sanitary conditions within the country need to be taken into account, observed in the exercise of the right to health and accessibility of health services and in the enormous inequitable gap prevailing in Argentina between the different regions and social classes. Poverty, inequity, and exclusion are conditions which, in addition to being ethical problems in themselves, necessarily cut across all the ethical problems emerging in the field of life and human health. This is the framework in which the central issues of bioethics must be considered, such as the value of life, dignity in death, respect for freedom of conscience and of choice (reflected in informed consent), equity and justice in the distribution of the goods and benefits of development. It is difficult to consider the fulfillment of values and application of principles proposed by bioethics in the framework of political conditions of oppression and extreme violation of human rights and basic freedom. It will be equally difficult if these values and principles are not related to the enforcement of social, economic, and cultural rights and, in particular, to the way in which the right to health can be exercised in the communities' real and concrete life.

The third aspect to be taken into account is the influence of the religious and historical cultural tradition in the development of an ethos for the region and for Argentina in particular (Tealdi, 2008). It is important to remember that the Catholic Church has had, and continues to have, an enormous influence on debates on ethical issues, in particular those related with the beginning and end of life. In the first place that influence is on medical ethos but also an enormous political influence, which, in many cases, has led to regulatory projects being postponed or changed (e.g., those on sexual and reproductive health, abortion, and issues regarding the end of life), and finally, in the judiciary field, as will be seen in many of the rulings by judges.

In their revision of the stages of development of bioethics in Latin America, Rodriguez del Pozo and Mainetti (2009) talk about the "bioethical revolution," and this would seem to coincide with a political-historical time in which human rights were apprehended by civil society, internalizing the sense of belonging of these rights to concrete practices and, therefore, the possibility of effectively demanding them when they could not be exercised. It was also the time when basic freedom crystallized in a social practice that, for this same reason, made it possible to have a critical outlook, reflect on the history, talk, and voice opinions and take free decisions in a pluralistic and democratic environment. It was around the year 2000 that a critical revision could be made of the Anglo-American model that had been transferred to Argentina uncritically in the 1990s. This model very shortly showed itself unable to respond to the complex ethical conflicts emerging from life and health in a region with great inequities that required new answers. In this way, the revolution was not only an academic one. Certainly, this standpoint removes bioethics from the academic shelf, to place it in the context of applied ethics which seems to be the richest way of looking at its history, as a reflection on social practices, individual acts, and the ways that *ethos* adopts in this specific location.

Bioethics as a program for social reform (Cecchetto, 1996), as a new discourse, is a bioethics linked to social practices and expresses as a result of a movement that is growing, self-creating, and establishing itself. Its field of study concerns the ethical aspects of life and human health and, therefore, cannot be indifferent to those lives ending before their time because of lack of satisfaction of their basic needs, such as food, or lives ending as a result of violence, injustice, or exclusion. The death of innocent people for social, political, or religious reasons is an example of a lack of respect for life and is an expression of the way in which people live and die in each society.

There is no doubt about the debt to write a history of Latin American bioethics, as in fact it happened with North American bioethics (Jonsen, 1998). It should start with the debates that arose with the conquest of America about the rationality of the indigenous people and the state of nature (Gracia, 1989, pp. 128–130). Saving this debt, the account of Argentine bioethics was only possible with the reestablishment of democracy and several years later was able to achieve a wider academic development toward the end of the 1990s and, more strongly in the twenty-first century, following almost 20 years of democracy in full force but crossed by three economic

crises that decimated the country. The last crisis in 2001, which was not only economic but also institutional, left over 40 % of the population under the poverty line. This background has affected in different ways the manner in which bioethics developed in the country, its institutional growth, its regulatory swings, and its difficulties to progress in the normative field.

The Institutional Framework in Argentina

A representative, republican, and federal government system is in force in the Argentine Republic based on the institutional organization of the 1853 Constitution and its subsequent amendments in 1860, 1866, 1898, 1957, and 1994. The Federal State comprises 23 provinces and the Autonomous City of Buenos Aires. Each of these has its own local constitution and conserves all the power and authority not expressly delegated to the national government, in accordance with a republican and representative government system respecting the declaration of rights and guarantees set out in the National Constitution. The country has 40+ million inhabitants and is placed among the region's medium-income countries. It is the second largest country in Latin America.

Some Background Information and Stakeholders Who Took the First Steps

Bioethics first saw the light in Argentina and also in Latin America at the Institute for Medical Humanities of the Dr. José María Mainetti Foundation for the Progress of Medicine, established in 1969. Shortly after, the Editorial *Quirón* was created, producing the first journal to publish bioethical contents in the country. This was followed by the creation of the Medical Humanities Chair at the School of Medicine at the University of La Plata, thus starting the stage of bioethics "assimilation" (Mainetti, 2010) with the organization of the first courses given by guest lecturers, particularly from US centers. But it was only in 1985 with the creation of the Program for Bioethical Research that the national situation was approached from a *comparative* bioethical standpoint (Mainetti, 1990). In 1986, the National Bioethics Reference Center was established, subsequently becoming the Latin American Bioethics School (ELABE) in 1990, reporting to the Mainetti Foundation and located in the City of La Plata. This was an academic extension project with a regional scope. Its president was José Alberto Mainetti, and Juan Carlos Tealdi was its director for almost 10 years. In 1989, the Mainetti Foundation organized the First Course on Health Ethics Committees with the aim of training future coordinators for these committees. Later, more specialized international courses in bioethics were organized, providing a high-level training to many of the pioneers in bioethics from other fields and provinces in the country.

By this time, there were around five Health Ethics Committees (HECs) among them those established in the Buenos Aires Clínicas Hospital (created in 1984),

the Italian Hospital's Neonatology Service (1984), the La Plata Excellence Center for Cancer (1987), and the Mendoza Hospital Emilio Civit (1989), later renamed the Humberto Notti Hospital (Tealdi, 1995). Subsequently many other committees arose in hospitals in the Province and City of Buenos Aires and in the Provinces of Córdoba, Santa Fe, and Mendoza (Vidal, 2008). ELABE coordinated the operation of the Regional Network of HECs, which for almost a decade gathered efforts at different levels and was headed subsequently by the president of the civil association Bio & Sur, Juan Carlos Tealdi.

Another center of importance was the one created related to the University of Mar del Plata with the Bioethics Commission set up in 1989 following a proposal by Pedro F. Hooft and Justo Zanier. From this initiative arose the degree course for Specialization in Bioethics at the University of Mar del Plata, which started in 1991 with a postgraduate course in bioethics and was later in 1994 reformulated as the Advanced Program for Research in Bioethics. The Bioethics Committee of the Private Community Hospital, PCH (established in 1995) contributed closely to this project and from 1984, had a Deonto-thanatology Committee and a section for palliative medicine, in which Jorge Manzini – a recognized specialist in end of life issues – participated. Presently, it also has a very rigorous research ethics committee (the institutional council for the revision of research studies (CIREI-HPC)). It was an initiative of the PCH Committee that led to the establishment of the Network of Bioethical Institutions of the Southeast of the Province of Buenos Aires, with 12 other institutions from Mar del Plata, Tandil, Bahía Blanca, and Necochea, in which many bioethics specialists from the Province of Buenos Aires took part. The Ethics Committee of the Inter-zone Acute Hospital also played an enormous role. The late Sergio Cecchetto, a well-known bioethicist, was part of this committee and of its numerous contributions to Argentine bioethics, particularly through the presentations of cases greatly contributing to jurisprudence. Likewise, other HECs in this network participated extensively in various activities that took place at that time.

In 1993, FLACSO (the Latin American School of Social Science) established a Certificate of Higher Studies in Bioethics. Presently, it is known as the Bioethics Program, under the direction of Florencia Luna. This school offers an educational program (which will be discussed below), develops a research program, and has been producing the Journal "Perspectivas Bioéticas" since 1996. In 1994, the International Association of Bioethics' Second World Congress took place in Buenos Aires, in collaboration with ELABE under the presidency of Juan Carlos Tealdi. This congress was an encouragement to national bioethics and led to encounters with voices from central countries and also from other countries of the region. In 1995, the Argentine Bioethics Association was created gathering most of the bioethicists working in the country at that time. Since then, it held an annual meeting where different voices and views met over several years.

It would be impossible to refer to all the people who took the first steps in Buenos Aires and in the rest of the country to develop this discipline. It must be said that many of them generated bioethics in their centers or provinces and were later followed by others who created new initiatives.

At the University of Buenos Aires, the Faculty of Law relied on the impulse of academics such as the late Gladys Mackinson from the Gioja Institute and the Bioethics Chair, one of the first in this subject in the country, and Salvador Bergel with the UNESCO Chair in Bioethics since 1994, developing considerable activities in the field known as *biolaw*. Mention should also be made of other lawyers like Luis Niño, Estela Maris Martinez, and Nelly Minyersky, who made a fruitful contribution to providing grounds from a philosophy of law for different subjects. They were later followed by other bioethicists such as Eduardo Tinant (La Plata) and Ignacio Maglio (Bs As), among others, who continued contributing to this task. Some philosophers such as Maria Julia Bertomeu, Maria Luisa Pfeiffer, and the late Sergio Cecchetto, among others, were there from the start working on issues of fundamental bioethics, close to ELABE and later at other academic centers.

Toward the end of the 1990s, the Ethics Committee of the Argentine Society of Intensive Care was set up, with the presence of two well-known referents, Carlos Gherardi and Francisco Maglio who contributed a lot to Argentine bioethics in terms of decision-making in end of life situations, among other issues.

Outside Buenos Aires, many experts developed not only local work but also became involved with initiatives at the national level that arose from Buenos Aires. It should be mentioned that at the end of 1999, there were over 200 Ethics Committees (both HECs and Research Ethics Committees (RECs)) in the whole country, as compared to the four existing 10 years earlier (EULABOR, 2005). These had mostly arisen spontaneously from the initiative of small groups of people.

From Bahía Blanca, the contribution of the bioethicists Norberto Cragno and Agustín Estévez was very considerable, giving vitality to the launching of bioethics on a local and national level.

In the Provinces of Rio Negro and Neuquén, the work of Luis Justo and Andrea Macías has been enormous. There, a Bioethics Chair was set up at the National University of Comahue (UNC) and the Provincial Network of Bioethics Committees by the Ministry of Health in Neuquén among many other activities. The network was established within a health model geared to primary health care starting toward the end of the year 2000, giving it a different profile and involving community participation. The project was a joint venture between the Provincial Bioethics Development Program and the Chair of Bioethics of UNC's School of Medicine (Justo & Macias, 2002).

In the Province of Santa Fe, Silvia Brussino was a pioneer in this discipline at an academic level, working systematically from the University of El Litoral, as well as from a lot of other places like the Bioethics Committee of the Iturraspe Hospital in the City of Santa Fe, established in 1994. Elisa Dibarbora, from the Faculty of Law of the National University of Rosario and the Bioethics Commission of the College of Physicians, was a promoter of bioethics in the province.

In the Province of Córdoba, Susana Vidal from the Bioethics Area of the Ministry of Health started her activities in 1994, continuing in 1996 with the establishment of the HECs Provincial Network (Vidal, 1998), and subsequently

with the project for biomedical research ethics, which went through many difficulties as did the various provincial commissions set up over the years. In 2001, the Bioethics Center of the Catholic University of Córdoba was created by the Rector's Resolution N° 289/01 under the leadership of Armando Andruet who has since developed many activities in the province. Over the past few years, the Province of Jujuy has launched a development initiative from the Ministry of Health, involving HECs and RECs under the initiative of Paz Bossio. The Province of Mendoza started its activities in the 1990s, with Marta Fracapani from the Faculty of Medicine of the University of Mendoza and the above-mentioned HECs, with the invaluable inputs of Aída Kemelmajer de Carlucci from the Faculty of Law and the High Court of Justice. Currently, all the provinces have developed some type of bioethics capacity, either committees or other activities of varying quality.

For their part, the RECs have had a complex history. To start off with, the ethics research evaluation was developed in some provinces and in the City of Buenos Aires by the HECs themselves, and as will be seen, it has only been over the past 10 years that these two types of committees have started to work separately. However, many committees still fulfill both functions in the City and Province of Buenos Aires and in some provincial commissions.

It should also be mentioned that there were at least three attempts at setting up National Bioethics Commissions in the country that ended in failure. The first attempt was made by the Ministry of Health of the Nation (MH) in 1992 and the second in 1998 by the Presidential Decree No. 426/1998, the National Commission for Biomedical Ethics, that operated in the MH and that was dissolved 2 years later as part of a scandal within academic institutions. Finally, the third was a proposal made in 2006 by the MH, which did not come to fruition. There are other more specific commissions: the National Committee for Ethics in Science and Technology set up in 2001 in the context of the Nation's Ministry of Education, Science and Technology of the time. Likewise, the Ethics and Human Rights Council in Biomedical Research was set up by Resolution n° 050/04 in the Secretary of Human Rights (Ministry of Justice and Human Rights). Finally, the Nation's Ministry of Justice and Human Rights Resolution 666/2011 was made public during 2011, creating the National Council for Bioethics and Human Rights, which it is envisaged will start to function in 2012.

Biomedical Research and Regulations in Argentina

Addressing research ethics in Argentina requires looking at the shape the model of biomedical research has acquired in the country over the past years. In this respect, it may be stated without the fear of committing a misjudgment that one must analyze a dual scenario: first the regulative scenario (always marked by a path of progress and setbacks related to conflicts of interest, particularly interests of economic and sectorial nature), and, secondly, a scenario not linked to the regulatory frameworks, of enormously heterogeneous practices.

The Regulatory Framework

Since 1997, Argentina has a regime of Good Clinical Practices in Pharmacological Research Studies, Provision 5330/97 of the National Administration for Drugs, Food and Technology (ANMAT) reporting to the Ministry of Health, with provisions that must be fulfilled by researchers and promoters undertaking research in which human beings are involved in the country. This was a technical regulation, which barely alluded to the ethical aspects of research and made no reference to the problems already present at international discussions on the subject. However, it established as mandatory that studies must be approved by an Ethics Committee and by the Teaching and Research Committee of the center where the research was to take place. It also established the responsibility of ANMAT regarding approval, control and monitoring of studies and the obligations of researchers and sponsors. Initially, this regulation had strong repercussions and represented a breath of fresh air for the new situation generated by multinational research that had been growing in an exponential way in the country during the 1990s, without much control. There is no doubt that the provision was insufficient vis-à-vis the growing development of research in the country and went unmodified until a few years ago when it was improved through various amendments. It was only in 2005 that *Provision 690* was adopted, formalizing the procedure for ANMAT to undertake inspections of Clinical Trials.

In 2007, Resolution No. 1490 was adopted as the "Guide for Good Clinical Practices in Research on Human Beings" (Ministry of Public Health, 2007), which adapts internationally accepted ethical and scientific standards to the Argentine situation regarding the design, implementation, recording, and reporting of experimental and nonexperimental studies carried out on human beings (Ugalde & Homedes, 2012a). One year later, Provision 6550 (ANMAT, 2008a) was adopted, strengthening points related with the functions of RECs and further advancing in the requirements for informed consent (IC) among others. Provision 1067 (ANMAT, 2008b) and Resolution 102 (Ministry of Health, 2009) advance on the report on Serious and Unexpected Adverse Reactions to Medication (ANMAT, 2008, Annex I) and establish the Registry for Clinical Trials on Human Beings, which so far had been inexistent on a national level. Finally, Provision 6677 (ANMAT, 2010) adopted in 2010 repealed Provisions 5330/97, 1067/08, and 6550/08 and became the reference document for undertaking clinical tests in the country, taking as a framework of reference international standards established by good clinical practice standards.

Some provinces, such as Córdoba and the Autonomous City of Buenos Aires, have followed their own paths on some occasions removing themselves from national regulations and making further progress regarding requisites to be demanded. A brief summary will be made further on.

Biomedical Research Practices

The 1990s marked Argentina with the emergence of new and more complex research at various centers in the country, mostly of a multinational nature and

funded by pharmaceutical industry. Although the regulatory framework was being progressively implemented, events took place that marked the development of research on a national level. Some of these events warrant a detailed examination and no doubt are among the reasons why low- and medium-income countries are exposed to greater and more complex risks in multinational research (Lorenzo et al., 2009) also showing the need for a stricter control of researchers and local institutions, both centers and hospitals, in addition to ethics committees. Homedes and Ugalde have written a detailed report on ethically questionable situations in the ethics of research in Argentina (Ugalde & Homedes, 2012a). Some of the cases described in this text show that not only did irregularities take place during research processes in public hospitals and on vulnerable populations (such as those carried out on children in the Province of Córdoba) but also various studies detected scientific fraud, corruption, and bad ethical behavior by the researchers. The judge's ruling on the claim made by ANMAT has become public recently (November 2011) sentencing the laboratory and researchers of a multicenter study of vaccines on children (COMPASS Study) aimed at assessing the effectiveness of a vaccine for the prevention of pneumonia and middle ear caused by a pneumococcal infection, to pay a fine. The study took place in three Argentine provinces on low-income populations and "irregularities in the procedure for selection and entry of some participants (were detected) related with errors in the procedure to obtain the informed consent of parents or tutors or the lack of compliance with criteria for the inclusion of participants" (ANMAT, 2012). In the many interviews carried out, failure to comply with procedure IC, signatures of illiterate patients or underage patients, and irregularities regarding witnesses for the signature of the document were detected.

Additionally, not only economic but also political influences have been found in the development of regulatory processes and in the approval of protocols of dubious benefit to the communities involved (Ugalde & Homedes, 2012b). A very notorious case was that regarding the claim lodged by the Nation's Ombudsman (Mondino, 2003, p. 67) on research on clinical oncology carried out in the country between 1998 and 2002 and was presented at a congress of the *American Society of Clinical Oncology* (ASCO). Serious anomalies were detected in these studies, such as studies carried out without informed consent (IC), or without the approval of the REC, showing the lack of control by the responsible bodies and the enormous difficulty to gather data on studies carried out in the country. Another case was detected at the Buenos Aires Naval Hospital (Deyoung & Nelson, 2000) regarding the so-called GUARDIAN Study (Guard During Ischemia Against Necrosis – with cariporide), in which very serious irregularities were found in the IC process. There were false ICs (80 of the 137 cases recruited), lack of knowledge on the part of the patients that this was research, and also forgery of the tests. The study was carried out between 1997 and 1998, and it was the laboratory itself that denounced that the signatures of some of the consents had been forged and that various medical histories, X-ray, and electrocardiograms had been replicated with the aim of "inventing" patients. Researchers received 2700 USD for each patient and had to meet certain "deadlines." The claim led to a criminal court case against the

researchers, the institution, and the laboratory sponsoring the study regarding the death of some of the patients. However, causality between the study and the deaths could not be proven, and finally, the case was dropped and the doctors continue to exercise their profession.

Problems that have been cross-cutting in international debates since the end of the 1990s, such as double ethical standards in multinational research, provision of post-research treatment, and the exploitation of vulnerable populations, although identified in numerous case studies carried out in the country, have not been the center of the debate among RECs until the time they make their assessments. They would seem to be more worried with primary issues related with good research practices, researchers' conduct, subject insurances, and how public funds are used when biomedical research is conducted in low-income populations and in public institutions.

Another issue causing great concern is the problem of the independence of ethics research committees (Vidal, 2004) that have only recently been taken more seriously with the establishment of the national registry and progressive accreditation of these committees. Increasingly in the provinces, the approval of studies by a local or institutional committee is being demanded. This requirement has broken up a circuit that had been operating since the 1990s for the approval of studies by a few private committees, known as "independent committees" located in Buenos Aires, that assessed studies being carried out all over the country and collected fees. They lacked any national public institutional monitoring system and provided assessment and follow-up of a doubtful quality while the studies were taking place (Gonorazky, 2008). Accreditation systems will doubtlessly raise the quality of the committees and lessen conflicts of interest insofar as the criteria demanded are rigorous. In the model described so far, researchers played a complementary role, sometimes as mere patient recruiters, and did not participate in research design and, in most cases, were not part of the final publication either. The number of medical researchers has grown from 961 in 1998 to 3,974 in 2005, which is more related to their capacity to enroll patients rather than their scientific and professional qualities (EULABOR, 2005). On some occasions, they have become actively resistant to the implementation of standards or regulations, in particular if these are restrictive, for fear of losing a source of income in a country that has been hard hit by economic crises, or of losing a certain degree of so-called prestige granted by being part of these protocols.

The City of Buenos Aires

The 1990s saw the first steps in regulating this issue. In 1999 within Basic Health Law N^{o} 153, the Health Research Council was created, entrusted with authorizing and monitoring all research in the public subsector in agreement with the guidelines set out in national and international documents regarding bioethics. The standard underscores the need for informed consent, and progress is made in terms of financial participation by the health institution where the research projects are being carried out. Several years later, Resolution N^{o} 1125/SS/2003, amended by

Resolution N° 1914/SS/2003, approved requisites and procedure applicable to research projects in hospitals depending on the Government of the Autonomous City of Buenos Aires (GCBA), thus decentralizing the assessment function and setting up a Central Committee for Bioethics in Health Research, which started to operate on a central level (Perelis et al., 2012).

In 2006, the Report by the General Auditor of the City of Buenos Aires was published on "Management of Research Projects in Public Hospitals – Period 2006," that covered 30 of the 33 hospitals reporting to the GCBA (Perelis et al., 2012). This report showed the precarious way in which assessments had been made so far with a high degree of heterogeneity in quality and defects in the procedure for assessing protocols. No standard criteria for the RECs were available, and, in many cases, IC standards for participants had not been respected. As a starting point to deal with this situation, Law N° 3301 of 2009 was adopted: "Protection of the Rights of Subjects in Health Research" (Law 3301, Ciudad Autónoma de Bs As., 2009). The law governs the regime for clinical research applied to human beings being undertaken in the City of Buenos Aires. In addition to the usual requisites, it includes the need to consider the relevance to the community of the research. It also requires, in all cases, insurances for research undertaken with private sponsoring in favor of the subjects. Finally, the law also establishes a system for accreditation of the RECs (Resolution N° 1012/GCABA/MSGC/08; 2011), a research registry, and a network with other stakeholders, thus completing the support involved in a system of research ethics evaluation for the city.

The Province of Buenos Aires

Since 1990, the Province of Buenos Aires has been implementing the first project to regulate this matter in the country (Law 11044/1990), which was very complete and innovative at a time when the whole of Latin America was practically virgin of regulations. This law took several years to be enacted, but finally, this was done by Regulatory Decree 3.385/08 Pcia. Bs As, a couple of years ago. It applies to public and private subsectors, by the Ministry of Health through the Joint Health Research Commission. The law is a little complex, creating two types of committees for the assessment of health research, separating ethical aspects from design and methodology (technical quality and scientific merit) and establishing that, on the basis of its findings, it is the person responsible for the institution who will give the final authorization for its implementation. It also establishes the cases in which research must be assessed by the central Ethics Committee (created by Resolution 4107. MS. Pcia. Bs As) as well as all the procedure that must be carried out for ethics assessment.

Province of Córdoba

In 2001, a project was implemented in the Province of Cordoba for the creation of a provincial system for ethics research evaluation, through one of the most rigorous

regulations in the country (Res: 729/02). The resolution created a Health Research Ethics Commission (COEIS), proposed criteria for the evaluation of biomedical research and to accredit RECs. In 2003, the regulation was amended, and the commission was dissolved by a political decision. A commission established by the then Minister of Health only comprising researchers was left in charge of assessing protocols, with flexibility in the criteria to set up the RECs, as in the rest of the country. The provincial regulation has been amended three more times with changes in the authorities and different types of negotiations among the sectors of interest involved: researchers, directors of private centers, political authorities, members of private committees, etc. Currently, a provincial law is in force, adopted in 2009 (Law 9694, 2009), establishing the System for Assessment, Registry and Monitoring of Health Research (SERFIS). The system comprises: (a) the ethical assessment of health research and (b) registry and monitoring of this research. It establishes the Council for Ethical Assessment of Health Research (CoEIS) and establishes its functions, which already existed in the previous resolution. In spite of establishing a registry of RECs, the criteria are not included in the text of the law. This regulation proved to be more flexible than the original resolution 729 regarding some of its points. However, it implements a system for registering researches and the RECs and also provides the way of their control. Furthermore, it maintains as a right of the patient some points that had not been considered in other regulations such as: (a) to receive the best diagnosis, preventive and therapeutic method existing when participating in research, particularly when this involves the use of a placebo and (b) access to the best diagnosis, and preventive or therapeutic method identified by the research.

Other Provinces

Other provinces are progressively advancing in the creation of regulations regarding the demands generated by increasing research and the need to adapt to national standards.

In the Province of Santa Fe, the Provincial Commission for Bioethics was created only a few months ago by Resolution 1084/2011 from the Ministry of Health, aimed at regulating the activities of biomedical research in public and private health services, from the standpoint of public health and the protection of the rights of research subjects. The Province of Neuquén has also adopted a regulation creating a Provincial Bioethics Commission and has a few RECs, mainly in private institutions. Likewise, in other provinces, such as Jujuy, Misiones (Law 4334), the Chaco (Law 4781), and Chubut (Decree 932/03), provincial commissions have been established and are systematizing the system for assessing biomedical research.

Ethical Issues at the Beginning of Life

Ethical issues regarding the beginning of life, as mentioned above, have been characterized in Argentina by a gap between legal standards, public policies, and

social practices. The 1980s, with the arrival of democracy, gave rise to a certain degree of opening regarding the decrees established by the military dictatorship's which had a clear trend toward the prohibition of contraception and the promotion of pronatalist policies of population growth. In 1985, Argentine ratified the Convention on the Elimination of All Forms of Discrimination against Women (CEDAW), new decrees were adopted and other previous ones repealed, and various proposals for a national law were proposed including Sexual and Reproductive Rights (SRR) as a matter of human rights and health policy.

The 1994 constitutional reform incorporated into the National Constitution international treaties and a proposal was made for a bill on a "National Program for Responsible Procreation" (Cecchetto, 1999). Nevertheless, the trend during the 1990s was set by: (a) provincial fragmentation of conflicts (on the basis of the country's federal division) and (b) judicial involvement in medical practices (participation by judges in decisions regarding contraception of various types, tubal ligation, requests for authorization to carry out an abortion under circumstances foreseen in the national law, etc.). In this way, justice made an "interpretation" of the formulations established by international treaties and declarations, according to subjective criteria. All these events coincided with the advent of a strongly neoliberal government in the country during the 1990s.

In 2002, Law 25673 established the National Program for Sexual Health and Responsible Procreation, enacted in May 2003 (Decree 1282/03). This program was a step forward regarding this issue and set out very important and wide objectives. For the first time, this law ensured access to a wide range of contraceptive methods (including intrauterine and copper devices) through public health services. However, shortly after, it became apparent that the situation in the provinces was complex. Under the federal system, they have to adhere to national laws explicitly, and therefore, there was a great degree of heterogeneity in their regulations, with a variability of criteria in the courts, numerous appeals lodged for different reasons, and the continuous use of "conscientious objection" on the part of doctors in complying with the law, particularly of those working in public health services. All this led to the national law progressively losing force.

By 2006, the situation in the 23 Argentine provinces and in the City of Buenos Aires was as follows: 17 had sanctioned laws on sexual and reproductive health, two only had an adhesion to the national law (Santa Cruz and La Rioja), and five had no regulations in this matter (Catamarca, Formosa, Santiago del Estero, Tucumán and San Juan) (Schuster & Garcia Jurado, 2006). Since then, the work carried out by many NGOs has been intense in the field of women's rights and particularly Sexual and Reproduction Rights, promoting that they can effectively be demanded and that women can achieve a true appropriation of these rights.

In the case of surgical contraception, in 2006, the Argentine Congress adopted Law 26.130-2006 on the regime for surgical contraception for men and women. This law has appeared after many years during which these practices were governed by the doctors' and judges' personal positions (Cecchetto, Urbandt & Bostiancic, 2007) and, in many cases, under the influence of religious groups, without

consideration of men and women's rights to decide on their own bodies. Even today, it may be stated – without any fear of error – that medical doctors and legal operators continue to give this law restrictive interpretations in the different jurisdictions.

Abortion

The debate on abortion in Argentina, as in most of the countries of the region, is fraught with socioeconomic and religious issues. In general, these lead to deep rifts in society, with double ethical standards among social classes and in the country's various regions.

Article 86 of the Criminal Code establishes prohibition of abortion with two exceptions that have given rise to various interpretations of the law: "abortion practiced by a qualified medical doctor with the consent of the pregnant woman is not a punishable offence: 1º If it has been done to avoid danger to the life or health of the mother and if this danger cannot be avoided by other means. 2º If the pregnancy is the result of rape or of indecent assault on an imbecile or demented woman."

Prohibition of abortion in Argentina has led to a double morality, particularly affecting underprivileged social groups and, especially, young women. That is, although abortion is prohibited in Argentina, women from the upper parts of society have the opportunity to make abortions in the country by paying high amounts of money to private clinics, while this is not an option for women belonging to the poorest sector of society. The rate of teenage mothers is high in low socioeconomic sectors and in some regions of the country (e.g., the average number of children per woman in Misiones is 3.2, in Santiago del Estero it is 3, while the national average is 2.3). In 2006, in the northeast region, 73 % of births were to mothers who had not finished secondary school. There is no doubt that these differences are related with educational levels, access to contraceptive methods and efficient health services.

In the City of Buenos Aires for every 1,000 teenage girls, 17.6 are mothers, while in the Chaco, this figure reaches 44.12. The case of maternal mortality is similar, with very different rates in the various geographic zones. Twenty-nine percent of the causes of maternal mortality are related to complications following abortions. In the City of Buenos Aires, the maternal mortality rate is 18 maternal deaths per 100,000 live births and rises to 165 maternal deaths per 100,000 live births in the Province of Jujuy. Seventy percent of these deaths take place in jurisdictions representing 40 % of the total number of births, in the poorest provinces of the country.

The number of illegal abortions carried out in the country per year is a sample of the deficiency of clear policies in this regard. It is estimated that some 700,000 illegal abortions are carried out per year in Argentina. Morbidity per abortion is established on the basis of releases from public establishments. Between 1990 and the year 2000, the figure increased by 46 % (78,894 releases) corresponding to the national average; however, in some provinces, the average is greater.

The situation is even more serious, if account is taken of the cases, in which even if abortion is not penalized, there are numerous obstacles before the doctors can carry out the abortion. In most cases, they request legal authorization for fear of legal proceedings against them, and in many cases, the judges take so long in coming up with the sentence that the decision arrives seriously delayed, if ever.

Over the past few years, the debate has been stepped up regarding abortions in the case of fetuses with pathologies making extrauterine life incompatible (in particular anencephaly). Dozens of petitions taken to the courts have ended in decisions making couples wait beyond the point establishing "viability" (week 24 of pregnancy) to authorize induced birth. These situations cause great suffering to the parents and involve enormous expenses in the legal process.

In 2011, a bill was submitted, extending the exceptions to penalizing abortion. The bill was only debated by the Commission for Criminal Matters of the Chamber of Deputies, and they did not reach a decision. The other commissions involved (health and family) did not want to address it, and on finalizing the session, the bill's parliamentary status was lost. Finally, in March 2012, the Supreme Court of Justice gave a ruling on the interpretation of this article, which represents an important step forward, allowing abortion in the case of rape.

Assisted Fertilization and Treatment of Cryopreserved Embryos

In spite of the fact that so far there is no legislation regarding the cryopreserved embryos stored in the banks of assisted fertilization centers, these practices are carried out in the country's main cities under the highest standards and with the best technologies. Numerous bills have been frustrated by the same questionings as set out in the beginning. In the first place, the debate on the status of the embryo has been the center of this discussion. Selection of the embryo before implantation has also been debated, although methods for prenatal diagnosis are available and, in many cases, used. Many of the centers affirm that they do not select embryos in a preimplanting way and that the embryos that are not implanted are offered up for "donation" (Luna, 2004). These issues open up enormous conflicts that cannot be gone into here. Unfortunately, no prompt solution is apparent. However, the lack of legislation in this respect obviously leaves the various parties participating in this process completely unprotected and those carrying out technical procedures in complete liberty.

Ethical Issues at the End of Life

Ethical issues related with the end of life have been on the country's bioethical agenda for several years now. Together with issues on the beginning of life, they are probably among the most controversial points in which progress has been difficult with regard to adopting regulatory measures. A regulatory framework would enable doctors to take decisions without fear of court cases being brought against them for

"mala praxis" and that would provide patients with a framework in which their decisions about the way in which they want to die are respected. Although academic debates on euthanasia and assisted suicide have been very rich, they have not been reflected in concrete projects for legislating on these issues. Most of the debates have addressed the decisions to be taken regarding patients with serious health deterioration and bad prognoses, in particular, situations of life support withdrawal (LSW) for seriously ill patients, for persons in a permanent vegetative state (PVS), or persons with progressive neurological disorders. Civil society has been involved in these debates in an interesting way through an enormous amount of articles in the daily press. However, they have not all given the issues an equally serious treatment, because of the enormous variability in the use of terminology, sometimes creating great confusion.

A particular issue that continues to occupy the legal system is requests for LSW by family members of patients who are incapable of taking their own decisions and who are suffering from permanent lack or deficiency of awareness, such as in the case of PVS or in some progressively incapacitating neurological diseases. When considering the arguments put forth in the courts by provincial and national judges in the resolution of these cases, it is evident that they mix elements taken from national and international jurisprudence with personal and, in some cases, religious convictions. Such convictions should not be included in court rulings in a country where religious freedom is safeguarded by the constitution. A clear reflection of the disassociation between the academic debate and the arguments put forth by judges can be seen in the ruling of the Supreme Court of Justice of the Province of Buenos Aires, where for the past 2 years the husband of a women in PVS has asked the legal system for the suspension of hydration and food (Gherardi, 2007). In the court ruling, the judges repeatedly quoted the report drawn up by the Minor and Incapable Peoples' Advisor who, in his description of the case, speaks of "the Creator" and the "parable of the talents" concluding "Hope of a Miracle must be kept. Love and faith will always demand rest in a heroic heart. This heroism may lie in knowing how to wait for God's time, which we know are not man's time" (S.MDC, SC BUENOS AIRES, 09/02/2005).

In 1999, the Ethics Committee of the Argentine Society of Intensive Care had already made recommendations in this respect in its "Guidelines and recommendations for the withdrawal and/or abstention of life support methods" (Comite de Bioetica de la Sati, 1999). These recommendations emphasize that the primary source of authorization for the decision to treat or not to treat comes from the patient and that this is independent from the nature of the disease and its evolution, while establishing that "the existence of a living will or advance directive made out by the patient (. . .) should be a priority to be respected independently from the opinion of the doctor (health care team) and of the family" (Comite de Bioetica de la Sati, 1999). Given that this fundamentally refers to patients in a critical condition, it establishes that "taking the decision on abstention or withdrawal of life support methods in a health care environment such as Intensive Care Services, generally depend on medical initiative, save for cases in which an advance directive exists" (Comite de Bioetica de la Sati, 1999). The recommendations also establish the

circumstances under which the medical team can suggest the possibility of abstaining or withdrawing life support (Comite de Bioetica de la Sati, 1999):

(a) When there is no evidence of having obtained the effectiveness sought (absence of response in the substitution of an organ or function), or events exist making it possible to presume that this effectiveness will not be obtained in the future
(b) When it is only maintenance and prolongation of a permanent and irreversible state of unconsciousness (e.g., PVS)
(c) When suffering is inevitable and disproportionate to the expected medical benefits
(d) When the opinion of the patient on the eventuality of such a circumstance in the case of a preexisting chronic disease is known without any shadow of doubt (personal report, by the family doctor if applicable or by a family member)
(e) When an irreversible state is manifest in the clinical case due to the successive collapse of vital organs, leading to the conclusion that the use of more and greater procedures will not be in the best interests of the patient

In spite of having these guidelines, today many of these points are still the subject of debate.

The debate on advance directives (ADs) or living wills prepared by adults with capacity has been a little more auspicious (Manzini & Tinant, 2008). A very abundant number of bills have been prepared under the name of "Death with Dignity," and they usually include all these aspects, rejection of treatment, abstention or LSW, decisions for patients without capacity, and the validity of ADs. But for diverse reasons, most of them have gone no further than parliamentary debates. There is a wealth of literature on this issue, addressed with great seriousness by academic circles. There are also different recommendations, from improvements in the doctor-patient relationship, in an attempt to have these decisions taken within this context, with the support of ethics committees and without involving the judicial system, to the creation a public registry of ADs on the basis of a document to be drawn up before a notary public.

Since 2009, Argentina has a Law (26529) regarding the rights of patients in their relationship with the medical profession. This has made progress in what is understood to be the autonomy of will, such as the right to accept or reject certain therapies or medical or biological procedures, with or without stating the cause. This is important because although there already existed jurisprudence on the rejection of treatment in a very much commented-on ruling of the year 1995 ("Parodi Case"), at the time of making decisions, difficulties still continue. The law emphatically defends patients' rights to decide on their integrity, dignity, autonomy, freedom, and personal values. It also refers to the right to reject treatments and, at the same time, legally endorses ADs in the case of capacitated adults.

However, it does not go into the issue of patients without capacity nor on abstention or LSW. In all cases, it discards any indication leading the doctor to "the practice of euthanasia." In 2011, a bill to amend the present law was submitted, in which issues relating to LSW and suspension of food and nutrients to unconscious patients were addressed. It also included a long explanation on AD.

Likewise, it included the provision of palliative care as a right of all patients. A bill was also submitted that year in the City of Buenos Aires, taking a very important step forward in this respect, in particular concerning LSW and a clear definition of what is understood as support (including food and nutrition). The law also makes an important clarification regarding conscientious objection, establishing that it must be done by health professionals on adopting the law, that it must cover public and private areas, and that it is only acceptable in the case that another medical professional is also involved. It also clarifies that institutions cannot put forth this argument: conscientious objection is an individual act.

Only two provinces have legislation on Death with Dignity, Río Negro (Law B 4264 adopted in 2007 and enacted in 2009) and Neuquén, while Córdoba (2003), Buenos Aires (2004), Tucumán, Mendoza, and the National Congress (2004) have submitted several bills, some that are still waiting to be dealt with, but they all open up a path regarding these issues. The Río Negro law defends the "right to a quality of life and to the dignity of terminal patients." The regulation includes patients suffering from irreversible, incurable diseases or who are in a terminal state caused by pathologies leading to death, those that have an uncertain ending or if death is estimated to take place within a short lapse of time.

Finally, progress has been made regarding palliative care (PC) and treatment of pains. Already in 2000, the National Program for Quality Guarantees established Standards for the Organization and Operation of Palliative Care, approved by Resolution N° 643/00 of the Nation's Ministry of Health. PC is included within the Obligatory Medical Program set out in accordance with Resolution 939/00 of the Nation's Ministry of Health, establishing the basic benefits that all citizens must have access to. At all events, and particularly in public health services, the benefit is still precarious and in no way homogeneous in the various parts of the country. Pain-killers for terminal patients are still a difficult issue, and some "barriers" are prevalent with regard to making opiates available. One of these barriers is the low prescription by physicians. The probable reasons behind this are not taking into account the importance of pain, the wrong understanding of the use of opiates, or, ultimately, the fear of side effects. A second barrier is related to the bureaucracy enforced by the authorities in relation to the provision of drugs in trying to prevent them from being used for other purposes (drugs abuse), and finally, a third barrier is related with some patients' own myths about the use of morphine and other analgesics (the use is related to drug dependence) (Mertnoff, 2008).

Terminal palliative sedation continues to be the center of enormous debate, as has been seen in the case of MG in the national news only 1 year ago (Carbajal, 2011). The case involves a teenager of 19 who suffers from a degenerative disease of the nervous system that has no cure. She is currently in a deteriorating state, and she has asked the court to be provided terminal palliative sedation, a request that had been rejected, both by her physicians and the HEC. Increasingly, decisions regarding so-called "terminal" patients are taken in the context of the professional-patient or family relationship, but this is not the case of innumerable different cases, where the courts seem to be the mechanism to solve these problems.

Bioethics Education

It has been said, quite rightly, that the development of bioethics can also be measured in terms of the number of experts and events taking place, such as congresses, meetings, seminars, etc. In this respect, Argentina has produced much, although of varying quality.

The issue of bioethics education has been a concern since the start when the first steps were taken in ELABE as already mentioned. Since then, many universities have taken up the issue of bioethics education as something that cannot be put off, particularly by the Schools of Medicine and Health Sciences. However, this was done to a lesser degree by the Law Schools and practically not at all by other academic disciplines. There are many initiatives in undergraduate and postgraduate education; however, it should be said that there is a great degree of heterogeneity in their content and in their achievements. No consensus has been reached on these issues as would be essential when designing a Bioethics Chair and consequently diversity is enormous.

Here will be mentioned only a few of the numerous postgraduate degree courses, some of which have been maintained over time, particularly with regard to master's degrees or specialization courses.

The Bioethics Master Degree Program at the National University of Cuyo in the Province of Mendoza arose from a partnership between the Faculty of Medical Science and the Bioethics Program of the Pan American Health Organization (PAHO/OMS). It was based on the master degree created under the same program in Chile University under the responsibility of Diego Gracia Guillén from Spain (Pfeiffer & Belli, 2012). Another experience that has managed to survive over time is the Master Degree in Legal Bioethics at the Faculty of Legal and Social Science at the National University of La Plata, which started operating in 2006 and has continued uninterruptedly to this date, under the direction of Eduardo Tinant. The Argentine Pontifical Catholic University (UCA) has had a Master's Degree Course in Biomedical Ethics for 12 full years with a religious dimension. The University of the Argentine Social Museum (UMSA) has a Master's Degree Course in Bioethical and Legal Aspects of Health, mainly pertaining to biomedical research issues and legal matters in this field, not only of a national but also of an international nature. Since 2005, the National University of Cordoba has a Master's Degree Course in Bioethics that started to be reformulated as from 2011. At its start, it was organized following the PAHO Bioethics Program like the University of Mendoza, with a strong stamp of Anglo-Saxon bioethics (Pfeiffer & Belli, 2012). Currently, it is undergoing a deep change.

There are numerous postgraduate courses. Particular mention should be made of the pioneer nature of the Chair for Medical Humanities of the Faculty of Medical Sciences, National University of La Plata, set up in 1980 (mentioned above).

The courses of the Permanent Education Program in Bioethics (PEPB) are an initiative launched in 2006 for the whole of Latin America and the Caribbean by a group of experts from the Province of Cordoba, endorsed by the UNESCO's Regional Bioethics Program (Montevideo Office) under the aegis of Latin American and Caribbean Bioethics Network (Redbioética UNESCO) (Vidal, 2010). Two 240-h

courses are Internet based and given through distance learning. One course is on Research Ethics on Human Beings and the other on Clinical and Social Bioethics (fifth and sixth editions, respectively). The courses have so far contributed to the training over 160 Argentine professionals in Bioethics.

The Latin American School of Social Science (FLACSO) presently offers a Higher Diploma and Specialization in Bioethics, obtained by following four courses, either by distance learning or face-to-face teaching lasting for a total of 190 h. Since 1999, FLACSO Argentina is hosting the Training Program in Research Ethics, funded by the Fogarty International Center of the National Institutes of Health, USA.

Many other initiatives are being developed in the country differing in qualities and results, and with different approaches.

Conclusions

Presently in Argentina, there is no organization that unites all the bioethicists. Different approaches, conflicting positions with regard to recent Argentine history and other less noble conflicts, such as simply struggles for power, have led to an enormous fragmentation in developments. The initial fascination with the bioethics from the First World countries somewhat ignored the need to join efforts started by ELABE and later the Argentine Association of Bioethics. Very shortly, various types of personal interests and group interests overcame the need to carry out a national program or to establish an association joining all the Argentines working seriously on this issue.

Regarding the concrete issues addressed in this paper, the distance between the development of regulations and practices showed very clearly that there are obstacles of different types in establishing national regulations. Regarding research ethics, the need to have a national system of research ethics evaluation is evident. This would avoid the enormous heterogeneity in the way of assessing research in the country and the way in which RECs are set up and function. This field continues to show double standards regarding the protection of participants' rights in the various locations and among the different social classes in the country. Something similar occurs with regard to Sexual and Reproductive Rights. There is a wide gap with regard to a full enforcement of these rights, primarily regarding the disparity between the text of the legislation and what is set out in international treaties. Secondly, there is a need to have public policies that will enforce the text of the law through concrete actions, for example, by allocating funds and resources for its implementation. Finally, the population's and particularly women's and teenagers' full access to these programs needs to be ensured. In this area, there is no doubt that a deep cultural change must take place, in which social practices can be modified without any type of interference or censorship by power or by religious groups. The ethical issues concerning the end of life are in a similar situation, like other related issues. Finally, bioethics education in the country is growing, but the great heterogeneity of programs regarding objectives, content, methods, and results shows the need to establish some minimum areas of consensus on what can be expected from each level of teaching.

Over the past few years, Argentina has been going through a time of true transformation in an attempt to lessen the gaps of inequity, double standards and particularly the gap existing between regulations and social practices, as the best reflection of a public moral and where peoples' convictions, ideals, and expectations are brought into being. Perhaps it is time for a deep sincerity and acknowledgement in this respect and for the application of public policies aimed at strengthening the protection of the rights of vulnerable people and groups such as research subjects, women, people who are dying, old people, and many other social groups who are in need not only of protection but of being respected for their decisions in the framework of pluralism and freedom that democracy offers.

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Australia

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Don Chalmers

Donald Chalmers is a distinguished professor of law and director of the Centre for Law and Genetics, University of Tasmania.

Foundation fellow of the Australian Academy of Law, chair of the Gene Technology Ethics and Community Consultative Committee, and chair of the Data Access Committee of the International Cancer Genome Consortium. Chair of the National Health and Medical Research Council (NHMRC) Australian Health Ethics Committee, 1994–2000, and deputy chair of the Embryo Research Licensing Committee, 2002–2012.

D. Chalmers
Faculty of Law, University of Tasmania, Hobart, Tasmania, Australia
e-mail: don.chalmers@utas.edu.au

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Introduction

Australia has an established record and tradition in bioethical debates, particularly focused on in vitro fertilization (IVF), healthcare, and human research ethics issues (Singer & Kuhse, 2006). Some of Australia's leading bioethicists have argued that the growth of bioethics in Australia may have an "ambivalent genealogy" but was stimulated by changes in technology, particularly IVF techniques and the need to develop new frameworks beyond traditional medical ethics (Irvine, Kerridge, & Komesaroff, 2011). Bioethics has been central to debates on human research ethics. Australia was one of the first signatories of the *Declaration of Helsinki*. The National Health and Medical Research Council (NHMRC) followed this up with human research ethics guidelines in the early 1980s (*Statement on Human Experimentation*) and requirements for all publicly funded research organizations to observe these guidelines. Australia has not experienced any medical research crisis incidents, like the United States Tuskegee revelations (Jonsen, 1998). Australia has had major ethical debates about research ethics as well as termination of pregnancy, IVF (now more commonly referred to as assisted reproductive technology, ART) and surrogacy (Freckelton & Petersen, 2006), Aboriginal and Torres Strait Islander health, medical indemnity, human embryo research, and genetic privacy. Australia has also debated the development of animal welfare and research ethics, building on the seminal and groundbreaking work on animal ethics and protection by Peter Singer (Singer, 1975). In addition, genetic modification of plants and animals (Sylvan & Bennett, 1994) was a major public debate during the 1990s and early 2000s with the introduction of a GMO regulatory framework for the development of biotechnology in Australia. The *Australian Biotechnology: A National Strategy* published in 2000 expressed a national commitment to safeguarding human health and environment protection, in developing the benefits of biotechnology for the community.

Bioethics Development

Modern bioethical development in Australia can be marked by "two epistemological breaks away from well-established biomedical technologies and traditional approaches to ethics" (Irvine et al., 2011, at 245). With respect to biomedical technologies, debates on IVF were prominent in Australia (Singer & Wells, 1984). The IVF debates in the state of Victoria in the early 1980s, which preceded Professor Waller's influential and pioneering reports on IVF, donor gametes, and surrogacy, shaped the national bioethical IVF debates that continue through the decade. These debates involved the churches, feminist scholars, and the community in public opportunities to express opinions on IVF to official government enquiries (Freckelton & Petersen, 2006, Chapter 10). These debates have been generally spirited but respectful of opposing views. The IVF debates extended into embryonic stem cell debates in later decades (Dodds & Ankeny, 2006; Oakley, 2002).

While principles of medical ethics were, and remain, significant starting points in bioethical debates, it has been argued that "...ordinary ethical and social and principles and categories simply [could not] cope with the novel issues raised by the manufacture of totally new living organisms by genetic engineering, the creation of live human embryos outside their mothers' bodies..." (Charlesworth, 1989, at 15). Nevertheless, Australian bioethics have been significantly influenced and shaped by the principles of medical ethics. The World Medical Association drafted and published the influential *Declaration of Helsinki* on ethical standards in medical research. Members of the Australian medical profession promoted its signature and implementation in the NHMRC's first *Statement on Human Experimentation*, in 1976. The ethical principles of patient consent and autonomy, medical beneficence, duty of confidentiality, best interest of the patient, and standard of care are recognized and expressed in the Australian Medical Association *Code of Ethics*. In addition, specialist colleges also have supplementary codes, for example, the Royal Australian and New Zealand College of Psychiatrists Code of Ethics in Principle 1 states that the practitioner should have "respect for the essential humanity and dignity of each of their patients." Standards of medical care and ethics were principally matters for the profession before bioethics "border crossings" (Annas, 2004) by others, including the legal profession, bioethics scholars and the range of administrators, health economists and healthcare advocacy, and consumer groups.

The term "bioethics" was coined in the United States (Reich, 1982; Jonsen, 1998; Tristram, 1995) and American scholars have been influential in the development of bioethics in Australia, but the emphases of many of the big-issue debates on IVF and embryonic stem cells have included uniquely national concerns about funding and regulation (Ankeny, 2003; Chalmers and Nicol, 2003). The neologism "bioethics" is an exegesis of philosophical and, more particularly, medical ethics. The Belmont Report (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and *Report Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, 1978) established three basic principles (respect for persons, beneficence, and justice) as the cornerstones for the regulation of research on humans. These principles have been influential and extended not only to researchers but into the clinical research setting (Beauchamp & Childress, 1973, who propose four principles: autonomy, beneficence, non-malfeasance, and justice). These principles were quoted in the NHMRC *National Statement on Ethical Conduct in Research Involving Humans*, 1999, and the current *National Statement on Ethical Conduct in Human Research* 2007 in references to researcher integrity, respect for persons, beneficence, and justice. However, some Australian hospitals had ethics-type committees discussing end-of-life treatments and other ethical dilemmas before the Belmont Report.

Another influential source of Australian bioethics can be traced to the principles embedded in the span of international human rights conventions and declarations. Both the *National Statement on Ethical Conduct in Human Research*, 2007, and the *National Framework of Ethical Principles in Gene Technology* make reference to

relevant international conventions and declarations. In fact, the UNESCO declared in 2003 "modern bioethics is indisputably founded on the pedestal of the values enshrined in the Universal Declaration of Human Rights" (UNESCO IBC, 2003). There are a many significant international instruments that position human rights within healthcare (e.g., World Medical Association *Declaration of Helsinki*; Council of Europe *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the application of Biology and Medicine*, 1996 (the *Bioethics Convention*); UNESCO *Universal Declaration of the Human Genome and Human Rights*, 1997). The UNESCO view is consistent with the view that modern bioethics can be traced historically to the horrors of the Holocaust, the Nuremberg trials, and the formulation of the Universal Declaration of Human Rights after the Second World War. The ten principles in the *Nuremberg Code* were the emphatic response to the inhumane experimentation conducted in Nazi concentration camps (Annas & Grodin, 1992). Of the ten principles of the *Nuremberg Code*, the most important provided that the "voluntary consent of the human subject is absolutely essential" and these principles were republished in the regularly revised World Medical Association *Declaration of Helsinki* on ethical requirements in medical research. There has been a proliferation of international instruments of *direct* application to bioethics. For example, the UNESCO *Universal Declaration on the Human Genome and Human Rights* 1997 deals with standards in genetic research and nondiscrimination based on genetic characteristics as well as the requirement of genetic privacy. The UNESCO *Universal Declaration on Bioethics and Human Rights* 2005 declares that its scope is "ethical issues related to medicine, life sciences and associated technologies as applied to human beings" and makes an explicit connection between human rights and modern bioethical approaches to not only healthcare but also the environment. The key underlying principles, in the provisions of these international conventions, are autonomy, beneficence and justice, but also human rights (Beyleveld & Brownsword, 2001). The *Universal Declaration of Bioethics and Human Rights*, however, is a non-binding instrument that aims to provide principles to guide signatory states in the formulation of bioethics legislation policies, as well as to promote respect for human dignity and to protect human rights; foster dialogue about bioethics issues; to promote equitable access to medical scientific and technological developments; and, finally, to stress the importance of biodiversity (Article 2). Notably, the declaration continues this wider view of bioethics in requiring respect for human dignity and human rights; the minimization of harm to patients and research participants; autonomy individual responsibility, inform consent to medical treatment and research; special protections for the incapacitated; privacy and confidentiality; equality, justice, and equity; nondiscrimination; cultural diversity; solidarity and cooperation; social responsibility in health; benefit sharing from scientific research; protection of future generations; and protection of the environment, biosphere, and biodiversity (Articles 3–17). In addition to the formal conventions, declarations, and treaties, there has been increasing internationalization of research, which has led a number of official agencies to develop harmonized standards. For example, in the area of clinical trials, the International

Conference of Harmonisation has produced standard *Guidelines for Good Clinical Practice* (CPMP/ICH: 1995). Similarly, the WHO and the Council for International Organizations of Medical Sciences (CIOMS) published ethical guidelines on human research, which also deal with the conduct of researchers in developing countries.

There is obviously considerable overlap between these "epistemological" approaches, which means that the boundaries between Australian bioethics, health law, and human rights are permeable, and "border crossings are common" (Annas, 2004). The utilitarian analysis of assessing the benefits promised by a proposed practice is outweighed by its possible harms is commonly invoked in Australian bioethical debates. Arguably, the UNESCO *Universal Declaration on Bioethics and Human Rights* has encouraged wider scholarly bioethical debates beyond individual autonomy and beneficence to more communitarian values encapsulated in "benefit sharing, solidarity and human dignity."

Governmental Institutional Development

Australia has considered many key bioethical issues, which have been debated in parliaments and parliamentary enquiries, by formal agencies, and among a broad range of bioethics centers and scholars (Charlesworth, 1993; Kasimba & Singer, 1989). These debates have involved the community, churches (Oakley, 2002), as well as the legal profession, administrators, health economists and healthcare advocacy, and consumer groups (Singer & Kuhse, 2006). Bioethical debate in parliaments and formal agencies is a significant characteristic of Australian bioethics. The NHMRC has played such a significant role in bioethical discussion in Australia and in the preparation of key guidelines in health research, particularly the *National Statement on Ethical Conduct in Human Research*. The NHMRC has a legal requirement to present guidelines for health research for formal public consultation and comment before publication. A unique two-stage public consultation process was set up, during the Commonwealth Parliament Senate Debates on the NHMRC legislation in 1992. This two-stage public consultation (stage one – comments on the proposed topic and stage two – comments on the actual draft guidelines themselves) was originally inserted to avoid perceived concerns that NHMRC guidelines were too "in-house" and medically biased. This public consultation is mandatory and requires any NHMRC committee to have, according to the legislation, "due regard" to all the submissions received. The NHMRC is required to give "genuine consideration to the material" according to the decision *Tobacco Institute of Australia Ltd v NHMRC* (1996 142 ALR 1). In this case, the TIA sued the NHMRC for failure to consider its copious submission. The TIA prevented the NHMRC from publishing its report on the effects of passive smoking on health, which was later issued as an information paper. Public consultation is an established process for the NHMRC. Apart from the NHMRC, the Australian Law Reform Commission (ALRC, Kirby, 1983) has conducted some important bioethical debates in relation to human tissue and genetic privacy.

Current Bioethics Infrastructure

The bioethical debates in Australia were stimulated by the creation of new centers particularly the first, the Monash Centre for Human Bioethics (Singer & Kuhse, 2006). Other centers have been established within universities, hospitals, and specialist bioethics centers. However, Australian bioethics is marked by significant government involvement through formal parliamentary public consultations, within official government bodies, particularly the NHMRC and its Australian Health Ethics Committee (AHEC) (Kasimba & Singer, 1989). Other bodies have made contributions to Australian bioethics, such as the NHMRC Animal Welfare Committee (AWC), Australian Law Reform Commission (ALRC), and Gene Technology Ethics and Community Consultative Committee (GTECCC). These bioethical debates are not confined to academia but have influenced public debate, government policy development, and, not infrequently, legal regulation (Freckelton & Petersen, 2006).

The National Health and Medical Research Council (NHMRC)

The NHMRC has been the peak Australian funding body for health and medical research (at http://www.nhmrc.gov.au/) since its establishment in 1937. The NHMRC is also responsible for medical research ethics and animal ethics. The NHMRC is an independent advisory body, which has a number of functions including inquiring and issuing guidelines on the improvement of health; the prevention, diagnosis, and treatment of disease; the provision of healthcare; and public health research and medical research. The NHMRC was established under the federal National Health and Medical Research Council Act 1992 with a principal committee, the AHEC, which is a multidisciplinary committee and develops and issues guidelines on health and medical research as well as promotes community debate on ethical issues. The AHEC's most important guidelines are the *National Statement on Ethical Conduct in Human Research*, 2007 (the *National Statement*), which is approved by Universities Australia and other research funding organizations, and represent a comprehensive national framework for ethics in human research. The AHEC reported on human cloning to the Federal Government in the 1990s. Following the joint ALRC and AHEC Report No. 96, *Essentially Yours*, a new specialist *Human Genetics Advisory Committee* (HGAC) was established within the NHMRC to advise on the developments in genetics in relation to human health including genetic privacy. The HGAC was also tasked with overseeing the developments in personalized medicine and biobanks. The NHMRC *Animal Welfare Committee* (AWC) advises on issues relating to the conduct and ethics on the use of animals for scientific purposes. The Australian *Code of Practice for the Care and Use of Animals for Scientific Purposes* requires Animal Ethics Committees (AEC) to ensure animal care and welfare in research. This Code of Practice sets out the general principles for the care and use of animals for scientific purposes, including the responsibilities of investigators and

institutions, and the use of replacement, reduction, and refinement techniques wherever possible. Where genetic modification involves animals, the Code of Practice specifies principles of conduct relating to the welfare of laboratory animals used to develop genetically modified animals and the genetic modification of production animals. Animal ethics has not received the same attention in bioethical debate in comparison with human research (Singer, 1975).

Bioethics Centers

Apart from the NHMRC, a number of established university-, hospital-, and church-based bioethics centers operate in Australia, which not only promote bioethical debate but often involved in presenting submissions to official enquiries and government bodies. The following is an illustrative and not comprehensive list of these centers. The Monash Centre for Human Bioethics, established by Peter Singer in 1980, is Australia's first established bioethics center. The Centre conducts seminars and education graduate programs and a range of specialized health programs. The state of Victoria had many leading IVF scientists, and the Centre produced work in ethical theory, reproductive ethics, end-of-life decision-making, and the development of utilitarian and virtue-based approaches to ethics. The Monash Centre for Ethics in Medicine and Society was established in 2001 in the Monash University Faculty of Medicine, Nursing and Health Sciences. The Centre is responsible for the development and conducts of teaching at undergraduate and postgraduate levels, fosters research in ethics and values in relation to medicine and society, and maintains a clinical ethics service at the Alfred Hospital.

The Southern Cross Bioethics Institute was established in 1987, in Adelaide by an independent provider of care and accommodation for Australia's older people. The Southern Cross Bioethics Institute adheres to universal human values, human rights, and the laws of humanity, including the inviolable and inalienable right to life of every member of the human family, whatever the age, status, or ability of that member, from conception to natural death.

There are some leading Catholic centers in Australia. The Plunkett Centre for Ethics is a center within the Australian Catholic University (ACU) and St. Vincent's & Mater Health, Sydney. The Centre was established in 1992 to promote the values of compassion and fellowship, intellectual and professional excellence, and fairness and justice. Its primary focus is on the realization of these values in the provision and the allocation of healthcare, from a Catholic perspective. The Caroline Chisholm Centre for Health Ethics also has a Catholic perspective and was established in 1995 with the aim of responding to the demand from Catholic hospitals' "for greater understanding and advice on ethical issues in healthcare."

The Centre for Applied Philosophy and Public Ethics (CAPPE) is a Special Research Centre, spanning a number of universities, and established in 2000. CAPPE has received competitive grant funding and claims to be the world's largest concentration of applied philosophers. CAPPE aims to assist members of the

community to make more ethically informed choices by making available resources in philosophical theory as well as other relevant information about empirical research and statements of fundamental human rights in international instruments on human rights. The Centre for Values, Ethics and the Law in Medicine (VELiM) is a bioethics center in the University of Sydney, established in 1995 to stimulate interaction and dialogue between the disciplines of medicine and science, public health, philosophy, ethics and bioethics, sociology, social linguistics, psychology, history, and law. The Centre for Law and Genetics based at the University of Tasmania was established in 1995 and specializes in research on the legal, ethical, and social issues arising from developments in genetic technology. The Centre has made regular submissions to ALRC and parliamentary enquiries and collaborates with related international centers. The St James Ethics Centre is independent and was established in 1989 and operates nationally and abroad. The Centre is unique and offers ethics assistance and advice to the community, public institutions, and not-for-profit companies. The Centre offers ethics education and training services and also consulting services.

The Australasian Association of Bioethics and Health Law (AABHL) is Australia and New Zealand's leading organization and aims to advance the study of bioethics and health law in Australasia by increasing public awareness, promoting public debate, and supporting scholarship (at http://aabhl.org/). Members come from many disciplines including medicine, nursing, law, ethics, philosophy, healthcare administration, allied health, and complementary healthcare. AABHL encourages discussion on bioethical issues and holds annual conferences and state-based activities. The AABHL is recognized uniquely in legislation as one of the bodies to be consulted when new appointments are made to the NHMRC Embryo Research Licensing Committee. The AABHL was formed in 2009 by a merger of the Australasian Bioethics Association and the Australian and New Zealand Institute of Health Law and Ethics, both established in the early 1990s. The AABHL, this body publishes an official, well-established and refereed international journal (*Journal of Bioethical Enquiry*).

Formal bioethics training, particularly at the graduate level, is offered through some of the centers mentioned above. As examples, at both Sydney University and Monash, full bioethics programs from the graduate certificate level to masters and to doctoral levels are offered. Sydney University offers these programs through its Centre for Values, Ethics and the Law in Medicine and at Monash University at its Centre for Human Bioethics. A number of other short courses are offered by many universities not only these mentioned.

Australian Law Reform Commission (ALRC)

The ALRC is the national law reform body. The ALRC undertakes public consultation on all its references. The joint ALRC and AHEC inquiry on genetic privacy that led to the report *Essentially Yours* (Report 96, 2003) was widely acknowledged, and Francis Collins, current head of the US National Institutes of Health,

described it as "a truly phenomenal job, placing Australia ahead of what the rest of the world is doing." The report made recommendations across the spectrum of activities in human genetics from healthcare, genetic testing, discrimination in employment and insurance, DNA fingerprinting, and parentage testing to human genetic databases and tissue collections. This body received over 300 formal submissions and held public consultation meetings throughout the country. This wide public consultation and the resulting public engagement of the various stakeholders in genetic research practice, development, commercialization, and government was a classic example of Justice Kirby's "Australian style" of law reform engagement (Kirby, 1983). The ALRC also produced one of the world's first reports on the complex ethical issues involved in human tissue in its report, *Human Tissue Transplants* (Report No. 7 ALRC 1977), which made recommendations about the collection and use of cadaveric and living donors.

Gene Technology Ethics and Community Consultative Committee (GTECCC)

Under the Gene Technology Regulatory Scheme (the *Gene Technology Act*), 2000, a regulatory framework for the licensing of dealings with genetically modified organisms (GMOs) was established in Australia. The regulatory scheme includes a comprehensive consultation process for any dealing with a GMO. GTECCC advises on the ethical issues in relation to GMOs and gene technology and has drawn up a *National Framework of Ethical Principles in Gene Technology*. This framework was developed after public consultation.

Major Bioethics Issues and Discussions

Assisted Reproductive Technology (ART) Australia was an early pioneer in in vitro fertilization (IVF), more commonly referred to now as assisted reproductive technology (ART). The first birth from a frozen embryo occurred in Australia. Australia was also very active in discussing the ethical legal and social impact of ART. The debates on ART and surrogacy involved churches and feminist groups and arguments about inter alia reproductive choice, autonomy, beneficence, exploitation, and commercialization (Charlesworth, 1993). ART created a major nationwide public debate in the 1980s (Singer & Wells, 1984) and was followed by debates on embryo experimentation and surrogacy. The Australian state of Victoria produced the first ART legislation in the world (*Infertility (Medical Procedures) Act* 1984), based on Professor Waller's reports on IVF, in the same year as the UK *Report of the Committee of Enquiry into Human Fertilisation and Embryology*, 1984 (Cmnd 9314, the Warnock Report). The pioneering Waller reports were the first in Australia and were followed by some 17 other Australian reports on ART. This near avalanche of Australian reports on ART included a Commonwealth Senate Select Committee report on Human Embryo Experimentation in Australia

and a report by the Family Law Council, *Creating Children: A uniform approach to the law and practice of reproductive technology in Australia*, both in the same year, 1985. These reports led to the establishment the first Australian bioethics body, the *National Bioethics Consultative Committee* (NBCC), to develop "a more coordinated national approach" towards ART in Australia. The NBCC was limited to issues of artificial conception and was requested to consider and made recommendations in the area of human embryo experimentation. The NBCC was multidisciplinary and for 4 years produced a number of reports (on donor gametes, access to information, surrogacy, counseling, and human embryo experimentation) before its amalgamation into the new AHEC, within the NHMRC. All the Australian states and territories introduced legislation recognizing the status of ART children as the child of the gamete recipient and not the gamete donor. This in turn raised legal and ethical questions about the right to access donor information. There was much debate about donor anonymity and whether a child reaching his/her majority was entitled to *identifying* or *non-identifying* information on any gamete donor. These issues were widely discussed and the Victorian Act also established the principle of access to *identifying* information, subject to the consent of the donor and the child's parents. Other states and territories took less prescriptive approaches. Access to ART programs was also a major aspect of the ART debates. Initially, ART was generally restricted to married heterosexual couples, but following challenges in the courts, on the basis of discrimination against single-sex couples (*JM v QFG, GK and State of Queensland* [1997] QSC 206) or single parents (*Pearce v SA Health Commission* (1996) 66 SASR), access was extended. There was also considerable debate about regulatory frameworks in Australia. Three states (Victoria, Western Australia, and South Australia) introduced specific ART legislation dealing with the broad range of issues, but the other states and territories relied on guidelines, developed by the Fertility Society of Australia and the AHEC (Freckelton & Petersen, 2006).

Surrogacy Surrogacy generated considerable debate in Australia. The NBCC, in the late 1980s, conducted public hearings on surrogacy and published a report in 1990. The churches and feminist groups were united in vehement opposition to any step towards recognition of surrogacy arrangements. Professor Waller in Victoria, while publishing recommendations against surrogacy, recognized that "altruistic" surrogacy, for example, between sisters could be envisaged. The early view was that surrogate motherhood was unacceptable. Gradually, the distinction between altruistic surrogacy and commercial-for-fee surrogacy was drawn. All states and territories in Australia prohibited commercial surrogacy in legislation but either recognized or did not prohibit altruistic surrogacy (Freckelton & Petersen, 2006). More recently, some jurisdictions in Australia permit noncommercial surrogacy, under restricted circumstances. The Australian Capital Territory introduced their *Parentage Act 2004*, which supports altruistic surrogacy by allowing parenting orders that transfer parental rights to the "commissioning" parents. A gradual acceptance of noncommercial surrogacy led to the Australian Attorneys-General proposing a national model to harmonize the various state and territory rules on surrogacy in 2009.

Prenatal and Preimplantation Genetic Diagnosis Both prenatal and preimplantation procedures have been controversial, with bioethical debate including considerations of abortion and embryo destruction. Prenatal procedures of amniocentesis and chorionic villus sampling test the developing fetus and may lead to a parental decision to abort the developing fetus, if a serious genetic condition is identified. More recently, preimplantation genetic diagnosis (PGD) of an embryo has been debated. Arguably, PGD offers an earlier opportunity for clinicians to identify embryos considered unsuitable for transfer and implantations, rather than the prenatal tests of amniocentesis or chorionic villus sampling. Australian guidelines (*NHMRC Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research*, 2007) accept PGD for medical reasons to identify embryos affected by an inheritable genetic condition. PGD for nonmedical reasons is generally considered ethically unacceptable, but the current NHMRC guidelines are expressed with ambivalence and state that it is generally to be disapproved, but "pending further community discussion." PGD is also possible in Australia for the so-called savior-sibling circumstance. PGD has been widely debated in Australia and raises serious ethical issues where it is for the purposes of sex selection, but this is not acceptable under the NHMRC guidelines. However, a leading Australian ART clinic advertises the availability of this procedure overseas in an associate overseas clinic in Thailand. The potential for PGD to become more widely used as genetic testing improves likely (Freckelton & Petersen, 2006, Chapter 11).

Research on Human Embryos Research on embryos remains a controversial bioethical issue in Australia (Dodds & Ankeny, 2006). The AHEC report, *Scientific, Ethical and Regulatory Considerations Relevant to Cloning Human Beings*, 1998, endorsed the Article 11 prohibition on human cloning in the *Declaration on the Human Genome and Human Rights*, which declared the procedure against human dignity. This AHEC report was referred to the Commonwealth of Australia, House of Representatives Select Committee, which undertook extensive public consultation before parliamentary debates on the *Human Embryo Research Act*, which were some of the longest in Australian history and focused on the dignity of the human embryo, the use of surplus human embryos in ART, and the scientific and therapeutic opportunities of embryo research, but only under strictly controlled licensing arrangements (Chalmers and Nicol, 2003). Human dignity was a common theme in these national and parliamentary debates on human cloning (and more recent debates about patenting of human DNA). In contradistinction to rights to individual autonomy to research or procreate, references to human dignity were expressed in terms of a *constraint* on pursuing research inquiry and setting ethical limits in biotechnology, beyond arguments about scientific safety of the procedures (Singer, Kuhse, Buckle, Dawson, & Kasimba, 1992). The *Prohibition of Human Cloning Act* 2002 prohibited cloning for reproductive purposes. The *Human Embryo Research Act* 2002 permitted limited research on surplus ART embryos, provided a license was issued by a special NHMRC Embryo Research Licensing Committee, established by the Act. The AHEC report, like its counterpart, the National Bioethics Advisory Council in the United States and the eventual United

Nations resolution against human cloning in 2005, was careful to distinguish between the use of cloning for human reproductive purposes and the use of embryos for a source for stem cells for therapeutic purposes (although terms "reproductive" and "therapeutic" cloning should probably never have entered the bioethics lexicon). The AHEC report cautioned that any regulatory action undertaken to prohibit creating a child by SCNT should be careful not to interfere with important areas of stem cell scientific research (Capps & Campbell, 2010).

Research Governance There has been much Australian bioethical scholarship on human research governance and the protection of participants in health research. Australia ratified the Declaration of Helsinki in 1965. This was an important symbolic act that was later realized by the introduction of research ethics committees to review the ethical aspects of experiments on humans. Some ethics committees operated in Australia in the 1960s and these influenced the development of the national ethics review system. A major response to the *Declaration of Helsinki* was the drafting of Australia's first guidelines on human experimentation, *Statement on Human Experimentation*, 1976, prepared by the Medical Research Advisory Committee of the NHMRC. Australia has had a comparatively creditable record of ethical research involving humans and has not experienced any medical research crisis incidents, like the United States Tuskegee revelations documented in Professor Beecher's New England Journal of Medicine article (Vol 274: 1354–60). However, Australia's record is not unblemished, and an Australian Government report into unsatisfactory aspects of the collection, manufacture, and injection of human growth hormone (Report of *Inquiry into the Use of Pituitary Derived Hormones in Australia and Creutzfeldt-Jakob Disease* AGPS, Canberra, 1994) recommended that aspects of the research structure be reassessed. Two other incidents in the 1950s, concerning the inclusion of orphans and State wards in vaccine trials conducted and, secondly, the experimental use of estrogens to reduce the height of "tall girls" were considered in the revision of research ethics in the 1990s that led to the introduction of the *National Statement on Ethical Conduct in Research Involving Humans* in 1999. This National Statement was drafted with careful consideration of the codes of ethical research practice developed in other countries, particularly the influential United States Federal Code of Research Practice, the Canadian Tri-Council Code, and the ethical guidelines of the United Kingdom and New Zealand. In addition, a number of international guidelines were examined, particularly the *International Ethical Guidelines for Bioethical Research involving Human Subjects*, published in 1993 by the WHO and Council of International Organizations of Medical Research (CIOMS) and the International Conference of Harmonisations (Guidelines for Good Clinical Practice (CPMP/ICH: 1995)).

The *National Statement on Ethical Conduct in Human Research* 2007 focused on "governance" arrangements for Human Research Ethics Committees (HREC), particularly with respect to institutional legal responsibilities, resourcing, monitoring of research, complaints handling, and accountability. As in other countries, Australia has shifted the focus from the HREC to the responsibilities of research institutions to ensure the integrity, safety, and ethical standards of research

under their control. Key governance issues include the proper functional roles of the HREC and the institution, the expedited review of "low risk" type research, the facilitation of single ethics review for multicenter research, ongoing training for REC members, and independent complaints mechanism to receive and handle complaints from research participants. Formal accreditation has not been introduced for HRECs in Australia but they are required to complete formal compliance reports annually, which are sent to the AHEC. A national system for accrediting HRECs involved in multicenter research (HoMER, Harmonisation Multi-Centre Ethical Review) has been set up. Within research governance, the accountability of researchers has been strengthened in the *Australian Code for the Responsible Conduct of Research*, 2007, which, like the *National Statement*, has been endorsed by all the leading research funders and research institutions in Australia. This Code deals with conflicts of interest in research, which, like elsewhere in the world, has been seriously discussed in Australia. In view of increasing commercialization and private funding of research, there are challenges to traditional ideas of impartiality and independence in research. Detecting and avoiding conflicts of interest are critical to public trust. This Code and the *National Statement* 2007 require researchers to disclose conflicting or competing interests and all sponsorships to be openly declared. A conflict generally excludes the conflicted researcher but an ethics committee may advice on how to "manage" a competing interests. Generally, competing interests are not disclosed to research participants.

Clinical trials are a critical aspect of medical research to assess the safety and efficacy of drugs and devices. The major debates in Australia about clinical trials have focused on the regulatory scheme for clinical trials. Until the 1990s, the national Therapeutic Goods Administration (TGA) administered the centralized system of drug and device assessment. This centralized system was replaced by a devolved Clinical Trials Notification scheme (CTN) under which trials could be conducted in large hospitals or research centers after notification and with the approval of the TGA. The CTN scheme proved very popular and almost all clinical trials are conducted under this scheme, which places additional responsibility on institutions and their RECs. Apart from the scientific design and results from clinical trials, the bioethical issues of recruitment, consent, monitoring, use of placebos, and competing commercial interests attract scholarly consideration.

Human Genetic Research In the 1990s, debates focussed especially on medical research and the emergence of the ethical, legal, and social issues (ELSI) around the Human Genome Project and human genetic research. The ethics of human genetic research was a major focus of the work of the AHEC during the 1990s. Consultation with the public and the Human Genetics Society of Australia (HGSA) led to the development of Guidelines *for Genetic Registers and Associated Genetic Materials* and *Guidelines for Ethical Review of Research Proposals for Human Somatic Cell Gene Therapy and Related Therapies*. The former provided guidance on the operation of genetic registers on the collection, use, and access to this material. The guidelines also deal with aspects of recruitment and storage of genetic material. The latter provided guidance to HRECs that dealt with gene therapy applications.

Australia became one of the first countries, the 1999 version of the *National Statement*, to include a specific set of ethical principles on human genetic research. Guidelines on somatic cell gene therapy (SCGT) provided higher-level advice by specialist committee wherever SCGT was considered. In Australia, as in many other countries, the genomics revolution raised the need for best practice ethical and legal regulation. The increasing volume of genetic research and the creation of specific genetic databases raise concerns about genetic privacy led to a reference by the Commonwealth Attorney-General to the AHEC and the ALRC jointly to consider the issue of genetic privacy, discussed below.

Research Involving Indigenous Communities Research on Aboriginal and Torres Islander peoples (ATSI) has at times been controversial with concerns that ATSI may not have been respected and protected and their genuine consent to research confirmed. ATSI peoples have some of the worst health statistics within the Australian population. Specific guidelines on ATSI research (*Guidelines on Ethical Matters in Aboriginal and Torres Straight Islander Health Research*) were debated and discussed and introduced as interim guidelines by the NHMRC in 1991. These guidelines stressed the need for respect for cultural differences and identity. These interim guidelines were replaced with the NHMRC *Values and Ethics: Guidelines on Ethical Matters in Aboriginal and Torres Straight Islander Health Research* in 2003. These guidelines emphasize the need for ethical conduct between researchers and the community to eliminate difference blindness to promote trust through six basic values of spirit and integrity: reciprocity, respect, equality, survival, protection, and responsibility. The concept of community consent as well as individual consent is recognized. The idea of justice in healthcare certainly extends beyond the individual. Justice has been a key principle in discussions not only about research but also about improving ATSI health and just access to equitable healthcare services.

Privacy has become a major bioethical issue with the expansion of electronic medical records and larger-scale epidemiological research. With the advent of genetic testing and research, privacy came to the forefront of public debate in Australia. Originally, concerns about privacy focused on credit ratings and government records. These were originally covered by Commonwealth legislation, which established Information Privacy Principles based on the original OECD standards in 1980. The ALRC and AHEC were asked to consider concerns about genetic privacy and the possible misuse of genetic information by insurance companies, employers, or immigration department. Over a nearly 3-year period, public consultation was conducted and a major report entitled *Essentially Yours* (Report 96, 2003) was published with recommendations on protecting genetic privacy and in the context of human research, specific recommendations on biobanks, and the conduct of human genetic research. A decade later, developments in personalized medicine in both the clinic and the laboratory necessitate continuing reevaluation of the reforms recommended in *Essentially Yours*, some of which have yet to be implemented. *Essentially Yours* recommended the harmonization of all federal and state health privacy legislation applying to genetics in Australia. Privacy remains an issue for bioethical debate as the national Health *Connect*

electronic health records initiative in unrolled, which will link all government, hospital, and doctor health records.

Medical Care and Informed Consent The standards of healthcare in diagnosis and treatments of patients by medical practitioners has been a major and continuing focus of the bioethical research agenda and frequently appear in articles in the leading *Journal of Law and Medicine*. There is established case law in relation to doctrines of informed consent and the duty to warn in the doctor/patient relationship. The High Court of Australia, in a leading decision of *Rogers v Whitaker* (1992) 175 CLR 479, decided that in cases of disclosure of information to patients, it was not for the doctor to decide what risks should be disclosed but what the reasonable patient was likely to attach significance if warned of the risk. This brought Australian law into line with the US and Canadian case law. Australia, like other countries, experienced a severe insurance crisis in the early 2000s. This general insurance problem extended to the collapse of a major private medical insurer and steeply rising medical insurance premiums. This so-called medical indemnity crisis prompted the Commonwealth Government to appoint a senior judge to review the position (the Ipp Review Committee). The Ipp Report recommended changes to standard of care required by law of medical practitioners. National legislation was introduced clarifying doctors' duties of care to patients in cases of medical negligence claims. Essentially, doctors are required to disclose risks that they know are relevant to their patients and to exercise the reasonable care expected of a medical practitioner of their standing. In Australia there has been considerable bioethical debate around the treatment of minors, the aged, the chronically ill, the mentally ill, and the mentally disabled. In all these cases, issues of competence, consent, duties of medical practitioners, and other medical carers arise. Where children, the aged, the disabled, or the mentally impaired are treated, the rules of consent are varied and surrogate consent may be valid for research. In addition, the courts have a protective jurisdiction and Australia also has specific guardianship legislation.

End-of-Life Decisions and Euthanasia Australia, like most western nations, has a rapidly aging population and there has been consistent debate about end-of-life medical care. In the *Human Tissue Acts* in all the states and territories, a revised legal definition of death was adopted, implementing the test of the irreversible cessation of all brain function (brain death). The introduction of this test and the issue of organ transplantation were widely discussed in ALRC report on *Human Tissue* in 1977. The validity of this test is generally accepted but still debated among some religious groups. This certification of death from a medical and legal standard enabled human organ transplantation to be facilitated has been accompanied by voluntary choice to end one's life. Human dignity has been invoked as one of the main arguments in end-of-life medical care and in the euthanasia debates. Dying with dignity has been widely discussed and was the topic of a parliament of Victoria inquiry into *Options for Dying with Dignity*, 1987. Later, South Australia introduced a *Natural Death Act* in 1993 as did the Northern Territory in 1998, which allowed a person of 18 years or older to sign a notice of direction preventing the administration of extraordinary medical measures to prolong life, in the case of

terminal illnesses. From time to time, other states have had vigorous debates about similar legislation. Some states have introduced medical treatment acts which allow refusals of treatment, except palliative care, and the making of enduring powers of attorney, allowing the attorney to make medical decisions on behalf of the incompetent patient. These advance directives (sometimes loosely called "living wills") are generally well accepted, provided that the advance directive or enduring power of attorney of statutory notice is properly understood, respected, and properly and independently witnessed (Otlowski, 1997). The expression "dying with dignity" encapsulates these discussions and has promoted wider public bioethical debate on dignified and humane palliative care at the end of life. The idea of dignity harm has been extended into discussions about a possible duty for medical practitioners to provide pain relief and palliative care to enable a person to have a dignified end of life.

Future Challenges

Healthcare Generally As a developed country with high-quality healthcare services, there are regular debates about the rising costs of healthcare, access to specific medicines, and the uniquely Australian arguments on the delivery of healthcare by the states and territories or the Federal Commonwealth Government. Two topics are often discussed with respect to the costs of healthcare and access by indigenous Australians. The Commonwealth Government, through its national Medicare scheme, pays 85% of scheduled fees, and this gap and the costs of private healthcare are regularly discussed. Secondly, the Commonwealth, through its pharmaceutical benefits scheme (PBS), pays subsidies for scheduled drugs, and the question of inclusion on this schedule is regularly debated. While most Australians enjoy access and the benefits of an excellent healthcare system, Aboriginal and Torres Islander peoples (ATSI) do not share the same access and benefits to equitable healthcare services. This is a continuing healthcare, equity, and bioethical challenge in Australia.

Human Tissue For the first time, the *National Statement* 1999 included principles for the use of human tissue in research. These guidelines were included as a response to public concerns and reactions to overseas reports about the possible misuse of human tissue samples in medical research. The research uses of human tissue raise legal as well as ethical compliance issues. Samples were defined to include diagnostic, statutory, (e.g., coroner's inquiry), and research samples but did not include fetal, reproductive, or autopsy tissue. Research institutions were requested to develop policies for research on tissues related to the source, nature, cultural sensitivity, and reason for collection in the purpose for the research. Generally, consent is required for the use of a person's tissue. Where there is follow-up research, the new research should be presented for new approval by an HREC. Bioethics has also embraced discussion on commercialization of human tissue. The legislation on organ transplants prohibits the sale of human organs, though there are unregulated markets in some countries in breach of the WHO resolution against this practice. There has also been discussion, including an ALRC report and parliamentary enquiry into the patenting of

human DNA (*Genes and Ingenuity* report 99, 2004). Similarly, the EC directive on the *Legal Protection of Biotechnological Inventions* (98/44) stated that "patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person (Recital 16)." The human dignity arguments are generally phrased in terms of a limit on the commodification of the human body. The argument runs that human DNA is unique and it is not legally possible to own body parts. The general position in law is that the human body cannot be owned. This has not prevented claims for the patenting of DNA sequences rather than entire genomes. Medical advances in organ transplantation have not been matched by an increase in the availability of organs for transplant in Australia. Recognizing this, the Federal Government promoted legislation to establish a new Organ Transplantation and Tissue Donation Authority in 2009, as part of the National Reform Agenda. The Authority's role is to establish, in partnership with the Australian states and territories as well as the clinicians, consumers, and the community, a nationally coordinated approach to organ and tissue donation for transplantation. The aim is to "deliver a highly effective national organ and tissue donation system" and there has been measurable progress towards achieving this aim, according to the annual donation statistics. Organ transplantation will remain a key medical and bioethical issue for the future.

Personalized Medicine The "genome era" and the increased knowledge base in genetic research aim to translate into improved drug development and healthcare applications. There is a growing understanding of individual variations in genetic profiles, and as a result, diagnosis and treatment are becoming more "personalized" and less generic. In 2008, the US President's Council of Advisors on Science and Technology ("PCAST") published a comprehensive report entitled *Priorities for Personalized Medicine*, which defined personalized medicine as the "tailoring of medical treatment to the specific characteristics of each patient" (http://www.whitehouse.gov/files/documents/ostp/. . ./pcast_report_v2.pdf). However this report was also careful to point out that personalized medicine does not actually mean the development and creation of drugs that are entirely unique to an individual patient. Personalized medicine does not differ greatly from the current strategies of drug companies that stratify populations into categories that respond or do not respond to treatment, and in this sense, personalized medicine is not new. Nevertheless, the systematic use of molecular and clinical information to optimize treatment of a particular patient is novel (Nuffield Council on Bioethics, *Medical Profiling and Online Medicine: The Ethics of 'Personalised Healthcare' in a Consumer Age*, 2010) (<http://www.nuffieldbioethics.org/personalised-healthcare-0>). There are high expectations for personalized medicine, particularly its capacity to match drugs more effectively to individual patients by using genetic tests that will indicate the best treatment for a patient with less guess work and trial and error; minimize adverse drug reactions; move generally towards preventative medicine through the use of genetic tests that indicate late-onset conditions; improve clinical trials, especially at phases II and III, the most expensive phases, by enrolling fewer participants in order to reliably measure safety and efficacy; and reduce

the overall costs of medicines. These aims raise bioethical issues for debate. In addition, biobanks are recognized as essential tools for genetic research and the development of personalized medicine. Large-scale collections offer opportunities to researchers to undertake genetics testing and soon whole genome sequencing (WGS) to advance identification of genetic causes of many diseases. Although these large biobanks are staggeringly expensive, they can be linked to more efficiently carry out focused and concentrated research, for example, the International Cancer Genome Consortium links biobanks in 14 countries, each specializing in allocated common cancers with a name of sharing all data to advance understanding of genetic aspects of these cancers. Biobanks are also recognized as essential tools for translating biomedical research into healthcare improvements. Australia has also participated in the international debates on biobanking and the need for fully informed participant recruitment, confidentiality and privacy of samples, public trust, public access to anonymized data, and the overall governance of biobanks (Dillner, 2011). Genetic research generally and the growing use of genetic biobanks are being accompanied by discussion on benefit sharing from these common community resources.

Summary Conclusions

Australia may have an "ambivalent genealogy" in bioethics but it has an established record and tradition in bioethical debates, particularly focused on in vitro fertilization, healthcare, human research ethics issues, human embryo research, and genetic privacy. Australia has also debated the development of animal welfare and research ethics, building on the seminal and groundbreaking work of Peter Singer. Bioethical debate in parliaments and formal agencies is a significant characteristic of Australian bioethics. In addition, Australian bioethical debate is conducted with reference to global bioethics, international conventions and declarations, and international literature. In an increasingly globalized research environment, where Australian research is influenced, and hopefully, influences overseas research, bioethical issues undergo "border crossings." Looking to the future, it is unlikely that bioethics debates can continue at the atomistic, individual level of right, and the UNESCO declarations, most recently in the *Universal Declaration on Bioethics and Human Rights*, may promote wider debates about communitarian values of "benefit sharing, solidarity and human dignity," which are within bioethical dialogue.

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Volnei Garrafa

V. Garrafa
Unesco Chair of Bioethics/Faculty of Health Sciences, University of Brasília, Brasília, Brazil
e-mail: garrafavolnei@gmail.com; volnei@unb.br

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Introduction

At the end of March 1997, the then President of the International Association of Bioethics (IAB), Alastair Campbell, visited Brazil at the invitation of the Brazilian Society of Bioethics. Firstly, he attended the Second Brazilian Congress of Bioethics, which was held in Brasília, "an architecturally planned capital and representative piece of artistic design" (Campbell, 1998, p. 01). Following this, he got to know São Paulo, where he participated in an International Seminar on Clinical Bioethics, which took place at the public hospital of Heliópolis, the biggest "favela" or shantytown in the biggest industrial and population center of South America. On his return to Great Britain, he wrote an emotional editorial in the issue of IAB News of that European spring, recounting what he had seen and felt during his trip. One of the paragraphs went like this: "When I left Brazil after a short visit, I felt especially grateful to my hosts, not only for their friendly and insuperable hospitality, but also for bringing out how much I have now started to perceive the nature of bioethics. I was able to see for myself how difficult it is to maintain a public healthcare service with minimal resources and huge problems of poverty. I could also see the developmental challenge of massive urbanization without an adequate infrastructure to maintain it. In the midst of all of this, I got to know people who were determined to build bioethics with the capacity to make a special difference to healthcare in their country and for the quality of its development" (Campbell, 1998 p. 02). The trip to Brazil further strengthened Campbell's conviction that he should fight for bioethics to return to the course initially traced out by Van Rensselaer Potter in 1970–1971 (Potter, 1971) and reinforced by the same author in 1988 through an organic and continuing work (and not just an isolated and time-limited study); in other words, for the objectives that came to sustain the proposal that was specifically called Global Bioethics (Potter, 1988).

Like the contradictions cited in the preceding paragraph, the thematic bioethics agenda for the twenty-first century follows two historically equidistant reference points: those relating to biotechnoscientific advances – "emerging situations," and others, derived from repetitive situations and the acute social inequalities observed worldwide – "persistent situations." In this manner, like what happens on a worldwide scale, this paradoxical phenomenon is also reproduced in Brazil, in strong colors, even though the country has undergone a significant improvement over the last 10 years, with the elevation of no fewer than 36 million people into the so-called middle class (more than 20 % of Brazil's population). In the specific case of Potter's global bioethics, the topic of biodiversity is of singular importance for Brazil, since the country's interests in the fields of environmental equilibrium are enormous. No less than 22 % of the planet's plant species are found in Brazil, while 1 g of Amazon rainforest contains approximately 10,000 microorganisms, just to have an idea of the magnitude of the subject of biodiversity in this country.

For those who are unfamiliar with Brazil, it is not easy to understand it. It comprises around 8.5 million square kilometers of flat and fertile land; more than 190 million inhabitants born through an extraordinarily rich mixture; and the eighth

largest GDP (gross domestic product) in the world. Alongside this, despite the significant improvements over recent years, its social indicators are among the most critical in Latin America, and its wealth distribution is one of the most unequal on the planet. While 80–100 babies out of every 1,000 live births will die in some needy areas of the northern and northeastern regions, this rate comes very close to an exemplary number of ten in the southeastern and southern regions. Thus, despite the significant changes recorded over the last decade, Brazil in 2012 is a country living with one foot in the nineteenth century and the other in the twenty-first. In contrast with having a national company that is the world's biggest producer of latest-generation medium-sized commercial airplanes (of up to 110 seats) and being the country with the world's greatest mastery of the technology for oil extraction from deep sea locations, and furthermore having the capacity to perform multiple organ transplants and to be a pioneer in discovering the human genome sequencing relating to malignant tumors in different anatomical areas, more than 18 million people who are still completely excluded from this recent process of evolution and development coexist in the fields and, especially, on the periphery of Brazil's major cities (Garrafa, 2010).

Between achievements and problems, the profound contradictions cited and the consequences derived from them form an inseparable part of the work of Brazilian scholars and researchers who have chosen to follow the difficult paths of bioethics. Brazil's contradictory realities, thus, not only require very hard intellectual exercise from its bioethicists but also further sharpen the conflicts that are observed in relation to individual versus collective rights; personal autonomy versus public fairness; participation versus omission in relation to social problems; beneficence versus equity; what is known as charity versus the true meaning of critical solidarity; establishment of theoretical limits versus practical control for investigations; freedom versus responsibility in relation to what is produced; and so on.

Bioethics Development and Current Bioethics Infrastructure

Brazilian bioethics developed relatively late, only emerging organically in the 1990s. A few isolated initiatives took place prior to this but without significant impact. On the other hand, there is no starting point or specific historical reference point for its development. On the contrary, some separate events went on taking place and, at the same time, causing positive repercussions with regard to publicizing and spreading the discipline (Garrafa, 2000). At the start of 1993, for example, the journal *Bioética* was created (http://revistabioetica.cfm.org.br/index.php/revista_bioetica/index), with a regular editorial committee, sponsored by the Federal Medical Council. This journal is indexed internationally and has maintained rigorous periodicity until today, initially every 6 months and more recently every 4 months (three issues per year). There are now another two regular scientific journals on bioethics: the *Revista Brasileira de Bioética* (RBB) (http://www.rbbioetica.com.br/rbb/), sponsored by the Brazilian Society of Bioethics, which has been published since 2005 under the responsibility of the Postgraduate

Program (master's and doctoral degrees) of the UNESCO Chair of Bioethics of the University of Brasília (http://bioetica.catedraunesco.unb.br); and *Bioethikòs* (http://www.saocamilo-sp.br/novo/publicacoes/publicacaoRevista.php?rev=b), published since 2007 by the São Camilo University Center, in São Paulo. Many other Brazilian scientific journals also frequently publish bioethics papers, especially those within the field of public health, such as *Revista de Saúde Pública*, *Cadernos de Saúde Pública*, *Ciência & Saúde Coletiva*, and *Saúde em Debate*, as well as the *Revista da Associação Médica Brasileira*.

In 1995, at a meeting convened by a group of around 20 Brazilian bioethics specialists, which was held at the Oscar Freire Institute of the School of Medicine of the University of São Paulo, the Brazilian Society of Bioethics (BSB) was founded. Today, the BSB has more than 800 associates and it has already held nine national congresses: 1996 (São Paulo); 1998 (Brasília); 2000 (Porto Alegre); 2002 (Brasília, jointly with the Sixth World Congress of the IAB); 2004 (Recife); 2005 (Foz do Iguaçú); 2007 (São Paulo); 2009 (Búzios, Rio de Janeiro); and 2011 (Brasilia). At the most recent events, the number of congress participants has ranged from 500 to 900. The BSB now has regional sections in 11 of the 26 Brazilian states plus the Federal District. Its board is elected by a direct vote among all the associates, and the board's mandate is 2 years. The BSB has an Internet website through which the board communicates and sends out news periodically to the associates (http://www.sbbioetica.com.br), as well as including texts of scientific interest.

In 1996, the National Health Council, a body linked to the Brazilian Ministry of Health, created the National Research Ethics Committee (CONEP), which has the task of regulating and controlling research on human beings within Brazilian national territory. Prior to this, federal legislation relating on this topic already existed, although compliance with it was lax. Since the creation of CONEP, the subject of ethic control in the research with human beings has started to be approached with the required rigor and today, Brazil has more than 600 local research ethics committees that are functioning regularly in universities, hospitals, and other public and private institutions. With regard to formal public matters, it should also be noted that there is a National Technical Committee for Biosafety (CTNBio), which is linked to the Ministry of Science and Technology and which, through a bill of law approved by the National Congress, has the task of analyzing, mediating, and regulating issues relating to research on and use of genetically modified organisms, including patent topics, transgenic foods, animal and plant cloning, and other similar matters.

Differing from large numbers of other countries around the world, including in Latin America, Brazil still does not have a National Bioethics Council. Rather than create its Council by means of a fragile Presidential Decree or even a Ministerial Decree (since this would allow a successor government from the opposition to cancel it), the country decided to follow the slower but safer path of implementing its Council through the legislature. Bill of Law No. 6032 has been under discussion in the National Congress since October 2005, when it was submitted by the then President Luiz Inácio Lula da Silva following hard work to construct a democratic proposal that would include participation by bioethics

specialists, jurists, and scientific specialists, as well as from the organized public, which participated massively in the public consultative hearings that were held in six important cities in different geographical regions of the country (Porto Alegre, São Paulo, Rio de Janeiro, Recife, Manaus, and Brasília). Currently, the bill is under a "special regime of urgency" in the National Congress, waiting for all the political parties to nominate their representatives for renewing it (Garrafa & Tenhave, 2010).

In an isolated manner and unfortunately very slowly, Institutional Clinical Bioethics Committees have started to be created. Concerned about this, the BSB and the Federal Medical Council organized the First Brazilian Congress of Clinical Bioethics in conjunction with the Ninth Brazilian Congress of Bioethics in September 2011, with the specific objective of stimulating creation of bodies of this type in this country. Some pioneering examples of such bodies have existed since the 1980s and 1990s (such as the committees in the university hospitals – Hospital das Clínicas – of Porto Alegre and São Paulo and in the National Cancer Institute in Rio de Janeiro), but these are very little for a country of the dimensions and population of Brazil.

Finally, one final important historical date needs to be specially mentioned: the holding of the Sixth World Congress of Bioethics in Brasília in October 2002, which brought together more than 1,400 participants from 62 different countries. This was the biggest congress that has ever been organized so far, anywhere in the world, and its official theme was "Bioethics, Power, and Injustice." In other words, following the Fourth World Congress, which was held in Tokyo, Japan, in 1998, and dealt with Potter's "Global Bioethics" (and moved somewhat away from exclusively biomedical topics), the event in Brasília definitively expanded the international work field of the discipline from specific biomedical themes to social and sanitary themes, thereby politicizing the international bioethics agenda with topics that until then had only been dealt with tangentially and occasionally (Garrafa & Pessini, 2003).

It needs to be recorded that during the Congress in Brasília, a group of Latin American researchers held a meeting in parallel to this event, at which it was decided to create the Latin American and Caribbean Bioethics Network (Redbioética). This action was subsequently consolidated with support from UNESCO on May 2nd of the following year (2003), at another parallel seminar, this time at a Human Genome Project meeting in Cancún, Mexico. This network, under the initial presidency of a Brazilian researcher (2003–2010) and with active participation from key players, particularly from Argentina, Bolivia, Brazil again, Chile, Colombia, Cuba, Dominican Republic, and Mexico, has since then come to have a decisive role in new epistemological and practical proposals for bioethics in this region, and even within the wider international context. Furthermore, Redbioética has held four congresses, published six books, held many subregional meetings, and run distance-learning improvement courses for interested individuals from all Latin American countries and some in the Caribbean. It has shown decisive action in relation to how it has followed international struggles, in the sense of inclusion of health topics (access to healthcare and medications), social topics

(poverty, vulnerability, and discrimination), and environmental topics (the right to clean water and pure oxygen and respect for biodiversity and the terrestrial ecosystem), in the text of UNESCO's Universal Declaration on Bioethics and Human Rights (Garrafa, 2010). Since this chapter aims to explain the development of bioethics in Brazil, it is also essential to signal the leading role of the Brazilian delegation in the discussions held at UNESCO, in Paris, in 2005, directed toward constructing the abovementioned declaration. Through approval of this document, which was formally homologated at a meeting held at the Brazilian Ministry of Foreign Relations, this declaration from then on came to dictate the new conceptual course of Brazilian bioethics (Barbosa, 2006).

Major Bioethics Issues and Discussions

During its first years of life, Brazilian bioethics took the reference point of the so-called principlism of the United States, based on its four supposedly universal principles: autonomy, beneficence, non-maleficence, and justice (Garrafa, 2005a). For example, resolution No. 196 of 1996, issued by the Brazilian National Health Council, which regulates research on human beings in this country and is still in force today, at the beginning of 2012, is based on a structure that absolutely follows this reference point. Nonetheless, this panorama is starting to change, especially in academic circles, coming from research groups dedicated to public and collective health in the second half of the 1990s and more widely since the Sixth World Congress of 2002 and its influence on the scientific associates of the BSB. Although many peripheral groups of lesser scientific importance have continued to use principlism as the guiding doctrine for their actions, especially in isolated disciplines within the field of health sciences, research centers that are more significant in terms of academic production have started to seek their own paths toward facing the bioethics topics and conflicts that have been detected in this country.

Through this, new proposals have emerged as alternatives to principlism and other, more traditional theoretical currents within bioethics (casuistry, contractualism, and bioethics of virtues). Among them, intervention bioethics, protection bioethics, and liberation theology bioethics need to be particularly cited, because of their prominence and especially because of their continuing presence in studies and publications. There is, without doubt, a wide theoretical and practical path that has already started vigorously and is being constructed through the proposals mentioned here, but it is interesting to see that they all coincide with regard to respect for moral pluralism and defense of the interests of weaker and more vulnerable individuals. This observation seems to demonstrate that the basic sources of inspiration for the "new Brazilian bioethics" lie in contextualization of the country's realities and its social exclusion, and defense of active citizenship (Oliveira, Villapouca, & Barroso, 2005).

There are three ways to explain this "unusual" line followed by Brazilian bioethics toward constructing its own autonomous course within bioethics,

especially among its more representative academic research groups: (1) The advanced levels of politicization of the country since the military dictatorship (1964–1985), with development of a strong sense of public commitment toward healthcare, as made explicit in the 1988 constitution ("Healthcare is everyone's right and the state has a duty to provide/bestow it"), and as reflected in the construction of the national bioethics, given that many of its representatives have been involved in these movements (Porto & Garrafa, 2011). (2) The holding of the Sixth World Congress of Bioethics in Brasilia that, in addition to having a theme that was ahead of its time (Bioethics, Power, and Injustice), gave rise to the creation of UNESCO's Redbioética, which has had a strong influence on the context discussed here. (3) The particular content and sense of UNESCO's Universal Declaration on Bioethics and Human Rights, in which, as already stated, Brazil had an especially important role; the proposition and content of this Declaration had direct repercussions on Brazilian bioethics, as will be seen in the next section.

UNESCO's Universal Declaration on Bioethics and Human Rights (2005) and its Impact on Brazilian Bioethics

Immediately after the Sixth World Congress, which was held together with the Fourth Brazilian Congress, at the end of 2002, bioethics started to experience a new impulse in Brazil. While on the one hand its development since then has generally always followed the course of public health in the country, these paths expanded and broadened from this date onward. In addition to dedication within this discipline to the usual topics of biotechnoscientific fields, of which many have a quantitative methodological basis (in the research fields of genetics, assisted reproduction, organ and tissue transplantation, end of life, etc.), other projects and lines of research have also started to focus on some persistent topics within Brazilian realities and have begun to use qualitative methodological tools that until now have preferentially been directed toward the field of social sciences.

This academic movement has opened the doors to a growing number of published papers that have started to center their efforts on social topics, such as exclusion, different forms of discrimination, poverty, access to healthcare, environmental problems, and so on.

When UNESCO's Redbioética was preparing to participate in a meeting in Buenos Aires convened by the Argentine government, in November 2004, anticipating strongly critical discussion about the conservative biomedical content that was being constructed around UNESCO's Bioethics Declaration, the Brazilian Bioethics Society sent three representatives – F. R. Schramm, J. E. Siqueira, and V. Garrafa. Together with researchers from another 11 Latin American countries, plus the host country of the meeting, these representatives signed the "Charter of Buenos Aires," which demanded a Declaration that was more forceful and politicized, and which would explicitly include health, social, and environmental topics. This "Charter" was decisive in the discussions of UNESCO's IBC that took place at

the beginning of 2005, toward reaching the content that is now known and homologated by 191 countries, through a memorable Assembly that was held in Paris in October of the same year (Garrafa, 2010).

Less than 1 year after this homologation, the Brazilian government (with support and intensive participation from the BSB and UNESCO's regional office) organized a formal seminar with cabinet ministers and more than 400 participants. On this occasion, the country's commitment toward the content of the Declaration was explicitly reinforced (Barbosa, 2006). From that occasion until now, starting from these reference points and other of importance within the national context, bioethics has had an expansion of a more organic nature within Brazilian public institutions, in ministerial work, and in universities. The number of books published within the field of bioethics has increased, along with a growing proportion of specialization monographs and a proportionally smaller number of master's dissertations and doctoral theses, which have been recorded from among the several hundred postgraduate programs in the fields of biomedical and health sciences, juridical sciences, and social sciences that exist in Brazil.

Particular Lines of Research and Epistemological Proposals

A study conducted by Oliveira, Villapouca, and Barroso (2005) presents some epistemological considerations about Brazilian bioethics from the point of view of tendencies whose theories are mainly based on the social, economics, and cultural context of the country. They pointed specially three schools to show that the emergence of a scientific community of bioethics researches, in terms of Thomas Kuhn's scientific theory (Kuhn, 2003), might be a reality in Brazil. The study provided confirmation that particular epistemological trends existed in the bioethics developed in the country, with specially defined paradigms, that is, with theoretical construction that, through a capacity to resolve problems that the scientific community considered important – specially in the fields of public health and poverty-social exclusion (Garrafa, 2005a) – acquired specific status in relation to other theories within the same field. These have been worked on organically By their authors/research groups and have repeatedly been mentioned in the regional and international academic literature: intervention bioethics, protection bioethics, and liberation theology bioethics. The authors (Garrafa & Porto, 2003; Schramm, 2003; Fabri-Dos-Anjos, 1996) used the methodology of reference points from a model containing a "discipline matrix" (a set of consensual elements from a given group of scientists) and "examples" (the concrete solution to a problem that was adopted in a shared manner by the members of the scientific community, for example, to resolve a problem of priority in the share of insufficient resources in public health, and concluded from this that all the trends reported had a convergent foundation in the theories of Brazil's socioeconomic and cultural context). In the following, a brief summary of these three bioethical lines or schools is presented.

School of Intervention Bioethics (IB)

Taking the reference point of criticism of the theoretical and practical insufficiency of principlism for managing health and social macro-problems, IB advocates that only greater depth of analysis of these issues, with new epistemological constructions appropriate for these characteristics, would be able to contribute toward building bioethical thinking that identified with developing countries (Garrafa & Porto, 2003; Porto & Garrafa, 2005). IB rejects uncritical and context-free importation of ethical theories from outside and proposes theoretical formulations that are appropriate for the contingencies of the so-called peripheral countries with severe problems of social exclusion (Garrafa, 2005a). It divides the field into two large thematic groups, with a historical basis: (a) Emerging Situations, resulting from the scientific and technological development observed over recent decades (genome research, organ and tissue transplantations, cell therapy, reproductive technologies, etc.); (b) Persistent Situations, which have been repeatedly occurring from ancient times until today (social exclusion, hunger, discrimination and stigmatization, environmental pollution, access to quality healthcare services, abortion, euthanasia, etc.).

IB also advocates that the state should have a regulatory role in relation to defending the most vulnerable segments of the population. Taking the basis of a proposal for utilitarian and consequential action, which advocates that the most appropriate ethical decisions for resolving the problems are those that benefit the greatest number of individuals, for the longest time possible, and result in the best collective consequences, IB furthermore proposes mutual collective action in situations or cases in which the state does not have a material or practical capability to resolve such problems. Nevertheless, IB emphasizes that such mutual action cannot be a replacement for the public commitments inherent to the state (Nascimento & Garrafa, 2011). IB argues in favor of lay bioethics that respects the moral pluralism that exists in contemporary human societies, governed by the reference point of liberty, but still without moving away from certain basic characteristics, such as protection for excluded individuals, affirmation of the state's role, and respect for human and environmental rights.

Moreover, IB uses two other basic delineations: the finite nature of natural resources and studies on corporeality relating to the feelings of pleasure and pain. In relation to the first of these premises, IB emphasizes the need for replacement of proposals to develop at any cost with proposals for controlled and sustainable development, thus stimulating the creation of a consumer society that relates to the obligation to constantly replace the world's renewable resources. On the other hand, regarding the feelings of pleasure and pain, although these can be perceived by everyone and a relationship line can be indicated, they are felt completely differently by rich people and poor people. These are considered by IB to be somatic regulatory markers for individual and collective quality-of-life value guidance. Other indicators used by IB, in situations of expanded regional proposals for more appropriate replacement or use of the principle of autonomy, especially in a collective and society-based sense, are empowerment, liberation, and

emancipation (Garrafa, 2005b). More recently, through stimulation from social sciences, IB has also started to expand its studies in relation to the concept of colonialism, thereby seeking to deepen its critical regional roots so as to become disentangled from the negative and obscure side of the inheritance from Euro-American colonization and globalization at any cost (Nascimento & Garrafa, 2011).

School of Protection Bioethics (PB)

PB is based on the fact that the state's role is to protect the physical integrity and assets of all individuals who are inside its territory. Nevertheless, it emphasizes that with the arrival of the so-called welfare state, the state's provisions have expanded: PB considers that not only does the state have a duty regarding public liberty, but also it needs to ensure that its citizens can have the so-called social benefits (Schramm & Kottow, 2001). Even though PB recognizes the importance for bioethics of the "solidarity principle" and "ethics of responsibility," proposed respectively by Lévinas and Jonas, it advocates that these two reference points have insufficient capacity to work on the state's role in relation to the weakest and most needy segments of the population.

PB also makes criticisms regarding the predominant currents of Anglo-American bioethics, in relation to the prominence place on the physician-patient relationship and the theory of the four principles of Beauchamp and Childress. It underscores that, with such proposals, essential themes like public health end up relegated to a secondary position, since the so-called principlist bioethics does not have theoretical contributions capable of facing up to the dilemmas within this sphere. In this respect, PB proposes that the state has to take on obligations within the field of public health on the basis of its social responsibility, while differentiating these actions from paternalism, given that according to PB, state agents only act in relation to healthcare policies in conformity with previously agreed collective decisions (Schramm, 2003).

This proposal starts from the prerequisite that health is essential for quality of life and, for this reason, it is indispensable for the development of personal potential. Despite the importance of state action for achieving what is proposed, PB emphasizes the need to respect the axiological plurality that is present in modern society and to incorporate lay morality. PB can be defined as lay bioethics that has the task of protecting the most unprotected individuals, with the aim of achieving social justice.

School of Liberation Theology Bioethics (LTB)

Brazilian bioethics has been greatly influenced by the so-called liberation theology, which sees God as the great creator of the world and sees humans as co-creators and responsible for their own conduct, for their full lives. This school proposes a relationship between Latin American Catholic theological concepts

and bioethics (Fabri-Dos-Anjos, 1996). According to LTB, there is a "mystic" that prepares bioethics, taking this to be the hidden reasons and motivations that sustain the criteria, arguments, proposed attitudes, and norms of bioethics; this is also understood as the ideals, utopian projections, or hopes of the theories (Fabri-Dos-Anjos, 2000a).

The advances of science and technology and their reflections within contemporary society are also a concern for this theoretical school, starting from new interpretations of the meanings and the particular direction of life, as well as the relationships between human beings and between humans and the environment. Along this line of ideas, according to theologians, and differing from what occurs with the majority of scholars who are dedicated to other fields of knowledge, bioethicists are touched with a special sense of justice, solidarity, and humanism, through their virtuosity (Fabri-Dos-Anjos, 2000a).

LTB divides bioethics issues into three interrelated dimensions: mini-social, midi-social, and macro-social. The first takes into account interpersonal and family relationships; the second, institutional and group initiatives (risk groups, research subject, etc.); and the last, large structures and systems of social life, such as public activities within the field of healthcare. The school of LTB makes the very particular interpretation that Brazil and the other countries of Latin America are fertile ground for its attention because of the social inequalities of these countries; in this sense, its main focus is on poor individuals and populations, interpreted as those of greatest vulnerability within society.

Postgraduate Programs

In accordance with the requirements of the Ministry of Education, there are two formal types of postgraduate program in Brazil: the so-called *Lato Sensu* (broad sense) programs, which consist of medium-duration specialization courses (with a legal minimum of 360 classroom hours); and the *Stricto Sensu* (strict sense) programs, which consist of master's courses (with a minimum of 1 year and a maximum of 2 years) and doctoral courses (with a minimum of 2 years and a maximum of 4 years).

The first Lato Sensu postgraduate program developed in Brazil was conducted by the UNESCO Chair of Bioethics at the University of Brasília. This started in 1998 and continues to be regularly offered every year between March and December. Through the 13 years in which it has so far been conducted, this course of approximately 400 classroom hours has trained 320 specialists, with a mean of 25 students per year. Similar courses within the category of "specialization" are offered, although without regular periodicity, in the following institutions: State University of Londrina, Paraná; School of Medicine of the University of São Paulo – Oscar Freire Institute; Federal University of Lavras, Minas Gerais (distance learning); São Paulo Institute of Bioethical and Legal Studies, São Paulo; Bioethics and Biolaw, Ribeirão Preto, São Paulo; Pontifical Catholic University of Rio de Janeiro; Pontifical Catholic University of Paraná, Curitiba (offered only once);

Pontifical Catholic University of Rio Grande do Sul, Porto Alegre (started recently); plus another course offered by a private institution in the city of Teresina, state of Piauí, in the northeastern region of the country, also without regular periodicity. Another traditional course, albeit directed especially toward the religious topic of "Bioethics and Pastoral Care of Health," has been offered since the 1990s at the São Camilo University Center, in São Paulo.

Today, there are three Stricto Sensu postgraduate programs on bioethics with regularized registration in the Brazilian Ministry of Education. The first regular program at master's level started only in 2005, at the São Camilo University Center, in São Paulo, which subsequently, in 2010, expanded its activities to doctoral level. Prior to this, the existence of a large number of isolated dissertations defended within the field of bioethics had already been recorded, starting in the 1990s. These were presented within different academic programs with broader specifications, such as Healthcare Sciences, Medical Sciences, Social Sciences, Law, and others, in which bioethics had a specific presence as an area of concentration or at least as a line of research offered by these programs.

In turn, the first regular doctoral program in bioethics was offered, together with a master's program, from 2008 onward, by the UNESCO Chair of Bioethics of the Department of Public Health, School of Health Sciences, University of Brasília. This program has regularly had around 60 students, of whom 40 at master's level and 20 at doctoral level. More recently, in 2010, a consortium of four institutions in Rio de Janeiro (Federal University of Rio de Janeiro, Oswaldo Cruz Foundation, Fluminense Federal University, and State University of Rio de Janeiro) started to offer the third program every year: a new program at master's and doctoral levels on Applied Bioethics and Ethics.

A good explanatory study on the situation of bioethics activities offered at Stricto Sensu postgraduate level in Brazil was recently presented by Figueiredo through doctoral research developed within the Health Sciences Program of the University of Brasília (Figueiredo & Garrafa, 2010; Figueiredo, 2011). This study evaluated 199 postgraduate programs registered in the Ministry of Education as being of interdisciplinary nature and another 691 master's and doctoral courses within the field of health. In addition to the three programs mentioned above that are destined specifically for training master's and doctoral students in bioethics, 163 courses (23.6 %) offer disciplines of bioethics within their programs, another 32 (4.6 %) have bioethics modules, and a further 36 (5.2 %) provide teaching conducted solely through the deontological tradition. Figueiredo's study also shows that federal public institutions concentrate the greatest number of courses with disciplines of bioethics, with an average of 25 classroom hours, within which the conceptual reference point is almost entirely the principalist theory of bioethics. This study concluded that postgraduate programs on bioethics are at the construction stage in Brazil, since despite the existence of three regular programs that already offer specific master's and doctoral courses on bioethics in this country, 460 (66.6 %) of the 691 course examined within the field of health did not offer disciplines relating to ethics or bioethics (Figueiredo, 2011).

Future Challenges

The contradictory social realities have made it necessary for "Brazilian bioethics" to seek alternatives to the traditional theories. Although principlism has been the springboard for this field in Brazil and still exerts a certain hegemony within the national academic context, especially among groups with less academic depth, an intellectual reaction movement has now been constructed, against the simple context-free nature of ethical proposals or "packages" that have been imported without any critical filtering, from developed countries. The proposed Brazilian theories presented here are still under construction and should not be understood as an "affront" or "scientific disobedience" to the traditionally constituted theories, but as an attempt to search in a contextualized manner for appropriate moral responses to this country's specific problems.

As stated at the outset of this chapter, bioethics development in Brazil started late, and only now are different postgraduate programs beginning to take place organically. The observed evolution over this historical period of development is the result or a dynamic process that is making up for the lost time. In this respect, it is essential to have exchanges with neighboring countries within the Latin American community, with the objective of developing closer and more workable relationships in order to search for common or similar solutions for problems that are often the same.

Conclusion

Perhaps the best interpretation of the importance of bioethics for Brazil in the twenty-first century is provided by Fabri-dos-Anjos. In a valuable essay on this topic starting from what this author called the "cultural and humanitarian context," he stated that in the midst of many social inequalities, Brazil had found that bioethics provided an important space for developing criticisms and concrete proposals toward constructing and ensuring a better future: "Bioethical perspectives are important in Brazil and for Brazil" (Fabri-Dos-Anjos, 2000b – p 45). Campbell's generous words were prophetic; his reflections served as stimulus and assurance for Brazilian bioethics to start to view its problems through its own eyes and not through others' eyes, and to think about these problems with its own brains and not from ideas formed by brains that were alien to its real sociocultural context, no matter how reliable these eyes and how friendly these brains may have been.

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Bulgaria

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Silviya Aleksandrova-Yankulovska

Bioethics Development

History of Bioethics in Bulgaria

The history of Bulgarian medical ethics and deontology is closely related to the cultural history. In ancient times, the emergence and development of ethical norms was related to the habits, customs, and traditions of different ethnic groups. Religious beliefs played an important role. Care for the ill and the elderly was

S. Aleksandrova-Yankulovska
Department of Medical Ethics, Management of Health Care and Information Technologies, Medical University of Pleven, Pleven, Bulgaria
e-mail: Silviya_aleksandrova@hotmail.com

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a sacred duty of ancient Bulgarians. Works of Hippocrates, Democritus, Galen, and Aristotle were well known, and Hippocratic principles were followed in medicine. The period between the thirteenth and eighteenth centuries marked a decline in all areas of life, including medicine. Traditions and moral norms were partially preserved and developed in the abbeys. During the Renaissance, a humanistic attitude toward the ill was proclaimed. Several works on ethical issues were written by Bulgarian physicians.

In 1901, the Bulgarian Physicians' Association (BPA) was established and, in 1904, the first ethical guidelines for physicians were adopted. In 1905, the Bulgarian Dental Association (BDA) was set up. Both associations have always been the main actors in regulating and strengthening the ethical norms in medical and dental practice.

In 1918, the Medical Faculty at the University of Sofia was established and the Hippocratic Oath became obligatory for all graduating physicians. Deontology was officially included in the undergraduate curriculum in medicine.

During the Communist period (1945–1989) medical science developed quickly and many changes in the system occurred. Initially, medical ethics was underestimated and deontology teaching was excluded from the curriculum. Some ethics was included in the discipline "Organization of health care" and deontology was transformed into a part of teaching in Forensic medicine.

In 1947, the existence and activities of the BPA were prohibited by law and, in 1952, the Hippocratic Oath was abolished as well. During the totalitarian period, there was a belief that specific ethical regulation in medicine was not necessary. Moral values in society – socialist values – were considered enough.

A change in thought occurred in the 1970s, and issues of physicians' ethics and deontology began to be seen as of theoretical and practical importance (Radanov, 2004). In 1973, the Moral Code of Bulgarian physicians was adopted. The code advances ethical norms such as physician's duties and obligations to the patients; maintenance and improvement of professional qualification; relations between physicians and other health professionals. At that time futile attempts to introduce the Hippocratic Oath were made. However, as a result of the strong Russian influence on all areas of life, the content of the Russian Oath was adopted in lieu of the Hippocratic Oath.

In 1988, Professor Vasil Prodanov, former director of the Institute of Philosophy at the Bulgarian Academy of Science, published the book titled, *Bioethics*, which was considered the first monograph on the topic in the Eastern European ethical literature (Prodanov, 2001).

In 1990, the BPA and the BDA were restored after 43 years of nonexistence. The legitimacy and independence of both associations became apparent in 1998 with the adoption of the law concerning professional organizations of physicians and dentists (State Gazette, №83/21.07.1998).

In 2000, the new Code of Professional Ethics of Physicians was adopted (State Gazette, №79/29.09.2000). In 2006, the Code of Professional Ethics of the Physicians in Dental Medicine in the Republic of Bulgaria was also adopted (State Gazette, №34/25.04.2006).

The ethical norms were also developed by the Bulgarian Association of Professionals in Health Care. The Code of Ethics (2003) was approved to guide the ethical behavior of nurses, midwives, and other health professionals (http://www.nursing-bg.com).

Major Actors and Forces

Since bioethics studies and research activities are spread throughout medical and philosophical institutions, it is difficult to encompass all professionals working and contributing to the field. Specific names of the main contributors are cited below.

Major Concerns

Although ethics in Bulgaria has developed greatly during the last decades, it is still associated with deontology. Laypeople as well as many health professionals continue to believe that ethics is mainly about the relationships between physician and patient and developing rules of professional conduct. This conceptual framework is not rejected in contemporary ethics but new issues are of importance as well: development of codes of research ethics, regulations for the protection of human subjects in research, the social and moral consequences of research, formulation of public policy guidelines for clinical care, allocation of health care resources, and patient access to health care services.

Resources

Medical ethics was introduced as a separate subject in undergraduate medical education in 1991, and since 1996 medical ethics has been taught in all medical colleges. At each medical university study materials had to be prepared in the absence of a comprehensive ethics textbook. In 1995, the first textbook on medical ethics, edited by Tzekomir Vodenicharov, was published (Vodenicharov, Mitova, & Gateva, 1995). In 2001, a team from the Medical University of Pleven published a textbook on medical ethics designed for medical students and students of other health professions (Grancharova, Aleksandrova, & Velkova, 2001). Silviya Aleksandrova developed this work further, and in 2007 she published a comprehensive textbook on the subject. In 2010, a textbook on bioethics and a book with case studies and practical assignments for medical students were published (Aleksandrova-Yankulovska, 2010a, 2010b). Sashka Popova and Tzekomir Vodenicharov from the Faculty of Public Health at the Medical University of Sofia published medical ethics textbooks in 2004 and 2010 (Vodenicharov, & Popova, 2010). Christina Jivkova from the Medical University of Sofia published a textbook, titled *Biomedical Ethics* (2002), designed for medical students. Darina Zinovieva and Petko Salchev developed materials on patients' rights (1998).

Additionally, study materials were developed by colleagues from the Medical Faculty at Trakia University in Stara Zagora (Marinova & Dimitrova, 1993), from the Medical University of Plovdiv (Liochkova et al., 1994), and from the Medical University of Varna (Kerekovska, 2005).

In 2011, the Faculty of Philosophy at Sofia University "St. Kliment Ochridski" initiated the first master's degree program in bioethics under the title "Integrative Bioethics" (http://www.phls.uni-sofia.bg/display.php). The program is designed for bachelor's and master's degree students in philosophy, sociology, political sciences, psychology, medicine, law, and theology. It is focused on ethical problems in the biosciences and medicine. The program aims to encourage bioethical research. Graduates will obtain a master's degree in philosophy in integrative bioethics.

In 2004, Assya Pascalev founded the Bulgarian Centre of Bioethics in Sofia. The Centre is an independent, nongovernmental organization, the mission of which is to promote the development and application of bioethics in Bulgaria. Its areas of concern include biomedical ethics, research ethics, the ethics of biotechnology, animal welfare, and agricultural ethics (http://www.bio-ethics.net/en).

Current Bioethics Infrastructure

Teaching of Bioethics at University and Other Levels

Ethics is studied as a separate discipline in all Bulgarian medical universities. Ethics courses are taught in different years of undergraduate medical education. At Trakia University in Stara Zagora, the course is placed in the second semester (first year of study). At the Medical University of Pleven, it is taught during the fourth semester (second year). At the Medical University of Varna, the course takes place in the fifth semester (third year). Teaching hours also vary from 30 (15 lecture hours and 15 h of seminars) to 45 (15 lecture hours and 30 h of seminars). The basic topics included in the curriculum are as follows:

- Introduction to ethics with definition of basic terms
- Methods and theories of ethics
- Ethical codes
- Confidentiality
- Models of physician-patient relationships
- Informed consent
- Rights of patients
- Reproductive ethics
- Ethical problems in the end of life – care of terminally ill, palliative care, euthanasia
- Research ethics
- Ethical problems of organ and tissue transplantation
- Justice and resource allocation
- Public health ethics

In 2010, a new program was initiated at the Medical University of Pleven: Bioethics for students specializing in public health protection and control. The course focuses on public health ethics, environmental ethics, and ethical issues of new technologies.

Medical ethics is also included in the curricula of all other health professions, including nurses, midwives, laboratory technicians, and X-ray technicians. According to the state requirements for these specialties, the course of "Medical Ethics and Deontology" consists of 30 teaching hours.

Interesting postgraduate ethics courses have been prepared by different medical universities. The course "Ethical Problems in Medical Practice," consisting of 30 teaching hours, is offered at the Medical University of Pleven by Silviya Aleksandrova. The course "Informed Consent in Medical Practice," consisting of 15 teaching hours, is conducted at Trakia University, Stara Zagora, by Svetlana Dimitrova.

Ethics courses are also included in the philosophical programs of Sofia University "St. Kliment Ochridski": Introduction to Ethics (a required course), and Bioethics: Values and Normative Problems around Human Life (an elective course) (http://www.phls.uni-sofia.bg/).

Bioethics Committees

In the Bulgarian Health Act, adopted in 2004, Chapter 7, Part IV is dedicated to medical research involving human subjects. Here the requirement for prior approval of the research protocol by an ethics committee is stipulated. This requirement is also stated in the law of medicinal products in human medicine (2007), according to which every medical institution conducting research should establish an ethics committee. Following this law, 195 research ethics committees were officially registered.

Ethics committees have been established in scientific institutions performing experiments with human beings – in medical universities and hospitals. In scientific institutions, the ethics committees deal mainly with nontherapeutic research and moral problems of these institutions. Research ethics committees in hospitals mainly oversee the therapeutic experimentation of new drugs. Standard procedures for ethical review of experimental protocols have been developed and adopted.

In 2005, Sylvia Tomova published a paper called "Research Ethics Committees in Bulgaria," which was included in a review titled *Research Ethics Committees, Data Protection and Medical Research in European Countries*.

In addition to research ethics committees, ethics committees have been established in all medical professional bodies on national and regional levels: the Bulgarian Physician Association, the Bulgarian Dental Association, and the Bulgarian Association of Health Professionals. On the national level, there is an ethics committee dealing with issues around transplantation.

Expert Bodies and Centers

Bulgaria participated in the European Information Network – Ethics in Medicine and Biotechnology project (EURETH). The aim of project was to develop an information network and a knowledge base in the field of European ethics in medicine and biotechnology, making relevant sources, value-added information, and related legal sources available to academics, researchers, bioethical professionals, decision-makers, and consumers. Several institutions and organizations involved in bioethics in Bulgaria were identified (http://www.medun.acad.bg/cmb_htm/EURETH_NET/Bg_institutions.htm):

- The Bulgarian Physician Association (BPA), which adopted its code of professional ethics in 2000 (State Gazette, №79/29.09.2000). Additionally, according to the law of professional organizations, the Bulgarian Medical Association has responsibility for controlling adherence to ethical norms in medical practice and imposing penalties on physicians. The BPA is also responsible for developing guidelines for good medical practice. These control functions are implemented through the ethics committees.
- The Ministry of Health. The official site of the Bulgarian Ministry of Health publishes all health legislation documents regulating health care and medical ethics.
- The Bulgarian Psychiatric Association
- The Bulgarian Centre for Bioethics
- The Index Foundation–Health is a nonprofit organization, working on the promotion and protection of patients' rights in Bulgaria through research and analysis of the European and international law, dissemination of best practices, creation of databases, raising awareness on patients' rights, consulting services, creation of complaints procedures, and bringing into being an ombudsman in health.
- Bioetika.org is a team of medical, ethical, and legal experts, working at the Medical University of Sofia, who intend to research attitudes toward some ethical and legal problems in biomedical practice.
- The Association for European Integration and Human Rights is an association of practicing jurists united by the idea of exercising law in the public interest and establishing human rights as a fundamental value of civil society in Bulgaria.
- The bioethics website of the bioethics club of the Faculty of Philosophy of Sofia University "St. Kliment Ochridski." This is an informative website designed mainly for students (http://philosophy-bioethics.eu/).
- The Bulgarian national patients' organization. Being concerned with patients' rights, the organization hosted a conference on "Health Inequalities in the New EU Member States: Policy Makers and Patients – Creating the Change" in September 2012.
- The "Intimate with the Nature Society" is a nonprofit volunteer organization for animal protection and welfare. The society organizes campaigns, provides legal help and humane education, and deals with complaints and signals.

- Animal Rescue Sofia
- The Bulgarian Society for Animal Protection and Preservation

Additionally, the EURETH project identified Bulgarian libraries, that have materials concerning the topic "Ethics and Bioethics" at their disposal.

Relevant Legislation

In 2004, the Bulgarian Health Act (BHA) was adopted. In addition to the main articles concerning the health system as a whole, some ethical issues were tackled as well. Chapter 2 of Part III is dedicated to patients' rights. Lots of similarities can be found between the rights declared in the BHA and the Lisbon Declaration of the World Medical Association on the Rights of the Patient, that is, the right to accessible and good-quality medical care without discrimination, the right to a second opinion, the right to confidentiality, the right to palliative care, and the right to give informed consent. Other relevant legislation is mentioned in the discussion of the major bioethics issues and discussions below as appropriate.

Public Debate Activities

Because there is no national ethical journal, ethics discourse usually takes place in philosophical journals and in the media. There have been debates accompanying the proposals for legalization of euthanasia and surrogacy. As for organized events, in 2008, the Bulgarian Centre for Bioethics organized a National Bioethics Conference, "Expanding Patients' Rights through Advance Directives for Health Care: Towards a Joint European Platform."

Also significant was the International Round Table Discussion "Organ Donation in Europe: Challenges, Opportunities and Exchange of Good Practices," organized by the Bulgarian Centre for Bioethics in October 2010. The event was attended by experts from the EU member countries, including members of the European forum ELPAT (Ethical, Legal and Psychosocial Aspect of Transplantation) and Bulgarian experts from Aleksandrovska Hospital, Lozenets Hospital, the Association of Patients with Kidney Diseases, Medical University of Pleven, and the School of Divinity, Sofia University, and by representatives of the media.

Major Bioethics Issues and Discussions

Beginning of Life

Being a secular country for decades, issues regarding the beginning of life have been rarely discussed in Bulgaria. A team of colleagues from Stara Zagora studied the opinions of medical students in Trakia University about moral acceptability of abortion (Marinova et al., 2007). Their results supported the pro-choice view on

abortion. Most of the respondents accepted abortion in case of medical indications, rape, or incest. Lower support was declared with regard to the abortion on social indications.

As for the Bulgarian law on abortion, it allowed the latter with some limitations during the Communist period and was liberalized even more after that period. Presently, every woman can opt for abortion until the 12th week of gestation, providing there are no contraindications to the abortion and she is competent to make a decision. After that period, an abortion is still possible until the 20th week of gestation if there is a medical indication such as a diagnosed genetic disease (State Gazette, 1990, 2000).

A few papers on sex preselection have been discussed at scientific meetings. Silviya Aleksandrova reviewed this debate in "Ethical Aspects of Sex Preselection" (2006).

End of Life

Considering the aging process in Bulgaria, issues of care for the terminally ill have recently been focused on. Moreover, the country has witnessed a boom in establishment of hospices in recent years. Different educational courses in the clinical aspects of terminal care have been organized. Additionally, ethical issues in palliative care have been discussed. At the Medical University of Pleven, a special course on "Management and Ethics of Hospice Care" was introduced in 2002. The following various topics are covered in the course:

- Preconditions for the emergence of palliative care
- Organisational forms of hospices
- Hospice care teams
- Ethical problems in palliative care: ethical principles in palliative care; communication and truth telling; withholding and withdrawing treatment; justice in resource allocation; research in palliative care; team work
- Psycho-social problems in palliative care – spiritual and religious problems, psychological distress, care of the relatives
- Philosophy of palliative care; the concept of "good death"

Death is not much discussed in Bulgarian society due to the secularization and the deeply rooted views of death as a medical failure. A few papers (mainly philosophical) tried to open discussion on the topic. Vasil Kolev (2000) wrote about the concept of death in modern medical technologies. Polina Balkanska (2005) discussed death from the perspective of the geronto-psychological practice. In 2002, Silviya Aleksandrova published a paper called, "How and When the Death Begins and What Is the Appropriate Way of Care for Dying?" Later, she reported findings of her studies on the idea of "good death." The author studied the concept of "good death" among the personnel of hospices, the relatives of terminally ill patients, and students of different medical specialties (Aleksandrova, 2009). More than half of the respondents (50.5 %) associated a death without pain and suffering with "good death." Next were the ideas of "good death" as death during

sleep and sudden death. The author analyzed interesting differences in the concept of "good death" within different age groups. She also compared medical students' ideas of "good death" of before and after ethical discussions on the issue. Additionally, the author studied the idea of "good death" for people with a real experience of death in their family as well as for health care professionals and people without any real encounter with death.

With the introduction of the concept of patient autonomy, informed consent, patients' rights, and advance directives appeared in Bulgaria, too. Advance directives were introduced in a document in 2002 as part of the clinical path for terminally ill patients with cancer. Studies by researchers from the Medical University of Pleven showed that the opinions of practitioners about the advance directive are negative. Practitioners perceive it more as an obstacle in relationships with their patients than as a useful tool in decision-making (Aleksandrova-Yankulovska, Grancharova, & Vekov, 2011).

In 2011, the legalization of euthanasia was discussed in the Bulgarian Parliament. The legal proposal stipulated that euthanasia should be performed on written request of the patient. In case of an incompetent patient, his or her relatives should be able to request euthanasia on the patient's behalf and the request could be granted accordingly if all relatives supported it. All requests are to be discussed in a special committee of five members, three of whom should be physicians. The other two members should be lawyers. There was an idea of holding a referendum on the issue, but in July 2011 the law was rejected unanimously by the Parliament.

Euthanasia was discussed by a variety of professionals in Bulgaria – philosophers (Kaneva, 2006), ethicists (Aleksandrova, 2008), and forensic medicine physicians (Lisaev, 1999).

Health and Disease

In Professor V. Prodanov's book, *Bioethics* (1988), there is a chapter called "Health and Disease" in which the moral meanings of these two concepts are discussed.

One of the great doctrines put in place over the last half century to ensure patients' self-determination is the requirement for informed consent. After the initial confusion, both health professionals and patients have become used to the concept of informed consent. The Bulgarian Health Act (2004) pays special attention to informed consent. Every medical procedure should be done only after obtaining informed consent from the patient. He or she should be informed about the diagnosis, the aim of the treatment, available alternatives, expected results and the prognosis, potential risks, side effects, and the health risk in case of treatment refusal. Surgical procedures and other medical interventions, which are life-saving, can be performed without a patient's explicit informed consent. In case of incompetent patients, consent is obtained from the legally entitled representative. Profound studies on informed consent in medical practice were done by Svetlana Dimitrova (2003) in her monograph, "Informed Consent in Medical Practice."

When discussing health, disease, and patients' care, the issue of patients' rights emerges. In the Bulgarian Health Act (2004), patients' rights are well formulated in Chapter III. In 2012, the preparation of specific law on patients' rights was begun. A working group of the health commission of the parliament was established to prepare the proposal of this act.

Health Care System, Access to Health Care

Since the end of the Communist period, the Bulgarian health care system changed from a state monopoly to a health insurance system. Accordingly, the issue of justice in health care provision has been discussed, and debates are ongoing on about what type of services should be covered by insurance, how insurance taxes should be calculated, what fee per visit should be paid by the insured patients, and so on. These debates have been led mainly by the media. In an attempt to provide a fair solution to waiting list for primary health care, some recommendations were adopted: patients with chronic diseases in need of prescription renewals should appoint their meeting in advance; emergency cases should be served at any time without waiting; pregnant women and babies under 1 year of age should also be served with priority.

Traditional Medicine

Traditional medicine has not entered the discourse on bioethics in Bulgaria. However, abuses of patients' trust have been often discussed in the media. In Chapter VI of the Bulgarian Health Act (2004), some requirements concerning traditional healers were adopted in order to protect patients and guarantee a certain quality of this type of care. The healers should have at least a high school education and have completed four semesters in medical university.

Genetics

Chapter IV in the Bulgarian Health Act (2004) deals with genetic health and genetic research. Genetic materials can be obtained only after written informed consent is given by the subject. Genetic testing on incompetent persons is possible only after approval is given by the local ethics committee. People cannot be discriminated on the basis of genetic test results. Genetic data are personal and should not be accessible to employers and insurance companies.

Stanka Hristova's book, *Ethics in the Era of Biotechnologies* (2009), discusses ethical problems in the sequencing of the human genome, the rights and property of genetic information, genetic discrimination, among other topics. Assya Pascalev (2003) also contributed to this topic, focusing on ethical dilemmas caused by genetically modified foods.

Reproductive Medicine

Recently there have been several interesting developments in the area of reproductive ethics in Bulgaria. In 2004, the regulations regarding assisted reproduction were officially included into the Bulgarian Health Act (Chapter 4). Soon after that, in 2007, the Ministry of Health issued a special decree about activities in the area of assisted reproduction (State Gazette, №55/06.07.2007). There was a discourse on whether assisted reproduction should be covered by health insurance. Finally, it was not included in the insurance package, but in 2009 the government established a special fund called "Assisted Reproduction." Although an age limit was established, allowing assisted reproduction only to women until the age of 43, in 2010 a successful procedure was performed on a 62-year-old mother. This case was widely debated in the light of the mother's age and the related ethical problems. One year later, the age limit for in vitro fertilization with a woman's own ova was revoked, but at the same time a new limit, 51 years, was set for IVF with a donor's ova. New debates over discrimination based on the age of the mother have led to a proposal of amendments to the regulation. In May 2012, an individual assessment of every female candidate for assisted reproduction was proposed. The age criterion was replaced by the menopause criterion. Ethical issues brought up as a result of the application of new reproductive technologies were discussed by Silviya Aleksandrova (2006a) in a comprehensive paper published in *Asklepios – International Annual of History and General Theory of Medicine*. The moral status of the embryo also was an issue of discussion in several other papers (Hristova, 1997; Todorov, 2006). Stanka Hristova published a book about cloning in 1999, titled *From Frankenstein till Dolly. Morality and Procreation.* An overview of the debate over human cloning was presented by Christina Jivkova in the book *Cloning* (2002).

Ethical aspects of surrogate motherhood have been discussed cautiously in a few papers. In 2004, Silviya Aleksandrova published an overview paper titled, "Should surrogate motherhood be prohibited?," long before the issue of surrogacy legalization was raised. In October 2011, the act on surrogacy was discussed in Parliament. It prohibited direct payments to the surrogate mother and allowed only reimbursement of expenditures during her pregnancy and recovery period after the delivery. The surrogate mother should be a Bulgarian citizen between 21 and 43 years of age with at least one child of her own. She should be in good physical and mental health and should not be a surrogate mother more than twice. The surrogate mother should not be the donor of the ova at the same time. The law is still under revision.

Medical Research

The Bulgarian Health Act (Chapter VII) deals with medical research involving human subjects. The principles declared in the act are consistent with the generally recognized ethical principles of medical research according to the Helsinki declaration. The requirement to obtain written informed consent prior to the initiation of the research is stated in it. Incompetent people should not be involved in medical

research. The researcher should be qualified in the areas of medicine, dental medicine, biology, pharmacology, or biochemistry. Research projects should be approved by a local ethics committee before their initiation. The ethics committee should monitor the conduct of the research.

Additional laws regulating medical research include the law on medicinal products in human medicine (2007), the decree on regulation of good clinical practice rules (2007), the decree on regulation of clinical experiments of drugs involving human subjects (2000), the law on vetting activities and the regulation about the minimal requirements for the protection and humane handling of experimental animals (2005).

Public Health

In 2010, one of the plenary lectures at the Jubilee Scientific Conference on the subject "Public Health in 21st Century," held at the Medical University of Pleven, was "Ethics in Public Health," delivered by Professor Marcel Verweij, editor of the journal *Public Health Ethics*. His speech has inspired the subsequent debates. Other relevant works include the following: Silviya Aleksandrova (2007b) presented a literature review, "Ethics and Public Health," at a national conference on "Ethics in Bulgarian Health Care." At the same conference, Valeri Lichev gave a speech, "Economic Constraint for Healthy Lifestyle," in which he discussed the economic measures undertaken by the government to limit smoking through increasing the price of cigarettes. This issue launched a great debate in the country, much larger than the debates about euthanasia and surrogacy. The protests of tobacco producers and lobbyists led to the partial adoption of only some restrictions, like the separation of places for smokers and non-smokers. It took a long time until the ban on smoking in public places was finally adopted in May 2012.

Infectious Diseases

Infectious disease control is described in the Bulgarian Health Act, Chapter V (2004). The measures are obligatory and are justified by the public benefit: obligatory immunizations, obligatory notification and registration of infectious diseases, and obligatory isolation and hospitalization for 13 diseases. There is no specific publication on the ethical issues regarding infectious disease control.

Transplantation Medicine and Organ Donation

Transplantation medicine is typically related to many ethical debates that are mainly focused on resource allocation problems.

Many ethical papers have been published focusing on different aspects of transplantation. Darina Zinovieva (2003) focused mainly on legal issues in

relation to transplantation. Assya Pascalev presented several papers on transplantation at the national conference on "Ethics in Bulgarian Health Care," where she discussed the importance of how informed consent for donation is stipulated in the law (2007). In 2010, at the Jubilee scientific conference of the Medical University of Pleven on "Public Health in the 21st Century," Pascalev presented ethical challenges with regard to unrelated living organ donation. Ethical problems of organ donation and tissue transplantation were the topic of doctoral studies as well.

The law on transplantation and organ donation was last amended in 2011. There was a radical change in the law that was adopted in 2009 in relation to the informed choice of potential donors. In the first version of the law (2003), there was a requirement for registered consent of the donor before death. However, the limited number of Bulgarian citizens who registered such consent fostered the debate and increased the pressure for change of legislation. As a result, the opposite prerequisite for donation was adopted, that is, the absence of explicit refusal for organ donation. The law also clarifies the conditions for living donation, it prohibits payments for organs as well as advertisements for organ donations, and it is detailed with regard to informed consent requirements.

Emerging Technologies

In the course of the development of new bio- and information technologies, some research and debate was initiated among philosophers, ethicists, and other specialists in the field. Stanka Hristova, in her book *Ethics in the Era of Biotechnologies* (2009), pays special attention to the ethical problems of nanotechnologies. Other authors, not specifically trained in ethics, have covered problems of protection of the patients' rights with the introduction of the basic elements of e-health, such as the electronic health dossier, the electronic health card, and electronic prescriptions (Mircheva, 2009).

Intensive Care

There is not much research concerning ethical aspects of intensive care. Nikola Ivanov and Nikolaj Kolev (2007) wrote the book *Intensive Therapy in Internal Diseases*, in which they present and analyze in detail patients' rights, informed consent, confidentiality, transplantation, professional duties, and legal responsibilities in intensive care of internal diseases.

Palliative Care

Palliative care was introduced relatively recently in Bulgaria. The first hospices were established in the late 1990s. Ethical discourse has focused on patient's

autonomy and truth-telling (Aleksandrova, 2007a; Jordanov and Stefanov, 2008), the introduction of advanced directives (Aleksandrova-Yankulovska et al., 2011), the concept of "good death," and the relationship between palliative care and euthanasia (Aleksandrova, 2008). Separate publications have appeared on the philosophical aspects of pain (Kaneva, 2007; Mihailov, 2007).

Care for the Elderly

In 2008, in Plovdiv, the Hasumi International Research Foundation-Bulgaria organized a scientific meeting titled "Elderly – Life with Future." Specialists from different areas as well as politicians were invited to discuss ways of improving the life of the elderly and enhancing their social support. Palliative care issues were touched on and an active discussion was held on the involvement of the Orthodox Church in care. Issues of care for the elderly are often discussed in the media and social politics but not so much in the academic ethical debate.

Chronic Diseases

In 2005, the Bulgarian Psychosomatic Society organized a conference in Plovdiv called "Ethical and Spiritual Aspects of Medical and Social Activities in Chronically Ill Patients" in collaboration with the Department of Health Care at the Medical University of Plovdiv. Mariana Liochkova and V. Mihaylova presented on chronic pain (2005). L. Gateva, G. Petrova, and Iv. Salabasheva (2005) underlined the challenges with regard to care for chronically and terminally ill patients.

Psychiatric Care

A separate chapter of the Bulgarian Health Act deals with mental health and psychiatric care. Psychiatric treatment cannot be imposed upon anyone unless within legally defined situations. They cannot be initiated on the basis of family, professional, or other conflicts. Patients' stays in psychiatric institutions should be shortened and the limitation of personal freedom should be reduced. Patients in acute situations, presenting a danger to themselves and to others, can be temporarily restricted for 6 h. If a patient's condition requires longer restriction, the institutional manager should decide about that and should inform the relatives. In case of necessary psychiatric care (obligatory hospitalization), the manager of the institution should appeal to the court for this decision (BHA, 2004, Chapter V).

Legal and ethical issues regarding patients with epilepsy have been discussed by Silviya Aleksandrova and Plamen Bozinov (2005).

Pediatric Care

New ideas for the physician-patient relationships in pediatric care, particularly in the treatment of terminally ill children, were presented by Silviya Aleksandrova at the tenth Congress of the European Association for Palliative Care, which took place in June 2007 in Budapest. The author discussed the direct approach to the ill child versus the family-centred approach, where the diagnosis is communicated to the parents and they talk to the child later on, with or without the assistance of the physician.

Emergency Care

At the conference titled "Ethics in Bulgarian Health Care," held in 2007 in Sofia, Dr. Spas Spaskov, the former executive director of the emergency care center "Pirogov," spoke about ethical problems in emergency care. He underlined the problems of recourse allocation as well as the responsibility people have for their own health. These problems are often debated in the media, but they have not entered the ethical discourse on a philosophical level.

General Practice

There are not many works on ethical problems related to general practice in Bulgaria. Svetlana Dimitrova studied the implementation of informed consent in general practice, and her results showed little familiarity of physicians with the concept or its legal regulation. The physicians who were surveyed had problematic opinions about the importance of the understanding by patients of the information they were provided. Most respondents preferred to inform their patients about the consequences of their refusal rather than to clarify alternative treatments and the chances of success (Dimitrova et al., 2007). Other discussions have been mainly targeted at organizational problems in general practice with little relation to the ethical discourse.

Health Promotion and Education

Some ethical issues relevant to promoting health have been mentioned earlier under the heading "Public Health."

Scientific and Professional Integrity, Conflict of Interest, Corruption

There are issues of professional conduct in the area of expertise of ethics committees. Ethics committees have been established at the Bulgarian Physicians' Association, the Bulgarian Dental Association, and the Bulgarian Association of Health Professionals. At an institutional level, there are also ethical committees at

universities and hospitals that are separate from the Institutional Review Boards. These committees develop ethical codes and guidelines for good clinical and scientific practice and monitor adherence by practitioners. They are also involved in settling conflicts of interests. A special standard procedure for authorship has been developed by the Ethics Committee of the Medical University of Pleven.

Future Challenges

The greatest challenge to the development of bioethics in Bulgaria is the establishment of collaboration between different professionals involved in bioethical research and teaching. Currently, some scientific events are organized and bioethical publications are released without adequate publicity promotion so that all colleagues in the field can benefit from them. A national ethics society or network would be of tremendous importance for furthering better collaboration among professionals with ethics expertise and for facilitating the public debate on bioethical issues. Another important need is the development of a national bioethics literature database.

Bulgaria does not stand apart from recent medical technology developments and related bioethical issues. Genetic tests, for example, are still not widely applied, but the accompanying ethical issues are recognized. Geneticists as well as other physicians, confronting genetic diseases in their practice, must deal with complex ethical dilemmas in genetic counseling. Consequently, there is a need for development of good clinical ethics consultation services.

Summary Conclusion

In Bulgaria, the field of bioethics has followed recent developments and has had its own national achievements. Bulgarian philosophers produced works in bioethics in the late 1980s, and a decade later physicians began to be trained in different ethics educational programs abroad. Thus, a good foundation for future bioethics development in the country has been built. However, bioethics is still perceived mainly as theoretical knowledge and remains to be incorporated more effectively into clinical practice.

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Burkina Faso

54

Jacques Simpore

Birth and Development of Bioethics in Burkina Faso

In Burkina Faso, there are four structures of bioethics or ethics committees: the Catholic National Bioethics Committee (CNBC), the National Committee of Ethics (NEC), the Ethics Committee for Health Research (ECHR), and the National Biosecurity Agency (NBA). These structures that are working in the field of ethics have had various sponsors. They were born in different circumstances and at different times and have had different but complementary goals and fields of application.

J. Simpore
University of Ouagadougou UFR / SVT, Department of Biochemistry /Microbiology/Molecular Biology, Biomolecular Research Center, Pietro Annigoni, (CERBA / LABIOGENE), University of Ouagadougou, Ouagadougou, Burkina Faso
e-mail: Jacques.simpore@yahoo.fr; Jacques.simpore@univ-ouaga.bf

H.A.M.J. ten Have, B. Gordijn (eds.), *Handbook of Global Bioethics*,
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The Catholic National Bioethics Committee (CNBC)

When and How Has Bioethics Committee Started?

This committee was born in 1998 in Ouagadougou under the inspiration of the Episcopal Conference of Burkina Faso and Niger. Indeed, facing the many challenges of social life and the progress of science and biomedicine, the bishops asked Professor Jacques Simporé to constitute a team of resource persons and work for thorough reflections on these problems of ethics and bioethics. That was how it was organized in 1999 the first National Congress of Bioethics. About 550 participants attended this conference, coming from Burkina Faso and neighboring countries such as Benin, Niger, and Mali. Participants stem from all levels and occupations (university professors, doctors, pharmacists, biologists, nurses, bishops, religious people, priests, economists, psychologists, sociologists, theologians, and philosophers). The topics discussed during these 3 days were general bioethics and methodology, African cultures and sexuality, bioethics and sexuality, bioethics and the beginning of life, identity and status of the human embryo, abortion, ethics and law, canonical references on abortion, bioethics and clinical experimentation of drugs on man, drugs in Burkina Faso, epidemiological data and the fight against AIDS in Burkina Faso, psychiatry and risk behavior, and, finally, bioethics in the terminal stage of life.

In 2007 the second congress of bioethics was organized with the topic "Together for the Promotion of an authentic culture of life." This conference was placed under the patronage of their Excellencies Mr. Bédouma Alain Yoda, Minister of State and Minister of Health, and Bishop Seraphim Rouamba, President of the Burkina/Niger Episcopal Conference. It also gathered 550 participants from the Vatican, Italy, Belgium, France, Benin, Cote d'Ivoire, Cameroon, Niger, Mali, Togo, Portugal, Morocco, Spain, Ghana and Burkina Faso.

What Have Been the Major Actors/Forces of This Committee?

The Catholic National Bioethics Committee (CNBC) composed of 16 members is a multidisciplinary team: jurists, bioethicists, moralists, philosophers, theologians, economists, biologists (biochemists, geneticists), pharmacists (pharmacognosy), doctors (pathologists, dermatologists, venereologists, obstetricians), and nurses.

What Have Been Their Major Concerns Over Time?

Their major concerns over time were to train, educate, to sensitize, and enlighten the populations and the leaders on the new problems raised by bioethics.

What Resources (Books, Programs, Media, Networks, and Societies) Have Been Developed?

During these years, the Catholic National Bioethics Committee (CNBC) has organized numerous conferences and debates on bioethics issues. Some lectures have been published as books; others are published on the Web site: www.cerbafaso.org. This committee has also hosted several debates on the national television and private radio stations. It is also currently developing a program for "a master's degree in applied ethics."

What Were the Steps/Measures (Policies and Legislation, Infrastructure, Teaching Programs, Committee, etc.) Taken?

The committee is a structure of the civil society, unrelated to the government; it does not dictate civil law but teaches, educates, and trains through lectures and writings published for the general public.

The National Ethics Committee (NEC)

When and How Has This Bioethics Committee Started?

The National Ethics Committee (NEC) has been created by Article 4 of the President of the Council of Ministers, the President of Burkina Faso (2001), presidential Decree 2001-278/PRES/PM of June 8, 2001 (OJ N 27 2001). This National Ethics Committee was established following the major sociopolitical events that occurred in the late 1990s in Burkina Faso. Indeed, there was a new and unprecedented strong social and political crisis from 1998 to 2000 in the country of "honest men." This committee's mission was to calm the social and political situation that was troubled by sordid assassination. The objectives of the National Ethics Committee was to be an observatory of the Burkinabe society; to ensure the preservation of republican and secular values at the moral, cultural, and human levels; and to propose and to suggest any measures for the preservation of good citizenship and morality in public and social life.

Who Have Been the Major Actors/Strengths?

According to Article 4 of the Presidential Decree of June 8, 2001 2001-278/PRES/PM (JON 27 2001), the National Ethics Committee is composed as follows:

- Three representatives of traditional and religious authorities appointed by the presidium of the National Day of Forgiveness
- Three representatives of the great control bodies of the state (Court of Audit, Inspector General of State, Ombudsman of Burkina Faso)
- Three high-ranking persons appointed by the President of Burkina Faso
- Members of the National Ethics Committee are chosen for their integrity and their sense of duty. They are appointed by decree for a 5-year nonrenewable mandate.

What Have Been Their Major Concerns Over Time?

The major concerns of the National Ethics Committee were to fight against corruption, to awaken a sense of civic responsibility among citizens, and to build a bridge of mediation between the parties of the opposition and the government in order to reestablish social peace in Burkina Faso.

What Resources Have Been Developed (e.g., Books, Programs, Media, Networks, Social Bodies)?

Since its inception (June 8, 2001) and installation (March 14, 2002), the committee was able to develop and enforce initiatives in many activities. According to its President, who is the Ouidi Naaba (traditional chief, minister of the Emperor

of the Mossi), the methodology that was used included meeting, listening, exchanging, and consulting, both in urban areas and in the provinces. This enabled them to produce three reports: the first report presents the current state of ethics in Burkina Faso; the second relates to more specific areas of the general administration, education, and health; and the third deals with ethics and politics. The National Ethics Committee organized in 2006, after 5 years of its existence, a special forum for ethics review in Burkina Faso. This forum was designed to measure the impact of the ethics committee on social peace. During this conference, the committee welcomed the positive management effort of the city, depoliticization of the military and administrative structures, complete communalization, the establishment of decentralized and deconcentrated structures, etc. However, the committee was concerned about the persistence of phenomena such as insecurity, corruption, and impunity.

What Have Been the Steps/Measures (Policies and Legislation, Infrastructure, Teaching Programs, Committee, etc.) that Have Been Taken?

The committee also developed draft codes of ethics in education, health, financial and general administration, defense, and security.

The Ethics Committee for Health Research (ECHR)

When and How Has This Bioethics Committee Started?

By Decree No. 2002 of November 21, President of the Council of Ministers, the President of Burkina Faso, 2002 536/PRES/MS/MESSRS, the Ethics Committee for Health Research (ECHR) was established. Subsequently, joint order Minister of Health, 2004/147/MS/MESSRS on the organization and functioning of the Ethics Committee for Health Research in Burkina Faso were signed. At the dawn of the year 2000, antiretroviral (ARV) drugs were still very expensive when many people infected with HIV died of AIDS in Burkina Faso. In this period, several types of pharmaco-clinical experiments took place: autohemotherapy of HIV, herbal medicine of HIV, research of vaccine against HIV, and so on. Certainly, health research, mainly on HIV, is an important component of the fight against HIV/AIDS. These social science and biomedical researches contribute not only to a better understanding of issues related to the access to quality care but also to providing new and more effective approaches in health issues. Faced with these conditions in health research, with possible bias, it was proposed to the Government of Burkina Faso to fill the legal vacuum by creating this committee in 2002 in order to regulate generally all health research in Burkina Faso. Thus, according to the Decree No. 2002 of November 21, 2002 536/PRES/MS/MESSRS, the Board of the Ethics Committee for Health Research (ECHR) has the following specific objectives:

- To analyze and evaluate all proposed health research in Burkina
- To state an opinion on compliance with the code of ethics and research protocols and issue a certificate of ethics prior to any authorization of health research
- To monitor compliance with ethical principles in the conduct of research

- To arbitrate any disputes of ethical issues arising from the implementation of health research
- To promote the ethics of health research in Burkina
- To develop a code of ethics for health research in Burkina Faso and revise it when necessary

What Have Been the Major Actors/Strengths?

According to Article 5 of the Presidential Decree No. 2002 of November 21, 2002 536/PRES/MS/MESSRS, the Ethics Committee for Health Research (ECHR) is composed of nine members:

- Three (3) representatives of the Ministry of Health
- Two (2) representatives of the Ministry of Animal Resources
- One (1) representative of the Ministry for Human Rights
- One (1) representative of the College of Physicians and Dentists
- One (1) representative of the College of Pharmacists of Burkina Faso
- Members of the Ethics Committee for Health Research (ECHR) are appointed by decree for terms of three (3) years renewable once. They enjoy complete independence in the performance of their duties (Article 6).

What Have Been Their Major Concerns Over Time?

The major concerns of the Ethics Committee for Health Research were to ensure that ethical standards for health research are met in Burkina Faso. In addition, they have to analyze and evaluate all research projects, to issue an opinion, and to promote research ethics. One major concern is the oversight of research projects implemented. The work load is so heavy and the members of the ECHR cannot find time for oversight.

What Resources Have Been Developed (e.g., Books, Programs, Media, Networks, Societies)?

Over the years, the Ethics Committee for Health Research (ECHR) met regularly to evaluate numerous research projects and to allow their implementation. It has also developed a framework and standards for the writing and presenting of research projects.

What Have Been the Steps/Measures Taken (Policies and Legislation, Infrastructure, Teaching Programs, Committee, etc.)?

According to joint order 2004/147/MS/MESSRS, sections 22–23, no projects for health research can be undertaken in Burkina Faso without the certificate of ethics issued by the Ethics Committee for Health Research. In addition, the committee's opinions are published in an annual report sent to the Minister of Health. The committee is currently developing legal standards for health research in Burkina Faso and has also organized training sessions on the writing of ethical research. Nevertheless, there is an important issue that it means to develop: the teaching of research ethics. On another hand, we are looking forward to have institutional ethics

review board (IRB) in research centers. Norms and standards to establish such IRBs are under development.

The National Biosafety Agency (NBA)

When and How Has This Bioethics Committee Started?

Since the dawn of the 2000s, biotechnology has become a hot topic in Burkina Faso with the cultivation of genetically modified cotton (DMC) or Bt cotton (Bacillus thuringiensis). After the experiment conducted from 2003 to 2008, Burkina Faso, the eleventh country in the world to adopt biotechnology, hopes to take advantage and leverage in order to ensure food security for its populations while protecting its environment U. S. Agency for International Development (2006), [www.assaid.gov]. In the context of exploitation of transgenic products, Burkina Faso ratified by Decree No. 2003-208-/PRES/PM/MAECR/MFB/MECV signed on April 25, 2003 the Cartagena Protocol on Biosafety. In July 2003, without designing an appropriate regulatory framework for the protection of its populations and environment from risks associated with genetically modified organisms, Burkina Faso became the first country in West Africa to test transgenic cotton. However, delivery of authorization for this confined field trial was based on prior work by a scientific board. This experimental phase was carried out in an opaque manner without substantial actions to inform and sensitize people on the subject. It was not until June 2004 that a beginning of regularization was initiated with the establishment of a legislative framework through the adoption of national rules for safety in biotechnology, with Decree No. 2004-262 / PRES / PM / / MECV / MAHRH / MS of 18 June 2004, which represents a significant step forward in the field of regulation of GMOs in Burkina Faso.

Subsequently, at the institutional level, a national authority on biosafety was created which is the National Biosafety Agency (NBA). Its three organs are the National Biosafety Scientific Committee (NBSC), the Internal Biosafety Scientists Committees (IBSC), and the National Biosafety Observatory (NBO). Safety in biotechnology would be all the measures taken to reduce or eliminate the potential risks arising from the development of modern biotechnology and the use of its products. A national framework for safety in biotechnology is a set of political, policy, institutional, legal, and regulatory instrument requirements established for the transfer, handling, or safe use of genetically modified organisms (GMOs) and products that are derived, in accordance with such instruments.

What Have Been Their Major Actors/Strengths?

National rules for safety in biotechnology were developed, and the following authorities are charged as far as they are concerned with the implementation of these standards related to biosafety:

- The Minister of Agriculture, Water, and Fisheries
- The Minister of the Environment and Quality of Life
- The Minister of Secondary and Higher Education and Scientific Research

- The Minister of Health
- The Minister of Animal Resources
- The Minister of Trade, Enterprise Promotion, and Handicrafts
- The Minister of Justice

On the technical side, the three bodies – the National Biosafety Scientific Committee (NBSC), the Internal Biosafety Scientists Committees (IBSC), and the National Biosafety Observatory (NBO) – helped to establish biosafety for products of transgenesis in Burkina Faso.

What Have Been Their Major Concerns Over Time?

The major concerns of the National Biosafety Agency (NBA) were:

- To ensure the strict application of the provisions stated for legislative and regulatory matters, including ensuring compliance with best biotechnological practice research in secluded or open areas
- To ensure that risk assessment and management are made
- To monitor and evaluate
- To sensitize the public for a respect of the practices and obligations under these rules
- To make decisions in a sovereign manner in consultation with the public, concerning applications for research on GMOs, their voluntary dissemination in nature, and their marketing

What Resources Have Been Developed (e.g., Books, Programs, Media, Networks, Societies)?

In legal terms, Burkina Faso has developed in 2004 national rules for safety in biotechnology, which aimed at helping to ensure an adequate level of protection for the transfer, handling, and safe use of genetically modified organisms. In 2006, the law on the security system in biotechnology has been adopted. This is a set of legal regulations for genetically modified organisms and derived products. Many reports and training programs, many educational conferences, and several standards were established to entrench the culture of biosafety in Burkina Faso.

According to Article 30 of the law governing the biotechnology security in Burkina Faso [The National Assembly, 2006. Law on security in biotechnology in Burkina Faso; National Biosafety Committee, 2005], an authorization can only be issued if the work:

- Will benefit the country without causing risks or harm to human health, animal, biological diversity, and the environment
- Will contribute to sustainable development
- Does not harm the socioeconomic environment
- Does not violate the rules of ethics

Thus, the present Law No. 005-2006/AN of March 17, 2006 determines the conditions for the use of genetically modified organisms and their products in Burkina Faso. In addition, the laws and decrees that follow were taken by the Government of Burkina Faso with a view to directly or indirectly promoting the objectives of the Convention on Biological Diversity (CBD):

- Law N° 005/97/ADP of 30 January 1997 on the Code of Environment in Burkina Faso and its Decree of 17 July 2001 N°2001-342/PRES /PM/MEE
- Law N° 006/97/ADP of 31 January 1997 on Forest Code in Burkina Faso
- Law N° 034-2002/AN of 14 November 2002 guidance law on pastoralism in Burkina Faso
- Law N° 002-2001/AN of 8 February 2001, on the management of water
- Law N° 023/97/II / AN of 4 December 1997 on the Code of Mining in Burkina Faso
- The Law on the Control of Pesticide. Law N° 41/96/ADP, 08/11/1996 amended by Law N° 006/98/AN of 26/03/1998
- Law N° 23/94/ADP, 19/05/1994, on health code
- Law N° 055 / AN of December 21, 2004, with the general code of local government in Burkina Faso
- Law N° 010-2006/AN of March 31, 2006, on the regulation on plant seeds in Burkina Faso
- Decree 2004-262/PRES/PM / / MECV / MAHRH / MS of 18 June 2004 regulating safety in modern biotechnology in Burkina Faso
- Law on the National Strategy for Genetic Improvement in Burkina Faso (in the stage of adoption)
- Decree N° 2001-342/PRES/PM /MEE of 17 July 2001 on the scope of application, content and procedure of study, and the instructions on environmental impact

What Have Been the Steps/Measures (Policies and Legislation, Infrastructure, Teaching Programs, Committee, etc.) that Were Taken?

The National Biosafety Agency (NBA) developed a communication strategy based on defining different target groups. Activities, topics, and means of communication used are identified, taking into account the specificity of each target group. Apart from communication, NBA organized training on the risks of voluntary and involuntary dissemination and on biosafety measures to be implemented in case of accidental dissemination. It has also published documents and developed standards on biosafety (Table 54.1).

Current Infrastructure in Bioethics

Teaching of Bioethics at University and Other Levels

Some members of the CNBC (Catholic National Bioethics Committee) such as Professors Jean-Baptiste Nikiema and Jacques Simporé and Doctors Joseph Sawadogo and Francis Sedgo teach bioethics in several African universities:

- At the University of Ouagadougou (UO)
- At University St. Thomas Aquinas (USTA)
- At the University Unit of Bobo-Dioulasso (UUB / WAUA)
- At the Biomolecular Research Center Pietro Annigoni, CERBA
- At the University of Lome (Togo)

Table 54.1 Summary table on the establishment of ethics committees and their objectives

Committees	Date of creation	Decree of creation	Name of president	Goals
CNBC	25 May 1998	N°2011CEBN-VIII-24/135	Prof. Jacques Simpore	Train, educate, sensitize, and promote the teaching of bioethics in Burkina Faso to help build the social peace, to promote solidarity, and strengthen human rights in Burkina Faso
NEC	08 June 2001	n°2001-278/PRES/PM	Dr. Tinga Douamba Ouidi Naaba	Being an observatory of society to ensure the protection of secular and republican values and propose measures for the preservation of civic and moral standards of public and social life in Burkina Faso
ECHR	21 November 2002	N°2002-536/PRES/MS/MESSRS	Dr. Bocar Kouyate	To analyze and evaluate all projects in health research in Burkina, to state an opinion on compliance with the code of ethics, to issue a certificate of ethical approval prior to any research promoting the ethics of health research in Burkina
NBA	2005	Decret 2005-040/PRES/PM/MECV du 03 Février 2005 portant organization du Ministère de l'Environnement et du Cadre de Vie	Pr. Chantal Yvette Zoungrana Kabore	To review applications for imports, exports, and uses of genetically modified organisms (GMOs) and products, to issue license for the marketing of food products containing GMOs, to carry out inspections and to carry out technical audits of structures through research on GMOs and products, to ensure compliance of the laboratory and field work on GMOs and derivative with national biosafety rules, and to inform and to educate public and encourage their participation in the decision-making process

CNBC, Catholic National Bioethics Committee
NEC, National Ethics Committee
ECHR, Ethics Committee for Health Research
NBA, National Biosafety Agency

- At the University of Abidjan (Ivory Coast)
- At the St. Thomas d'Aquin Institute for the Theology of development of Yamoussoukro (ISTAY) (Ivory Coast)
- At the University of Brescia in Italy
- At the High Seminary Colleges of Koumi and Lavigerie, in Burkina Faso

The lessons are mainly related to research ethics, biosafety, medical ethics, ethics and social policy, pharmaco-clinical experiments, and morality in general. The lessons take place at all levels: 1st, 2nd, and 6th year of medicine, in 2nd year of the faculty of sciences of life and earth, for master's and doctorate cycles. In addition, numerous workshops, congresses, and conferences on bioethics are held periodically by the CNBC for students and the general population.

Bioethics Committees

In Burkina Faso, there are, as mentioned above, four types of bioethics or ethics committees: the Catholic National Bioethics Committee (CNBC), the National Ethics Committee (NEC), the Committee of Ethics in Health Research (ECHR), and the National Biosecurity Agency (NBA). Each committee works according to its action plan in accordance with the objectives dictated when it was created.

Expert Bodies/Centers

Each committee has its headquarters and structures of its own. But the activities of these committees may be held in several structures or centers: universities, institutes, research centers, training centers, and seminaries.

Relevant Legislation

The National Ethics Committee (NEC), the Ethics Committee for Health Research (ECHR), and the National Biosecurity Agency (NBA) are empowered to create civil standards for the Government of Burkina Faso. The Catholic National Bioethics Committee (CNBC) can suggest ethical standards for the Burkina/Niger Episcopal Conference of the Catholic Church.

Public Debate Activities

When required all four ethics committees in Burkina Faso organize conferences and debates (see Table 54.2). The following topics of bioethics or ethics are often discussed at these conferences and debates: the beginning and end of life, customs and traditions (female circumcision, wife inheritance, and sororities), diseases (AIDS, malaria, genetic diseases, and cancers), traditional medicine (herbal

Table 54.2 Summary of activities of institutions working in the field of bioethics

Committees	Objectives	Publications	Teaching/ training	Conferences	Research authorization	Legislation
CNBC	Social ethics and political science	Publications	Many university courses	Performs numerous lectures	–	–
NEC	Social and political ethics, social peace	–	–	Conducts conferences	–	Propose laws
ECHR	Scientific research	–	–	–	Propose laws	Issue permissions
NBA	Biosafety	Many publications	-Training for members of national biosafety framework (CSNB, NBO, NBA); extension agents for cotton production	Performs many lectures	Gives practitioner	Implement laws

medicine), palliative care, corruption, citizenship, medical ethics, business ethics, and social and political ethics.

Major Bioethics Issues and Discussions

Main Issues in Bioethics and Discussions Faced by the Ethics Committees

Each committee has its specificities, its general purpose, and specific goals.

National Catholic Bioethics Committee (CNBC)

Beginning of Life

The Catholic National Bioethics Committee organizes congress, conferences, workshops, and discussions on the early life. The themes that are developed include the following:

- Sexuality
- Natural or artificial fertilization
- Genetic manipulation of the preimplanted embryo

- Eugenics,
- The voluntary termination of pregnancy (abortion)
- Identity and status of the human embryos
- The culture of life and AIDS (Simpore et al., 2011)

In this sense, for example, the following presentations and publications have been made:

- African Culture and Sexuality (Sanon, 1999)
- Bioethics and Sexuality (Sedgo, 1999)
- Bioethics and the Beginning of Life: Birth Control and Prenatal diagnosis (Pignatelli, 1999)
- Identity and Status of the Human Embryo (Flore, 1999)
- Abortion: Ethics and Law (Sawadogo, 1999)
- Canonical Benchmarks on Abortion (Ouedraogo, 1999)
- The New Frontiers of Genetics and the Risk of Eugenics (Simpore, 2010)

End of life

The National Catholic Bioethics Committee also addressed in presentations that it organized the topic of the end of life: euthanasia, dysthanasia, the dignity of the dying person, the quality of human life, bioethics, and the terminal stage of life.

Other Topics

The CNBC also has developed the themes of gender, traditional medicine, problems related to genetics, biomedical research, infectious diseases, African anthropology, the personalism in Africa (Simpore, 2004), bioethics, and human rights culture in Africa (Sawadogo, 2007).

Ethics Committee for Health Research (ECHR)

The ECHR, whose mission is to analyze and evaluate all research projects in Burkina health, addresses all the issues of health. However, conscious of not being omniscient, the committee appealed to any persons or corporation, for its jurisdiction, whenever necessary, in an advisory capacity. Note that so far, the committee does not develop and does not publish a theme related to the beginning and end of life, genetics, reproductive medicine, medical research, palliative care, and infectious diseases.

The National Ethics Committee (NEC)

The NEC is the observatory of society in Burkina Faso. Thus, by its functions, it ensures the preservation of republican and secular values in the moral, cultural, and human matters. It is also responsible for proposing and suggesting any measures for the preservation of civic responsibility and the morality of public and social life. Therefore, the policy of the NEC aims primarily at stimulating peace and social

justice, to fight against corruption, promote good citizenship, patriotism, good governance, and human rights. The conferences and public debates that it organizes relate primarily to these themes.

The National Biosafety Agency

The NBA, meanwhile, develops themes of discussions and debates related to biosafety in basic scientific research, food security, and environmental security. Indeed, the use of genetically modified organisms generates both hopes and fears within the general public, and, therefore, is the origin of controversial public debate. Based on state's funds through the Programme d'Appui aux Filières Agro-Sylvo-Pastorales (PAFASP) and supports from other partners such as US Agency for International Development (USAID), under the West African Cotton Incentive Program aimed at Strengthening the Cotton Sector in West and Central Africa (WACIP) in 2010, NBA struggles to strengthen its capacity and fully play its role by carrying out several important activities:

- Training on control and inspection of sites containing GMO
- Training on Biosafety-Clearing House (searching information on GMO) for members of the National Biosafety Framework, educational institutions (including professional schools), and professional workers such as customs officers and phytosanitary agents
- Training of 60 members of the National Biosafety Framework structures in evaluation and management for Biosafety
- 6 workshops of sensitization to raise awareness on Biosafety in six regions or a number of 3,658 participants
- Workshops of sensitization for decision makers (Conseil Economique et Social), opinion leaders (religious people)
- Open days of the agency, focused primarily on youth, with the participation of 8,000 students and secondary schools pupils in Ouagadougou and Bobo-Dioulasso
- Training on the content of the law in favor of 555 extension agents in cotton production and media workers (communicators)
- The translation of excerpts of the law on security system in biotechnology in three national languages or more than 10,000 copies distributed to producers
- Their wide dissemination in local languages on local radio antennas.

Future Challenges

In the Field of Bioethics Infrastructure: Need for Legislation, Ethics Committees, Ethics Education

In Burkina Faso, in the field of bioethics infrastructure, it is necessary to develop standards and strong laws against certain obsolete and outdated practices such as cutting of sex organs of girls (the phenomenon of female circumcision),

polygamy, sorority, and witchcraft (the murder of old women falsely accused by people of their village to be soul eaters). Some issues such as impunity, poor governance, and the heinous crimes are a real challenge for Burkina Faso. It would be an urgent need to educate and train people about the realities that hinder the country's progress towards peace and social harmony.

In the Field of New and Emerging Issues

In Burkina Faso and Africa in general, there are many new and emerging issues such as management of biotechnology products (transgenic organisms), biodiversity, conservation and protection of nature, the patenting of genes (markers or DNA sequences), bioterrorism, ICT, emerging diseases (HIV, AIDS, cancer, new deadly flu, and fatal hemorrhagic fevers that rise up from time to time), the issue of stem cells and their possible therapeutic use, and the standards and laws that guide and indicate clearly the way forward.

Summary/Conclusions

In this chapter topics such as birth, development, challenges, and perspectives of bioethics in Burkina Faso have been exposed. The promotion of ethics has been achieved through the action of the four structures that work in the field of ethics: the Ethics Committee for Health Research (ECHR), the National Ethics Committee (NEC), the Catholic National Bioethics Committee (CNBC), and the National Biosafety Agency (NBA). The challenges in the field of bioethics are enormous. From the beginning to the end of life through social and political ethics, human rights, corruption, good governance, social justice, emerging infectious diseases, biotechnology, gene therapy, to the science of the genome, transcriptome and proteome, man, facing 1000 challenges, is expected to act with a double-edged sword. Thus, the future of humanity seems to be in the hands of scientists who will handle almost freely, life. One thing is certain, in this early twenty-first century, the culture has become less theoretical and more pragmatic, and the fulfillment of human hopes today more than ever goes through science and its practical implications whose consequences are going to challenge the very basis of the civilization. The first challenge of genetic engineering, biotechnology is the dizzying pace of its own progress. How surprising to see the scientists themselves dizzy when they feel being authors and actors of this incredible development? The most immediate danger threatening the researchers is to believe that everything is allowed in this rat race. The search goes from conquest to conquest in biotechnology, and some scientists are convinced: there cannot and should not be any limits to their activity, progress itself justifying everything. With this regard, having dismissed the criticism prompted by a bioethics assessment, scientist mentality has succeeded in having many people accept the idea that what is technically feasible is automatically acceptable. However, everyone is now aware: science without conscience and

without wisdom is but the ruin of the soul and the deprivation of mankind. All errors are not forgiving. Could not an error of genetic manipulation cause monsters, imaginary beings? Would not this type of error cost much to humanity in terms of biological, anthropological, cultural, psychological, and social matters? But should one resign and let themselves be invaded by those fears without trying to distinguish what is ethically feasible from what is hazardous and therefore adventurous? No matter the precautions taken by the researchers, they will never get zero risks in biotechnology. There is always a risk, however, nothing ventured, nothing gained. But you have to know how well to risk. To do this, after evaluating, weighing everything against the integral good of man and the cosmos, you have to know how to risk it. The worst does not always occur. And perhaps countless fears might not even materialize. Still, in the criticisms about the performance and prospects of biotechnology, fears and expectations are inextricably intertwined and interwoven to make one believe that the human being, with his or her elusive and impenetrable ideas, is both actor and protagonist of a new booming biotechnology.

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Cameroon

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Godfrey B. Tangwa

Introduction

Cameroon, a former German colony (1884–1914) and subsequently a United Nations mandated territory entrusted partly to France and partly to Great Britain, is a Central African country with a population of approximately 20 million inhabitants (EDS, 2004) of which about 50 % are youth. Cameroon is a multiethnic, multicultural, and multilingual country (Tangwa, 1999), having English and French as its official languages, with French clearly predominating. The section of Cameroon that had come under French administration (about ¾ of the total

G.B. Tangwa
Department of Philosophy, University of Yaounde 1, Yaounde, Cameroon

Cameroon Bioethics Initiative (CAMBIN), Yaounde, Cameroon
e-mail: gbtangwa@yahoo.com

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population and land mass), following the departure of its German colonizers in 1914, had its independence in January 1960, while that under British administration (about ¼ of the total population and land mass) had its own independence in October 1961 at the same time that it reunified, following an 11 February 1961 United Nations–conducted plebiscite, with the French section. Cameroon shares territorial boundaries with the following other African countries: Nigeria, Chad, Central African Republic, Republic of the Congo (Brazzaville), Gabon, and Equatorial Guinea. Because of its great representative diversity, Cameroon is often referred to as "Africa in Miniature." The country has enjoyed political stability since the mid 1960s but the governing system is not easy to characterize using objective data and parameters. It might be described as a dictatorship slowly attempting to transform into a democracy. Cameroon's current ruler has been in power continuously for three decades and counting, in spite (or perhaps because) of the existence of over 200 opposition political parties and regular "democratic" elections. Cameroon is a country of many contradictions. It has remarkable biodiversity and enormous material and human resources, yet it ranks among the less developed of sub-Saharan African countries. The road infrastructure has experienced little change or improvement in the last three decades; youth unemployment and underemployment combined, by conservative estimates, is around 30 % and electricity and pipe-borne water are a luxury in nearly all of its towns and villages; urbanization and rural–urban migration have been quite intensive in the last three decades and several towns now have a population of over one million inhabitants; and yet, none of Cameroon's cities, including the capital city, Yaounde, has street names, let alone street numbers; and yet again, Cameroon's political elite count among the wealthiest and most highly educated on the African continent.

Disease Burden

Cameroon's great diversities and representativeness can be said to extend to the disease profile of the country. As in most other African countries south of the Sahara, a number of both communicable and noncommunicable diseases are endemic in Cameroon, of which malaria, drug-resistant tuberculosis, and HIV/AIDS are currently a major concern in the health sector because of their high prevalence and deadly nature. According to the Global Health Observatory of the World Health Organization (www.afro.who.int/index.php?option=com_docman&task=doc_download&gid=26&Itemid=2111, accessed 24 April 2011), 17.1 % of the population of Cameroon live below the poverty line (less than $1 a day). The infant mortality rate stands at 87 per 1,000 live births and the under 5 mortality rate at 149 per 1,000 live births. The major causes of death in children under 5 include neonatal-related causes, malaria, pneumonia, and diarrhea. The maternal mortality ratio for Cameroon is 730 per 100,000 live births.

This disease profile shows clearly some of the disease burden of Cameroon that should be the concern of public health authorities and researchers alike. For most of

the diseases mentioned above, the public health authorities in Cameroon do have long-term programs aimed at eradication or at least containment and general improvement of the situation, and there has been a significant increase in health research activity in the country in the last two decades or so, during which time a number of advanced medical technologies, such as endoscopic surgery or in vitro fertilization (Tangwa, 2002, p. 56), have been experimented or introduced. But the whole health situation of Cameroon raises ethical problems and challenges at several levels that may not be quite evident for the time being. For example, the introduction of sophisticated expensive technologies in a few urban centers of a country where potable water is still a rarity and where primary health-care diseases like cholera and meningitis still exist in epidemic proportions, or carrying out diverse intensive medical researches on human beings in a situation where prior ethical review of such research, let alone research governance and regulation, are still problematic (Tangwa & Munung, 2011) clearly raise ethical problems and challenges that need immediate and sustained attention.

Overview of the State of Bioethics

Like most developing countries, Cameroon is still in the process of embracing modern concepts and practice of bioethics, and the rate of progress is rather modest. Despite the multidisciplinary nature of bioethics, very few academic institutions in Cameroon have embraced it as a permanent subject on the curriculum and there are very few initiatives with an interest solely in bioethics. The increased incidence of health-related research, progress in molecular biology, research on genetically modified organisms (GMOs), particularly in the agricultural sector, the presence of fertility clinics, etc., have so far failed to generate or stimulate in Cameroon the sort of lively discourse, controversies, and debates that could lead to appropriate regulation and legislation as have been witnessed in other countries.

Traditional medical ethics is the only branch of bioethics with which many medical professionals in Cameroon are somewhat familiar. The first medical school in Cameroon (Centre Universitaire des Sciences de la Santé – CUSS) was created in 1969. Today (2012) a number of medical schools, both public and private, exist in different higher institutions of learning. But the contact of medical students with bioethics in Cameroon, up to the present, is more or less limited to the occasional lecture or seminar and those portions of traditional medical ethics related to the Hippocratic and Nightingalean Codes. At graduation, students of the Faculty of Medicine and Biomedical Sciences of the University of Yaounde 1 (formerly CUSS) take the following oath:

> *En présence des maitres de cette école, de mes chers condisciples et devant l'effigie d'Hippocrate. Je promets et je jure d'être fidele aux lois de l'honneur et la probité dans l'exercice de la médecine. Je donnerai mes soins gratuits à l'indigent et n'exigerai jamais un salaire au-dessus de mon travail. Je ne permettrai pas que des considérations de religion, de nation, de race viennent s'interposer entre mon devoir et mes patients. Admis à l'intérieur des maisons, mes yeux ne verront pas ce qui s'y passe, ma langue*

taira les secrets qui me seront confiés et mon état ne servira pas à corrompre les mœurs ou à favoriser le crime. Respectueux et reconnaissant envers mes maîtres, je rendrai à leurs enfants l'instruction que j'ai reçue de leur père. Que les hommes m'accordent leur estime si je suis fidele à mes promesses: Que je sois couvert d'opprobre et méprisé de mes condisciples si j'y manque!

In the presence of the teachers of this school, my dear fellow students and in front of Hippocrates' effigy, I promise and swear to be loyal to the laws of honour and probity in the practice of medicine. I will freely care for the poor and will never demand pay that exceeds my work. I will not allow matters of religion, nation and race to interfere with my duty and my patients. If I get into a house, my eyes will not see what is happening there, my tongue will not reveal the secrets which are confided to me and my presence will neither break manners nor favour crime. Respectful and grateful to my teachers, I will impart to their offspring the knowledge I have acquired from their father. May people respect me if I keep my promises: May opprobrium be heaped on me and my fellow students despise me if I fail! [English translation by the translation unit of the AMANET Sub-Hub (ASH), Yaounde].

The version of the Florence Nightingale Oath, as modified by the Cameroon Nurses Association and which is read by nurses during convocation ceremonies reads:

I solemnly swear before GOD and in the presence of this assembly, to faithfully carry out and fulfill the duties of my profession. I shall not willfully take or administer any dangerous drug. I shall do my best to improve the level of my profession.

I shall keep in total confidence anything private that will be confided to me and all the secrets of the family, as well as those of the services made known to me. I shall do my best to faithfully collaborate with other members of the health team and see to the well-being of those left under my care.

So help me God

Even as attempted adaptations and modernized versions, the text of these Codes harbor many archaic elements and important gaps that would surely have been addressed were there adequate consciousness of the current global state of the art of medical ethics, nursing ethics, or bioethics in general. It is instructive to compare the version of the Hippocratic Oath above with, for example, the version used by the Faculty of Medicine of the University of Bristol, UK, or that written in 1964 by Louis Lansagna, academic Dean of the School of Medicine, Tufts University, used by many other medical schools the world over. These other adaptations are succinct and free from both archaic ideas and language.

Biotechnology, molecular biology, bioinformatics, and genetic and genomic studies are not completely unknown in Cameroon, as they have recently been introduced at several institutions in connection with programs or projects in the health, agriculture, or environmental sectors. Some Cameroonian researchers and research institutions are taking the initiative in some of these novel and important fields of research, either alone or in collaboration with northern colleagues and institutions, as can be gleaned from some of the publications emanating from the country.

However, these novel fields of research raise equally novel ethical problems and challenges. There are, for example, ethical questions and issues that are related to research that uses bioinformatics tools (Marturano, 2009a, b) and others that are

related to genetic and genomic research (De Vries et al., 2011; Dubochet, 2009; Roche, 2009; Trinidad et al., 2010). Some of these problems, in the case of Cameroon, have recently been highlighted in a published paper on the ethical aspects of human genetic studies in sub-Saharan Africa (Wonkam, Kenfack, Muna, & Ouwe-Missi-Oukem-Boyer, 2011).

In 2003, Cameroon's Ministry of Environment and Nature Protection proposed a law (Law N° 2003/006 of 21 April 2003) that had been adopted by Cameroon's Parliament or National Assembly. This law focuses on "Safety Regulations Governing Modern Biotechnology in Cameroon" and has as main objectives the following:

- To regulate the safety, development, use, manipulation, and cross-border movement of genetically modified organisms that may negatively affect human and animal health, biodiversity, and the environment
- To ensure safety and ethics in modern biotechnological research and development and lay down the procedure for cross-border movement of genetically modified organisms
- To provide mechanisms for assessing, managing, communicating, and controlling the risks inherent in the use of genetically modified organisms or those having new traits as a result of modern biotechnological activity that may negatively affect the environment. . . ."

This law addresses a number of issues in the area of biotechnology including a chapter on "Approval and Authorization." This section states that any research activity, development, production, or manipulation of genetically modified organisms (GMOs) shall be subject to approval by a competent national administration whose decisions are taken within a national committee made up of services and concerned bodies. The "competent national administration" and the "national committee" are not specified nor are the "collaborating services" named. In any case, this law covers only the agricultural domain and does not address genetic technology and manipulations in the domain of human health and health research. Moreover, it is not evident that this law is enforced and it is doubtful that the majority of researchers and users of GMOs in Cameroon are even aware of the existence of this law.

A section of the above law addresses the socioeconomic concerns connected with the use of GMOs. It requires that, before the deliberate release of GMOs into the environment, a thorough study of their ethical and socioeconomic impact on the local population be conducted by a competent authority. This shows, at least, some general awareness that ethical issues/problems are linked with biotechnology but the method and detailed procedures for dealing with them are nowhere specified.

Assisted Reproduction

The WHO estimates that one in four of ever-married women of reproductive age in most developing countries are infertile because of primary or secondary infertility (WHO-DHS, 2004). However, the country statistics for Cameroon fails to report on the infertility rate of the country and rather reports on the fertility rate, which stands at

approximately five children per woman in 2004 (http://www.afro.who.int/index.php?option=com_docman&task=doc_download&gid=26&Itemid=2111). The problem of infertility in Cameroon and Africa in general is an important one especially as people increasingly are taking biological parenthood much more seriously than in the traditional past. This poses social pressures on infertile couples, often leading to a frantic desire to have their own biological child(ren) by all means. In Africa, infertility is considered a curse and having children is still the main reason for marriage and a good reason for polygamy (Tangwa, 2002). As a result, some Cameroonians would surely be celebrating the discovery of in vitro fertilization. Generally speaking, assisted reproduction is not new in the Cameroon context, as it is an important cultural aspect of most tribes or ethnicities. However, this is assisted reproduction mostly in the form of, say, a brother or close relative helping an impotent or infertile kindred by having children for him with his wife or a wife getting a second wife for her husband, if she believes herself to be responsible for their childlessness (Tangwa, 2008). However, "in vitro fertilization," "frozen gametes," "surrogate mother," "hired womb," and "postmortem parenthood" remain new concepts and vocabularies almost unheard of by many in Cameroon. Though the treatment of infertility is not yet included in Cameroon's health priorities, Cameroon witnessed the introduction of a fertility clinic in the health sector as early as 1972 and, by 14 April 1998, the first success story of clinically assisted reproduction was registered with the birth of Tommy, the first "test tube" baby born in the central African subregion (http://www.cliniqueodyssee.com/2fivpress.htm – accessed 29 April 2011).

It is interesting to note that IVF, for example, which has generated so much debate and even litigation in other parts of the world, could be so quietly introduced in Cameroon. Although IVF certainly solves an important societal problem (infertility), it raises a plethora of ethical concerns, especially for traditional cultures, ranging across considerations related to artificiality, justice, autonomy, risk/benefit ratio, status of the embryo, etc., awareness of which would be incompatible with indifference. At the moment, the law in Cameroon remains silent on these issues and there is little or no discussion on the ethics of these technologies. Some of the reasons for this state of affairs may be related to the fact that such discussion would traditionally be considered taboo in some areas and, in any case, IVF is a service that is unaffordable to the vast majority of those who may need it.

Health Research Ethics

As of 2010, research studies on HIV/AIDS in Cameroon had given rise to a total of 2011 scientific publications (which is partly attributable to the fact that there exist a variety of HIV strains in Cameroon (Peeters, Toure-Kane, & Nkengasong, 2003) which the international research community finds fascinating. However, health-related research in Cameroon is not limited to HIV but includes other communicable and noncommunicable diseases, as most of these diseases are endemic in Cameroon. Most of this health-related research is, however, externally funded (Nyasse, 2005).

With the ever increasing research activity going on in Cameroon (Tangwa, 2007), one would expect that research ethics should also be gaining ground in the country. And, compared to the other branches of bioethics, research ethics can indeed be said to be relatively more developed in Cameroon, but still in general terms rather rudimentary, when compared to the state of research ethics in the developed world or in other African countries, such as South Africa, Ghana, Kenya, or Tanzania. Currently, there are initiatives aimed at building capacity in research ethics for both members of research ethics committees and researchers involved in health-related research. Most of the training in research ethics in Cameroon has been done directly or indirectly (through funding) by the African Malaria Network Trust (AMANET) and the European and Developing Countries Clinical Trials Partnership (EDCTP). A recent Initiative, the Central African Network for Tuberculosis, HIV/AIDS and Malaria (CANTAM) has as one of its objectives to build capacity in clinical trials and ethics in the Central African subregion. Other initiatives concerned with capacity building in research ethics include the Cameroon Bioethics Initiative (CAMBIN), the Cameroon Bioethics Society (CBS), and the Reseau sur l'éthique, le Droit et le SIDA, (REDS), Cameroon.

But in spite of these efforts at capacity building in research ethics and awareness creation, Cameroon's Minister of Public Health, as recently as February 2011, in a circular letter addressed to all stakeholders in health research, could justifiably still open his letter with the following statement:

"Mon attention a été attirée sur le fait que malgré les différentes instructions relatives à la mise en oeuvre de projets de recherche en santé au Cameroun, un grand nombre d'activités de recherche continuent d'être menées dans vos différentes structures sans autorisation préalable du MINSANTE." [My attention has been drawn to the fact that, in spite of the various instructions regarding the implementation of health research projects in Cameroon, a good number of research activities continue to be carried out in your various structures without the prior authorization of the Ministry of Health]. (Lettre-Circulaire No. D36-13/LC/MINSANTE/SG/DROS/YC). The minister here is, of course, primarily concerned about administrative authorization of health research, but this should go hand in glove with ethics clearance, which is even more important for such research, but things are evidently not yet perfectly united in Cameroon for a human-subjects research environment free from serious ethical concerns. Efforts are currently underway in the Ministry of Public Health to formulate clearer guidelines related to the creation and functioning of research ethics committees which fall under its administrative jurisdiction. But, while this is a very welcome development, it is in principle still a far cry from what is urgently needed, namely, overall country regulation and guidance of biomedical research, especially human subjects research (Tangwa & Munung, 2011).

Animal Ethics

Very little or nothing is heard about animal ethics in Cameroon in spite of the fact that a number of research laboratories use animals such as mice, rats, rabbits, and

nonhuman primates for experimental purposes. There are no animal research ethics committees in Cameroon, and human research ethics committees are scarcely ever concerned about the welfare of animals used in research.

However, some Cameroon-based researchers in the biosciences are increasingly using methods like computer simulations and bacteria and cell culture techniques, and a few laboratories are already working toward the production of monoclonal antibodies (Cho-Ngwa, Daggfeldt, Titanji, & Gronvik, 2005) which could help in reducing the need for animals in research. Based on this, it could be said that researchers in Cameroon are gradually moving toward promoting the 3R principle (Replacement, Reduction, and Refinement) which features among the principles of good clinical practice (GCP).

Training in Bioethics

Currently there are no academic institutions that provide formal training in research ethics in Cameroon and the majority of researchers and members of Research Ethics Committees (RECs) have to rely on web-based courses or workshops and seminars to obtain training in research ethics (Ateudjieu et al., 2009; Nyika et al., 2009). There is, therefore, only very nominal training in bioethics in Cameroon, most of which is focused on health research ethics. Such training is predominantly in the form of workshops or symposia, usually lasting 1–5 days. The target group has predominantly been members of RECs, though a few have targeted investigators or members of drug regulatory bodies. Long-term (greater than a month) training in research ethics is atypical in Cameroon (Tangwa & Munung, 2011). An intensive 2-week course for preclinical and clinical medical students at the Faculty of Medicine and Biomedical Sciences (FMBS), University of Yaounde 1, introduced as part of a cooperation program with the University of Geneva, ran for a few years but floundered on organizational and communication problems and the lack of appropriate interest by the Faculty authorities. Recently, the University of Dschang introduced a course in research ethics to be taught to students in the biological sciences involved in research, but whether such initiative will be sustainable and how it may evolve remains to be seen, especially as it is not evident that the University disposes of qualified teachers for such a course.

Research in Bioethics

There are few empirical studies on bioethics in Cameroon and these mostly are concerned with research ethics. The primary focus has been on assessing the needs or identifying training gaps of RECs (Ateudjieu et al., 2009; Nyika et al., 2009), while a few others have focused on the failed tenofovir trials of the early 1990s in Cameroon (Mack, Robinson, Macqueen, Moffett, & Johnson, 2010). Other researchers have used a bibliometric approach to assess adherence by scientists in

Cameroon to some basic research ethics requirements (Munung, Che, Ouwe-Missi-Oukem-Boyer, & Tangwa, 2011a; Wonkam et al., 2011) and publication ethics in Cameroon journals (Nchangwi, Asahngwa, & Che, 2009). Besides the few empirical studies in bioethics, there exist few academic writings on bioethics in Cameroon. These have mostly been authored by students (theses and dissertations written as partial requirements for obtaining an academic qualification in the university) and researchers (books, book sections, journal articles) in the humanities faculties of universities. The bibliography on bioethics in Cameroon is therefore rather small at present.

Current Bioethics Infrastructure

There are very few structures in Cameroon which can be said to be wholly or partly dedicated to bioethics issues. In fact, most of the structures that exist are in the form of research ethics committees, created in response to the needs of various researchers and research institutions but most of which are not officially recognized let alone accredited by the government. Aside from RECs, there exist a few nongovernmental and not-for-profit organizations dedicated to bioethics issues. These organizations usually have very little funding for their activities as a consequence of which their actions and sphere of influence is rather limited. The activities of these organizations vary but are mostly geared toward sensitization through training workshops or seminars and publications in journals, magazines, and newspapers. Some of these organizations are briefly highlighted below.

Cameroon Bioethics Initiative (CAMBIN)

CAMBIN was created in 2005 and officially recognized in 2006. It is the Cameroon chapter of the Pan African Bioethics Initiative (PABIN). CAMBIN is a not-for-profit, non-governmental, non-political and non-discriminatory, multidisciplinary association with official seat in Yaoundé. The overall objective of CAMBIN is to enable the development of bioethics in Cameroon with the main focus on capacity building and empowerment in biomedical research, through the promotion of research ethics. CAMBIN equally shares the goals and objectives of PABIN and coordinates its activities in such a way as to foster the development of biomedical research through the promotion of bioethics in Africa (Tangwa & Munung, 2011). CAMBIN is equally involved in empirical research in bioethics, organization of training workshops and sessions in bioethics and active participation in bioethics debates in the country. CAMBIN has a research ethics review and consultancy committee, which in addition to reviewing research protocols also provides consultancy services for biomedical research and ethical review of research in Cameroon and the Central African subregion. The administrative structure of CAMBIN is made up of the General Assembly, the Executive Council and the Ethics Review and Consultancy Committee. Membership into

the organization is open to all persons and institutions interested in bioethics. The current membership of the institution which stands at about 75, is divided into three categories: ordinary members, institutional members, and honorary members. The academic background of its current membership is diverse and is mostly in the biosciences, social sciences/humanities, clinical sciences, law and engineering.

Since its creation in 2005, CAMBIN has registered a number of successes in the area of capacity building through the organization of training workshops for members of research ethics committees as well as for researchers. In recent years CAMBIN has teamed up with AMANET and CANTAM to conduct capacity-building in health research ethics in central Africa for members of ethics review committees and medical products regulatory authorities. The research arm of CAMBIN has recently also become active and is involved in empirical research in bioethics which has led to a number articles in international peer-reviewed journals (Munung, et al., 2011a; Nchangwi et al., 2009; Tangwa & Munung, 2011) and presentations (oral and poster) in international scientific meetings (Munung, Tangwa, Che, Vidal, & Ouwe-Missi-Oukem-Boyer, 2011b; Ouwe-Missi-Oukem-Boyer, Nyika, Munung, Tangwa, & Ntoumi, 2011).

The major setbacks to the daily operation of the organization have been the lack of adequate legislation governing research and bioethics in Cameroon as a whole and the fact that there is very limited funding available for its activities.

Cameroon Bioethics Society (CBS)

Created in 1995, the Cameroon Bioethics Society (CBS) is, perhaps, the earliest nongovernmental and apolitical organization solely interested in bioethics issues. The mission of the CBS, according to its own report, is to promote information and debates on ethics and morality of life and health and also to organize meetings on scientific and cultural issues on bioethics. Its activities involve promoting specialized studies in the field of Public Health and Human Rights, continuous training of health professionals and members of Ethics Committees, the provision of scientific documentation of high quality, generating interest in bioethics within the scientific community in Africa, promoting the development of ethics and bioethics research in Africa with particular emphasis on African perceptions of bioethics, increasing scientific capacity for multidimensional ethics review and public health in Africa (Cameroon Bioethics Society and the Public Health and Bioethics Research Centre. Report of the Cameroon Bioethics Society, 1990–2008). The CBS has in the past years organized some training workshops in research ethics. It does not, however, seem to have been very active in recent years.

Reseau sur l'éthique, le Droit et le SIDA (REDS), Cameroon

REDS is the Cameroon branch of the African Network on AIDS, Ethics and Human Rights, better known by its French appellation: Réseau Africain sur l'Ethique,

le Droit et le VIH. REDS Cameroon has its headquarters in Yaoundé and is an activist group, created in 1998 and officially legalized in 2000. The main mission of this organization is to advance knowledge and improve education in the ethical and legal fields and to promote actions and measures that respect especially human rights in the fight against HIV/AIDS in Cameroon. The current areas of intervention of REDS include public policy and human rights, ethics and biomedical research, clinical ethics, resource mobilization, and direct aid, including legal and judicial assistance for persons living with HIV/AIDS (PLWHA) and their relatives.

In 2005, together with eight other organizations, REDS set up an interassociative working group on biomedical research in Cameroon (GTIA), whose objectives consist of effective and appropriate ethical review of research protocols especially on HIV-related research; ensuring that sloppy and unethical research does not go through unnoticed; participating in the protection of persons recruited as research participants in biomedical research; helping researchers and research agencies in optimizing their research protocols and acting as a watchdog for research studies carried out in Cameroon (Yomgne, 2008, 2009b).

REDS participated actively in the attempt at protecting research participants that were recruited in the controversial Tenofovir trials in the early 1990s in Cameroon. However, REDS Cameroon admits a couple of challenges and these include the fact that GTIA is yet to convince many researchers and research agencies of their ability to be neutral and to protect the ideas of researchers who submit their research proposals for review (Yomgne, 2009b).

The presence of these nongovernmental, bioethics-related organizations in Cameroon has helped to spark up some bioethics discussions, if not debates, in the country. Of particular note here are current discussions within the Ministry of Public Health to better organize health research and research regulation within the ministry, including the creation of a more credible nation-wide ethics review committee, subsequent to, if not perhaps consequent on, the critiquing of the "national ethics committee" (Tangwa & Munung, 2011).

Current Bioethics Issues, Discussions, and Debates

As already stated, research ethics is relatively more advanced in Cameroon when compared to other branches of bioethics. Accordingly, the majority of bioethics issues, discussions, and debates in Cameroon occur around research ethics. Nevertheless, very little progress has been made even in the area of research ethics. As a matter of fact, most of the discussions and debates on research ethics began after the Tenofovir trials were suspended in Cameroon and Cambodia. A couple of workshops to build the capacity of researchers and members of RECs in research ethics have been organized in Cameroon, mostly with foreign institutions taking the lead and/or footing the bill. There is very little effort in terms of funding from the government of Cameroon to build capacity in research ethics. The initiative to organize training is taken by some nongovernmental organizations with very little

funding or with funding from international organizations. Consequently, the level of research ethics in Cameroon is still rather embryonic. Very few members of research ethics committees have even basic training in research ethics (Ateudjieu et al., 2009), while many investigators, graduates, and medical students have only the most rudimentary notions about research ethics.

There are a good number of research ethics committees in Cameroon though, for the time being, only two – the National Ethics Committee (NEC) and the Ethics Committee of the Chantal Biya International Reference Centre (CIRCB) – are officially recognized by the Ministry of Public Health which is charged with the approval or recognition of RECs in Cameroon. Researchers in Cameroon have in the past years obtained or at any rate documented research ethics approval from a plethora of RECs and IRBs in Cameroon (Munung et al., 2011a). In 1987, there existed just one ethics committee in Cameroon and by 2009 the number had greatly increased. It is arguable if "unrecognized" RECs in Cameroon, some of which conform fully to international standards and regulations, should continue to exist unrecognized. In this regard, some of the RECs/IRBs have submitted files to the Ministry of Public Health requesting official recognition though, till date, a decision on their official status is yet to be obtained. In the meantime, these RECs continue to review research protocols in spite of the uncertainty and lack of clarity regarding their official status. The state of RECs in Cameroon thus remains rather controversial (Tangwa & Munung, 2011) when compared to other countries like South Africa, Kenya, Ghana, Tanzania, or Nigeria that have a clear system of accreditation of RECs.

The status of Cameroon's National Ethics Committee (NEC) remains contentious and has been a topic of debate amongst individuals and groups/organizations involved in research and bioethics in Cameroon. Though the government of Cameroon created the first research ethics committee in 1987, the committee had no specific appellation as the text of creation referred to it simply as "an ethics committee." Today, there exists a National Ethics Committee (NEC) in Cameroon, which is assumed to be the ethics committee that was created in 1987, though its mode of operation, membership, financing, and accommodation appear to be very different from what is stated in the 1987 ministerial decision creating the first ethics committee (Tangwa & Munung, 2011). There exists no ministerial decision creating or explicitly recognizing the National Ethics Committee (NEC) of Cameroon as it is today, whereas there does exist one creating the ethics committee of the CIRCB. There have been calls on the authorities to create a national ethics committee, which, Tangwa and Munung (2011) proposed, should have the status of an overseeing body as is the case with some other national ethics committees elsewhere. In an era of increased scientific research in the country and ongoing debates on bioethics worldwide, coupled with the high incidence of scientific misconduct globally, it is important and urgent that such a situation be rapidly regularized to meet up with the global challenges of scientific research.

Equally significant is the fact that both government-recognized ethics committees are located in Yaoundé, Cameroon's administrative capital, whereas research is going on in universities and research institutions located in many other parts of the

country. It has been urged that the government should move quickly to recognize credible IRBs/RECs, in the interest of facilitating research review, as the current situation could easily lead researchers to consider ethics review as a bottleneck to research. None of the RECs in Cameroon receives any funding from the government despite the fact that the 1987 ministerial decision clearly stated that funding for the ethics committee that was created was to be the responsibility of the government of Cameroon. All the existing RECs in the country therefore seek external funding, charge fees for review, or rely on the generous contributions of their members. Overall, there is no national framework for the operation of RECs in Cameroon and the current situation appears rather chaotic (Tangwa & Munung, 2011).

Concerning the legal and administrative underpinnings of research ethics or bioethics, there exist, in addition to a single law governing modern biotechnology (Law No. 2003/006 of 21 April 2003), only two "ministerial decisions" pertaining to research ethics in Cameroon. The very first of these decisions was signed in 1987 creating an ethics committee and the second in 2009 stating conditions for obtaining administrative approval for research studies. Outside of these, recourse has to be made to the general criminal law or the constitution to find a legal basis for arguments in research ethics or bioethics in Cameroon.

The Tenofovir Trial in Cameroon

The controversies surrounding the tenofovir trials have been among the liveliest in the area of research ethics in recent times in sub-Saharan Africa.

The tenofovir trials were carried out not only in Cameroon but also in Cambodia and other countries. They were carried out on commercial sex workers and were prematurely suspended in February 2005, after a Paris-based organization – Act Up-Paris – criticized the trials on ethical grounds. Some studies have attributed the failure of the trial to insufficient media preparation and understanding of the study (Mack et al., 2010; Mills et al., 2005), while some hold that there were substantive ethical problems in the way the trials were conducted in Cameroon (Munday, Lubangi, Mukandu, & Leyens, 2006). The trial sought to recruit approximately 400 commercial sex workers in Cameroon as research participants. The research protocol for the trial had been reviewed and approved by the National Ethics Committee of Cameroon. Several reasons have been advanced for the failure of the trial in Cameroon, including inadequate access to care for sero-converters, participants not sufficiently informed of risks, inadequate number of staff, exploitation of study participants, and unethical study design (Mills et al., 2005). Trial documents pertaining to research participants such as informed consent forms were only in English whereas the city of Douala where the trial was taking place is predominantly French speaking. There was also no provision for future access to tenofovir for trial participants (Yomgne, 2009a) in case the trial was successful. Follow-up studies by the team of REDS (Yomgne, 2009a) indicate that, though the National Ethics Committee of Cameroon had approved the trial, it was unable to

conduct visits to the trial site, owing to lack of funds. According to the REDS team, which had interviews with some officials involved in or, in some other way, connected to the tenofovir trial:

- The president of Cameroon's National Ethics Committee did not recall if the protocol made reference to medical care for sero-converters, did not offer female condoms, or made provision for future access to tenofovir, should it be found effective. He nonetheless noted that he was informed that care was to be provided to participants who sero-converted during the course of the trial.
- The principal investigator (PI) of the study agreed there was no French version of the trial documents and that the provision of the female condom was not included in the trial protocol, but, however, he argued that potential participants were not familiar with the female condom and that incorrect use of the female condom could only help in increasing their exposure to HIV infection. He promised to ensure that trial documents were translated into French and to discuss the other issues raised with Family Health International (the sponsor of the trial).
- An official responsible for oversight of HIV/AIDS trials in the National HIV/AIDS Committee of Cameroon said he was not aware of the planned trial.

Following the controversies surrounding the trial, France 2, a Paris-based television station aired a program on "what the pharmaceutical companies don't tell us" (Yomgne, 2009a). This was closely followed by demonstrations that condemned the trial (Tangwa & Munung, 2011). The trial coordinator noted that though he had been interviewed by France 2, his interview was greatly censored while the Cameroon minister of public health announced that the study was quite ethical (Yomgne, 2009a). In his write up, Yomgne (2009a) further noted that the investigations of the National Medical Council of Cameroon showed that there were both administrative and legal gaps in the conduct of the study.

The tenofovir trials could have provided insights about a potential microbicide for HIV prevention, an initiative with important implications for developing countries. However, owing to administrative and ethical shortcomings, in addition to poor media coverage and rumors, a potentially important study was prematurely suspended in Cameroon.

Future Outlook and Challenges for Bioethics in Cameroon

The current state of bioethics in Cameroon poses a whole lot of challenges. Its growth and development are not matched by the global growth and trends in bioethics and health research as a whole. The current lack of interest in research ethics by government and policy makers has been a serious handicap in the growth of bioethics in Cameroon. For research ethics and bioethics as a whole to develop firm roots in the country, the government needs to participate in and to encourage bioethics initiatives in the country. Such interest should go beyond taking part in opening ceremonies for bioethics workshops. Policy makers should be able to

follow up and execute recommendations reached at such workshops and to provide the necessary conditions for those who have been trained to practice bioethics in their various institutions.

Overall, there exist as already stated three regulations related to bioethics and research ethics in Cameroon and two of these are in the form of "ministerial decisions." Only one (the law governing modern biotechnology) has passed through Cameroon's law-making body (the national assembly or parliament). Though the presence of these regulations can be said to be proof of government's efforts to promote bioethics, they are clearly still quite inadequate in the face of current global challenges in bioethics. For such laws to be comprehensive and effective, a wide range of different kinds of expertise drawn from several fields including bioethics, the biosciences, medicine, law, and the humanities need to be sought in the conception and drafting of such regulations. The government of Cameroon therefore has the challenge of ensuring that adequate regulations and laws on bioethics are put in place, for Cameroon to be able to meet up with some of the ethical challenges arising from the rapid progress in the bio-sciences, the health sciences, and health research.

Many authors have identified the need for African countries to draw up regulations that govern health-related research in their various countries. The recommendations are that such country-specific laws should be guided by international guidelines but should take into account the local, cultural, legal, and medical situation of each country (Chima, 2006). Chima (2006) further argues that such regulations should address issues of local research ethics committees, standard of care, informed consent, and compensation for injuries that are sustained through participation in any sponsored research. However, the current focus and emphasis on regulation in bioethics in Africa has been on the development of regulations governing biomedical research in Africa. Africa, and Cameroon in particular, needs to draw up guidelines that go beyond biomedical research. Such guidelines should address issues pertaining to all forms of research involving the use of humans as research participants as well as other bioethics-related issues like animals in research, end of life decisions, routine medical care, in vitro fertilization, the use of genetically modified organisms, reproductive health, access to essential drugs, intellectual property rights, and global health training.

Access to essential medicines which has even been described as a basic human right is at the center of bioethics discussions around the globe. The WHO defines essential medicines as medicines that satisfy the priority health-care needs of the population and are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. Thus, essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford (http://www.who.int/topics/essential_medicines/en/).

In Cameroon, essential medicines are sold at relatively reasonable prices in the pro-pharmacies located in public hospitals and there is a National Centre for Essential Drug Supply that is charged with the responsibility of supplying these

drugs to hospital pharmacies. Provision of essential drugs in pro-pharmacies has been possible thanks to international aid such as that of Merck and Co. Inc. (which provides Ivermectin free of charge for the treatment of onchocerciasis), the Global Fund, and the Clinton Foundation that subvention antiretroviral drugs. Recently (2011), the Cameroon government has also announced that treatment for uncomplicated malaria in children below 5 years will be provided free of charge. However, all these measures are not yet adequate or sustainable. Most Cameroonians do not use public hospitals for a variety of reasons, including, but not limited to, poverty, inaccessibility owing to the horrible condition of the roads infrastructure, and studies have shown that many people in Cameroon buy drugs from sources other than the pro-pharmacies located in public hospitals (Chana & Bradley, 2011). And, in spite of international and local efforts, Cameroon is one of the African countries yet to achieve universal treatment for HIV/AIDS. The government of Cameroon is evidently still facing the task of providing accessible and affordable health care to its 20 million inhabitants.

Education in bioethics is, for the time being, the most important precondition for the promotion of bioethics in Cameroon. Training in bioethics in Cameroon has mostly been in the form of short-term training (1–5 days) and it has in most cases been focused on research ethics for members of ethics review committees. Overall, there has been a general apathy toward introducing courses in bioethics in the curriculum of universities in Cameroon. This situation needs to evolve if the growing needs for human capacity building in bioethics in Cameroon are to be met.

The tendency in training in bioethics in Africa and Cameroon in particular has been to focus on individuals in the biomedical sciences. However, with the current global situation in bioethics and the fact that bioethics is by its very nature multidisciplinary, there is a need to train students across a wider range of disciplines relevant to bioethics and to encourage them to take up research and professional careers in bioethics. It is only with such approach that adequate human capacity in bioethics can in the long run be achieved in Cameroon.

Conclusion

Cameroon is in many ways a very remarkable country with enormous potential in many domains. Given its remarkable bio and other diversities, its material and human resources, its disease profile, and even available local expertise, Cameroon is a country where all aspects of bioethics should be exciting and flourishing. But, while the main outlines of bioethics activities are indeed present and visible, they are evidently underdeveloped. The underlying fundamental reasons for this situation of underdevelopment must be linked to the overarching politico-administrative-economic system of the country, because other mainly Francophone countries operating similar systems, especially in the same central African subregion, present very similar profiles. Innovative efforts at capacity building in bioethics need to be experimented in Cameroon and other Francophone countries, especially of the central African subregion.

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Michèle Stanton-Jean, Hubert Doucet, Thérèse Leroux, and Julie Cousineau

M. Stanton-Jean (✉)
Centre de Recherche en Droit Public, Université de Montréal, Montreal, QC, Canada
e-mail: michele.stanton-jean@international.gc.ca; michele.stanton.jean@sympatico.ca

H. Doucet
Faculty of Theology and Religious Studies, Université de Montréal, Montreal, QC, Canada
e-mail: hubert.doucet@umontreal.ca

T. Leroux
Centre for Research in Public Law, Université de Montréal, Montreal, QC, Canada
e-mail: therese.leroux@umontreal.ca

J. Cousineau
Centre de Recherche en Droit Public, Université de Montréal, Montreal, QC, Canada

Research Center, CHU Sainte–Justine Mother and Child University Hospital Center, Université de Montréal, Montreal, QC, Canada
e-mail: julie.cousineau@umontreal.ca

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Bioethics Development

When and How Has Bioethics Started?

The launch of the Bioethics Centre at the *Institut de recherches cliniques* de Montréal in November 1976 essentially represented the birth of bioethics in Canada. It was the initiative of Dr. Jacques Genest, founder of the *Institut*, who believed that his research center needed to have within it an ethics "laboratory" that would foster interdisciplinary discussion on the moral and social issues posed by developments in biomedicine. David J. Roy, philosopher and theologian, was the center's first director.

Who Have Been the Major Actors/Forces?

The creation of the Centre for Bioethics was not an isolated event (see section "When and How Has Bioethics Started?"). During the same period, other organizations were interested in certain biomedical ethical issues.

In 1978, the Medical Research Council of Canada (MRC) published its first ethical standards for research with human participants (Medical Research Council of Canada [MRC], 1978). It obliged universities receiving grants from it to put in place local research ethics committees. The MRC played a determining role in the development of research ethics in Canada.

The Law Reform Commission of Canada (LRCC), a federal government agency founded in 1971, played a major role in the study of the new biomedical ethical issues emerging at the time. From the beginning, it placed great importance on these subjects and created a section called "Protection of Life." and published various documents that were authoritative in the areas involved.

Other centers were established later and had a major influence on the development of bioethics in this country like the University of Toronto *Joint Centre for Bioethics* founded in 1995, the *John Dossetor Health Ethics Centre* at the University of Alberta where activities in bioethics started in 1985 and the *Centre de recherche en droit public* (CRDP) of the Faculty of Law at the *Université de Montréal*, founded in 1962 which began in the early 1980s to develop a large bioethics sector.

In the 1970s, names appeared of people who can be considered pioneers of bioethics in Canada. These scholars wrote articles, produced collective works, or played an official role in one of the organizations mentioned. In ethics per se, the names of David J. Roy, Edward W. Keyserlingk, Guy Durand, Benjamin Freedman, Abyann Lynch, Susan Sherwin, Guy Bourgeault, Barry Hoffmaster, Eike-Henner Kluge, and Hubert Doucet are worth mentioning.

What Have Been the Major Concerns Over Time?

In the early days of bioethics, attention was on the following questions:

The first actors were called on to specify the nature of this new field. Many physicians held that traditional medical ethics and professional ethics were sufficient to resolve the issues raised by the extraordinary advances in biomedicine. Philosophers wondered about the pertinence of this new form of ethics, which related to concrete cases rather than fundamental issues. Theologians, concerned with concrete behaviors, were more involved in this field. The tensions in the early 1980s over the creation of a Canadian association of people interested in bioethics are evidence of the differences in points of view on the very nature of this new field.

When the Medical Research Council published its first guidelines on research ethics (MRC, 1978), there was a lack of consensus on the new requirements for researchers, on the creation of local ethics committees, on the presence of lay people on the committees reviewing scientific projects, and on the obligation imposed on researchers to obtain the participant's consent.

Debate raged over abortion in the 1970s, owing to, among other things, the various proceedings brought against Dr. Henry Morgentaler, a pro-choice advocate who challenged abortion law in Canada, but this question did not really capture the attention of the emerging bioethics community. Rather than being interested in the issue of the freedom of women, bioethics was concerned about the condition of the fetuses and of children with congenital malformations. Discrimination against disabled persons was at the heart of the debate, since fetal malformation was the reason for rejection of the fetus. Another concern at the time was the sterilization of persons with a mental disability. A quasi-consensus in favor of authorizing sterilization in this context had developed, following the LRCC document *Sterilization*: *Implications for Mentally Retarded and Mentally Ill Persons* (Law Reform Commission of Canada [LRCC], 1979). A Supreme Court decision in 1986 opposing this trend puts an end to the discussions.

With regard to end-of-life issues, interest was on the appropriateness of treatment withdrawal that could lead to the patient's death. The focus was on two points: the criteria for withholding and withdrawing treatment and the responsibility for decision-making. Consent was a central issue in the debate.

These subjects are still being debated, although their content has undergone major changes. Other topics have been discussed and only those not addressed in the section "Major Bioethics Issues and Discussions" will be addressed here.

There were a lot of debates in clinical ethics (the term "clinical ethics" was born in the late 1970s) on the role of ethicists in ethical consultation and on the mandate of the clinical ethics committees that were formed in hospitals during the same period.

The AIDS pandemic gave rise to fierce debate about such things as the care to be provided, the policies to be promoted, the social behaviors to be encouraged, and the types of research to be put in place.

The tainted blood scandal which, in Canada, conducted to the infection of 30,000 Canadians because the Red Cross, the federal, the provincial, and the territorial governments did not act fast enough to control the spread of HIV led to the establishment in 1993 of a Royal Commission of Inquiry chaired by Judge Horace Krever that revealed the challenges faced by the various health organizations of the period and the weaknesses in the blood system management (Royal Commission of Inquiry on the Blood System (Krever Commission), 1997). Following the Report, Canadian Blood Services and Hema-Quebec were established in 1998. Resource allocation remains the central issue at the heart of all the health debates. In the 1970s and 1980s, discussions on the lack of resources focused more on the importance of increasing resources by developing drugs, injecting more money into the system, or educating the public on the need for more organ donation. Beginning in the early 1990s, due to the economic context, the question becomes the following: What system should be developed, given the cost of services and the limits of the ability to pay? (Evans, 2002).

What Resources Have Been Developed (e.g., Books, Programs, Media, Networks, Societies)?

Among the monographs that contributed to the debate on ethical issues in Canada during the 1970s were the working documents and reports of the Law Reform Commission of Canada (Protection of Life Series) and a series of four works, in French, published by the *Centre de bioéthique of the Institut de recherches cliniques de Montréal* (IRCM), affiliated with the Université de Montréal (Centre de Bioethique, 1979, 1980a, b, 1982). Moreover, *Biomedical Ethics in Canada* by John R. Williams (1986), which provides an overview of the field during this period, is a very useful reference work.

What Have Been the Steps/Measures Taken (Policies, Legislation, Infrastructures, Teaching Programs, Committees, etc.)?

Canada's initial approach was to promote ethical reflection and the self-regulation of relationships in the health-care sector and in the development of the biological sciences. This ethical reflection mainly occurred within the academic milieu, professional associations, and religious groups. Overtime, professional health associations adopted codes of ethics, and in 1978, the Medical Research Council of Canada published a guide for research involving human subjects (MRC, 1978).

Current Bioethics Infrastructure

Teaching of Bioethics at University and Other Levels

The database of the Association of Universities and Colleges of Canada provides a list of bioethics programs currently offered in Canada (Association of Universities and Colleges of Canada [AUCC], 2013). It is interesting to note that, even at the graduate level, only the Université de Montréal, University of Toronto, and Dalhousie University use the term "bioethics" to describe their programs. The University of Ottawa, for example, offers an Honors BA with a major or specialization in Ethics and Society, while the University of Guelph offers a BA minor in Ethics in Life Science, which could appear broader in scope than a traditional bioethics program. The Université de Sherbrooke and Université Laval have chosen the term "applied ethics" and Mc Gill University has a Biomedical Ethics Unit. Students can also obtain a diploma or degree with a bioethics component (certificate, Bachelor of Arts, or Bachelor of Science with a minor or major). In these cases, the courses are offered by faculties of arts and sciences, philosophy, and religious studies or as part of joint programs involving various biomedical science faculties, such as medicine, nursing, and pharmacy, and faculties of health administration, social sciences, philosophy, law, and religious studies. In addition, bioethics courses are included in the curricula of health science faculties such as medicine, nursing, and pharmacy. There are two universities offering PhD in bioethics and four offering an MA degree.

Bioethics Committees

Canada does not have a national bioethics committee. The province of Quebec is the only one to have established an ethics commission for science and technology, including biomedicine. In Canada, local research ethics committees and health-care committees have developed substantially since the 1980s. Other types of ethics committees have also been put in place, according to the needs of organizations (e.g., professional associations, institutional associations, and policy institutes). Two types of committee will be discussed here: research ethics boards (REBs) and clinical ethics committees (CECs).

A research ethics board (REB) is required in all Canadian institutions that conduct research involving human subjects and receive funding from one of the three research agencies – the Social Sciences and Humanities Research Council (SSHRC), the Canadian Institutes of Health Research (CIHR), and the Natural Sciences and Engineering Research Council of Canada (NSERC) which are run by the federal government.

The Tri-Council Policy Statement (TCPS, 2010) sets out the responsibilities and composition of REBs, which must provide an ethics review and approval, before the work commences, of "(a) research involving living human participants; (b) research involving human biological materials, as well as human embryos,

fetuses, fetal tissue, reproductive materials and stem cells. This applies to materials derived from living and deceased individuals" (TCPS, 2010, p. 15). The mandate of the REB is to "review the ethical acceptability of research on behalf of the institution, including approving, rejecting, proposing modifications to, or terminating any proposed or ongoing research involving humans" (TCPS, 2010, p. 69). Private companies that do not receive funding from federal granting agencies are not subject to the TCPS. However, their projects involving new drug development such as clinical trials must be reviewed by an independent ethics committee, according to Health Canada's Food and Drug Regulations.

In 1997, Health Canada adopted Guidance E-6 of the International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use (Health Canada, 1997). This has resulted in the formation of private REBs. Despite certain criticisms, the independence and competency of these private ethics boards are generally recognized.

Health-care facilities have a second ethics committee known as a bioethics committee, a clinical ethics committee (CEC), or simply an ethics committee. The private, not-for-profit, independent organization Accreditation Canada, which measures the performance of health-care and social service organizations against national standards of excellence, has in recent years required organizations to establish an ethics framework that could take the form of a committee (Accreditation Canada, 2013).

Since the early 1980s, when the first committees were established, their mandate has remained essentially unchanged (Doucet, 1985). Despite their evolution over the past 30 years, a recent study on clinical ethics committees in Canadian hospitals confirmed a high degree of stability (Gaudine, Thorne, LeFort, & Lamb, 2010). In general, CECs do not have decision-making powers but act in an advisory capacity.

Although research ethics boards and bioethics committees are firmly established in Canadian health-care facilities, they are the subject of frequent debate. A common criticism is that REBs are not sufficiently aware of realities on the ground and tend to focus too much on the finer points of law and not enough on research participants' ability to understand. In addition, research has changed substantially since REBs were first introduced, with projects being carried out by researchers from different institutions and countries. How, in this context, should multi-jurisdictional research be reviewed at the local level? In some provinces, the answer has been to create provincial ethics boards, like in Alberta with the Health Research Ethics Board (HREB) (University of Alberta, 2013).

As far as CECs are concerned, many feel that ethics consultations on difficult cases should be carried out in collaboration with all parties concerned. In such instances, the CEC seems inefficient, particularly since certain professionals see it as a court of law. A common difficulty for both types of ethics committee has to do with the presence of a community member. While it would not be acceptable to exclude these members from ethics committees, the exact nature of their contribution and the expertise they require remain somewhat unclear.

Expert Bodies/Centers

Canada does not have a national bioethics commission. Quebec is the only province to have a science and technology ethics commission, the *Commission de l'éthique en sciences et en technologie* whose primary mission is to encourage open, pluralistic, and ongoing reflection on the ethical issues associated with scientific and technological activity.

The federal health department created the Health Canada Centre of Expertise in Bioethics which is dedicated to promoting and advancing bioethics in Canada. This is achieved by providing service, information, and a platform for collaboration on bioethics issues within the Government of Canada. The Centre of Expertise in Bioethics is an initiative of Health Canada to integrate ethical principles into public policy, regulation, health promotion activities, and health programs.

As part of a collaborative effort to promote the ethical conduct of research involving human subjects, Canada's three federal research agencies, CIHR, NSERC, and SSHRC, created in 2001 the Interagency Advisory Panel on Research Ethics (PRE), which develops, interprets, and implements the *Tri-Council Policy Statement*: *Ethical Conduct for Research Involving Humans* (TCPS). Finally, a list of academic centers with primary or significant activity in the area of bioethics is available on the website of the Canadian Bioethics Society.

Relevant Legislation

Canada has no federal legislation specifically devoted to bioethics or aimed at establishing a national bioethics commission. However, depending on the activity sector or social issue in question, legislators might consider it appropriate to intervene. New reproductive technologies, for example, are regulated by the 2004 *Assisted Human Reproduction Act* (AHRA). Section 2 of the act evokes ethical values and principles (AHRA, 2004, Sect. 2).

Any sponsor seeking to conduct a clinical trial in Canada involving a therapeutic product must adhere to the *Food and Drugs Act* and associated regulations specifically aiming at protecting human subjects who participate in clinical trials (Health Canada, 2012 *Food and Drug Regulations*, Part C, Division 5).

Since health care in Canada is a shared jurisdiction among the federal, provincial, and territorial governments, some ethical issues applying to nurses and physicians come under provincial and territorial laws. In addition, the protection of vulnerable populations, such as those with a mental disability, falls under specific provincial and territorial legislation.

Public Debate Activities

Canada does not have a national infrastructure specifically devoted to public consultation on bioethics issues. However, when faced with certain potentially

contentious issues, the federal health department has held national public consultations, for instance, on xenotransplantation and on the appropriate use of placebos in clinical trials. In the province of Quebec, the *Commission de l'éthique en science et en technologie* held public consultations as part of its examination of specific issues and also gathered public opinion through online surveys like Online Public Consultation on Assisted Procreation. Canadian researchers can use various forms of public consultation during the course of their research projects, including public debate. There are also research teams who are specifically interested in evaluating citizen participation.

Other

A number of Canadian organizations encourage and participate in debates on bioethical issues. Some granting agencies fund research on topics related to bioethics, while groups and associations promote discussion among individuals interested in these issues.

The Canadian Institutes of Health Research (CIHR), the major federal funding agency for health sciences, is mandated by the parliament to "foster the discussion of ethical issues and the application of ethical principles to health research" as well as "monitor, analyze and evaluate issues, including ethical issues, pertaining to health and health research" (CIHR, ACT, 2000, 4 g, 5d).

Genome Canada, a not-for-profit organization established in 2000, is mandated by the Canadian government to develop and implement a national strategy for supporting large-scale genomics and proteomics research projects, for the benefit of all Canadians. Genome Canada encourages reflection on ethical issues raised by genetic and human genome research by requiring, as a funding condition, that ethical, legal, and social aspects be integrated into all genomics research funded.

Among the various groups promoting discussion in the field of bioethics, the following have made noteworthy contributions: the Canadian Bioethics Society, the Provincial Health Ethics Network (PHEN) of Alberta, and the Quebec Ne3LS network who has, since 2011, funded research on the ethical, environmental, economic, legal, and social aspects of nanotechnology development.

Major Bioethics Issues and Discussions

Beginning of Life

The issue of the beginning of life has been addressed from a number of angles and in relation to various situations. The debate began with the various legal proceedings against Dr. Henry Morgentaler who performed abortions, contrary to the regulations defined by the Criminal Code of Canada. In 1988, the Supreme Court of Canada declared the Canadian law on abortion unconstitutional. On August 8, 1989, the same court recognized that the fetus, regardless of its stage of

development, does not have the legal status of a person either under Canadian common law or under the Quebec Civil Code. From that perspective, a termination of pregnancy could be performed, even if the age of the fetus made it completely viable. The court's interpretation still governs Canadian abortion practice, but requests for third-trimester abortions, although rare, are the subject of much debate in specialized hospitals (CHU Sainte-Justine (Centre hospitalier universitaire mère-enfant), 2007).

With advances in neonatology, discussions regarding beginning-of-life decisions have increased. In the 1970s, new issues arose that were discussed at one of the first bioethics meetings in Canada. At a 1976 symposium, the following questions were addressed: Are all of these babies to be given the most active treatment regardless of the results this treatment will produce? If no, should some babies be allowed to die? Helped to die? How should the decisions be made? In any event, whose notion of life worth living is decisive? (Roy, 1978) In the present context, the Canadian Paediatric Society, the statements of which are the product of collective work, is recognized as the authority on that matter.

Developments in the field of medically assisted reproduction have also given rise to intense debate on the beginning-of-life issue. One of the most controversial subjects relates to the status of the embryo. Does the handling of the embryo required by these technologies respect the embryo? Is the embryo to be seen as a simple biological product? Is it already a human being? What respect is it owed?

End of Life

Since the late 1970s, end-of-life care has been studied from several angles. Initially, three main questions fed the debate.

Question 1: Is it permissible to withhold or withdraw treatment? The theme of quality of life, at the heart of the current debate, was early on very important (Keyserlingk, 1979). Some felt that all available medical means had to be used to respect the sanctity of life.

Question 2: Who should make the decision to withhold or withdraw treatment or to continue or discontinue therapy? Should it be the doctor, family, or patient? The various stakeholders concerned soon reached a consensus: doctors should make the recommendation and competent patients should make the decision, except in emergency situations.

Question 3: On what criteria should such a decision be based? When a patient is competent, the decision has to be based on respect for the person's autonomy because it is the patient who must decide whether the treatment poses serious personal risks, regardless of whether another person has a different opinion. The Civil Code of Québec clearly recognizes this moral perspective. In 1992, Justice Dufour referred to the Code in granting Nancy B.'s request for the withdrawal of the artificial respirator that was keeping her alive, without which she could only survive a few hours (Dickens, 1993). This judgment has set a precedent in Canada. Other criteria must also be taken into account. As noted

by the Law Reform Commission of Canada in its working paper *Euthanasia, aiding suicide and cessation of treatment* (1982), "considerations of quality of life can be legitimate factors in decision-making" (LRCC, 1982, p. 38). A number of citizens might fear that quality-of-life criteria will open the door to discrimination against vulnerable individuals whom society tends to disregard. That is why it is important to put in place rules to protect the interests of incompetent patients as well as patients who are recognized as legally competent but whose vulnerability puts them at a risk of being left out of the decision-making process. The process itself is considered a criterion. It was in this spirit that, in 1984 and 1995, the Canadian Medical Association, the Canadian Nurses Association, the Canadian Healthcare Association, and the Catholic Health Association of Canada issued guidelines for health-care providers working with patients in the terminal phase. These guidelines emphasized the need to establish quality communication among all concerned (Canadian Healthcare et al., 1995).

Two further questions have since been added to the original three that characterized the ethical debate on end-of-life care. The first is related to palliative care (see subsection "End of Life" in the section "Major Bioethics Issues and Discussions") and the second to dying with dignity.

Canadians are still deeply concerned about the issue of dying with dignity. In the past few years, euthanasia and physician-assisted suicide have occupied a central position in public debates. Despite the Supreme Court's refusal to allow assisted suicide in the 1993 Sue Rodriguez case (Rodriguez, 1993), calls for changes to the law and the decriminalization of euthanasia have multiplied. The same court will no doubt soon have to revisit Canadian laws that criminalize euthanasia and assisted suicide, since various Canadian courts are currently deliberating such cases. In 2009, the Quebec National Assembly created the Select Committee on Dying with Dignity to hold a province-wide consultation on end-of-life issues. The two topics that dominated the debate were the autonomy of competent patients and the dignity of individuals suffering from a disease. The committee's report was tabled in March 2012 (Select Committee on Dying with Dignity, 2012) and was followed by another report that was in charge of proposing the content of a legislation that would permit doctor-assisted dying, under very strict conditions (QUEBEC, 2013).

Health and Disease

The WHO definition of health which includes the social aspects of health marks a shift from a disease-driven to a holistic approach. Although the discussion around health in Canada is often linked to disease, there has always been strong support for the WHO definition.

In fact, the WHO definition served as an inspiration for the 1974 Lalonde report, named after Canada's health minister at the time (Government of Canada, 1981). This report put forward a comprehensive notion of health based on four key elements: human biology, environment, lifestyle, and health-care organization. It is considered one of the founding documents of health promotion. At the time of its

publication, the report gave rise to numerous discussions around ethical issues. One of the concerns was that the government was shifting its responsibility from health care to individuals who did not have healthy lifestyles. By putting the accent on lifestyles and individual risk factors, was the government not ignoring the impact of social and economic factors?

The definition also led to the development of numerous actions and therapies designed to promote overall well-being. While many Canadians recognize the limitations of modern medicine, it continues to be the dominant model, transforming the various problems of human life into medically treatable diseases. Pathologies that were nonexistent in the past are today recognized by the health system. This is the case with conditions such as infertility. Viagra is another good example of this tendency, as are certain cosmetic procedures aimed at reconstructing the human body in cases where individuals do not feel good about themselves. A negative body image is seen as a form of disease for which medicine has a cure. A final example is the steady rise in diagnoses and drug prescriptions for mental health issues, including depression and attention disorders. This situation has created a number of ethical challenges in different sectors of society (CEST, 2009b).

Health-Care System, Access to Health Care

In Canada, where the health-care system is a shared jurisdiction between the federal and provincial/territorial governments, the first province to have a publicly funded health-care system was Saskatchewan in 1946. Today, the health-care system is governed by the *Canada Health Act*, adopted in 1985. The federal government monitors the application of the act which is based on five criteria: universality, portability, comprehensiveness, accessibility, and public administration (Canada Health Act, 1985). The federal government transfers money to the provinces for health-related matters and can reduce the funding amount if provinces do not fully implement the act. The ten provinces and three territories are the key providers of health care. They are responsible for planning, financing, and evaluating the provision of hospital care, negotiating the salaries of health-care professionals, as well as fees for physician services. As a result, each provincial insurance plan differs in terms of how far public insurance coverage is extended beyond medically necessary hospital and physician services. All hospital costs are reimbursed, but costs outside hospitals, such as home care and pharmacare, are not automatically refunded.

Since its inception, this system has been the pride of Canadians. At present, the health-care system is facing major management challenges: overcrowded emergency wards, a shortage of family physicians and nurses, inadequate home care, and surgery delays. In response to these problems, provincial governments have established commissions or working groups to examine and make recommendations on the system, its administration, resource allocation models, and service delivery. At the federal level, the government established the Royal Commission on

the future of Health Care in Canada (Romanow Commission) in April 2001. The commission tabled its report *Building on Value*: *The Future of Health Care in Canada* in April 2002. The report included 47 costed recommendations (Royal Commission on the Future of Health Care in Canada (Romanov Commission), 2002).

Resource allocation models are currently under discussion as are issues related to the cost of an aging population. However, a report released by the Canadian Institute for Health Information (CIHI) noted that "population ageing is a cost driver of modest importance relative to other drivers" and that "After hospitals, physicians represent the second-largest category of public-sector health care spending" (Canadian Institute for Health Information [CIHI], 2011, n.p.).

In their search for answers, some researchers have proposed a new, integrated governance model necessitated by the fact that, over the past few years, there has been a move from a hospital-centered model to a model where the hospital is just one component of a complex network (Leatt et al., 2000). For the time being, it is difficult to say where the Canadian health-care system is headed and where it will end up. Some researchers are calling for a move from a focus on health care to a focus on health, paying more attention to the determinants of health. The provision of health-care services to every citizen, based on the values of justice and solidarity, is considered an important part of Canadian identity. Whether this mindset will continue into the future remains to be seen.

Traditional Medicine

The *Report of the Royal Commission on Aboriginal Peoples* (1996) defined traditional healing as "practices designed to promote mental, physical and spiritual well-being that are based on beliefs which go back to the time before the spread of western, 'scientific' bio-medicine. When Aboriginal people in Canada talk about traditional healing, they include a wide range of activities, from physical cures using herbal medicines and other remedies, to the promotion of psychological and spiritual well-being using ceremony, counselling and the accumulated wisdom of the elders" (Royal Commission on Aboriginal People (Erasmus-Dusseault Commission), 1996, p. 348).

The creation of the Institute of Aboriginal Peoples' Health (IAPH) within the Canadian Institutes of Health Research confirms the government's interest in traditional medicine. In a slightly different vein, medicinal plants, which are becoming increasingly popular in the West, are a very lucrative form of traditional medicine and Health Canada maintains a registry of approved.

A 2010 IPSOS Reid survey revealed that 73 % of Canadians regularly use natural health products such as vitamins and minerals, medicinal plants, and homeopathic remedies. The sale of over 1,400 traditional Chinese medicines is authorized in Canada. Recognizing their unique nature, the Canadian government recently created an advisory committee on traditional Chinese medicines with the

mandate to provide Health Canada's Natural Health Products Directorate with advice on current and emerging issues related to traditional Chinese medicines, such as the importation, sale, and use of those medicines in Canada.

Genetics

Since the discovery of the structure of DNA in 1953, followed by the Human Genome Project, there has been an explosion of research in the field of human genetics. As in many countries, human genetics in Canada does not have a glorious past. In the early twentieth century, there was a eugenics movement in the provinces of Alberta and British Columbia, each of which enacted a *Sexual Sterilization Act*, which allowed for the screening and sterilization of mentally disabled persons (Eugenics Archives, n.d.). In research, abuses were committed against Aboriginal population. For example, in the 1980s, blood samples were collected from members of the Nuu-chah-nulth Nation for research aimed at discovering whether this population had a genetic predisposition to rheumatic disease. The participants were never informed of the research results or ensuing publications (Wiwchar, David, 2004).

In Canada, human genetics has generated a lot of interest, particularly among researchers in the province of Quebec, home to several pioneers in the field. This interest is due in part to the presence of a founder effect in the Quebec population, especially in the Saguenay–Lac-Saint-Jean region, where settlement patterns favored genetic homogeneity and the prevalence of certain traits (Laberge & Dallaire 1967).

Clinical Genetics

As a result of the development of assisted reproduction techniques, databanks, and genetic testing to screen for risk factors or vulnerabilities before birth or later on in life, Canadians now have access to a variety of new services. The science of genetics has also been used to screen for risk factors in specific ethnic groups (e.g., sickle-cell anemia and Tay–Sachs disease). However, the accessibility and variety of genetic tests have also increased the complexity of related ethical issues. Canadians have started asking questions about the reliability of consent obtained from patients in clinical settings and the effects these tests may have on privacy, families, and individuals' insurability and employability (Commission de l'éthique en science et en technologie [CEST], 2003).

Genomics and Population Genetics

In Canada, there are several guidelines for genetic research and clinical work, the main one being the *Tri-Council Policy Statement*: *Ethical Conduct for Research Involving Humans*, published in 2010 (TCPS, 2010).

The main ethical issues related to human genetics in both research and clinical settings are tied to the collection, storage, and use of genetic data. The development of biobanks has raised new questions for ethics review boards, which need to

know whether consenting participants are fully aware of the planned retention and secondary use of the data. For example, for the CARTaGENE project in Quebec, a total of 20,000 participants were recruited in the first phase, and the project is now a well-coded open resource for researchers seeking to use collected data to conduct studies on various aspects of genetics.

There are also the issues of preimplantation genetic diagnosis, stem cell research, personalized medicine, unforeseen effects of tests and research, and the quality of information provided to patients and research participants.

Reproductive Medicine

In the 1980s, women's groups and health organizations campaigned in favor of a national debate on assisted reproduction. In reaction to this mobilizing movement, in 1989, Canadian authorities launched an extensive consulting process by implementing the Royal Commission on New Reproductive Technologies which issued its report in 1993. The debates went on for more than 10 years before the adoption, in 2004, of *An Act respecting assisted human reproduction and related research* (Canada 2004). Further, discussions on the management of assisted reproduction have been pursued; for example, the *Commission québé coise de l'éthique en science et en technologie* issued in 2009 a report on that matter (CEST, 2009a).

With regard to the Canadian situation, three main debates have captured the attention of the public: the anonymity of gamete donations, reproductive tourism, and surrogacy, as well as free access to assisted reproduction services.

When developing the Canadian law, the requirement for federal leadership and consistent legislation across the country was repeatedly affirmed. In this regard, the coming into force of the law on *Processing and Distribution of Semen for Assisted Conception Regulations* (Canada, 1996) constituted a first step toward the legislative framework of assisted reproduction by the federal government. It also demonstrated the desire to ensure conformity with quality and control measures with respect to sperm donations across the Canadian territory.

The question of free access to assisted reproduction care raises several issues. The free access would help reduce the number of multiple pregnancies. Another issue was related to the "right" to a child for people who cannot have a child to a natural way. What is the limit of reproductive autonomy with respect to free assisted reproductive care? For example, the Quebec program also includes preimplantation genetic diagnosis (PGD). This can only be done on embryos for the sole purpose of identifying severe monogenic diseases and chromosomal abnormalities.

In summary, assisted reproduction raises issues where the borders of ethics and rights are often interwoven.

Medical Research

In Canada, there has been a considerable evolution in the design of research aimed at improving population health. Up until the 1990s, such research was referred to as "medical research" and was overseen by the federal Medical Research Council (MRC). The MRC was replaced in 2000 by the Canadian Institutes of Health Research (CIHR) who are now funding research projects that cover all aspects of health; from cellular communications to health-care economics, CIHR integrates research through a unique interdisciplinary structure made up of 13 "virtual" institute networks of researchers brought together to focus on important health problems. This change in approach has made it possible not only to expand the field of health research but also to introduce new research methodologies. Quantitative methodologies, which are essential for the advancement of biomedicine, have been complemented by qualitative methodologies. This shift has considerably added to the body of knowledge in health-care services.

The shift in perspective is today widely recognized and these changes have had an impact on research ethics. Since 1998, researchers applying for grant from governmental agencies and whose work involves human subjects must abide by the ethical guidelines, known as the *Tri-Council Policy Statement* that aims to ensure that all types of research involving human subjects are reviewed in a manner that is systematic and adapted to the chosen methodology (TCPS, 2010).

This approach does not please all researchers. A number of epidemiologists, for example, do not see how the review process concerns them, since their area of research is not focused on individuals but on groups and populations (Doucet, 2002). In other situations, both researchers and research ethics boards have expressed a degree of uneasiness (Doucet, 2002; Trudel & Jean, 2010).

Despite considerable progress, as reflected in the CIHR approach, mutual understanding among health research disciplines has not yet been fully achieved. Although some research agencies require project proposals to include an ethical component, they do not yet require an interdisciplinary dialogue involving the social sciences, for example, which take a broader view of the issues and future of our society than the field of bioethics.

Public Health

In *The Future of Public Health in Canada*: *Developing a Public Health System for the twenty-first Century*, the Canadian Institutes of Health Research define public health as "the combination of sciences, skills, and beliefs that is directed to the maintenance and improvement of the health of all the people through collective or social actions"(CIHR, 2003).

Three national organizations strongly advocate bringing ethics into the public health domain: the Public Health Agency of Canada, the Institute of Population and

Public Health of the Canadian Institutes of Health Research, and the National Collaborating Centres for Public Health. Viehbeck and her colleagues provide an overview of these agencies and their respective activities (Viehbeck, Melnychuk, McDougall et al., 2011). While each has its distinctive characteristics, all share the same objective: to protect and promote the health and safety of all Canadians.

National Collaborating Centres for Public Health

The six National Collaborating Centres (NCCs) for Public Health, created in 2005, aim to promote and improve the use of scientific research and other knowledge to strengthen public health practices and policies in Canada. To this end, the National Collaborating Centre for Healthy Public Policy published a preliminary inventory of public health ethics (PHE) researchers and educators across the country in order to forge ties among PHE practitioners, researchers, and policy makers This initiative responds to a growing interest in the relatively new field of public health ethics, which encourages interdisciplinary dialogue and collaboration about collective interventions aimed at protecting and promoting the health of groups and populations. In Canada, as elsewhere, public health challenges often involve a clash between individual and collective approaches.

Infectious Diseases

Although health care in Canada falls under provincial jurisdiction, responsibility for public health is shared by all levels of government. The federal government has been responsible for monitoring infectious disease threats across national borders since the Spanish flu pandemic of 1918. Currently, the federal government plays an important role in the following areas: quarantine legislation and programs, the control of pathogens, and emergency and pandemic preparedness. The prevention and control of infectious diseases in the provinces and territories fall under their respective jurisdictions.

Interest in public health ethics has grown following recent crises involving infectious agents, such as the tainted blood scandal, the occurrence of severe acute respiratory syndrome (SARS) and the A(H1N1) influenza pandemic.

The prevention of infectious diseases was the target of the first public health measures. Some infectious diseases must be disclosed in order for the authorities to assess their spread and take appropriate action. The notion of isolating infected persons, limiting their movement, or recommending (or requiring) immunization of the population brings individual rights into sharp conflict with societal rights. Other principles that come into play are respect for privacy and individual autonomy, as well as solidarity, reciprocity, the common good, and quality of life in society. In some circumstances, it is justified to infringe on an individual's rights for the public good.

Transplantation Medicine and Organ Donation

The rules in Canada regarding organ donation (living or cadaveric) are clear: explicit consent is required. However, the ways in which this consent is expressed vary, depending on whether the donor is an adult or a minor and on the type of donation (living or deceased).

The values underlying organ donation and allocation are solidarity, altruism, and respect for the dignity and autonomy of the person, as well as efficiency, fairness, and justice. The degree of emphasis placed on each of the latter three values in standard organ allocation procedures depends on organ types.

Since organ transplantation is part of physicians' therapeutic arsenal, and medical practice falls under provincial jurisdiction, certain provincial or regional organizations have a mandate to promote organ donation or to allocate recovered organs.

Moreover, the medical care team in charge of patients requiring a transplant is responsible for registering them on the waiting list. This decision is usually made by a multidisciplinary team.

Cadaveric Donation

In Canada, cadaveric donors outnumber living donors. Until quite recently, organs were only retrieved once neurological death had been confirmed. Now, four provinces (British Columbia, Ontario, Quebec, and Nova Scotia) are retrieving organs for donation following cardiac death, which is defined as the irreversible absence of circulatory and respiratory function. This new approach was the subject of national recommendations which are based on the following core values and ethical principles: respect for the life and dignity of all individuals, optimal end-of-life care that respects the holistic well-being of the dying patient, respect for patient autonomy, support for the grieving family and loved ones, public trust and avoidance of actual and perceived conflicts of interest, and, finally, respect for professional integrity (Shemie, Sam et al., 2006). While organ donations following cardiac death are on the rise, the numbers remain low.

Donation after cardiocirculatory death (DCD) raises the issue of determination of death. In addition, the protocol put in place will have an impact on the family of the dying patient, since the organs must be retrieved as soon as possible to preserve their quality, leaving little time for last goodbyes. All of these issues were the subject of extensive deliberation by the *Commission de l'éthique en science et en technologie* (CEST), which issued a position statement titled *Organ Donation and Transplantation*: *Ethical Dilemmas Due to Shortage* (CEST, 2004).

In the context of cadaveric donation, anonymity between the recipient and the donor's family must be maintained. In 2009, Transplant Québec's ethics committee reiterated this position in its *Avis sur la question de l'anonymat des échanges entre les donneurs ou leurs proches et les receveurs* (Comité d'éthique de transplant Québec, 2009).

Living Donation

Until recently, this form of organ donation almost exclusively occurred within families, mainly for immunological reasons. However, the development of improved antirejection drugs has now made it possible for patients to receive an organ from a living donor to whom they are not biologically related. Specific rules have been put in place to prevent the exploitation of vulnerable populations such as children and incompetent adults. To promote living organ donation, certain provinces such as British Columbia, Ontario, and more recently, Quebec have decided to reimburse expenses incurred by donors so they are not unduly penalized.

In November 2010, the Living Donor Paired Exchange (LDPE) registry conducted a paired exchange which, for the first time, included patients and donors from across Canada. The LDPE facilitates kidney donations through exchanges between incompatible donor/recipient pairs. Since its creation in 2009, the registry has facilitated in 2 years the transplantation of 75 kidneys.

In response to the growing demand for organs, Health Canada has looked into xenotransplantation as a possible avenue. For the time being, however, this approach has been ruled out, following a public consultation held in 2000 and 2001 by the Canadian Public Health Association. It is important to underscore that although there is general opposition to organ trafficking, some Canadians are going to other countries to get transplantation.

Emerging Technologies (Nanotechnology, Information Technology, etc.)

Over the past few decades, emerging technologies have helped change research and medical practice considerably. This growth in information and communication technologies was made possible by developments in devices related to informatics, microscopy, engineering, and nanotechnologies. With the advances promised by the convergence of a number of video, telephone, computer, Internet, and scanner technologies come ethical issues that, while not necessarily new, have to be examined from a different angle.

Study of the applications and issues connected with emerging technologies is complex, since jurisdiction over health is shared in Canada and the strategies therefore vary from one province to another.

Nanotechnologies

Nanotechnology is a good example of a technology that has come out of the convergence of information, biotechnologies, and cognitive sciences. In Canada, as early as 1999, the Canadian Institute for Advanced Research launched its advanced microelectronics program. In the years that followed, there were many developments in this field.

In 2003, the Canadian Institutes of Health Research started up a research program on regenerative medicine and nanomedicine that included a section on biomedicine and biotechnology.

With regard to ethics, in 2006, the *Quebec Commission de l'éthique de la science et de la technologie* produced a position statement, *Ethics and nanotechnology: A basis for action* (CEST, 2006). In the same vein, in 2011, following the production of an action plan, Quebec officially launched Ne^3LS, a knowledge network on the ethical, environmental, economic, legal, and social aspects of nanotechnologies. The main objective of this network is to foster the development of nanotechnology research activities.

The capacity of nanotechnology applied to regenerative medicine opens windows on improved health and increased longevity for human beings, but how far should we go in that direction? This question is being addressed in Canada, as in a number of other countries, by researchers in the humanities and social sciences. Those researchers are analyzing the possible applications of nanotechnologies to diagnostics and treatments, as well as to regenerative medicine, and are trying to determine whether the enthusiasm over them is justified and whether, to some extent, the wool is being pulled over consumers' eyes (Caulfield, Timothy, 2011).

Personal Health Records

The possibility of using technology to build and transmit patients' personal records is another application of the emerging technologies that is researched in Canada. It offers indisputable advantages in terms of speed of access to the data. However, it can lead to breaches of confidentiality and invasions of privacy. There is also a risk that it will help focus medicine and resources on the individual, and not on the needs of the community, leading to a displacement of the health system costs.

Embryonic Stem Cells

In 2002, the Canadian Institutes of Health Research published guidelines for human pluripotent stem cell research (CIHR, 2010). The guidelines emphasized that stem cell research must be based on the following guiding principles: health benefits for Canadians; free and informed consent, provided voluntarily and with full disclosure of all information relevant to the consent; respect for privacy and confidentiality; and no direct or indirect payment for tissues collected for stem cell research and no financial incentives. These guidelines announced the creation of a stem cell research oversight committee and of a registry of stem cell lines generated in Canada. These guidelines were reviewed in 2006, 2007, and 2010. In March 2004, the *Assisted Human Reproduction Act* came into force and applies to the obtaining of stem cells from human embryos and allows the use of unwanted embryos, but not research on germ lines.

Neurosciences

The development of medical imaging research and the increase in health professionals' and researchers' access to scanners have created great hope for treatment of, among other things, mental illness and cerebral palsy. However, this exploration of the brain may also lead to shifts in directions that, again, may cross certain boundaries and interfere with research subjects' and patients' autonomy.

Neuroethics, which is aimed at the study of these issues, has developed in a number of Canadian provinces, for example, there are the National Core for Neuroethics at the University of British Columbia, the Neuroethics New Emerging Team (NET) at Dalhousie University, and the Neuroethics Research Unit at the Institut de recherches cliniques de Montréal. In addition, at the Canadian Institutes of Health Research, there is the Institute of Neurosciences, Mental Health and Addiction (INMHA), which provides financial assistance for neuroethics research.

Intensive Care

Intensive care plays a key role in modern medicine. Its successes pose considerable challenges to practitioners in the field. The ethics sections of many Canadian critical care societies "have proposed a number of policies describing the goals of intensive care unit (ICU) care and providing broad guidance on the diagnoses and physiological criteria that would mandate using the specialized skill and technologies of an ICU environment" (Hawryluck, Bouali, & Meth, 2011, pp. 254–262).

Although it has been clearly established, both ethically and legally, that there is no distinction between withholding and withdrawing treatment, the same is not true at a practical level. In all situations where the life of an individual is at stake, cultural, religious, family, and personal values come to the fore and interact with medical criteria, making the form and content of communication critically important. To date, the policies "do not provide any definitive guidance in the difficult decision making faced by clinicians" (Hawryluck et al., 2011, p. 262).

Another broadly debated issue in Canada is that of resource allocation. ICUs often have insufficient beds to meet the demand. In addition, ICU costs are extremely high, and the development of increasingly sophisticated technology is only driving them higher. Ethical discussions here tend to revolve around two questions: Must we ration intensive care services and refuse to start or continue futile treatments? Nurses play a critical role in intensive care units. Their work is extremely demanding, on both a technical and human level. They often find themselves in a difficult position, because they have to enforce decisions in which they played no part. The most common example is when a decision is made to withdraw treatment, with all of the ensuing implications for the patient and family. Such situations cause a great deal of distress for many nurses (Pauls, McRae, Campbell, & Dungey, 2004).

Palliative Care

The concept of palliative care originated in Montreal in 1973, when Dr. Balfour Mount introduced at the university-based Royal Victoria Hospital the "hospice care" approach. Mount believed that, with its potential to change prevailing attitudes, hospice care would be a boon to all patients receiving end-of-life care in hospital. The debate continues (Senate of Canada, 2010).

When palliative care was first introduced, there was extensive debate around various ethical issues like pain control. The first concerned pain control. Few hospitals run palliative care units, and reports have consistently emphasized the shortage of beds for this type of care. In some parts of the country, there is a move toward building hospices. The focus of palliative care is on achieving comfort and ensuring respect for the person nearing death and maximizing quality of life for the patient, family, and loved ones. In current debates on the decriminalization of euthanasia and assisted suicide, some authors propose seeing palliative care as one stage in a continuum of care that could include euthanasia (Collège des Médecins du Québec, 2009). For others, such an approach undermines the basic philosophy behind palliative care.

Care for the Elderly

Care of the elderly is becoming a major source of concern in Canada. It is impossible to discuss the challenges faced by the country's various health systems without mentioning the burden of the aging population. Will care of the elderly cause health costs to skyrocket? The answer provided by the Canadian Institute for Health Information (CIHI, 2011, pp. 15–20) is far more nuanced: the pressure of aging on health costs is moderate compared to other factors such as inflation, technologies, and salary increases.

In her study on the evolving care needs of older Canadians, gerontologist Neena Chappell (2011) notes that when health fails, care is increasingly provided by unpaid family and friends, more often women than men. Caring for people with chronic conditions (particularly dementia) is often stressful for caregivers, who might be seniors themselves. It is therefore important to develop policies that support the needs of informal caregivers and to make provision for formal long-term home care. Chappell calls for a reexamination of the assumption that "medical care is the most appropriate means to ensure the health of an ageing population" (Chappell & Neena, 2011, p. 1).

A second problem concerns treatments provided to the elderly. The question of upper age limits for treatment is the subject of frequent debate among caregivers and the general public. The discussions reflect our views on aging. For years, the refusal to offer treatments to people who had reached a certain age was based purely on the fact of aging. This position is no longer tenable: the person's health condition is now the determining factor. Acute care for certain illnesses is certainly provided, but is the patient's age taken into account?

Care for the elderly is developing in a fairly paradoxical manner. Concurrent with ageism is the fight against aging. Signs of ageism include a tendency in certain settings to infantilize the elderly, to qualify hospitalized patients in long-term care as "bed blockers," and to move older patients to the bottom of the waiting list for a medical procedure. The fight against aging is a rapidly growing trend, spurred by the development of new technologies. A number of scientists see aging as a painful biological decline that can be controlled through regenerative medicine.

Although the potential of biomedical gerontology research is unknown, it has become a key focus of scientific endeavor and has the potential to extend the average lifespan.

To prevent situations of discontinuation of therapy or aggressive medical intervention, organizations overseeing the practice of medicine and citizen groups are now promoting advance care planning (Health Canada, 2008). The procedure involves discussing with the patient and loved ones the type of care the person would like to receive in the event they become incapable of providing informed consent.

Chronic Diseases

The burden of chronic illness is increasing dramatically in Canada. The current health-care system, which was designed to handle short-term illnesses, injuries, and infections, cannot meet the care needs of the growing number of Canadians living with chronic and complex medical conditions. According to the Health Council of Canada, "The burden of chronic health conditions on Canadians, the health care system, and our economy is enormous and growing. Canadians with chronic conditions account for over 70 % of all nights spent in hospital" (Health Council of Canada, 2008).

Canada's public health-care system does not cover long-term care. The *Canada Health Act*, which was adopted in 1984 replaced various laws dating back to the 1960s, covers only "medically necessary services." There is therefore no national coverage of chronic care. Services delivered to patients with chronic conditions fall entirely under provincial jurisdiction and vary widely from one province to another.

Since the 1980s, approaches to chronic conditions have changed substantially. The new perspective "represents patients as analysts of their chronic illnesses experiences, articulates disease management within the context of a more general life management and, more recently, depicts patients as active agents in attaining a desired outcome" (Paterson & Thorne, 1998, p. 73).

Psychiatric Care

Toward the mid-nineteenth century, there was a move across Canada to improve the treatment and living conditions of the "insane." However, the social role of psychiatry was primarily to protect society against the risks of deviance posed by mentally ill patients. In addition, the rights and dignity of institutionalized patients were barely respected. One has only to think of what happened during the 1950s and early 1960s at the Allan Memorial Institute in Montreal, where Dr. Ewen Cameron was investigating a "psychic driving" treatment for depression (partially funded by the CIA), which consisted of massive amounts of electroconvulsive therapy, heavy sedation, and endlessly repeated tape-recorded voices. Many patients did not respond to this treatment and some suffered irreversible damage. The revelation

of these treatments had a major impact on the development of research ethics in Canada.

Debates around deinstitutionalization in the 1960s reflected the profound changes occurring in the mental health field at the time. Several factors explain the transformation of psychiatry. There was, of course, the shift from large asylums to community psychiatric services, supported by the advent of psychopharmaceuticals. These drugs significantly advanced the treatment of psychotic disorders but also led to major debates on optimal therapeutic approaches in mental health care. The process of deinstitutionalization was also inseparable from the growing civil rights movement throughout the West (Davis, Simon, 2006). These three factors played a major role in shaping existing psychiatric practices in Canada.

The therapeutic objectives at the outset of deinstitutionalization included improved access to services adapted to patients' needs, more favorable treatment in the community, and maximum social integration. However, 40 years later, the public perception is that this policy was largely borne of fiscal and legal necessity and not of logically analyzed mental health considerations. Critics charge that mentally ill patients have simply been released onto the streets. According to some studies, the policy of deinstitutionalization has not been implemented consistently across geographical areas and does not articulate either the conditions under which full implementation would exist or the expected outcomes from successful implementation (Barnes & Toews, 1983).

The question of how best to organize psychiatric care and mental health programs is still under discussion in Canada. The final report of the Ontario Legislative Assembly's Select Committee on Mental Health and Addictions, tabled in 2010, shows the challenge of developing programs tailored to the needs of different clienteles (Select Committee on Mental Health and Addictions, 2010).

More than in any other medical specialty, the epistemologies informing mental health care have major consequences for the patient. Depending on whether a biomedical or biopsychosocial model is adopted, the treatment and care provided to the patient will be completely different. The person of the patient is not viewed the same way. Canada has adopted the second model. The goal of mental health promotion for people with mental illness is "to ensure that these individuals have power, choice and control over their lives and mental health, and that their communities have the strength and capacity to support individual empowerment and recovery" (Public Health Agency of Canada, 2005).

In Canada and throughout the world, there has been a marked increase in the prescription of psychotropic drugs and in the diagnosis of certain mental disorders. At the same time, it has been noted in recent years that healthy people are using this type of medication to enhance their intellectual and job performance. As noted by the Commission de l'éthique en science et en technologie du Québec, "Western societies are experiencing the medicalization of events, emotions and things that are not necessarily part of the biomedical field. In medicalizing life events, this phenomenon promotes the expanded 'non-traditional' use of medications" (CEST, 2009b, p. xviii). The medical field is now more aware of mental health issues, but it is also helping to promote ideal notions of performance and normalcy.

Pediatric Care

Children occupied an important place in the first Canadian bioethical debates. The decisions to be made concerning newborns born prematurely or with congenital defects prompted debate on the obligation to continue or stop treatment. Since then, in both neonatology and other areas of pediatrics, advancement of knowledge and discussion has led to the establishment of rules on which there is generally consensus when a decision must be made to start, continue, or stop treating a severely ill child (Harrison, 2004). It is up to the parents to make the decision. However, they must base the decision on the child's best interests, which are not always easy to identify. In the case of a major disagreement, where it is believed that the parents' decision is not in the child's best interests, the institution may go to court to resolve the conflict – for example, when the parents of a Jehovah's Witness refuse a blood transfusion when it is considered the only way to save the child's life.

In recent years, children have become active participants in their care, with legal and ethical development of informed consent and recognition for the role of the patient in decision-making. In most Canadian jurisdictions, it is now recognized that adolescents can give independent consent for reproductive health services. When children lack legal force to give informed consent, health-care providers are strongly invited to ask them for their assent. This approach is the same in research with children and adolescents (TCPS, 2010, pp. 43–45).

Particular attention is now paid to new concerns regarding treatments for severely ill children. One relates to advance care planning, which requires "effective communication to clarify the goals of care and establish agreement on what treatments may or may not be appropriate to achieve these goals, including resuscitative and palliative measures" (Tsai, 2008, p. 791). Another issue relates to the conditions for the ethical acceptability of withholding or withdrawing artificial nutrition and hydration. Concerning the latter, the Bioethics Committee of the Canadian Paediatric Society has raised two questions. In some specific cases, may withholding or withdrawing artificial nutrition and hydration be considered as part of a palliative care plan? Since artificial nutrition and hydration are "medically assisted" or "medically provided" nutrition and hydration, should they not be considered on the same basis as any other treatment? (Tsai & Canadian Paediatric Society, 2011) Another ethical issue in pediatrics is related to the fact that many parents are opposed to the immunization programs put in place by the public health authorities and pediatricians' associations. They oppose them out of concern for their children's well-being, while the programs are designed to protect public health (MacDonald & Pickering, 2009).

Cases of abuse are another occasion of tension between parents and professionals working in the health sector. Here, the question of parental authority arises. Is it absolute? Under what conditions can it be diminished or even nullified? The guidance documents produced in that connection put forward some principles that are not specifically defined as ethical principles, even though that is what they are. The child's best interest is affirmed in them as a basic principle, but respect for

parents is also affirmed as follows: "While the needs of the child are paramount, all interactions must take into account diversity with respect to family, culture, language and abilities" (CPS, 2007, p. 6).

Emergency Care

Emergency care immediately evokes the image of a hospital emergency department (ED). It also refers to the job of paramedics and the measures put in place to protect the public in cases of infectious disease such as the H1N1 outbreak. Each of these practices has its own ethical requirements tied to the different settings and situations in which health-care professionals operate.

In Canada's major cities, hospital EDs is often overcrowded. The emergency team has to decide whether to refuse new patients by redirecting ambulances to other hospitals in the city. Evidently, this increases risks to patients' health and life. However, admitting new patients to overcrowded departments will affect those already admitted, who may not be able to receive the care they need. In ethical terms, what is the legal duty of the hospital and physicians to provide care to patients in such circumstances? (Walker, 2002). For many, behind this first question lies another, more basic question, related to both ethics and management. For many years, it has been said that "the cause of ED overcrowding generally lies outside the ED. Efforts to maximize ED efficiency are important, but overcrowding is a symptom of system failure" (CAEP, 2001, p. 83).

The work of emergency health-care professionals is different from the one done by their colleagues working in other hospital units. This context also casts classic ethical questions in a different light. What to do when a patient refuses recommended care, without which his or her life cannot be saved? How to interpret the advance directives of a patient whose decision-making capacity is temporarily impaired as a result of an accident? (Pauls et al., 2004).

Paramedics, formerly referred to as ambulance attendants, are another face of emergency care. In most Canadian provinces, they are considered health-care professionals. One of the difficult situations faced by them is how to deal with homeless people when they have urgent health problems and respond within a reasonable time frame especially in rural areas.

General Practice

In Canada, general practice "is the branch of medicine concerned with providing care (known as 'primary and continuing care') to patients irrespective of their age, sex or type of problem. General practice is also known as 'family practice'" (McWhinney, 2012). General practitioners are supposed to know their patients well and to be able to identify health problems early on.

General practitioners are faced with an aging population, the feminization of the profession (female physicians wanting to spend time with their family), and

a growing corpus of knowledge generated by the development of science and technology. In response to these challenges, the medical establishment has authorized GPs to receive assistance from specialized nurse practitioners ("super-nurses") who are able to carry out certain procedures that were formerly limited to physicians. Models like capitation or family physician teams have also been implemented in some provinces to ensure the population has ongoing access to health care. On the knowledge front, the provinces have tried out different models to promote knowledge sharing. One of these is the concept of "community of practice," borrowed from the business sector. This model has been applied in various ways and has received mixed reviews in Canada (Lee et al., 2009).

Health Promotion and Education

Since hosting the first International Conference for Health Promotion in November 1986, Canada has played a leading role in health promotion. Given this fact, it is not surprising that health promotion occupies a central position in a number of national health initiatives and strategies. These strategies clearly demonstrate the need to combine approaches, propose interdependent strategies, and encourage partners to promote behavioral changes aimed at improving population health. Tobacco use is not the only behavior the authorities would like to cut down. Alcoholism, overweight, and physical inactivity are also drawing the attention of those who want to promote better health among all Canadians, irrespective of their age, gender, ethnic background, or social status. The ultimate goal is to encourage healthy behaviors, a guarantee of well-being. However, the adoption of a legal framework raises questions about the state's interference in private life on the pretext of seeking to modify people's behavior for their own good.

Scientific and Professional Integrity, Conflict of Interest, Corruption

As in many countries, the research context has changed dramatically over the past 20 years. It has become very competitive and global and is funded by both the public and private sectors. Consequently, the pressure on researchers to produce results has been growing. The rapprochement between the pharmaceutical sector and the public sector increases the likelihood of conflicts between researchers and sponsors in clinical settings and in publications.

One well-known instance in Canada is the Olivieri case. In 1996, she came to believe, during the clinical trials she was performing, that an experimental iron-chelating drug (deferiprone) in patients with thalassemia was losing efficacy and causing serious adverse effects. At that time, "it was possible for clinical investigators to sign contracts with industrial sponsors for research trials containing provisions that protected the sponsors' interests, but not the public interest or the safety of trial participants [. . .]. The academic freedom of an investigator to publish

adverse findings and inform the scientific community could be at issue" (Thompson, Baird, & Downie, 2001, p. 3).

The case became public in 1998, when Olivieri published her findings. She lost her position and then received the support of the Canadian Association for University Teachers (CAUT). CAUT became involved in 1999 and commissioned a report defending academic freedom and scientific integrity (Thompson et al., 2001). Olivieri got her job back and has become an icon of scientific integrity across the world.

In Canada, publication guidelines have been reviewed recently. In 2009, the *Canadian Medical Association Journal* revised its policy with a view to strengthening the credibility of medical literature (Stanbrook et al., 2009). Researchers are required to declare their conflicts of interest to a Research Ethics Board (REB) when they are submitting a research project. Since 1994, researchers and universities have also been required to follow policies developed by the *Tri-Council*.

In 2009, the Canadian Minister of Industry asked the Council of Canadian Academies to conduct an assessment of research integrity in Canada, and in 2010, the Expert Panel on Research Integrity published its report entitled *Honesty*, *Accountability*, *and Trust*: *Fostering Research Integrity in Canada*. It provides the best overview of the history and the current status of research integrity in Canada. The Expert Panel recommended the creation of a Canadian Council for Research Integrity (Research Integrity & Council of Canadian Academies, 2010).

Following the Expert Panel Report and a consultation process, the Canadian granting agencies issued, in December 2011, a new framework entitled *Tri-Agency Framework*: *Responsible Conduct of Research*. This new framework is an umbrella document that describes agency policies and requirements related to applying for and managing agency funds, performing research, and disseminating results. It also outlines the process that institutions and agencies follow in the event of an allegation of a breach of agency policy (Panel on Responsible Conduct of Research, 2011).

Relations with Industry and Donors/Sponsors

There are close ties between industry and health both in biomedical research and clinical activities in the health services network.

In recent decades, medical research has become increasingly dependent on industry financial support. Universities encourage their members to enter into partnerships with industry to finance research. Government funding agencies insist on permanent ties with the private sector to ensure knowledge transfers and facilitate the marketing of products resulting from the research. As a result, there is an increasing emphasis in biomedical sciences on applied research, to the detriment of basic research. These situations can lead to conflicts of interest related to financial affiliation between researchers and industry.

The Canadian Medical Association (CMA) has a policy titled *Guidelines for Physicians in Interactions with Industry* (Canadian Medical Association [CMA], 2007).

Canada's Research-Based Pharmaceutical Companies (Rx&D), a national association representing over 50 companies, has echoed the concerns of the Canadian Medical Association by adopting a Code of Ethical Practices with chapters on the various aspects of the relationship between the pharmaceutical industry and health-care providers (Rx&D, 2012).

Future Challenges

In the Field of Bioethics Infrastructures (Need for Legislation, Ethics Committees, Ethics Education, etc.)

In Canada, the development of laws and the implementation of new infrastructures (ethics committees or ethics education programs) are always tributary to the distribution of power between provinces, territories, and the federal government. Health being a shared jurisdiction and education a provincial jurisdiction (there is no National Education Ministry). Therefore, the challenge is, and will be in the future, to proceed with federal–provincial negotiations for everything related to the legislation or the harmonization of bioethical practices. Generally, the federal government and provinces have agreed upon frameworks and standards that can be implemented differently in the provinces and territories. Bioethics, which is a part of health, is managed in the same way. Therefore, if a national accreditation system must be put into place, the provinces must hold prior consultation on its administration. Otherwise, if there is a dispute, the cause may end up in Supreme Court, as was the case with assisted reproduction.

The challenge remains to ensure that the frameworks and practices do not differ too much from one jurisdiction to another in order to prevent the exodus of researchers that would benefit more from working in a less severe jurisdiction with respect to management.

In the Field of New and Emerging Issues

Although in Canada they may vary from one province to another, the main challenges in the field of new and emerging issues are as follows:

Multiculturalism

Canada is a country of immigrants, and most of its regions promote multicultural policies. This context explains some of the bioethical debates taking place in this country. To combine respect for diversity with common citizenship, the Supreme Court of Canada uses a criterion it calls "reasonable accommodation."

Being a country where Francophones and Anglophones coexist, as well as aboriginal communities and several multicultural communities, it is often difficult to resolve ethical and bioethical issues when developing legislations and practices, particularly in a clinical setting. Without wanting to fall into cultural relativism

allowing everyone to do what they want, Canada seeks to establish practices in order to accommodate everyone, which is not easy and renders the decision-making process rather difficult for health stakeholders and bioethicists.

Sharing of Power

The increased interest of citizens about their health and the possibilities offered on line continue to solicit medical power. The paternalism of doctors is challenged more and more and the patient–doctor relationship must change in order that there is a more equal relationship between them. Feminist bioethics, with the work of Susan Sherwin, marked the bioethics discourse in Canada and helped expand narrative ethics. The future challenge will be to continue this work and train future doctors in this practice. Lastly, the development and expansion of new professions, such as clinical nurses, occupational therapists, and psychotherapists, have also contributed to challenging medical power and requiring more participatory approaches with respect to making decisions.

Citizen Participation

Citizen consultation on several questions has been instrumental in Canada for a long time in making decisions about several issues. Bioethics is no exception and several citizen consultations and forums have taken place over the past few years. The future challenge is to evaluate when to consult the public (Jean, Deleury, Duquet et al., 2007) and whether or not these mechanisms attain their goals or if they are merely tools for seeking credibility of the decision or a form of assent in face of the proposed solution.

Bioethics as a Disciplinary Field

In Canada, contrary to other countries, bioethics encompasses several clinical and research disciplines. Social sciences are considered as being part of the definition of bioethics, as well as health sciences. However, despite appeals for interdisciplinarity, there remain several barriers to overcome before this idea becomes a reality.

Discussions on an approach based on universal principles versus local principles have been held in Canada. Decisions made on principlism are often challenged when other decision-making techniques based on question contextualization or human rights or narrativity are proposed.

Collective Disasters

Given that bioethics is traditionally focused on the individual, it is difficult to examine the questions at the population level. The emergence of infectious diseases in recent years, such as AIDS and H1N1, and the possibility of bioterrorism pose the question of public health and common good. Policies and practices that limit the freedom of individuals are sometime needed.

Questions About End of Life

These questions that include palliative care and euthanasia or organ transplant are largely discussed in Canada and several working groups have recently discussed the

matter. In the years to come, this challenge will surely be a part of the discussions on the allocation of health resources, home care, and the use of new technologies.

New Technologies

New technologies have led to promising research and practice possibilities. Accordingly, in Canada and around the world, these possibilities have given rise to enormous hope for improving or even curing cancer or Parkinson's disease or Alzheimer's disease. The possibility of creating population databanks has opened the possibility of their use in public health in order to target the cohorts of people susceptible of having certain diseases. However, all of this has raised questions about privacy, discrimination, the right not to know, and the risk of no longer obtaining insurance or employment. In Canada, there is no law that requires the nonuse of genetic profiles by insurance or employment applicants. Insurance companies cannot request genetic tests but can ask whether or not the person wanting to be insured has undergone the tests. The challenge would be to determine the best way to find a solution to this practice because possible predictive medicine research participants, for example, can refuse for fear of being prevented from being insured.

For each new innovation, critical evaluations of all applications must be carried out in order to evaluate the risks and the benefits. Researchers and clinicians will require an ethical conscience that goes beyond the submission of a question or project to an ethics committee.

Globalization

Most of the challenges that have been raised for Canada include a global justice aspect. In effect, Canada, although pockets of poverty exist, remains a rich country where taking poor countries into consideration is not always a concern. One of the major challenges that Canada will have to overcome is its participation in global justice. Will it be ready to allocate a percentage of its resources to the physical and mental well-being of the citizens of less fortunate countries? Will it be ready to contribute to the education of researchers in these countries?

At a time when drugs or surgeries help Canadians have a healthier life, one might wonder whether or not their individual concerns will prevail over their traditional solidarity.

Summary and Conclusion

The challenges explained in the section with respect to this question constitute Canada's agenda for the future of bioethics development in this country. The issues related to the sharing of skills within the Canadian federation and its proximity to the United States forced Canada to constantly strive to develop high-quality researches and clinical practices while respecting the dignity of its citizens.

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Haihong Zhang and Yali Cong

Bioethics Development

Introduction

The development of biotechnology in the twentieth century, especially after the Second World War, raised a series of tough issues that challenged traditional moral

H. Zhang
Department of Philosophy, Peking University, Haidian District, Beijing, People's Republic of China
e-mail: zhanghh@pku.edu.cn

Y. Cong (✉)
Department of Medical Humanities, Health Science Center, Peking University, Haidian District, Beijing, People's Republic of China
e-mail: ethics@bjmu.edu.cn; ethics@mail.bjmu.edu.cn

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ideas about medicine and human life. Without a doubt, these new technologies and skills give people more power than ever: seriously ill persons can be cured by organ transplantation or other treatments and infertile couples can have babies by assisted reproductive technologies. However, in the field of medicine that is intimately connected with life quality and human dignity, limitations still exist, particularly in the context of modern civilized society. How decisions are made in this context in a justifiable and moral manner requires precaution and prudence. The word *bioethics* was coined by Van Rensselaer Potter in 1971 in his book *Bioethics: Bridge to Future*. Later, the implications of this terminology changed from its original use by Potter, though people still use *bioethics* to refer to a new, multidimensional research including biology, medicine, anthropology, sociology, life science, and moral philosophy. The United States took the lead, with the founding of The Hastings Center in 1969 and the Kennedy Institute of Ethics in 1971. This resulted in the rise of bioethics as an interdisciplinary subject in the 1970s.

Development of Bioethics in China

In the early 1980s, new technologies and concepts such as artificial insemination (AI), assisted reproductive technologies (ART), and euthanasia were introduced in China and ethical discussion began concurrently. Thus, bioethics, as a new phase of medical ethics, emerged in China nearly 30 years ago. Professors Renzong Qiu, Zhizheng Du, Ruicong, Peng, Zhaoxiong He, Hongzhu Zhang, Benfu Li, and Dapu Shi were the first generation of scholars who introduced bioethics and have been the major disseminators and researchers in the field of bioethics and medical ethics in China since then. Whereas, in the West, bioethics referred to a new field devoted to human survival and improvement of life quality (Callahan, 1995, p. 250), Chinese scholars placed it in the domain of the much older field of medical ethics. They considered bioethics as an extension of medical ethics (Qiu, 1987, p. 6), as bioethics was closely related to the application and use of advanced biomedical technologies. Gradually, bioethics has become more independent, with a broader scope than medical ethics. Scholars began to emphasize that bioethics and medical ethics should not be taken as two unrelated branches of learning; rather, bioethics is both the heir to and the further development of of medical ethics (Du, 2000, p. 155). With regard to several topics, the distinction between bioethics and medical ethics no longer exists.

The development of bioethics in China is partly driven by the same factors as in Western countries, however, it has its unique background. The rapid progress of life science and medical technologies has directly motivated the rise of bioethics, and, in addition, philosophers and ethical researchers became more interested in practical issues, which lead to the development of bioethics from a theoretical perspective. At the same time, a number of practical problems caused people to consider ethical issues in a more comprehensive and focused way. Two remarkable events in particular too place in China in the 1980s that not only initiated the public

discussion but have also been the direct cause of people's interest in bioethics. One was the development of artificial insemination (AI) technology and the legal cases concerning the use of AI, and the other was the case of the first patient who asked for euthanasia in Shaanxi Province in 1986. In 1988, Professor Qiu and his colleagues organized the first national symposia on Euthanasia and Assisted Reproductive Technologies in Shanghai and Yueyang (Hunan province), respectively.

The major concerns of Chinese bioethics, as well as medical ethics, have broadened significantly during the past three decades. Besides issues like the physician-patient relationship, it is reasonable to say that bioethics research in China began by mainly focusing on both ends of the life span – the ethical implications of assisted reproductive technologies and the ethical problems or dilemmas surrounding euthanasia. Now, nearly 30 years later, these problems remain vivid and active in the discourse of bioethics in China, even though the discussion and research go far beyond them, including clinical ethics, research ethics, public health ethics, genethics, neuroethics, and emerging technologies like stem cell research and biobanking.

Current Bioethics Infrastructure

During 30 years' development, bioethics research in China has been fruitful. First and foremost, a series of textbooks and monographs have been published. The first textbook of medical ethics after the Cultural Revolution was *Outlines of Medical Ethics*, edited by Zhizheng Du in 1985. Renzong Qiu published a textbook titled *Bioethics* in 1987, which was the first book that systematically introduced Western bioethics in China. Zhaoxiong He's *History of Chinese Medical Morality*, published in 1988, introduced the development of medical ethics in China. Benfu Li published the *Textbook of Medical Ethics*, which is still widely used by medical universities, in 1996. Another influential book, *Collections of Chinese and Foreign Medical Moral Standards*, published by Hongzhu Zhang in 2000, contains a full and accurate understanding of moral codes. The *Encyclopedia of China Medicine* (*Medical Ethics volume*), chiefly edited by Zhizheng Du, is due for publication in 201•. Other books, like *The Review of Chinese Medical Humanities*, are becoming increasingly influential. There are significant translated works in bioethics as well. Shen Liu translated Singer's *Practical Ethics* in 2005; Ruiping Fan translated the *Foundations of Bioethics* (H. Tristram Engelhardt, Jr., second edition) in 2006. The translation of the *Classic Cases in Medical Ethics* (fourth edition) was published by Jingbao Nie and Linying Hu in 2010, and *Intervention and Reflection: Basic Issues in Medical Ethics* was translated by Xia Lin in the same year.

Influential journals appeared, witnessing and contributing to the development of bioethics in China. *Medicine and Philosophy* (started in 1980) and *Chinese Journal of Medical Ethics* (started in 1988) have played an indispensable role in the promotion of ethical research and public debate in China. Other journals such as *Medicine and Society, Research of Natural Dialectics, Morality and Civilization, Philosophy Trend*, and *Medical Education*, are also influential. Over the past three

decades, these journals have played an increasingly significant role in disseminating the knowledge of bioethics in China. Many research projects and theses on euthanasia, human embryonic stem cell research, and reform of health policy have been published.

Several societies and associations related to bioethics were founded at various levels in China. One of the most prominent is the Medical Ethics Society, founded in 1988 as a branch of the Chinese Medical Association (CMA). In July 2011, the 16th Annual Symposium of the Medical Ethics Society, held in Liaoning Province, was regarded as one of the most important platforms for Chinese experts in medical ethics and bioethics. The Chinese Bioethics Society, founded in 2007 under the auspices of the Chinese Society for Dialectics of Nature/Philosophy of Nature, Science and Technology, has been organizing the annual National Bioethics Conference since 2007. Over 4 years, a number of scholars, experts, and researchers from mainland China, Hong Kong, and Taiwan worked together to study ethical problems in the fields of stem cell research, public health ethics, animal research ethics, and biomedical research involving human subjects. One landmark particularly worth mentioning was the eighth World Congress of Bioethics, held in Beijing in 2006. Bioethicists from all over the world came to Beijing and exchanged their investigations on public health ethics and health policy, life science technology and research ethics, clinical ethics and medical professionalism, bioethics, culture, religion, and human rights (Li, 2006, pp. 11–15). Other organizations, such as the Chinese Medical Doctor Association (CMDA, founded in 2002), established the Morality Construction Committee, which is responsible for promoting theoretical research in medical ethics and providing ethical consultation for medical professionals. This committee issued the Chinese edition of the Physician Charter in June, 2011. This Charter declared six principles as health professional behavior norms: (1) Be equal and beneficent; (2) Patient's interest first; (3) Be sincere and trustworthy; (4) Diligence and prudence; (5) Honesty and justice, and (6) Lifelong learning to be competent.

A number of bioethics centers and medical ethics centers were established in universities and institutions. To date, the Chinese academy of medical science and Peking Union Medical College in Beijing, Fudan University in Shanghai, Huazhong University of Science and Technology in Wuhan, Shandong University in Ji'nan, Southern University in Nanjing, and Peking University Health Science Center have established bioethics centers and medical ethics center as platforms for further communication and for national and international exchange.

Along with the development of resources mentioned above, crucial steps have been taken in regard to teaching and training programs in China. Medical ethics courses are required by the Ministry of Education in all medical universities, and bioethical courses are provided in some comprehensive universities. Recently, a growing number of universities, medical colleges, and particularly their young scholars have engaged in bioethics, investigating cutting-edge issues, including human reproductive cloning, human embryonic stem cell research, and the Genome Project. The bioethics courses and lectures are more abundant now than 20 years ago, not only because new content and cases have been added, but also because the

interaction between teachers and students has become more active and flexible. In recent years, a credit-based continuing medical education system has been introduced, accompanied by some international collaboration programs (e.g., the cooperation between China and the School of Public Health, Harvard University).

The development of bioethics in different areas of China varies greatly. For some issues, Chinese scholars have reached their unique opinions, while others are still under discussion. So far, China has developed legislation and regulations about ART and gene research, organ transplantation, public health, stem cell research and human subject protection in biomedical research. Related regulations include (but not limited to) *Ethical Guidelines on ART and Sperm Bank* (Ministry of Health in 2001, 2003 Revised); *Quality Management Regulations on Drug Clinical Trial* (*GCP*, State Food and Drug Administration in 1999, 2003 Updated); *Ethical Guidelines for Human Embryonic Stem Cell Research* (MOH and Ministry of Science and Technology in 2003); *Regulations of Coping with Public Health Affairs Outbreak* (Central Government in 2003); *Ethical Guidelines of Research on Human Fetus Stem Cell* (MOH and MOST in 2004)*; Regulations of Human Organ Transplantation* (Central Government in 2007); *Regulations on Ethical Reviews of Biomedical Research Involving Human Subjects* (MOH in 2007); *Management Rules on Clinical Practice of Medical Technology* (MOH in 2009); and *Guidelines for Ethical Review of Clinical Drug Trials* (SFDA in 2010).

Bioethics in Taiwan and Hong Kong also experienced rapid progress during this period. Professor Shui Chuen Lee is the leading scholar in Taiwan who initiated bioethics research. He published *Confucian Bioethics* in 1999, and many theses like *Confucian Perspective on Some Issues of Bioethics* (Nobuhiko Takase ed., 2000, pp. 113–120); *The Reappraisal of the Foundation of Bioethics: A Confucian Perspective* (Julia Tao Lai Po-Wah ed., 2002, pp. 179–193); and *A Confucian Evaluation of Embryonic Stem Cell Research and the Moral Status of Human Embryos* (Shui Chuen Lee ed. 2007, pp. 149–157). In addition, mainland scholars regularly visit Taiwan to participate in international seminars on bioethics. In Hong Kong, Ruiping Fan and his colleagues are making an effort to construct Chinese bioethics by exploring sources from traditional Chinese philosophy and social values. Hong Kong Baptist University founded a Center for Applied Ethics in 1992 and has so far organized four symposiums on Chinese Bioethics Construction and Summer Class on Sino-American Perspectives in Bioethics to provide training for young scholars in China. Fan also published his book *Contemporary Confucian Bioethics* in 2010, in which he attempts to establish a framework for Chinese bioethics in the context of Confucianism.

Main Characteristics of Bioethics in China

Virtue, as a particular dimension of personality, is infiltrated into every aspect of people's lives, especially in the field of medicine. China has a long (5,000 year) history of civilization that is closely connected with ethics and morality and deeply rooted in Confucianism, Taoism, and Buddhism. Benevolence (*Ren*), the core

foundation of Confucianism for nearly 2,000 years, has advocated that good people always love others and get along well with others. Mencius (another leading Confucian philosopher) claimed that people had an inborn nature of humanity, which implies that all people have four senses: a sense of compassion, a sense of shame, a sense of respect, and a sense of distinguishing right and wrong. When time comes, anyone can be a sage after proper cultivation by the social life.

Such fundamental beliefs are rooted in every aspect of Chinese society, including medicine, which formed the most remarkable feature of the Chinese physician: a virtuous personality. In ancient China, doctors, also called "Confucian physicians," bear the goal of curing the sick and saving the dying. Sun Simiao (581–682 A.D.) stated in his book *Da Yi Jing Cheng* (*The Refined Sincerity of the Great Physician*) that the great physician was not only competent in his medical skills but also endowed with noble morality and compassion. People should be treated equally on the basis of their sickness and medical condition regardless of their social status, wealth, age and race, education, or whether they were friends. Shigong Chen (1555–1636 A.D., Ming Dynasty) illustrated the famous "five commandments and ten requirements" in the only standard Chinese work collected in the appendix of the *Encyclopedia of Bioethics* (first edition), Volume 5 for physicians, and claimed that the first requirement for somebody to become a doctor was to understand Confucianism before learning medical knowledge and skills, so that being a virtuous person comes before being a competent physician. Another physician during the Ming Dynasty named Tingxian Gong reiterated the same idea in his *Ten Requirements for Physicians;* and added a benevolent heart before understanding Confucianism (Li, 1996, p. 14). Thus, in its long history, China has a tradition concerning the moralities of professionals, mainly at the individual level.

Furthermore, the family is the basic unit of Chinese society, and the special value place on family by Confucianism contributed tremendously to forming the special physician-patient relationship pattern in China that remains as something cherished by Chinese people. These duties and values also play an extraordinary role in some prominent ethical problems like informed consent and truth-telling in the context of medicine. Medical decision making in China usually involves three stakeholders: doctor, patient, and family member. Such a model can be protective for patients on the one hand, and harmful in some circumstances on the other hand.

The introduction of bioethics from Western countries substantially broadened the ethical discussions in China. In the last 20 or 30 years, Chinese scholars learned much from Western countries in the area of bioethics concerning topics and theoretical resources. The four principles (autonomy, beneficence, nonmaleficence, and justice) were first introduced by Renzong Qiu in the 1980s, and have been widely used both in the discussion and justification of various bioethical issues ever since. China is a community-based and family-oriented society, respecting collective decisions more than single individual's decisions, which makes the situation and concrete problems much more complicated.

Major Bioethical Issues in China

Chinese bioethics shares topics and problems with Western countries in clinical ethics, research ethics, public health ethics, and other related areas. Some issues are widely debated, such as the physician-patient relationship (PPR), ART, euthanasia, organ transplantation, health policy and health resources distribution, human subject protection, and related leading-edge technologies like genetic engineering, human embryonic stem cell research, therapeutic cloning, and food safety.

Physician-Patient Relationship (PPR)

In China, the PPR has its own pattern and historical origin. When PPR is mentioned in China, it actually refers to the relationship among the physician, the patient, and the patient's family members, and primarily the relationship between the physician and the patient' family. This special Chinese physician–patient–patient family model of the PPR is deeply rooted in the long history and social values of China. On the one hand, family support, both material and emotional, is crucial for every patient not only because the family pays the medical cost, but also because the emotional support, to some extent, helps the patient to overcome the disease. Family engagement also makes things more complex and controversial.

The deteriorated PPR in China today is one of the most serious problems in bioethics research, theoretically and practically. The decrease of trust between health professionals and patient/patient family makes PPR not only an issue in medical ethics but also a social problem. More legal cases go to court, and in some extreme conditions, patients have even wounded or killed their physicians. The reasons for such a fragile PPR in China are multidimensional. Take the example of a big hospital: from the perspective of doctors, the imbalanced patient/physician ratio cannot guarantee enough time for physicians to treat their patients carefully enough. The heavy financial burden of outpatients (nowadays the government is taking efforts to cover as much as possible, and this is helping to make PPR harmonious) is usually among the major reasons, inasmuch as patients spend everything they have and still find no hope for cure. In addition, defensive medicine in China is also a problem. Afraid of being sued or bearing some other responsibilities, many physicians take the way of defensive medicine when treating patients, which seriously affects the quality of health services. Moreover, some physicians devote so much time to their own scientific research or other personal concerns that it conflicts with their professional obligations. From the patients' point of view, awareness of their personal rights has increased rapidly in recent years, coinciding with the collapse of traditional authority of physicians. The improvements to the health service and related health infrastructures are far from satisfying the patients' needs medically and nonmedically, resulting in difficulties accessing health services and high costs. According to one national survey carried out in 2010, about 50 % of patients would give a "red envelope" (filled with money or other kinds of gifts) to their physician in order to purchase their "special care" and "higher quality treatments" (Kong & Du, 2011, pp. 34–37). At the administration

level, there are some more fundamental reasons for this development. First and foremost is that the health system in China still needs more improvement to guarantee, at a bottom line, decent minimum health services and health equity.

All the factors above contribute to make the PPR in China a vicious circle. Adoption of comprehensive measures to enhance related reform based on the real situation is urgently needed.

Beginning-of-Life Issues

In China, artificial abortion is not as controversial as in Western countries because of its particular cultural background, social beliefs, and moral intuition. Even when there are debates, people are more concerned about the morality of behavior than the moral status of embryos. Some surveys showed that many Chinese people do not regard abortion as an ethical issue. This can be attributed to the traditional idea that human life begins just after birth. Another reason is closely related to birth control and the one child policy in China that started in the 1980s (Cong, 2003, pp. 239–260).

Interestingly, the issues regarding the beginning of life, especially ethical problems of assisted reproductive technologies (ART), are receiving more attention. A number of problems have been debated in China surrounding ART. In 1978, the world's first test-tube baby, Louise Brown, was born. The first legal case of AID happened in Shanghai in 1987 and initiated the public ethical discussion of ART in China. One year later, the first Chinese test-tube baby on the mainland was born in Beijing. Since then, assisted reproductive technology has developed continuously. In the beginning, some opponents argued that AI violated the nature of human reproduction and destroyed marriage, which was considered as one of the most significant relationships among people. Others suggested such a technique could enhance family happiness for some infertile couples without doing any harm to others. With in vitro fertilization and embryo transfer (IVF-ET), the primary issue was its difficulty in identifying the "parents" of a baby under the culture of addressing blood relationship. Meanwhile, some scholars held seminars and symposia to discuss problems systematically. Nevertheless, the toughest challenges that accompany ART are not the debates described above that conflict with Chinese moral intuitions. There are much more radical and controversial ethical problems, for example, the problems evoked by surrogate mothers were closely linked with women's rights and social justice; and whether IVF embryos have the same moral status as normal embryos before transfer.

After years of discussion, the Ministry of Health (MOH) promulgated *Technical Regulations of ART; Basic Standards and Technical Regulations of Human Sperm Bank; Ethical Rules for ART and Human Sperm Bank* in 2001 and revised them in 2003, to regulate the application of such technologies, guarantee its safety, and protect the welfare of Chinese people. The advantage of ART is that it helps infertile couples to have their own child; however, seven specified ethical principles, including the principles of informed consent, descendant protection, social public welfare, confidentiality, commercialization prevention, and ethical supervision, should be implemented. Some cases that have occurred in ART clinics

came under discussion, for example, families requesting for a surrogate mother for various reasons, and parents requesting to take sperm out for AI after their son died in an accident.

End-of-Life Issues

Euthanasia, which means dying with dignity and without suffering, was a big issue in Chinese society a decade ago. Chinese people generally hesitate to talk about death. The direct cause of such debates in China was the first euthanasia case that happened in Hanzhong City, Shaanxi Province, in 1986. Mrs. Xia was hospitalized for her liver disease on June 23, 1986, and diagnosed with liver cirrhotic ascites, hepatic encephalopathy, and exudative ulcer and bedsores. She felt better after some treatment; however, her condition worsened on June 27 and she suffered pain and anxiety. On the morning of June 28, she fell into a coma. Her son Wang knew that it was impossible to cure her and asked for help from the physician Pu. Finally, Pu prescribed 100 ml chlorphomazine after Wang signed on the prescription to take all responsibilities. Xia died in the early morning of June 29. Xia's death raised fierce public debate. In September, Wang and Pu were arrested by the police for causing the death of Xia. Then after 14 months of investigation, Wang and Pu were accused of intentional homicide. Since there was no prior case or legislation, the court finally considered that the direct cause of Xia's death was her liver disease rather than the chlorphomazine, and pronounced in 1992 that the accused were not guilty. The legal case lasted for 5 years, and Wang and Pu were arrested and released many times as there was no evidence or any related regulations to refer for such cases.

The discussion continued even after the final verdict. Today in China, there is still no consensus on euthanasia, and there is less discussion on euthanasia than there was a decade ago. At both ends of the spectrum of arguments, some radical views reject any kind of euthanasia in the name of professional ethics violation and illegality, while other views support euthanasia unconditionally only for relief of suffering for people with incurable diseases. However, people have their own reasons for being for or against euthanasia. Reasons like the right to die, human dignity and quality of life, and efficient use of scarce health resources all provide justification for endorsement of euthanasia. On the other side, people argue that euthanasia conflicts with medical professional ethics that concern saving lives above all else; moreover, there may be some miracles or possibilities for cure in the future, and informed consent given by the patient in these cases might be unreliable.

In recent years, some representatives participating in the National People's Congress have tried to propose euthanasia legislation, but such proposals have been rejected. Legislation regarding euthanasia still has a long way to go in China. Given the imperfections of the Chinese Health System and the Social Security System, it is hard to identify and guarantee the voluntariness of informed consent. Financial factors, as well as family decision-making patterns, make informed consent in China more complex than in other countries, especially for uneducated, poor, and older vulnerable persons. Furthermore, such discussion is also mixed with numerous disputes surrounding the death standard and newborns with birth defects.

Along with the debates of euthanasia legislation, the issue of whether brain death should be regarded as the death standard is another unresolved issue. According to the basic principles of nonmaleficence, beneficence, autonomy, and justice, the first dimension of the brain death issue is a scientific and medical problem, that is, whether or not brain death means the end of life. However, in the context of organ transplantation and health resource allocation, brain death is far beyond a scientific problem. Another concern is whether people should accept the concept of "brain death" and why should they give up the traditional concept of heart death (Qiu, 2004, pp. 30–33). Since the 1990s, some scholars in China have worked on promoting legislation of brain death; however, the impediment is not the scientific evidence and knowledge but the culture norms and acceptance by the public; thus, brain death remains controversial. In addition, a lack of trust in the Chinese physician-patient relationship is one of the main obstacles to accepting brain death in China (Hu, 2008, pp. 20–22). Another reason for not accepting brain death in China is related to ethical worries around organ transplantation, though the relationship between brain death and organ transplantation is to some extent exaggerated.

Organ Transplantation

The first successful transplantation of a kidney in China took place in 1974, followed by a liver in 1978 and a heart in 1978. As in other countries around the world, organ transplantation in China faces common problems, such as serious lack of donor organs, disparities in distribution of organ resources, and long-term complications resulting from imperfections in transplant techniques. In 1999, a doctor in Beijing removed the eyeballs of a dead body without informed consent or authorization to treat another patient, which caused strong debate and reflection in both the medical and legal professions. It was unethical but no proper regulations existed to cope with it. To regulate human organ transplantation and to protect the rights of citizens, the Chinese Central Government promulgated in 2007 *Regulations of Human Organ Transplantation*, which regulated that the basic principle of organ donation should be voluntary and freely consented to. The living donor must be at least 18 years old and all the living donations should be submitted for review and approval by an ethics committee. If a dead person has not expressed any opinion on the donation his or her organs before the death, a spouse, adult children, or parents can make the decision in their stead on written forms.

In recently years, organ transplantation in China has become more controversial. It has become a social and legal problem. A criminal case in Hebei Province in 2006 shocked all of China. A 40-year-old beggar was murdered and five of his organs (two kidneys, liver, spleen, and pancreas) were taken by the murderers to be sold on the black market, via the Internet. One hospital was involved in the surgery. After the "operation," a physician suspected that they might be involved in a murder and called the police. The murderer was sentenced to death in 2007; the physicians involved were not punished because they came to court as witness (Xinhua Net, August 21, 2007). Though it was an extreme case, it raised a series of ethical problems related to organ transplantation in China.

Infectious Disease and Public Health

Infectious disease research in China has mainly focused on disease prevention and related ethical problems invoked in the control strategies. In 1989, the *Communicable Disease Control Act* (revised in 2004) was passed to regulate the administration of infectious prevention and control. In the case of AIDS, which first appeared in China in 1985, Prof. Renzong Qiu began his exploration of the ethical problems of AIDS prevention and treatment in the 1990s. He claimed that AIDS was not like other public health problems; its infectious mechanism and susceptible population had their own features, so the first step in AIDS control was the transformation of traditional concepts about infectious diseases (Qiu, 2010, pp. 224–226). He also promoted in the following research theses respect and preventing discrimination and stigmatization of those testing HIV positive: *AIDS Prevention and Behavior Change: Protect Public Health and Individual Rights* (1993, pp. 129–135); *Ethical AND Policy Issues in HIV/AIDS Prevention in China; Recommendations on Legal Reform of HIV/AIDS Prevention and Control* (2003, pp. 121–139). In 2006, the Chinese central government issued its regulations on AIDS prevention and control.

In China, public health research was put on the agenda immediately after the outbreak of SARS in 2003. The SARS epidemic alerted people of the significance of public health as the gatekeeper to guarantee health at a population level. It is widely accepted that it is government's responsibility to play a major role, including health education and improvement and regulating people's unhealthy lifestyles and behaviors. However, the government itself cannot bear the burden alone. Citizens cannot passively wait for legislation to assure an equal distribution of health resources and outcomes, nor should they ask for help without taking any actions. Public health requires solidarity and cooperation among different bodies, societies, and organizations. In addition, one thing worth mentioning is that the *Regulations of Coping with Public Health Affairs Outbreak* issued by the central government in 2003 strongly emphasized the network of collaboration among different levels of governments and health administrations. In 2011, Prof. Benfu Li and his research team submitted their report, *The Framework of Public Health Ethics and Public Health Research Review* to the Ministry of Health (MOH). Some core values were clarified and suggested in the report, such as protection of vulnerable people, individual compensation, proper interventions, public participation, solidarity, and prevention, as guidelines to regulate the public health practices.

Human Genome Research and Emerging Technologies

China founded the new Human Genome Research and Ethical, Legal and Social Implication Committee when the Human Genome Research made its vital achievement in 1999. Since then, the HGR and related ethical problems were widely discussed in China. Scholars mainly focused on international cooperation and informed consent. The most controversial case was a project carried out in Anhui Province by an investigator at the School of Public Health, Harvard University. The researchers took blood samples from peasants and transferred some samples to the US without government permission. Though there were debates from different

sides, it was the consensus that there must be fully informed consent in genetic research to guarantee the rights and deserved benefit. When it comes to international genetic research, the collection and transfer of genetic resources and samples must comply with the *Interim Measures for the Administration of Human Genetic Resources* issued in 1998. Besides the importance of informed consent, three other principles should be stressed: (1) principle of respect, not only for the autonomous individuals, but also the procedure of informed consent; (2) principle of beneficence, fully inform the possible harm and risks, constructing a fair evaluation system to assure the rights of vulnerable ones; and (3) principle of justice, calling for fair benefit/burden sharing and independent supervision.

Human embryonic stem cell research is currently another controversial cutting edge issue. In China, the MOH and MOST issued *Ethical Guidelines for Human Embryonic Stem Cell Research* in 2003. It is crucial for people to use such technologies in an appropriate way. Thus, the guidelines stipulate that human embryonic stem cell research must follow three basic norms: (1) the in vitro culture period of blastosphere cannot be more than 14 days before fertilization or transfers happened; (2) such human blastula cannot implant into any human or animal reproductive system; and (3) hybridization between human germ cells and other species' is prohibited. The guidelines also announced that all such research should be reviewed by an independent ethical committee made up of biologists, lawyers, sociologists, and scholars in related fields. During the process of conducting research, investigators should focus on informed consent, making sure the informed consent was signed voluntarily and the privacy is protected.

As for other emerging technologies, the study of ethical issues in China focused on areas of human-nonhuman animal mix embryo research, biobanks, neuroscience, synthetic, and convergent technology. Chinese scholars published a number of essays to illustrate such issues, including *Ethical Issues in High-Techs of Life Science* (Qiu, 2001, pp. 20–27) and *Ethical Issues in the Biomedical Frontier* (Qiu, 2006, pp. 449–455).

Healthcare Reform

On March 18, 2009, China formally launched its new health reform. The reform aimed to provide primary health services to all citizens and guarantee full access with the basic strategy of taking fairness as priority to construct the primary health service system. The five priorities of reformation concentrated on (1) construction of a health insurance system with full coverage; (2) setting up a national essential drug system; (3) perfection of the health service system at the basic levels; (4) popularizing the primary public health services; and (5) promoting the reform of public hospitals. After 2 years' efforts, nearly 95 % of the citizens were covered by health insurance; the national essential drug system efficiently reduced drug prices by 30–40 %; the infrastructure of health services at the basic level was enhanced by the investment of the central government; ten packages of public health services were provide freely to citizens, and 17 cities were designated to carry out public hospital reformation. However, many challenges remain. First, urbanization and industrialization combined with ecological problems created

a complicated context for Chinese healthcare reform. Second, as a rapidly aging country, chronic diseases severely threaten the health of Chinese population; particularly, the morbidity of noncommunicable chronic diseases (NCD) is constantly increasing and constitutes one main reason for mortality. Third, the Chinese health system itself is problematic, which to some degree impedes the reform.

Lessons learned from the previous health reform initiated in 1980s indicated that the intensified health disparities were among the crucial indicators of its failure. Today, social justice is one of the basic values treasured all over the world. People have the right to health and the government bears the duty of safeguarding health, at least providing the decent minimum health services for all the citizens. Though it is still too early to evaluate the new health reform in China, some ethical standards have been developed as indicators to justify whether or not the reformation succeeds. These criteria are accessibility of health services, the appropriateness of health needs, sharing of benefits and burdens, efficiency, responsibility, and alternative choices (Qiu, 2010, p. 264).

One pilot pioneering reform effort in China that deserves mention is the implementation of Shenmu "free health care" carried out by the county government of Shenmu, Shaanxi Province. All citizens of Shenmu county covered by health insurance can access primary health care for free. Health insurance funding, social donations, and local government together pay the financial cost for this system. For hospitalization expenses, they set up an up-pay system of 200RMB at the village level and 400RMB at the county level, which means that the government pays the balance for a patient's inpatient fees. This effort attracted broad interest and triggered fierce debates in China. The Medical Ethics Society of CMA held a symposium at Shenmu in 2010 specifically to discuss its creative work in health reform. Meanwhile, journals, such as *Chinese Medical Ethics*, published a series of multidimensional research essays on the Shenmu health system.

Human Subject Protection

Since the 1980s, international research cooperation, for example, between China and the US, has been set up in large medical universities, hospitals, and public health research institutions. Peking University Health Science Center (PUHSC) was one of the entities that started the cooperation with US Centers for Disease Control (CDC) in 1989 (on the folic acid project). In the same year, PUHSC established the first institutional review board (IRB) in China specifically for this research project. Since then, IRBs have rapidly developed in China.

In the last three decades, many large hospitals and medical universities in China set up their own IRBs to review biomedical research protocols involving human subjects to protect the rights and the welfare of subjects, as well as to guarantee the quality of investigations. Especially in the areas of clinical drug/medical device trials, ART, human embryonic stem cell research, and organ transplantation, ethical review by IRBs is required by laws and regulations. At the provincial level, the Shanghai Health Bureau is one of the pioneers in setting up ethical committees (ECs). More importantly, at the national level, the MOH established the *Ethical*

Committee of Biomedical Research Involving Human Subject in 1998, later renamed the *Medical Ethical Expert Committee MOH* in 2000.

The legislation in research ethics has improved significantly. In 1999, the State Food and Drug Administration (SFDA) issued *Good Clinical Practice*, which regarded ethical committees and informed consent forms as the principal measures to protect the rights of human subjects in clinical trials; China's GCP was revised in 2003. In 2007, the MOH issued *Ethical Review Regulations for Biomedical Research Involving Human Subject*. This regulation pointed out that at least five IRB members should have different scientific and nonscientific backgrounds. The principles of ethical review were: (1) respect the autonomy and decision of the subjects; (2) the safety, health and right of the subjects always come above any other scientific and social benefit; (3) release or avoid the financial burden of the subjects during the research; (4) respect the privacy and confidentiality; (5) make sure compensation is available should hurt or harm happen; (6) pay special attention to vulnerable populations, including minors, pregnant women, mentally retarded persons and patients, prisoners, the poor, and uneducated people. In addition, SFDA published *Guidelines for Ethical Review of Clinical Drug Trials* in 2010, which illustrated in more detail norms about ethical review of clinical drug and medical device trials.

Another noteworthy activity was that Peking University launched its Human Research Protection Program (PKU HRPP) on October 18, 2010. It is the first HRPP in China. As human research protection becomes more complicated in the context of collaborative global health research, it is necessary to go further to ask for more collaboration and a comprehensive network for protecting research subjects.

Conflict of Interest

In 2001, Jeffrey Kahn from the University of Minnesota and Renzong Qiu published articles on COI in the *Journal of Medicine and Philosophy*, which might be the earliest literature in China discussing and introducing COI in medical research. To date, there are about 30 theses on COI in domestic medical research. Existing research, however, mainly focuses on the introduction of research development and cases in Western countries. With regard to academic discussion, COI is one of the themes in the annual China-US Conference on Medical Professionalism organized by the Center for China-US Medical Professionalism, PUHSC since 2006. Distinguished bioethicists, physicians, and health administrators from China and the US participate in this conference regularly to discuss COI problems and their management.

Challenges

It is undisputable that, during the past three decades, the research of bioethics in China has greatly advanced. However, China still faces some tough challenges that not only concern concrete leading-edge issues, but also the construction of bioethics appropriately in Chinese style.

The first challenge is the institutionalization of bioethics research outcomes, especially legislation of controversial issues in China. As mentioned before, there are a few laws and regulations in China to set the standard norms and basic principles in particular fields, such as ART, stem cell research, organ transplantation, and human subject protection, however, some unaddressed areas still call for more attention. It is unacceptable to simply complain the lag in legislation for brain death as a death standard in China or strike repeated comparisons with the progress abroad without taking any actions to verify and justify the real problems in Chinese society. However, no laws or regulations can solve everything once and forever since new technologies are constantly emerging and changing, which leads to new difficulties and unanticipated problems. Thus, it is necessary to keep in mind that the laws should be flexible and updated appropriately in time.

The second challenge is that Chinese scholars must be more active and engaged in order to solve practical problems in everyday life. Take human subject protection as an example: more attention should be paid to the capacity building of IRBs in China. This means not only establishing such committees in institutions, organizations, and administrations where it is necessary; but also building institutional capacity. Presently, IRBs in China mainly focus on biomedical research, like clinical drug/device trials; public health research and social behavior research are severely overlooked. Another issue is the variation in the quality of ethical review in China from one committee to another; most work is limited to initial review rather than continuing review or quality assurance. This can be attributed to the lack of a systematic training program in China for IRBs to enhance their qualification and capacity. Meanwhile, the lack of proper incentives provides another account.

Third, a reasonable multidisciplinary bioethics curriculum is necessary at the national level of professional training in China. Nearly 30 years ago, medical ethics courses were carried out in some medical universities, and during the last two decades, an increasing number of bioethics courses have been made available. However, there is no formulated bioethics curriculum yet. Graduate students who major in bioethics study in the department of philosophy (e.g., Peking University), the School of Humanities, and the School of Public Health. For example, in China, no School of Public Health (except PUHSC) has ever offered a public health ethics curriculum.

Fourth, the future development of bioethics is intimately combined with the unique mission of bioethics research in the context of China. The mission of bioethics is to explore local bioethical issues and to try to find solutions. It is time to make further efforts to articulate bioethics and medical ethics in China (Du, 2010, pp. 1–5), which would be very helpful to advance not only problem solving but also theoretical development. Moreover, "patient interest comes first" should be treated seriously and emphasized.

The fifth and most important challenge is the lack of effective mechanisms or channels to guarantee the transformation between theoretical research outcomes and legislation/policy. It is deeply affected by the quality of investigations, the operational pattern of social structures, and, more radically, ideas of administration, all of which determine that bioethics scholars cannot handle it alone. Thus, it is

necessary that more researchers with diverse knowledge backgrounds engage in bioethics research in China. Meanwhile, more public engagement, involvement, dialogues, exchanges, and collaborations are urgently needed. Most recently, gene-trans food has attracted public attention, sparking hot debates on whether China should adopt a policy regarding use such kinds of modified seeds and on other related issues. Mutual understanding is hindered due to the lack of platforms for dialogue.

Conclusion

In two or three decades' time, scholars have set up the basic framework of bioethics in China and initiated national and international dialogue. This discussion touched upon a variety of issues, including fundamental arguments at both ends of life, concerns about the quality of human life and well-being, and some reflections on the limitations of human power and creativity. More importantly, the nature of bioethics determines its problem-based research methodology. Thus, bioethics is not philosophical pondering confined to an ivory tower, but is closely connected with real life and human welfare.

China has a long tradition of medical ethics and medical humanities that has significantly impacted its medical professional codes. It is definitely true that China shares fundamental values, such as beneficence, respect, treating patient equally, and doing no harm. Sometimes, unique Chinese thinking has meant that China has developed its own ways and styles of implementing such values. Take "respect," for example: one of the most effective ways is to emphasize "informed consent" in practice. The Western style focuses more on the individual, whereas in China decisions are always made by the whole family or by some family members. In the context of bioethics discussions, the final consequence and the procedure jointly make the justification for its rightness. The same issue may have different implications in different situations, like artificial abortion in China and Western countries. Therefore, examining issues in a broader context is important.

Above all, at the global level, on the one hand, Chinese scholars must develop their own ethical discourses in bioethics research to confront the particular problems China faces. On the other hand, being part of humankind, people still need to work together globally to find common ways and common values instead of addressing only some particular points. Only then people can understand each other better.

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Colombia

58

Mónica Rincón

Introduction

Bioethics in Colombia began through ethical reflection in medicine and spread to other disciplines. A desire to disseminate bioethics is evidenced by its presence in teaching, assistance, and research by means of a plural and interdisciplinary orientation. Human problems and/or information affecting or having something to do with life in the widest sense possible have been discussed publicly in different environments, while diverse stances have been openly exposed and confronted in

M. Rincón
Children's Heart Foundation Cardiology Institute, Nueva Granada Military University, Bogota, Cundinamarca, Colombia
e-mail: mrinron@hotmail.com

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order to find feasible solutions to these issues by favoring the exchange of new knowledge in harmony with a pluralist and right-respecting society determined to pursue the good of all.

Bioethics Development

It is possible to trace some manifestations of ethical concern in Colombia back to 1960, in professionals' writings published in newspapers and journals. Dr. Fernando Sanchez-Torres is an example; his articles began to appear in 1954, and many of them made reference to matters that were not limited to professional ethics for physicians but aimed at extending over wider horizons (Mendoza-Vega, 2002). In retrospect, Dr. Sanchez asserts how the ethical implications of organ transplantation, human reproduction, patients with terminal conditions, abortion, and AIDS began to be discussed (Sanchez, 1994).

In 1954, the Colombian Medical Federation approved a moral code for medicine, but it was seldom used. Later, however, with the increasing number of schools of medicine and the emergence of new technologies, the same Federation proposed to the Colombian Congress a new code to be enacted. After extensive debates, both the Chamber of Deputies and the Senate passed Act [*Ley*] 23 of 1981, "whereby rules regarding medical ethics are issued." This Act establishes that "the teaching of medical ethics at the Faculties of Medicine is obligatory."

This is why, in 1987, the Colombian Association of Faculties of Medicine (ASCOFAME) created a program aimed at teaching ethics to medical students and training professors in teaching this subject. Act [*Ley*] 23 awakened a strong interest for medical ethics since its promulgation and, in 1988, the work "Ética Médica y Bioética. Principales Problemas" (Medical Ethics and Bioethics. Major Problems) was published. Previously, only one book existed, under the title of *Deontología Médica General* (Sánchez, 1994).

In the city of Bogotá, the Nueva Granada Military University (UMNG) has been a pioneer in bioethics development since 1998, at both national and international levels. The principle of bioethical development at the UMNG was born when the medical ethics chair was initiated by the Jesuit priest Father Alfonso Llano SJ., followed by Dr. Gustavo García C. After many years, this chair was reassumed by professors Fabio Garzón, Maria Mercedes Hackspiel, Cristian Galvis, and Mónica Rincón R., who initiated the trans-curricular bioethics chair at the Faculties of Medicine and Biology (García, 1999).

The Colombian School of Medicine (currently El Bosque University) started its bioethics activities in 1976. Dr. Jaime Escobar-Triana, as head of the first intensive care unit in the country at the San Juan de Dios Hospital in Bogotá, carried out jointly with the surgery department of the National University's Faculty of Medicine the first seminars relating to patients' rights, dignified death, and end-of-life decision making.

Subsequently, with respect to physicians' attitudes vis-à-vis the dying patient (*actitud del médico ante el paciente moribundo*), these aspects were developed

at the Colombian Gastroenterology Society, the Colombian Surgery Association, and the University of El Rosario's Faculty of Medicine.

The initial history of bioethics at the University of Rosario can be traced to the initiation of the chair of holistic ethics and bioethics at the Faculty of Medicine, led by Dr. Juan Mendoza-Vega, and particularly aimed at training undergraduate medical students. Subsequently, other health science programs have integrated bioethical instruction into their undergraduate curricula. In 2002, the *Centro Interinstitucional de Estudios en Bioética* (inter-institutional centre for bioethics studies) was founded, led by Dr. Ana Isabel Gómez, and with the involvement of teachers of the School of Medicine and Health Sciences.

At La Sabana University, bioethics was included in the program since the beginning of the Faculty of Medicine, with Professors Pablo Arango and Pedro José Sarmiento-Medina. The Bioethics Institute (BI) at Pontifical Javeriana University (PUJ) was created in 1997 and is oriented towards research, teaching, and advising in the field of bioethics.

In 1989, Jesuit priest Father Gilberto Cely began the first interdisciplinary bioethics seminar at the Faculty of Sciences. His work focuses on ethical and political problems arising in the clinical setting, public health, and the environment. The main functions of the seminar are research and teaching developed through involvement in investigative interfaculty seminars. Specialization and a master's degree in bioethics, and the rendering of services through courses in undergraduate and postgraduate programs have been specially developed by the Faculties of Basic Sciences, Odontology, and Medicine, among others, for research and ethical reflection on issues affecting life in its broadest sense.

Since its creation, the Institute has had different directors, beginning with Father Alfonso Llano-Escobar (1997–2005), and followed by Germán Calderón (2005–2007), Father Gilberto Cely (2007–2010), Eduardo Rueda (October–December 2011), and Dr. Guillermo Hoyos-Vasquez (from 2010 to present).

At the National University of Colombia, in the early 1990s, Professors Nelly Garzón and Beatriz Peña introduced the subjects of ethics and bioethics in postgraduate programs in the Faculty of Nursing. The Faculty began to carry out systematic work on this matter, and a course in bioethics has been taught there for more than 15 years.

In 1986 in Medellin, the country's second major city, Father Guillermo León Zuleta, upon completing his studies in bioethics in Paris at the Louis Pasteur Institute, under an agreement with the Borja Bioethics Institute, was engaged as chaplain of the Faculty of Medicine of the Pontifical Bolivariana University (UPB) and was placed in charge of coordination of the medical ethics area. In 1987, the first bioethics syllabus at this Faculty was structured to become one of the first programs in the country. At that time, medical ethics shifted to medical bioethics. Subsequently, this work would be supported by physician Carlos Alberto de Jesús Gómez, a permanent guest at the Inter-sector Committee of Bioethics created by the former Colombian President Andres Pastrana's Decree 1101 of 2001.

In the field of bioethics, the main actors and institutions in Colombia have been, in the city of Bogota, the Nueva Granada Military University, El Bosque University,

the Pontifical Javeriana University, La Sabana University, the University of Rosario, and the National University of Colombia; and in Medellin with Pontifical Bolivariana University and other institutions; in also in cities such as Barranquilla, Bucaramanga, Florencia, Manizales, Cali, and Cartagena, among others.

Resources Developed

The UMNG has been organizing bioethics congresses since 2001, some of them jointly with the University of Rosario and the National Bioethics Centre (CENALBE).

Table 58.1 shows data regarding the organization of events in bioethics.

El Bosque University organizes annual seminars through its bioethics program, with the involvement of distinguished researchers and academics. The main topics discussed include quality of life, teaching bioethics, human rights, allocation of resources, global bioethics, armed conflict, technology, science, and social perspectives in bioethics – dignity, integrity, and vulnerable populations, among others, seeking to reflect on the problems facing the country and their relationship to the field of bioethics. These efforts seek to bring the scientific community to develop strategies for solutions through bioethics.

The University of Rosario, together with the UMG and the National Bioethics Association ["Asociación Nacional de Bioética"] (ANALBE), has carried out three international congresses. The International Bioethics and Sanitary Law Congress was held with the Pontifical Javeriana University (PUJ). With the Foundation in Favour of the Right to a Dignified Death [*Fundación Proderecho a Morir Dignamente*] (Mendoza-Vega, 2002), an event on the Limitation of the Therapeutic Effort took place in association with the Children's Heart Foundation [*Fundación Cardioinfantil*], as well as many other training activities dealing with end-of-life matters in different Colombian cities. With ANALBE, forums, public debates, and cine-forums have been held to discuss current issues such as conscientious objection, organ transplantation, abortions, the so-called savior siblings or donor babies

Table 58.1 UMNG's organization of scientific events in bioethics

Year	Event	Organizers	Attendees	Special guests
2001	I International Congress of Scientific Research Ethics	UMNG	400	Francesc Abel
2003	II International Congress of Scientific Research Ethics	UMNG	320	Henk ten Have
2005	III International Congress of Scientific Research Ethics	UMNG	380	Jorge Ferrer
2008	International Bioethics Week, and IV International Bioethics Congress	UMNG-CENALBE-UNIROSARIO	580	Héctor Gros Espiel
2010	V International Congress of Scientific Research Ethics	UMNG-UNIROSARIO	320	Adela Cortina

Table 58.2 Issues and titles of the *Latin-American Journal of Bioethics*

Year	Title
2001	Javier Gafo Relato de un hombre por la Ciencia
2002	Bioética y Manipulación GenÉtica
2002	Bioética y Medio Ambiente
2003	Bioética y Clonación
2003	Bioética y Dignidad
2004	Bioética en el Mundo (1)
2004	Bioética en el Mundo (2)
2005	Bioética y Complejidad
2005	Bioética y CélulasTroncales
2006	Bioética y ConsentimientoInformado
2006	Bioética 35 Años
2007	Bioética-Biopolítica y Bioderecho
2007	Bioética Aplicada
2008	De la Bioética Clínica y la Bioética Global
2008	Globalización de la Bioética
2009	De la Bioética Clínica a la Bioética Social e Institucional
2009	¿Fritz Jahr, Padre de la Bioética?
2010	Bioética Médica y Biojurídica
2010	Bioética, Tecnología y Sociedad
2011	Bioética: Problemas Persistentes y Emergentes

[*bebés medicamento*], and euthanasia, among others. La Sabana University offers training courses in subjects such as hospital ethics committees, research, and various bioethics issues such as informed consent, doctor-patient relationship, confidentiality, palliative care, and pain management.

The UMNG's bioethics program has three types of publications resulting from its research:

A journal is published: *Revista Latinoamericana de Bioética* (*Latin-American Journal of Bioethics*) started in 2001. It is the first bioethics journal in Colombia, and the second in Latin America.

Dr. Fabio Garzón is the creator and editor of this publication. In addition, he is the first bioethicist in Colombia to publish an interactive bioethics book.

The mission of this journal is to publish original articles based on bioethics research in the form of an interdisciplinary dialogue, in order to disclose them to the modern university community and other people interested in new advances and applications of bioethics in different fields.

This publication is bi-annual. To date, it has produced 20 issues and 172 articles dealing with research, reflection, and review of various subjects. It has more than 60 bioethicists on its various committees and has been indexed in 7 databases (Publindex B, Latindex, Redalyc, Dialnet, Ebsco, Bireme-Lilacs, and Scielo). Table 58.2 lists the titles of the journal's 20 issues.

There are two book collections: the *Pedagogical and Humanistic Collection* and the *Bioethics Collection*. The mission of the former is to publish the research

Table 58.3 Humanistic and pedagogical collection

Book title	Author
La Concepción Cualitativa de Currículo y la Formación Integral del Profesional	Gustavo García-Cardona
Pedagogía y Epistemología. Ensayos Críticos	Gustavo García
La Educación: Entorno Ético Moral	Gustavo García
La Protección de la Vida, un Compromiso Ético y Científico	Gustavo García
	Fabio Alberto Garzón
Biotecnología y Salud Humana	Salvador Dario Bergel
	Gustavo García
Salud y Medio Ambiente	José D. Cardona
Bioética y Capacidad Mental	Susana Zarama
Liderazgo una Propuesta Pedagógica Eficaz	Yolanda Guerra
	Gloria Salamanca
	Hernán Rodríguez
Manual de Expresión Oral y Escrita	Cesar de Jesús Areiza
	Jaime Alberto Correa
Enseñanza y Comprensión	Cesar De Jesús Areiza
	Fabio Garzón
Bioética y Pensamiento Complejo: Un Puente en Construcción	Sergio Néstor Osorio
Manual de Iniciación a la Antropología desde el Paradigma de Complejidad	Sergio Osorio
	Hugo Sotomayor
Pensar desde la Educación Superior. Una Reflexión Transdisciplinar	Sergio Osorio
De López Pumarejo a Rojas Pinilla Partidos, Violencia Y Ejercito	Adolfo León Atehortua
Derecho Natural en Tomas De Aquino y Francisco Suárez	Manuel Losada

outcomes of its teachers' and professors' in matters such as education, ethics, pedagogy, didactics, humanities, and their bond with bioethics (Table 58.3).

The *Bioethics Collection* publishes the outcomes of its teachers' and professors' research dealing with applied ethics and bioethics, in an interdisciplinary dialogue with other areas of knowledge (Table 58.4).

In El Bosque University, the bioethics program publications gather works, studies, and research carried out by students, teachers, and professors, as well as the contributions of both national and foreign authors in order to encourage an interdisciplinary multi (inter-trans) dialogue. The following collections are available: the Bios and Ethos Collection (28 volumes); the Pedagogy and Bioethics Collection (10 booklets); the Bios and Oikos Collection (9 issues); the *Colombian Bioethics Journal* (*Revista Colombiana de Bioethics*) (12 issues); and a bi-annual Bioethics, Science, Technology, and Society bulletin (12 issues) (Ovalle, Escobar, & Aristizabal, 2010).

Table 58.4 Bioethics collection

Authors	Title
Fabio Garzón	*Aspectos Bioéticos del Consentimiento Informado en Investigación Biomédica con Población Vulnerable*
Misael Tirado	*El Esclavo Frente al Espejo de la "Modernidad o Su Autocolonialismo"*
Sergio Néstor Osorio (Ed.)	*Historia y Filosofía de la Ciencia*
Misael Tirado	*Investigación Juridical y Socio-jurídica*
Sergio Osorio	*Transformación Educativa, Historia y Filosofía de la Ciencia*
Yolanda Guerra (Ed.)	*Trasplante de Órganos, Bioética y Legislación Comparada*
Cristian Galvis (Ed.)	*Biopolítica: Aproximaciones a Su Origen y Evolución*
Yolanda Guerra (Ed.)	*Bioética y Tecnoética, Alternativa para Una Sociedad Deshumanizada*
Fabio Garzón (Ed.)	*Educación, Universidad y Bioética*
Yolanda Guerra (Ed.)	*Liderazgo, Bioética y Educación*
Sergio Osorio	*Bioética y Pensamiento Complejo 3*
Sergio Osorio	*Ciencias de la Complejidad*

The University of Rosario has published several books with an emphasis on education – *Bioethics and Education: Research Problems and Proposals*; *What Is Research in Bioethics*; *Bioethics and Research Training; Education in Bioethics*; *and Teaching Bioethics: Why, How and Why?* Another aspect requiring investigation relates to training and education in the faculties related to the field of health, including the following topics: medical ethics and relevance of training; ethics for medical professionals and citizens; requirements for doctors today and projections for the future; bioethical implications of the processes of vocational training in physiotherapy, speech therapy, and occupational therapy; and teaching of bioethics in medical schools in the Western and Eastern international experience. This University is affiliated with ANALBE, and Dr. Juan Mendoza-Vega, head of the Faculty of Medicine, presides over the Foundation for the Right to a Dignified Death ("Fundación Proderecho a Morir Dignamente").

La Sabana University publishes *Revista Persona y Bioética* (*Journal of Person and Bioethics*), created in 2001 and available on the web. To date, with the contributions of world-renowned authors, more than 36 issues have been published. The journal deals with a broad array of topics, from clinical bioethics to the doctor-patient relationship and the beginning of human life, as well as assisted reproduction techniques, end-of-life matters, and other subjects such as palliative care, dysthanasia, environmental problems and ecology, and other subjects relating to biomedical research.

The National University of Colombia has been involved in publications on subjects such as modern bioethics, social responsibility in health, ethics in research

with animals, ethics and odontology, a Latin American bioethics dictionary, and fundamentals of bioethics, among others.

Anamnesis Revista de Bioética (*Anamnesis Journal of Bioethics*) of the Pontifical Javeriana University (PUJ) is a publication first created in 2007 as the *Clinical Bioethics and Philosophy of Medicine Bulletin* by the initiative of the group of researchers in clinical bioethics and philosophy of medicine coordinated by Eduardo Díaz and Fernando Suárez. Notwithstanding its beginning focus on biomedical subjects, *Anamnesis* has become PUJ's bioethics journal, published bi-annually, providing alternative and critical space for debate in bioethics and similar fields in Colombia; it accepts a variety of contributions. The objective of this publication is to offer quality articles in a flexible and accessible format to all those expecting either to be well informed or wishing to take part in debates dealing with bioethics.

Revista Selecciones de Bioética (*Journal Bioethics Selections*), founded in 2002, was the first journal with a selection of articles on bioethics or relevant to bioethics originally published in other national and international journals. It was first sponsored by the PUJ's IB and CENALBE, and it became CENALBE's publication exclusively beginning with number 16; to date, 18 issues have been published. Its present director is Father Alfonso Llano.

In Cali, it was Father Gilberto Osorio who introduced subjects dealing with bioethics and produced, as a study text, some of his lectures under the title of "El Significado de la Bioética en las Instituciones de Salud" (The Meaning of Bioethics in Health Institutions), published by the University of El Valle's Faculty of Health.

Associations

Colombian Institute of Bioethical Studies (ICEB)

In 1986, Dr. Fernando Sanchez-Torres, who had been serving as dean at the Faculty of Medicine in the National University of Colombia and then as its rector, side by side with a group of well-known professionals recognized for their work in medical ethics and deeply interested in bioethics matters, created the Colombian Institute of Bioethical Studies ("Instituto Colombiano de Estudios Bioéticos") – ICEB (Sanchez, 1990).

Colombian Bioethics Centre (CECOLBE)

In 1988, Father Guillermo León Zuleta and Father Jose Emilio Lema; physicians Ramón Cordoba, Norman Harry Hinestrosa, Mario Montoya-Toro, Carlos Gómez-Fajardo, and Jorge Humberto Echeverri; psychologist Luis Fernando Velasquez; and attorney William Botero created a group devoted to the study of bioethics and providing advice in this discipline jointly with teaching and research activities. Under the name of

the Colombian Bioethics Centre (*Centro Colombiano de Bioética*) – CECOLBE, the group later headed the creation of the Colombian Association of Bioethics Institutions (ASOCOLBE). In 2000, ASAIBE, the Association of Bioethics Institutions of the Department (geographic and administrative region) of Antioquia was organized.

Colombian Association of Bioethics Institutions

In June 1998, the creation of the Colombian Association of Bioethics Institutions (ASOCOLBE) was discussed. In July 1999, Father Alfonso Llano called a meeting for all those interested in belonging to the National Association and proceeded to appoint its advising board. In November 1999, the National Colombian Federation of Bioethics and Ethics Institutions (FENCIBE) was founded.

Cenalbe

In 1990, while working at ASCOFAME, Father Llano created CENALBE. This national bioethics center has been at all times concerned with the study and spread of bioethics in and outside Colombia. CENALBE, which is today associated with the Bioethics Institute of the Pontifical Javeriana University – PUJ, contributed to the foundation of ANALBE and the establishment of the Inter-sector Bioethics Committee created by presidential decree in June 2001.

Felaibe

En 1991, CENALBE decided to organize a Latin American Federation of Bioethics Institutions (FELAIBE), more oriented to promote the creation of institutes and centers in all the regional countries to federate those not yet existing. In order to make FELAIBE known, CENALBE organized forums and meetings in several countries of the American continent and the Caribbean.

In 1995, FELAIBE began organizing Latin American bioethics congresses for the purpose of publicizing and promoting them. The first took place in Sao Paulo, Brazil, in 1995, and the second was held at Bogotá, Colombia, in 1998, with 1,050 attendees, followed by a third congress in Panama City in 2000, and a fourth in Puerto Rico in 2003 (Llano, 2007).

Colombian Research Academy for Bioethics (ACIB)

The ACIB was created in 2000 by a group of teaching staff from El Bosque University for the purpose of promoting research in the field of bioethics.

Inter-institutional Centre of Studies in Bioethics and Medical Law

This center was created in 2002 by a group of professionals from Rosario University and professors from other universities.

Colombian Ethics and Bioethics Foundation (FUCEB)

FUCEB was founded in 2009 by a group of teaching staff from La Sabana University, and presided over by Dr. Mario Fernando Figueroa. Their first concerns in the field of bioethics turned around the human genome (genetics), in vitro fertilization, cloning, AIDS, and medical ethics matters dealt with in terms of medical bioethics (informed consent, professional secrecy, confidentiality, and clinical history, among others).

Current Bioethics Infrastructure

Bioethics Education

The UMNG work team carries out the following activities:

Teaching at the Undergraduate Level: Bioethics has become the transversal axis of the social medicine area at the Faculty of Medicine. The outstanding work of María Mercedes Hackspiel on the Values Committee and the preparation of the *Cartilla de Valores* (values handbook) is worth noting. Likewise, in the Applied Biology Program it is possible to take part via the Bioethics Seminar; in addition, elective subjects in the field of bioethics are offered to all programs in the different faculties of this university.

Teaching at Postgraduate Levels: This includes bioethics subjects and seminars in 42 medical specialties and, in addition, seminars in the University Teaching Specialization Program. Bioethics is part of a line of research in the master's degree program in education. Work is being done in the structuring of the bioethics doctoral program to be submitted with official entities for evaluation and approval in 2012.

El Bosque University has had a specialization program in bioethics since 1995 and a master degree's program since 2001. In 1997, the teaching of bioethics was extended to 22,568 teachers having followed the various distance education specializations in the different Colombian regions. Subjects of interest to bioethicists have been introduced in faculties such as medicine, odontology, psychology, nursing, administration, education, and environmental, industrial, electronic, and systems engineering. The bioethics doctorate program, the first of its nature in the country, began in 2006, conducted by Dr. Jaime Escobar. Also the specialization and master's degree programs were the first of their kind. The doctorate program consolidates a long experience in the training of professionals in the field of bioethics; it aims at broadening and developing knowledge and practices for the

solution of ethical problems in a pluralistic and interdisciplinary manner; it empowers students as researchers in the area of bioethics and trains them in both theoretical and in-depth conceptual insight and practical application. Doctoral students' research theses and dissertations deal with topics such as autonomy in pregnant adolescent girls; rescuing wild fauna; private and public school education in bioethics; biofuel bioethics; and introspection in the mentally ill to examine their decision-making ability. One hundred and sixty professionals in different disciplines have obtained master's degrees in bioethics; 296 have completed their specialization, and 5 have been conferred PhD degrees (November 2011). The University of Rosario has extended its teaching action not only to the undergraduate medicine program but also to new undergraduate and postgraduate curricular areas, among which the following programs are worth mentioning: undergraduate biomedical engineering, psychology, and nursing; PhD in biomedical sciences; master's degrees in public health, genetic health administration, biomedical sciences, occupational health, and public health.

La Sabana University offers a 12-month semi-residential specialization in bioethics, including residential classes (3 days per month). To this date, seven cohorts with around 100 professionals in different areas have completed this program. Likewise, medical-surgical specialization with more than 150 physicians under training offers 40-h instruction in clinical bioethics.

The National University of Colombia has a bioethics network as its sole institutional referent in this field, consisting of both internal and external members who have become involved via meetings or through the web page. It is fundamentally aimed at promoting respectful and well-argued dialogue among participants, allowing for the emergence of particularly citizen-oriented stances based on the different training angles where there is no predominance or power of any of the areas of knowledge involved, because there is a constant concept construction where new categories and views unlikely to be experienced in other scenarios can be shaped.

At the National University of Colombia, the creation of ethics committees has shown a contextual dynamic with the institution's public and open nature, making it changing, episodic, and at times ambiguous in its decisions and actions. In 1996, a proposal for the creation of an institutional research ethics committee was submitted by the Research and Scientific Development Committee to the Academic Council, the highest governing body, this proposal not having been welcome by the collegiate body.

This situation led the National University to organize ad hoc committees from time to time in order to answer to notices of meetings – particularly from *Colciencias* – until 2002 when, thanks to the bioethics network itself, the Institutional Research Ethics Committee was finally created.

By the first decade of the twenty-first century, the Faculty of Medicine's Ethics Committee, as well as those of the Biotechnology Institute, the Faculty of Nursing, Odontology, Human Sciences, and Veterinary Medicine had already been introduced.

At present, there is a network integrated by nine faculty committees, including the Medellin headquarters. Its institutional committee was organized in 2008, and

there is a central committee of a normative nature for its creation purposes; in exceptional cases, it becomes a second instance for all those requiring it with relation to the functioning of area or faculty committees.

In the early 1990s, the Pontifical Bolivariana University, aside from medical bioethics, began to work with environmental bioethics, research bioethics, theological bioethics, fundamental bioethics, and biolaw by offering bioethics and biolaw courses and degrees (*Diplomaturas*).

At the Pontifical Javeriana Univesity (PUJ) Bioethics Institute, bioethics is being consolidated towards the articulation of the three tasks – research, teaching, and services – with a more secular orientation so as to approach bioethics mainly in relation to Colombian society and problems, without excluding regional and world issues.

All teachers and professors have either master's degrees or doctorates in diverse areas of knowledge, such as philosophy, medicine, sociology, biology, law, nursing, economics, anthropology, or theology.

The master's degree in bioethics program has been offered at the Bioethics Institute since 2008. Its main purpose is to train scholars and researchers with sound philosophical and scientific foundations, and engage in the generation, transfer, appropriation, and application of bioethics in such a way that, as an academic community, they may contribute to the development of knowledge and an ethical-moral attitude reflecting on the associated public policies, along with the search for solutions to practical problems in the field of bioethics.

Linking students' research projects with the Institute's research lines is a priority. In close cooperation with professors of different universities and CENALBE, Father Alfonso Llano conducted in 1998 the first PUJ's postgraduate specialization in bioethics program. The general objective of this specialization is to establish bioethics both conceptually and virtually as a practical knowledge in its shaping process, supported with discourse and interdisciplinary practice so that students may obtain the conceptual tools required and become involved in a qualified manner.

Elective undergraduate courses include general and/or basic bioethics; environmental bioethics; bioethics and animals; ecological and environmental bioethics; health, risk and technology, and clinical bioethics (these courses are open to different undergraduate programs).

For postgraduate students, master's and PhD degrees are available in the Faculty of Sciences and Basic Bioethics applied to biological sciences.

The Bioethics Institute offers graduate and continuing education courses as a response to several institutions' requests. With an important practical component, these courses meet needs in research ethics training with human beings and good clinical practices, as well as bioethics committees, clinical ethics decision-making, ethical and legal aspects in biobanking, introduction to bioethics, and specific courses for medical specialties, among others.

Bioethics training services have been provided to professionals in several companies in the area of health, and also to school students and governmental social service institutions. Likewise, bioethics training has been offered to students at

other universities at national and international levels. Starting in 2010, debates on bioethics have been carried out to encourage reflection and discussion.

A radio show called, *En Clave Bioética* (literally: In Bioethics Key) was created in 2011 as a way to focus on bioethics issues and/or problems, particularly in the university community. *En Clave Bioética* is a means to understand concepts likely to be analyzed and applied to modern societal problems from diverse disciplines. At the same time, *En Clave Bioética* offers a deliberative point of view with respect to a problem or relevant topic.

Institute professors also take part in diverse academic events at which the results of their researches, studies, and reflections in the field of bioethics are presented.

Bioethics Research

UMNG teachers/researchers are qualified in different disciplines: the areas of health, social sciences, and human sciences, along with biological sciences, the different engineering branches, and administrative and economic sciences, always with an emphasis on bioethical matters and concern for life care in all its aspects. The university's research group (bioethics group) has organized networks with several organizations and institutions in order to create, develop, and carry out research projects jointly with prestigious national and international institutions. A team of interdisciplinary teacher/researches is devoted to research and intellectual production, many with more than 20 years of working in bioethics at educational institutions and other entities, particularly in the area of health. They belong to national and international bioethics associations (listed below), and some are both pioneers and founders of other associations, like the ICEB, attached to the National Academy of Bioethics, or FELAIBE.

A fundamental axis of the bioethics program at El Bosque University is the development of investigative activity, which includes, in addition to research, the creation, organization, and functioning of committees in the different university divisions, such as the Institutional Ethics and Research Committee and the Ethics Research Committee of El Bosque University Clinic, as well as active involvement in the creation of the National Bioethics Council, by the Colombian Congress Act ["Ley"], 1374 of 2010. The "Bioética, ciencias de la vida" (literally: Bioethics, life sciences") research group was endorsed by Colciencias in 2008, and rated under Category A; currently, it belongs in Category C (Bioethics Department, El Bosque University, 2002).

At the University of Rosario, the Education Research Group, in the Bioethics and Medicine Law research line, works in bioethics education, patient safety, and genetics. Likewise, it has a science, technology, and professional research group dealing with humanities, health professional training, and medical professionalism.

The PUJ's Bioethics Institute supports a bioethics research group whose purpose is to develop philosophical explorations of the moral acceptability of diverse courses of biomedical, biotechnological and environmental action, apart from the critical development of social and institutional processes upon which hegemonic

practices depend and, therefore, are ethically unacceptable in these domains. The group's organizational basis includes four research lines, which, in turn, are manage projects including clinical bioethics and medicine philosophy; environmental bioethics, ethics, bioethics, and social sciences; and bioethics and multiculturalism. The Bioethics Documentation Centre ("Centro de Documentación en Bioética") is part of the Javeriana University Bibliographic System. Its mission consists of supporting bioethics teaching, research, and diffusion work carried out by the Institute within the PUJ and nationwide. It seeks to be acknowledged as a Model Bioethics-Specialized Information Unit at the national level, and is equipped with basic bibliographic material complementing bioethics development at the international level and the thematic interests of a well-rounded bioethics program in accordance with the cultural context. Also, given the recent emergence of bioethics and its accelerated theoretical-practical development worldwide, it is not yet possible to talk univocally of a single knowledge matter or of a single specific and unique research method. Therefore, development of new knowledge is necessary, but is only possible through research training and investigative practice. Some research sources in this new field of knowledge come from other disciplines and sciences like biochemistry, genetics, medicine, ethics, philosophy, law, theology, economics, politics, education, and social sciences, among others. These research sources provide essential theoretical and methodological support for a complex reality where diverse and multiple problems converge, all requiring study and a wide interdisciplinary discussion of valorative nature, particularly in the ethical and biopolitical environment.

Bioethics Legislation

In Colombia, only at the turn of the twenty-first century, bioethics began to be given political importance. A bill was submitted in 2000 by Senator Carlos Corsi-Otalora, but it was not passed by the Colombian Congress. A year later, however, former Colombian President Andres Pastrana issued Decree 1101 of 2001, published in the official journal "Diario Oficial" number 44,450 of 9 June 2001, "whereby the Inter-Sector Bioethics Commission is created and its members appointed."

The Universal Declaration on Human Genome and Human Rights, adopted by the General Conference of UNESCO on 11 November 1997, called on the world's states to take all appropriate measures to promote conditions conducive to the free exercise of research on the human genome and to consider the ethical, legal, social, and economic investigations. Beginning with the 18th World Medical Assembly in June 1964 and subsequently ratified by the 29th and 35th Assemblies World Medical in Tokyo and Venice in October 1975 and October 1983, respectively, the "Helsinki Declaration" document was adopted, containing a series of recommendations to health professionals engaged in biomedical research and setting forth rules to be observed as a guide in human studies. As a result of recent advances made in biomedical and biotechnology, there is a need for a multidisciplinary committee of the highest professional level to advise governments worldwide and provide conceptual tools from an ethical-philosophical perspective to reflect on, analyze, and guide

decision-making posed by these sciences. The eighth article of Law 10 of 1990, which is organized by the National Health System, and the fifth article of the Law 60 of 1993, which established rules on organic division of powers, determine, through the Ministry of Health, the rules binding the entities comprising the system.

The Inter-Sector Commission on Bioethics is the consultative and advisory body of the national government under the Ministry of Health. Its charge is research and analysis of public policy issues related to the protection of human life when doing research, development, and publication of scientific and technological knowledge. The tasks set were as follows: Formulate and submit to the government a document that comprehensively addresses the analysis of the ethical questions posed by scientific and technological advances involving human beings and make recommendations to reconcile the freedom of research with respect to human dignity. The document will also analyze the existing legislation on the matter and propose a policy framework to develop ethical principles that should guide research in humans, and the desirability of creating an Advisory Council on Bioethics with binding decisions for the scientific community and society in general. Similarly, the advisory body will recommend what the government must do directly or indirectly with ethical issues arising from scientific research and provide advice and recommendations on matters relating to the ethical implications of intervention and research into the human genome, cloning, biomedical research, in vitro fertilization, transplantation of organs and tissues, xenotransplantation, and with individuals and special communities, especially ethnic minorities, children, and the disabled; research using human cadavers and animals is also included. The advisory body also will prepare reports or opinions on ethical issues arising in the activity of clinical bioethics and research committees, in support of hospitals in the country.

Act ["Ley"], 1374 de 2010 January 8 created "the National Bioethics Council,"; articles 3 and 4 of the Act are regulated by COLCIENCIAS. The entity produced a draft for the introduction of a decree in compliance with this mandate, which was socialized in regions of the country prior to submission to the Colombian President (Bioethics Department, El Bosque University, 2009). "Developing actions leading to the promotion of Education in Bioethics and the society's involvement in the debate of related subjects" (Act ["Ley"], 1374 of 2010, Art. 5, paragraph h.) is one of the functions of the National Bioethics Council (CNB).

The following juridical rules relate to bioethics subjects:

The 1991 Political Constitution of Colombia, where characteristic bioethical matters can be identified, such as life and human dignity, scientifically assisted procreation, health, the environment, and so forth.

Ministry of Health Resolution No. 8430 of October 4 1993, "Whereby the scientific, technical and administrative rules required in health research are established." The enactment of Law 100 in 1993 (which amended the previous National Health System, in force since 1976, and established the current Social Security System in Health (SHSS)) sought to carry out the mandates on health and social security in the Colombian population referred to in Title 2 of the Constitution promulgated in 1991. One of the main foundations of this Act is the goal of increased health care coverage for the Colombian population.

Judgment C-239 de 1997 on euthanasia: Colombia, constituted as a unitary state of law, is pluralistic and based on respect for human dignity. Just as the Constitution gives everyone the right to free development of his personality, no other restrictions than those imposed by the rights of others and the legal system, as the person is recognized by the supreme law as an autonomous moral subject, which means that each person who must choose the principles and moral values that should govern their conduct. The State then is assumed as capable of deciding about good and evil, without the State can legitimately be replaced in this radical decision. Thus, pluralism is a necessary consequence. This implies, of course, the paths drawn, goals set, and decision made regarding what meaning must be given to life, conferred by a Supreme Being or Nature, are among many possible options. A person can judge that life is sacred, invoking religious morality (possibly also of more than one interpretation), considered a valuable good (not sacred), or may not even value it as a good. "The right to life is inviolable." Clearly, if life is a right, no one can legitimately deprive one of life against their will, but any person can freely choose between life and death; when a person chooses to keep still, that is a way to exercise their freedom of movement. If life is enshrined as a right, not as a duty, a person can legitimately continue to live or to stop their life course.

Decree 1546 of 4 August 1998: "Whereby Acts ["Leyes] 9 of 1970 and 73 of 1988 are partially regulated with respect to the obtainment, donation, preservation, storage, transportation, destination and final disposal of anatomic components and procedures for transplantation thereof on human beings, and the minimal conditions required for the functioning of Reproductive Biomedicine Units, Centres or the like are adopted."

The purpose of Reproductive Biomedicine Units is to provide health services in the area of reproductive biomedicine accordance with the principles of quality, timeliness, and logical-scientific rationality. Any program of reproductive biomedicine should ensure the selection of healthy donors and absence of genetic alterations involving risk of congenital anomalies, for as long as the donors remain active in the program.

Ministry of Health Resolution 3199 of 6 August 1998 (which supplements Decree 1546 of 1998): "Whereby technical, scientific and administrative rules for the functioning of Anatomic Component Banks in the Reproductive Biomedicine units, centres or the like are established and other provisions issued." This decree established the functions of transplant ethics committees; the information to be submitted by the agency for the coordination officer; the national network of donation and transplants of anatomical components; health and personnel requirements for these procedures; the production, extraction, and conservation of anatomical parts; and health requirements of the units of reproductive biomedicine. Several teachers and professors have participated on the working board in the preparation of a new medical ethics code and the regulation of organ transplantations.

Act ["Ley"] 599 of 2000 (Criminal Code) in Chapter VIII, "On Genetic Manipulation," typifies as criminal conduct the following: genetic engineering, defined as gene manipulation with purposes other than treatment, diagnosis, or scientific

research relating to the field of biology, genetics and medicine, aimed at relieving suffering and improving the health of the person and of humanity (art. 132); repeatability of human beings by cloning or other procedures (art. 133); and human ovule fecundation for purposes other than human procreation.

Act ["Ley"] 1412 of 19 October 2010: "Whereby the free of cost performance of the procedure of cutting, tying and cauterising vas deferens, known as vasectomy, and Fallopian tubes ligation as means to encourage responsible paternity and maternity are authorised and promoted."

One of the most controversial topics to be debated in Colombia has been abortion. Judgment C-355 of 2006, Judgment T-209 of 2008, Judgment T-388 of 2009, and Judgment T-585 of 2010 were related to this issue. On 10 May 2006, the Constitutional Court of Colombia put forth a landmark ruling in favor of human rights of women. By Judgment C-355/06 of 10 May 2006, the Plenary of the Constitutional Court decriminalized abortion in three circumstances: (a) where the continued pregnancy endangers the life or health of a woman, certified by a physician; (b) where there is severe malformation of the fetus that makes life unviable, certified by a physician; (c) when the pregnancy is the result of conduct, duly reported, constituting rape or sexual intercourse without consent, abusive or artificial insemination or transfer of the fertilized egg without consent, or incest.

Bioethics Committees

At the Military University, the bioethics group took part in the Faculty's Research Committee, integrating the Doctorate in Bioethics Project. Some teacher/researchers are involved in other bioethics committees at health institutions in Bogotá, including the Hospital Ethics and Research Ethics Committees of the International Sanitas Organisation (2000–2010), the Ethics and Surveillance Commission of the Association for Clinical Research in Colombia (1998–2008), the Hospital Ethics Committee of the ("Fundación Cardioinfantil"), and the Children's Heart Foundation.

At the National University of Colombia, the creation of ethics committees has shown a contextual dynamics with the institution's public and open nature, making it changing, episodic, and at times ambiguous in its decisions and actions. In 1996, a proposal for the creation of an institutional research ethics committee was submitted by the Research and Scientific Development Committee to the Academic Council, the highest governing body, this proposal not having been welcome by the collegiate body. This situation led the National University to organize ad hoc committees from time to time in order to answer to notices of meetings, particularly from Colciencias, until 2002 when, thanks to the Bioethics Network itself, the Institutional Research Ethics Committee was finally created. During the 2000s, the Faculty of Medicine's Ethics Committee, as well as the committees of the Biotechnology Institute, the Faculty of Nursing, Odontology, Human Sciences and Veterinary Medicine, had already been introduced.

At present, there is a network incorporating nine faculty committees, including the Medellin headquarters. Its institutional committee was organized in 2008, and there is also a central committee of normative nature for its creation purposes; In exceptional cases, exists at the central level to the Vice Rectory of Research a committee that is normative, and has the purpose to be the second instance for those who require in relation to the operation of the area committees or faculty.

Major Bioethics Issues and Discussions

Different Colombian representatives have taken part in the discussion of major bioethics matters through several academic initiatives, public debate, assistance and research activities, and publications, as described below. Some of the issues are detailed below.

Abortion decriminalization in special circumstances was the topic leading to one of the most intense debates held about the beginning of life in Colombia. In 1975, Senator Ivan Lopez-Botero submitted the first bill in the country *whereby the therapeutic interruption of pregnancy is regulated*. This bill was shelved by the Colombian Congress and, after several failed legislative attempts to succeed in achieving this objective, it was finally passed by the Constitutional Court of Colombia under Judgment C-355 of 2006.

The end-of-life debate began in 1979 with the creation of the *Fundación Solidaridad Humanitaria*, which changed its name in 1983 to the *Fundación Pro Derecho a Morir Dignamente* (Foundation in Favour of the Right to a Dignified Death).

The debate became increasingly intense with the pronouncement of Judgment C-239 in 1997 on euthanasia, which has been previously discussed. Subsequently, several bills attempting to legalize both euthanasia and assisted suicide have been submitted and shelved.

With respect to the health system, the debate on this subject began some years prior to the issuance of Act [*Ley*] 100 of 1993, when the need to change the existing health model was exposed, in order to increase health care coverage for the Colombian population.

With regard to reproductive medicine, the Colombian Fertility and Sterility Society was created 1977; among its founders is gynecologist Elkin Lucena, a pioneer of assisted human reproduction in Latin America and founder and director of the Colombian Fertility and Sterility Centre. There is some debate about assisted human reproduction techniques and the ethical quality of their use, relating as well to the beginning of life, embryo selection, the so-called neo-eugenics or new eugenics, or liberal eugenics, among other ethical objections.

Colombia wished to be at the forefront of bioethics, thus different educational institutions, especially those in the field of health, are constantly integrating their programs of study and their committees the possibility of the study and practice of bioethics. Today in Colombia, health care ethics committees and research ethics committees are required by the government and are evidence of quality in health care.

Future Challenges

There is currently too much noncoordinated activity, and sometimes duplication of functions is combined with non-unified human and economic action.

> There is a tendency to copy foreign efforts; for example, many themes and developments in bioethics are mere duplicates of North American and Spanish proposals. New subjects are omitted and scarcely treated from an endogenous perspective and for regional problems not taken into account in foreign proposals.
>
> Latin American governments, as in Colombia, are usually concerned about urgent situations relating to public order, economy, and public service crises. . .
>
> But they do not pay attention nor give any thought to financing, legislating and instituting National Councils in Bioethics aimed at advising politicians about how humans should treat each other or how humans should treat today's threatened life and nature. (Llano, 2007, p. 57)

There is a strong wish to continue to promote the teaching and study of bioethics from the early school years through the highest levels of instruction, and with the institutional recognition and support they deserve.

Conclusion

Bioethics leaders in Colombia have tried to encourage the study of bioethics by different faculties and promote training at both undergraduate and postgraduate levels. They also have carried out instruction and research activities through renowned national and international publications, active involvement in health institutions' research and hospital ethics committees. Public debates and the formulation of juridical rules, the creation of associations, institutes and networks, as well as participation in federations and societies at national and international levels have increased in Colombia.

The introduction of specialization and master's degrees in bioethics in different universities are worth mentioning, as well as a doctorate program and others currently under a consolidation process for the multiplication and training of researchers.

In the future, an interdisciplinary and holistic approach to human life and the environment is expected (Schmidt & Garzón, 2006). In Colombia today, the objective is to join the efforts of the various institutions doing work in bioethics in order to achieve a sounder integration of knowledge through scientific activities, public debates, and research.

The first Congresses and public debates have already taken place jointly with the different universities. Nonetheless, all those currently involved in bioethics expect to further consolidate the work they are carrying out.

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Evariste B. Likinda

Introduction

Bioethics debate is currently widespread all over the world. The adoption by the United Nations Educational, Scientific and Cultural Organization (UNESCO) of the Universal Declaration on Bioethics and Human Rights could be considered as a milestone assigned to be a reference for the whole humanity, with regard to the respect of human dignity and human rights in the specific field of health care, biomedical research, clinical practice, or even medical education.

E.B. Likinda
Chief of Department of Surgery, University Hospital Centre of Mbandaka, Mbandaka, Equateur, Democratic Republic of the Congo

University of Mbandaka, Mbandaka, Democratic Republic of the Congo
e-mail: Evalik2@hotmail.com

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On the understanding that ethics relates to moral conduct, it is widely influenced by variation between cultures, religious beliefs, and mentalities as diverse as the existing peoples in the world. The hierarchy of values does not seem unequivocal at first.

This disparity in the value scale could partly be due to the large rift separating industrialized countries and those which are aspiring to development, with regard to scientific and technological progress. Diverse perspectives coexist side to side, but more and more often, they confront each other in a globalized world. On the one side, there are people who have mastered mysteries of science and give impression to have the best life conditions, and on the other side, those who are yearning for development and better life; and all that in the same world which, thanks to increased power of communications, is being globalized.

As bioethics concerns matters relating to human dignity, all of the earth inhabitants are inevitably sooner or later assigned to enter this debate; solidarity of all human being is at stake, anywhere one could be in the planet. However, even if problems like disease, sterility, old age, and death are common human realities, the way for them to be solved could vary according to place and time circumstances. Any situation will, indeed, be perceived by different observers from their own particular vantage points, which is focusing on what they consider important. Where the peoples of poor countries such as the Democratic Republic of Congo are concerned, it would make sense for their participation in what is now supposedly a global debate, to emphasize some issues important to them.

The chapter is meant to be a synthetic picture showing how bioethics activities are undertaken, seen, and have evolved since the concept's inception until now in the Democratic Republic of Congo (DRC), while trying to foresee future challenges.

Development in an Academic Framework

Medical Ethics Education

In 1968, the Zairian (Congolese at present) legislature issued a law decree based on the constitution, providing terms of reference and procedures of the Ordre des Médecins (National Medical Council). Then in 1970, a second decree affixed the code of medical ethics. This code is inspired by the International code of medical ethics adopted by the World Medical Association (WMA). Later the Ordre des Médecins has become member of the WMA which has already treated some bioethics issues like *informed consent* emphasized in the Declaration of Helsinki, as it concerns the medical researches involving human subjects.

Since this period, medical ethics education has been introduced into DRC university faculties of medicine. One faculty members, Professor G. Kabakele, an orthopedic surgeon, was in charge of this matter. A manual designed for medical students' ethics education was written by Likinda (2001b), a neurosurgeon and former secretary of the Congolese Medical Council. This book entitled "Principes

de Déontologie Médicale" is essentially focused on the regulation of medical practice, relying on a code established in a juridical text that physicians, nurses, and other health professionals have to respect without giving rise to a debate. It is a compendium of rules of conduct towards patients.

Previously the same author had written "La faute médicale" (Likinda, 2001a), essays on malpractice in which he tackled subjects like abortion and euthanasia, both absolutely prohibited by criminal law in DRC. As the Congolese health minister was the guest of honor at the book presentation ceremony, the author took the opportunity to propose the creation, by government, of a national bioethics committee, emphasizing the last aim of the book. In fact, it seems clear that the questioning raised by subjects like abortion, euthanasia, artificial insemination, and other medical methods made possible by the development of scientific knowledge and new technological progress relating to it pushes the limits of the only ethical code regulating the medical profession. A need to extend the debate has become evident.

Bioethics Classes and Academic Works

By 1987, a bioethics class was already included in the course of theology and philosophy students of Catholic Faculties of Kinshasa (at present, Catholic University of Congo). In the same year, this university institution organized the 16th Semaine Théologique (theology week) with the theme "Christian ethics and African societies"; some bioethics items were placed on the meeting agenda. The first academic dissertation on a bioethics topic entitled "Artificial insemination. Approach to a biomedical ethics" (1987) was written by Muyengo S., a Roman Catholic priest, one of the students of the same university, for a theology degree. Later, he prepared a thesis at the University of Toulouse on "The Status of a Human Embryo. A Fundamental Ethical Issue" (*Du statut de l'embryon humain. Problème de fondement de l'éthique*) (1997). Returning home as professor of moral theology, he successively published "Introduction to Bioethics" (*Introduction à la bioéthique*) (1999) and then "Ethics and Genetic Engineering" (*Ethique et génie génétique*) (2003).

More recently, two theses related to bioethics subjects were written up: "The Fight against Reproductive Crime in DRC" by N. Mvaka (2011), an outline of criminal policies applicable to a bioethics matter, and "Philosophie et prévention du VIH/Sida en Afrique. La pauvreté éthique comme source de persistence des comportements à risque par le VIH," a thesis treated by F. Munday (2010).

Social Context and Questioning

Bioethics has been gaining public interest. Information about unceasing advances made in the field of medicine is generously given by the media, particularly in genetic engineering and innovations in biotechnology. In certain places, some

intellectual initiatives have been formed as discussion forums to debate the main bioethics topics each time they are diffused by the media. This was the case, for example, when the Dutch Parliament adopted the law legitimating euthanasia and even when human cloning was demonstrated to be possible after the birth of Dolly.

At the moment bioethics issues began to raise intellectuals' interest, the suggestion was raised to create an organ in charge of reflection on bioethics questions. Meanwhile, the country was experiencing indescribable and multifaceted socio-economic, politico-military, and humanitarian crises; the country was put through a sustained civil war in its eastern provinces. Subjects such as bioethics were among the last concerns of public authorities focused on reestablishing minimum conditions for a secure life in society. Moreover, strictly speaking, the country was not until then facing problematic dilemmas such as whether or not to permit genetic engineering research, human cloning, organ transplantations, etc. So, on several conference occasions, the question was turned around: What is the propriety, the relevance, and the urgency of bioethics debate in a society where people are still dying from hunger, unsafe water, malaria, and other infectious diseases that would be perfectly curable if medical resources were available, in a country badly under-medicalized, where expectant mothers have no access whatsoever to prenatal care and give birth without medical assistance because there are no adequate medical facilities or competent medical personnel in their area? To sum up, the majority of the population is languishing in poverty. The country is struggling with poverty-related problems that require resolute policies, if they are to be solved. There admittedly are problems into which basic research could be carried out, in order to improve scientific understanding, but in practice, all that is sometimes needed to enhance the people's well-being and promote human dignity are some logistics and a modicum of organization. The country is still in the elementary phase of its search for solutions in the struggle for survival. How to improve the conditions of human beings in this situation is surely the first ethical question that must be raised, a socio-ethical question rather than a bioethical one, if we concede that by definition, bioethics is related to life sciences. Given this picture, to delve into the issues raised by technical and scientific progresses might seem like mere intellectual indulgence that is very far from offering any prospect of practical solutions to the real problems of society.

Institution of Bioethics Structures

National Bioethics Committee (NBC)

Probably because of these above-mentioned reasons among others, institutionalizing a bioethics committee was not seen as an urgent necessity to the eyes of the public authorities getting bogged down in other priorities dictated by the crisis. While the government, given this crisis, delayed its action, a private initiative arose, bringing together a panel of intellectuals from different fields, who already were

used to meet for informal bioethics debate, and they began to discuss the possibility of establishing an advisory organ in charge of providing advice on bioethical problems for adequate legislation, fostering debate, education, and public awareness, contributing eventually to the preparation of guidelines. Indeed in the meantime, without involving a true genetic engineering, there were already some cases where procreation has taken place outside the womb; in a private center of in vitro fertilization, test tube babies have been born in Kinshasa since 2002, which reveals the ease of technology transfer in our time and the necessity of appropriate legislation. These sorts of technology applications, underway in the field of medically assisted procreation, take place in a complete legal vacuum. So that a legislator might make laws in full knowledge of the facts, formalizing an institution was also motivated by the necessity to effectively participate in the world debate. So the informal group drafted a statute for the National Bioethics Committee (NBC) and submitted it to the Minister of Education who chairs the National Commission to the United Nations Educational, Scientific and Cultural Organization (UNESCO), a United Nations specialized agency with a role conducting the said world debate. The Education Minister's agreement (2003) allowed the so-established NBC to play the role of bioethics adviser and to represent the DRC at international meetings concerning bioethics issues.

The NBC is a multidisciplinary and pluralist organ made up of 17 members from different fields (medicine, law, philosophy, theology, sociology, communication, etc.). The multidisciplinary and pluralist nature of bioethics speaks for itself; it is actually evident that no one, not even a scientist, could monopolize for oneself bioethics debate relying only his manner of living and thinking. If, indeed, technical aspects of biology and medicine fall unquestionably within the competence of these disciplines' practitioners, these could not solve by themselves ethics questions relating to use of the said techniques. Bioethics questions are proving to be so much more complex that a proper analysis could not be reduced to a limited view: it is not wise to exclude someone from discussion. Bioethics debate has to make the best of the multiplicity of links between individuals with different angles and diverse interests, but living in the same society; its method has become established as a collective research, each one taking part with his comprehension of existence (Likinda, 2006).

National Committee of Health Ethics (CNES)

In another area, a branch of the University of North Carolina (from the United States of America) planning to undertake biomedical research in DRC, aware of international guidelines, suggested to the DRC Health Minister to form a research ethics committee to be responsible for analyzing and conferring an advice on the research protocols before their implementation. That is how a ministerial decree (2007) gave birth to the National Health Ethics Committee, an independent, multidisciplinary, and pluralist committee whose members are appointed by the ministry.

Bioethics Education Structures

In the aim of promoting bioethics education so that it be widespread over the country, and even over Africa, the NBC of the DRC organized, with UNESCO support, a workshop (July 2009) bringing together the experts who lecture on ethics at French-speaking universities of Central Africa and Madagascar so that they could jointly review the different teaching programs with a view to mutual enrichment and possible harmonization. Some other initiatives have started since the last decade and are currently organizing bioethics courses, seminars, workshops, conferences, and public debates. Some are listed below:

(a) The International Center of Bioethics in Francophone Africa (CIBAF, Kinshasa School of Public Health)
(b) The Circle of Bioethics Study of the Catholic University of Congo (Kinshasa)
(c) The Center of Medical Ethics and Bioethics of the University of Mbandaka (Mbandaka)
(d) The Center of Training and Health Support (CEFA, Kinshasa)

Committees' Activities

NBC Members' Education and Public Awareness

Right from the start, before it could even begin to issue opinions, the NBC had to engage in a major operation to obtain information on the issues involved in what is emerging paradigm. The aim was to obtain as much knowledge as possible on bioethics and enhance capacity in the committee so that the committee would efficiently grasp the essence of the ethical matters raised.

The NBC made efforts to implement a communication campaign by publishing a review entitled *C'est quoi la bioéthique?* (What is bioethics?), a sort of glossary which, for each bioethics concept, gives the definition, what made it problematic, and notably the ethics questions it raises, where the discussion remains open. The aim is to bring readers to assess elements on each subject, to form his own opinion or, if he already has one, to compare it with others, and finally to participate more usefully in bioethics debate.

Conferences and seminars as well as television programs have been organized with the same objective to lead more people to know what it is to analyze and to participate in a dialogue on bioethics issues.

Public Debate Before UNESCO Consultation

At the outset, the members of the NBC have made a big effort of communicating on the meaning of the concept bioethics and all that is at stake. Aiming to bring the contribution of the DRC to the global consultation within UNESCO within

the time frame of process of developing international norms on bioethics, the NBC also organized some public opinion studies and seminars just so as to generate a contribution to the international debate sufficiently representative of the national opinion.

Research Protocols Examination by the NCHE

Meanwhile, the NCHE members had been appointed by the health minister; they are in charge of examining research protocols before implementation; in doing so, they must carefully take into account aspects like informed consent, security of research participants, possible risks, and expected benefits.

Contributing to Assisting Bioethics Committee (ABC) Project of UNESCO

The president of the NBC participates in the ABC project as an expert. By means of this UNESCO project, ABC experts are helping in the earliest phases of establishing national bioethics committees in some countries, and once established, the experts also assist NBC members to implement their actions.

Objectives and Priority Themes

Education

Looking back to just a few years ago, bioethics was an academic subject, treated in a limited way by just a few people in a small circle (the philosophy faculty); the term "bioethics" was familiar neither to public at large or politics figures nor even to university experts. Particular emphasis has therefore to be placed on ethical education. It rapidly turned out necessary for everyone to become informed on ethics issues related to biotechnology development. So there is cause to consider that a great deal of efforts should be devoted not only to place bioethics courses on the education syllabus in universities but also to adapt it for secondary and down to primary school.

Public Awareness

Bioethics has to cease being limited as if it were an academic matter for expert's concern. The debate on bioethics topics has to be generalized. It seems useful to increase public awareness of its issues, by removing barriers within which scientific and technology experts are often locked, whereas ordinary people, indeed, perceive and reason, perhaps in an insufficiently structured manner, at times a casting back

for some values that give a sense to their existence. This openness to the public has a sense only if there can be a thorough popularization and social appropriation of scientific knowledge. Whereas "bioethics for all" certainly requires academic's effort to raise the level of debate and avoid pitfalls, its process also needs more democracy, attracting greater interest of people who therefore not only need to be honestly well informed but also need to give their opinion. Scientific research will play, indeed, its real role only if the men and women, the first and foremost concerned, appropriate it as part of dialogue with researchers about issues and possible consequences relating to science and technology. After all, it is the public that is supposed to benefit from advances in science and technology.

In this approach, media is proving to be an indispensable tool for public awareness; it is, though, of the utmost importance to try to have harmonization of views and in every way with journalists who are the professionals of communication and so very useful for assuring that messages are passed to the public according to their proper sense, without exaggeration or omission. Seminars organized with journalists permit them to progressively perceive what is at stake in bioethics issues; with such knowledge, the journalists will better communicate information.

Popularization of bioethics issues also has to take into account the problem of language understood by those whom the message is intended for, bioethics being no more reserved to academicians, technologists, or their institutions and having become a concern for everyone: not only those who speak and understand French or English but also those who speak other native languages which are not taught at school or at university. An effort is therefore to be done for translating messages into many languages. In DRC, for example, despite the fact that French is the official language, only a few people can use it and even fewer speak English.

Socio-ethics or Bioethics

Bioethics activities in a country like DRC must be first of all a social ethics. It could not be understandable to delve into real ethics issues where the majority of people languish in darkness and poverty. Bioethics activities would not be useful if they do not take into account the public's capacities. For example, it will be an illusion to expect some efficiency in public health planning, while many are illiterate. And how should one fight effectively against AIDS or other sexually transmittable infections where many of the men and women are illiterate and when hunger dictates sexual behavior? How should one improve relations between physicians and patients when citizens ignore and have negligible experience of asserting their elementary rights?

In the strictest sense suggested by its etymology, bioethics should refer to ethics issues arising from the invasive application of biomedical technologies. This development has, indeed, raised a lot of problematic questioning in terms of human values. What is at stake here is ethics or morality concerning human life. Bioethics is here reduced to a minimalist definition concerning "morality study in the field of human life" (Reich, 1994). In this scenario, bioethics is defined as

biomedical ethics. It considers all medical practices and techniques taking place at the beginning of life (contraception, abortion, prenatal diagnosis, medically assisted procreation, cloning), during the course of life (researches on embryonic cells, psychiatric diseases, experiments on human beings), and at the end of life (euthanasia, patients in persistent coma).

The more extensive definition refers to "systematic study of human conduct in the field of life and health sciences, examined in the light of human values and morale principles" (Peeters, 2007). In addition to human and other livings beings (animal and vegetal), the biosphere is taken into account, in so much as it provides the conditions of their harmonious existence (air, water, earth). In this definition, bioethics goes beyond the frontiers of human medicine. Medical questions, demographic problems, environmental issues are in question; all are examined with reference to moral values and principles.

The current sense of the concept bioethics suggests a comprehension of reality in a more extended perspective, in every sense of the word. The Universal Declaration on Bioethics and Human Rights includes effectively a vast field of application consisting of diverse issues; questions of peace, solidarity, and cooperation; distributive justice and equity; future generations; social responsibility; and health; in brief, in addition to biomedical and environmental subjects, social questions and even government systems are concerned. Bioethics is defined here in the widest sense, that is to say all scientific interventions in life in general. It is examined from every angles, biotechnological as well as social. Bioethics, far from being limited to the ethics consequences of scientific and biotechnological advances, extends to social problems which are to be taken into account as a primary concerns in a country like DRC. The main challenge of bioethics activity here and now will be to consider social matters on its agenda. So people of countries like DRC should recognize themselves in these issues, because their critical ethics problems are of social nature. At the very beginning of the bioethics debate in DRC, the same question kept coming up at every conference, as the first ethical question that must be raised: How should bioethics improve the conditions of human beings in the elementary phase of their search of solutions in the struggle for survival? Problems centered on social themes such as malnutrition and resource allocations in the context of scarcity, unemployment, literacy training, life conditions in prison, social security, refugees, and war are part of bioethics, but they have a particular specificity: they have roots in social issues. Value conflicts around life here are expressed as socio- rather than bio-terms. As a result, in this sociocultural context, bioethics is meant to be a field of multidisciplinary reflection concerning entire life conditions. It is also a question for government. For example, it could be that a prevention program for some diseases is to be implemented; despite the fact that people are abandoned and the government fails to keep its obligations on public health, it should be important and indispensable to undertake some initiatives so as to establish the preconditions for the efficient delivery of the prevention project; restoring peace, prompting democracy, encouraging distributive justice and sense of common good, and setting up community structures able to arouse, organize, and manage solidarity and generosity within a state would all certainly help.

Vigilance for Appropriate Legislation

In spite of bad conditions of social life, without involving true genetic engineering, a great deal of biomedical research is now being conducted in DRC; some projects are initiated in the developed world and are conducted at any given time in a number of countries, particularly in Africa. Population groups there are thus affected as human subjects in clinical trials or other studies. Vigilance is therefore required: it would be unacceptable for research institutions or pharmaceutical firms to carry out clinical experiments on human subjects without applying the same rules of ethics and risk reduction as is expected in developed countries. In DRC, there is a risk that research participants may not be in a position to provide informed consent due to the lack of their independent capacity to evaluate the associated risks and benefits in the form of medical care during the trials.

It is also to be feared that, in a situation of widespread deprivation, poor people may easily be turned into guinea pigs, with ethically unacceptable experiments being performed on them for some payment. In other cases, these experimental subjects may simply be excluded from realizing even remote benefits. Impoverished people have risked participating on trials of vaccines or drugs despite that, once the drug or the vaccine is developed, they would not have the financial possibility to buy the product that they have contributed to develop (De Castro, 2001). Moreover, some tested techniques may be unashamed luxuries and their development squanders huge resources: only a few people would derive small benefit from them, while many men and women will not gain any advantage and tested subjects suffer risks and side effects.

Another example is the following: Media reports have revealed also that human organs are being traded illegally in various places; the victims of these sorts of affairs are, in general, poor people. Public vigilance has therefore to be aroused given the possible risk of devaluing and even marketing of life. Even in research locally initiated, the history of the country included experiments where the respect of ethical rules should have been problematic to say the least. In fact, in the year 1987, two physicians, Lurhuma (Congolese) and Shaffik (Egyptian) had to test a drug occasionally named MM1 (Mobutu-Mubarak) against AIDS virus; it was reported that 200 soldiers, although healthy, had been designated by president Mobutu as participants in this experiment without a real informed consent. Groups like soldiers may, indeed, be considered as vulnerable because they could be prone to subtle pressure especially under a totalitarian government.

Even though the resources and infrastructures are not currently available to undertake biotechnological engineering, the experts of research ethics committees must be able to keep abreast of the outcomes of scientific work and give them their proper place among global concerns, concerns for policy-makers and concerns for public opinion. It is important for them to strive not only to understand the issues involved in technical and scientific progress but also to anticipate its future directions. Where clinical trials are concerned, they must not only look out for the well-being and safety of their subjects but also – and vitally – ensure that the research undertaken is truly in line with the priorities of the populations concerned.

Every cloud has a silver lining, an adage says. Poverty and underdevelopment give advantage to know in advance what has happened elsewhere; in full knowledge of the facts, people could think about an innovation before it reaches them. There is no doubt that development will reach these countries with globalization; maybe bioethics debate and, why not, laws will precede biotechnologies. In bioethics approach of life problems, the big challenge here in Africa is to know how to receive science and technology without diluting essential of anthropologic values deeply rooted in cultures and traditions. Attention has to be drawn to what it means to answer bioethics questioning: the answer should not hurt conscience and coherently fit the sense of human which is to be preserved or promoted, the signification or the belief of what persons are. Such an answer to questions raised by such practice or research protocol should not contain the risk of transforming the image that people have of the human being and the basis of the respect due to him? A method which apparently comes up against a limited or individual need, even concerning health, should not contradict fundamental ethics and social ideals, should not it risk being destructive for familiar links and favorable to social collapse?

Participation in the World Debate

Endless Extent of Technical Possibilities

In the past, culture and religion imposed taboos. Values and morale were philosophically and theologically stable as immutable truths. Value bases were referred to transcendence. At present, genetic engineering has shaken this confidence. For example, the capacity to work with embryonic cells has given rise to a lot of promises that organs can regenerate. Human cloning has overtaken the step of technical difficulties so that only ethics questioning remains in discussion. Human genome deciphering has paved the way for not only predictive medicine and genetic therapy but also the possibility of genetically modified organisms, including for the species *Homo sapiens*. All of these technical and scientific realities give the endless extent of possibilities open at present to human power. Biotechnology advances have a real influence on the evolution of mentalities, to the extent that one could say they are moving out of the thinking field. All that becomes technically possible tends to become feasible for an effective application and even for a legitimate claim.

Ambiguity of Progress

It is not about discrediting science and technology. Everyone agrees that science and technology have to aim for human well-being, happiness, and prosperity. Actually, scientific progress has significantly improved the human conditions so that people have longer and better life today. Since the time of our understanding of harmful effects of the atomic bomb, however, no one can have a naïve confidence in all possibilities offered by science. Innovations are often made without anticipation of their consequences. Many technical

exploits have been applauded as progress, but then have been revealed dangerous afterwards. Indeed, supposed progress was the cause of the crisis of mad cow disease; cows, naturally herbivorous, were nourished with meat powder; once a number of cows were ill, they transmitted a spongiform encephalopathy to humans; then, in the distress caused by this situation, bovine populations have unfortunately been decimated (Muyengo, 2004). The growth hormone scandal in France or the StarLink affairs in the USA are likewise well known. Humanity should have understood the necessity of maintaining a sustained vigilance about possible excessive dangers.

Universality is nowadays the key word of bioethics. After having been philosophers', theologians', and physicians' concern, bioethics has later aroused lawyers' interest. Then it, more and more, turned public's attention to its questioning. And at present, the debate is a world concern; the world in its entirety. Globalization is made easier by increased power of communications. Geographic or national barriers are systematically broken down, mentalities tossed, problems universalized, and values standardized. There is cause to fear that this globalization be unilateral, too much empowering those who have mastered science and technology. There is a natural inclination to place inventors and promoters of progresses in a position of authoritative superiority; there is then a risk to give in too easily in each area of debate, seeking the easy way out consisting in breaking off the debate in advance, considering as decisive the arguments put forward by holders of technological and scientific powers: "it is so done in Europe or in USA*;* it is lawful*;* it is therefore legitimate," as sometimes they say. And yet, those who master technical and scientific powers are like holders of weapons of mass destruction; they know very well their complicated tools and mechanisms and how exactly to use them, but they are not necessarily the best placed to know that these arms should precisely and simply have not to be used; they do not have the monopoly to assess the acceptability of actions relating to these arms, according to global human values. Nowadays, while offering beneficial perspectives of improving human life conditions, biotechnological power exceeds by far, in potential nuisance, the devastating capacity of nuclear arms. Today, technology and science result from improvement of knowledge in detail of a given sector of activity: things are studied in depth, giving rise to working efficacy in a closed system. This is mechanic rationality, via hyper specialization. And yet, a compartmentalized knowledge and enclosed rationality could not be omniscient; it brings lots of knowledge, but seems to have trouble understanding multidisciplinary problems and recognizing fundamental and global issues. A real rationality would not ignore the anthropologic complexities. Global rationality has to take in consideration the subjectivity, affectivity, and the part of myth which are integral part of the human mind (Morin, 2007).

Universality and Common Destiny of Humanity

In this stage of history, humanity needs an exceptional wisdom to determine the best possible understanding of human responsibility in the world and to know what could be reasonably done and what could, eventually, not be undertaken. It is time to face the challenge of planetary complexity and recognize ambivalences and

contradictions present in all fields. Wisdom means the crucial realization of solidarity among humans and the planetary community of destiny. Climatic changes have fortunately obliged that every earth inhabitant rediscovers to be on board of the same boat, whose motors derived from human science and technology seem to be out of control. The problem is to establish the control of these engines by ethics. The destruction of the ozone layer, for example, due to excess of industrialization, affects people of forest living without the least product of civilization and of whom are required not to exploit forests for their survival, in favor of the whole humanity. So development admittedly brings scientific, technical, medical, and social progresses, but it also brings biosphere destruction, cultural destruction, and new inequalities and constraints (Morin, 2007). As well as equity problems at stake here, it is essential to realize that the common destiny of humanity has no more to be left in the hands of the one and only Western rationality which seems to become established as the only system of thinking. It therefore would seem wise to consider the problems from every point of view. It is about seeing with our heart as well as thinking with our head, as they say. Instead of assisting, it is an assignment for each people to contribute with its culture, philosophy, and religion which are not to be brushed aside with the back of one's hand, because they constitute the common sense acquired and developed for ages by intuitive understanding, for a responsible management of life and the survival of humanity, through future generations.

Fundamental Humans Values

In this global approach, Congolese people as well as Africans in general have got some difficulties when it comes to dialogue with others on some essential bioethics questions like the respect of human life, human dignity, and consequently human rights. The notion of human rights is today the most shared concept to which infallibly peoples agree. The concept of human rights is closely attached to the one of human dignity in the Universal Declaration on Bioethics and Human Rights. The possibility of equivocal interpretation of human dignity has made that a concrete content has been attributed to it in law terminology, in other words, in terms of obligations. Human rights are rights any living human being is entitled to enjoy, without any other condition than to exist as a human being. This principle is equally applicable to all humans, is not to be gained because of some merit, and cannot be lost because of some failure. However, when the issue is about making precise who is a human being, the concept seems to become equivocal. Each one speaks about human being and his rights while evading essential questions which require coherent answers as basic reference for everyone on the required respect.

In DRC as well as in Africa in general, human being and human life constitute the criterion for every moral judgment (Ngoma, 1994). All acts which contribute to the promotion, the protection, and the conservation of life are morally good acts; (Munday, 1982) on the other hand, all acts damaging individual or community life are considered as morally bad (Mujinya, 1969). The respect of human life is therefore the first norm guiding human acts. It is by the yardstick of human life and human being that the value of other values is measured. Being human appears as fundamental value. Human life is to be protected from the moment it gives sign of life (Muyengo, 2012).

Embryo Status and Abortion

The fundamental question to know if the embryo could be considered as a human being is fairly an academic question, coming close to be a theoretical debate. For an African, even the most cultured, the answer to such a question is, of course, obvious. What else should be found in a pregnant woman's womb apart from a child, that is to say a human being? The concept of embryo is neglected in Africa (Nothomb, 1992); the question is treated nowhere but within the framework of human life. Reflections on the embryo throw back into doubt a whole of anthropology from which results an anthropocentric morality where a child is a gift; he is not to be accepted or refused when he is smoldering. His reason for living has another root than only the willingness of his parents (Eggen, 1996). Parenthood is horizontal as well as vertical; there are vertical links between the invisible world (God, ancestors), therefore a transcendental dimension, and the visible one (group, family). Even in the West where debate on the status of the embryo has taken place, the question is sparked off by new powers that humans had acquired at present in the field of medicine. Even the best understanding of human biology, as deeply as to the molecular scale, would not be possible without putting into perspective the embryo's dignity, it is also the same light that biotechnologies throw on the embryo and his potentialities impose to considering him again, to respect him simply as a full human being. Reticence about the human status of the embryo seems to be driven by utilitarianism. The status of the embryo would be treated in the framework of Kant's doctrine according to which the human person must be considered as an end, not as an object or a means to reach some objectives; he is not to be regarded in terms of value, profitability, or utility, but is to be considered in terms of dignity and humanity.

Whatever has been said about a woman's rights, abortion is quite a scandal for Africans because it contradicts the vocation of woman whose mission is to give and to promote life. Even if a woman has recourse to such an extreme, she is aware of the bad act she commits according to the value of life; she does not throw back into doubt the anthropologic statute of the child she is carrying, neither she claims some right on her body and liberty to match against the child rights. She just is sorry to find herself in a fait accompli which prompts her to such a regrettable act. The fait accompli could be social (misery), moral (incest or rape), or psychological (fear or shame). So the debate here does not concern only the use of a technique, but rather the conception, the ideology, and the aspirations on which are based values and motivated choices (Muyengo, 2012). In DRC, abortion is prohibited by law, in keeping of DRC Constitution which stipulates that human life is sacred from its beginning. According to the Maputo protocol relating to women rights, adopted on the 11 June 2003, in the second ordinary session of the African Union, states have to protect the woman's reproductive rights, especially in authorizing abortion in case of sexual violation, incest, and when pregnancy endangers mental or physical health of the mother or the fetus. Abortion, being considered as a fundamental right in the protocol in question, is proposed to all African governments for ratification (Peeters, 2007); until then, DRC had not ratified it. On June 2009,

without any public consultation, or even debate in the Parliament, the president of DRC did nevertheless sign the protocol at issue, and hardly on the sly. That caused general outcry and protest marches, primarily from Congolese women, when by some indiscretion the fact was revealed to the public knowledge.

These are questions essentially about giving a sense to the respect of life and persons, to the human dignity and values, and giving coherence to the concept of human rights. On these questions, there are real difficulties to dialogue with Westerners who, without taking account of other cultural or religious a priori assumptions, impose outlines in which they would make acts like abortion widespread.

Autonomy and Community

In Africa, life is individual as well as communal. All education system aims to link human to human by multiple solidarity relations for vital social requirements. Any individualistic or egocentric attitude is counted as one of a number of social sins. So, in addition to murder which is an objective and direct infringement to life, disagreeable welcome, incitement to discord, theft, and adultery are considered as serious moral faults (Tshama lenga, 1980). In Africa, the concept of human life becomes exhausted in a perspective of union which means community, unity. The participation in a same life constitutes the fundamental basis of all customs among most African people. Life is led in family and clan community where are united reciprocal influences. Each individual feels that one has a kind of obligation to add his link in the chain. Autonomy is always understood in the social framework linking individual to the community in which family is the important element where human life is conceived and would optimally fulfill its potential; autonomy cannot in this context be proposed as a supreme rule, because community is sometimes entitled to protect an individual despite himself. Africans find it strange that the claim of autonomy is sometimes excessively emphasized, giving the impression of parallels with concepts of individualism or egocentrism, and yet, no individual liberty could withstand sacrificing the bases of human rights. Concerns for maintaining social stability and public order are among collective values which could serve as a protective shield for human rights; favoring individual interest could contribute to disturb the same individual liberty if such a balance is sacrificed. There are in each society collective interests which are to be safeguarded for the good of each constituent individual. The preservation of such collective interests, although exceptionally sacrificed in the name of human rights, may nevertheless generally be the best rampart to preserve the same rights (Terre & Lequette, 1994). Moreover, with all of today's knowledge acquired on the human genome, even our concepts like free and informed consent may sometimes need redefinition; indeed, knowing that genetic data relating to one individual person could concern also his blood relations, one could wonder if someone's right to participate freely as subject in a genetic research would not affect the privacy rights of his brothers and sisters, parents, or progeny who would be reluctant to be part of such study.

Conclusion

The irresistible advances of scientific knowledge in biology and medicine as well as associated technologies have given rise to a real ambiguity: on the one hand, biotechnology developments undeniably offer admirable perspectives of improving human life and health conditions; scientific and technical progress can help human well-being, happiness and prosperity, especially humankind's fight against the suffering generated by diseases. On the other hand, several new serious and difficult questions call out to the conscience. There are distinctly perceptible breaches infringing the most precious principles a human may hold dear, that is to say life and dignity, the sense he attaches to his existence, and the signification he gives to his destiny. These questions apply to several sectors of life, ethics, law, social, cultural, and human rights, and have given rise to bioethics.

In the Democratic Republic of Congo (DRC) like in other African developing countries, bioethics topics have begun to be seen as a relevant, especially in the light of broadcasted news about unceasing scientific advances and innovative biotechnologies. The country, indeed, is still on the fringes of biotechnology experiments.

In spite of unfavorable socioeconomic conditions characterized by poverty, DRC has been among the first in Africa to be concerned about bioethics issues. A bioethics class existed already on 1987, the first thesis on this matter has been written up by a Congolese on 1997, and a private initiative to create a National Bioethics Committee had taken place on 2001.

Facing the reality consisting in a lack of the state-of-the-art biotechnology, the outdated state of medical infrastructures, the mentality, the intellectual level, and the social status of many among the people, bioethics questions are posed first in terms of social problems. Value conflicts around life here are now expressed in term of poverty. It is good that the current definition of bioethics, as it is brought out by the Universal Declaration on Bioethics and Human Rights, has a more extended perspective including social problems at the root of value conflicts.

Nevertheless, African people, sooner or later, are about to confront the same bioethics problems as people from industrialized countries are facing; indeed, transfer of technology is growing, whether it could be done through cross-border researcher or by research centers set up by Northern countries. There is a great deal of research now conducted in developing countries like DRC. It is feared that, in a situation of widespread deprivation, poor people, not being well informed on their rights, may easily be turned into guinea pigs, with ethically unacceptable experiments being performed on them for some undue financial incentives.

Globalization reveals how all earth's inhabitants are in the same boat. It does not really matter which place one lives on the planet; today, the destiny of humanity must be seen as a whole. Because it concerns everyone, it is not to be left to the discretion of those who master arcane aspects of science. New human powers have to be carefully managed, taking into account all wisdom people all over the world have acquired and developed, including by common sense and intuitive understanding. In this connection, Africans have something to bring at the table.

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Croatia

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Ana Borovečki

Introduction

In Croatia, the impetus for the developments in the field of bioethics were the changes in the political system. Croatia used to be a part of the former Socialist Federative Republic of Yugoslavia. In the 1990s, the socialist political paradigm was abandoned and the democratic changes began. Thus, Croatia entered the same process as the other countries in the Region of East, Central, and Southeast Europe. The transition from a socialist to a democratic society for Croatia was further complicated by the Serbian aggression and the war experienced in the 1990s (Borovecki, ten Have, & Oreskovic, 2004).

A. Borovečki
School of Medicine, Andrija Stampar School of Public Health, University of Zagreb, Zagreb, Croatia
e-mail: abor@mef.hr; abor@gmail.com

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Bioethics Development

In Croatia, the subject of medical ethics, or bioethics, was introduced into the curriculum in the early 1990s at the medical schools of the University of Rijeka and the University of Zagreb. With the advent of the new political changes came the changes in the concept of a subject of medical ethics, which was until that time scarcely taught, mainly as a few hour lecture and seminar at the Zagreb School of Medicine. Moreover, the previously taught obligatory subject of Marxism was abandoned leaving a place for the introduction of a new course in the medical curriculum. Further impetus for the development of bioethics in Croatia was created by the Hastings Centre, especially Daniel Callahan, who through the program of exchange invited several teachers from medical schools of Zagreb and Rijeka for a visit to the Hastings Centre providing them later on with additional materials for the development of future courses in bioethics. Croatian scholars were invited to the Hastings Center in the United States; they came from various disciplines. Some of them decided to take this opportunity to reinvent themselves as teachers of a new discipline leaving behind their past teaching experiences and subjects. However, this encounter with the Hastings Centre was not the first one for Croatian scholars interested in the subject of bioethics. In the 1980s, the Andrija Stampar School of Public Health, School of Medicine, University of Zagreb, introduced an annual workshop at the Interuniversity Centre in Dubrovnik called *Human Rights and Medicine*. There with the cold war still present and the former Socialist Federative Republic of Yugoslavia being more open than other socialist countries at that time, both scholars from the East and the West had an opportunity to meet and exchange their ideas and some of the founders of the Hastings Centre were present at those discussions. Moreover, the *Yugoslav Centre for Medical Ethics* was established at the Andrija Stampar School of Public Health, School of Medicine, University of Zagreb in the 1980s, which was active until the 1990s. Furthermore, a column dedicated to medical ethics was introduced in *Liječnički vjesnik*, the oldest medical journal still published in Croatia at the beginning of the 1980s. These developments, started by Professor Slobodan Lang, although not entirely devoid of the influences of the ideological background present at that time in the former Socialist Federative Republic of Yugoslavia, were important for the development of the field of bioethics in Croatia. In 2010, the Zagreb School of Medicine founded the *Centre for Communication Skills, Palliative Medicine and Medical Ethic*s (Nicholson, 2004; Borovecki et al., 2004).

It comes as no surprise that with these influences new courses of bioethics emerged in Croatia in the1990s. Almost at the same time in the curricula of the Schools of Medicine at the University of Zagreb and at the University of Rijeka new courses were introduced dealing with ethical issues in medicine. The course at the University of Rijeka was started by Professor Ivan Šegota, a former teacher of social sciences whose ideological background was linked to social sciences ideas rooted deeply in the frameworks present in the former Socialist Federative Republic of Yugoslavia. He reinvented himself as a teacher and started a new discipline through the development of the course and subsequent books dedicated to the issues

of bioethics. His work is mainly influenced by the work of Van Rensselaer Potter. The new course was elective. It was at first called *Hippocratic Oath Today* in 1991. Later, in 1992, when the course became an obligatory course in the curriculum, it was called *Medical Ethics*. In 1993, an elective course *Introduction to Bioethics* was introduced. The School of Medicine in Rijeka also briefly published a journal called *Ethics and Medicine* (*Etika i medicina*) (1993–1994), and in 1999 started to publish a students' journal *Bioethics Notebooks* (*Bioetičke sveske*) (still published today). The first PhD in the field of bioethics was also defended at University of Rijeka at the School of Medicine (Gosić, 2000; Zagorac & Jurić, 2008).

The course at the School of Medicine at the University of Zagreb was introduced by Professor Niko Zurak (neurologist by training), Professor Gordna Pavleković (a GP and a public health expert) and Professor Zvonko Šošić (a public health expert). This course was called "Medical Ethics" and its founders were oriented more toward medical practice itself and the problems that emerged in this context, with a critical approach to Van Rensselaer Potter's concept of bioethics, which some of them strongly rejected. Later in two other schools of medicine in Osijek and Split that used to be part of Zagreb School of Medicine the subjects connected with ethical issues in medicine became a part of their curricula as well (Zurak, Derezic, & Pavlekovic, 1999; Zurak, 2007).

Significant influence on the field of bioethics came also through the clinical trials implementation, which began in 1970s with the creation of the so-called commissions for drugs. These committees were the first institutional review boards, which were established for the purpose of joint Croatian-international clinical research projects in main clinical and teaching hospitals in Croatia. Just before their foundation, in order to get well-trained members of such committees, a new postgraduate and specialty training was introduced – clinical pharmacology, and the first department of clinical pharmacology was founded at Zagreb University Medical Centre. As a part of training in clinical pharmacology, courses were introduced dealing with good clinical practice and research ethics issues. Although, at that time some legal provisions concerning medical research were put in place, the majority of professional and ethical decision making concerning approval of clinical trials was left for the committees to decide upon. The main figure in these developments was Professor Božidar Vrhovac, an internal medicine specialist and a founder of the field of clinical pharmacology in Croatia (Borovečki, Francetić, & Mujkić, 2010).

The second phase of the development of research ethics structures began in the 1990s, during the period of transition in Croatia. With the changes within political structures came the changes in education as well as the development of ethics. This shift toward a more an institutional approach can be observed in the legal provisions from that period. In the 1990s, the legal requirements for the work of ethics committees changed. The establishment of ethics committees became required by law, with articles 51 and 52 of the 1997 Law on Health Protection devoted to setting the framework for their duties. The further development of the field of research ethics and the development of ethics committees in Croatia came about in the year 2003 with the implementation of the European Directive 2001/20/EC. One of the

principles set by the Directive was the introduction of a single ethics review opinion for multicenter trails for each member state of the European Union. Prior to 2003, the review of clinical trials in Croatia was done locally by an ethics committee in each healthcare institution. Such approach created a lot of problems and conflicts of interest. In 2003, Croatia decided to follow the recommendations of the Directive and established centralized review of clinical trials. Also under the influence of the Directive in 2003, the new Law on Drugs and Medical Products was implemented. This law was implemented in order to regulate all the activities connected with marketing, production, and research of drugs and medical devices (Vitezić, Lovrek, & Tomić, 2009; Borovečki, Babić- Bosanac, & ten Have, 2010).

The Croatian Academy of Sciences and Arts also played a major role in the introduction of bioethics in Croatian scientific discourse in the 1990s. Professor Biserka Belicza, a historian of medicine who was a head of the *Division for the History of Medical Sciences* at the *Institute for the History and Philosophy of Sciences at Croatian Academy of Sciences and Arts*, with help from the Hastings Center and UNESCO, soon became actively involved in this field, organizing several conferences in Croatia and establishing the *Committee for Biomedical Ethics of the Croatian Academy of Sciences and Arts*. She also served as the Croatian representative at UNESCO's *International Bioethics Committee* (Fatović- Fernečić, 2005).

In the 1990s, Professor Ante Čović, a professor of ethics at the faculty of philosophy in Zagreb, became more and more interested in bioethics. He soon started to publish articles on the subject in the journal of the Croatian Philosophical Society, *Filozofska istraživanja*, and in *Synthesis philosophica*. In 2001, the Croatian Philosophical Society in cooperation with the Croatian Bioethics Society started, a today well-established series of symposia *Lošinj Days of Bioethics* and in cooperation with Bochum University in Germany the *South East European Bioethical Forum*. Professor Čović soon became interested in forming a new concept of bioethics, which he called "integrative bioethics." Integrative bioethics tries to expand the methodological field of bioethics. It dismisses the concept of bioethics as a science or a scientific discipline. It is against the narrowing of bioethics to a version of (bio) medical ethics or to a subdiscipline of applied philosophical ethics. Integrative bioethics is, therefore, an interdisciplinary field of dialogue and encounter of humanities, social, natural, and technical sciences, but also an extra scientific field, where different worldviews and cultural perspectives meet in an open dialogue, and approach the issues of life as a whole with an integrative bioethical sensibility. Professor Čović, in cooperation with partners in Bonn, Bochum, and Eichstätt in Germany and with the help of Zagreb University, founded the Referral Center for Bioethics in South East Europe. With these efforts from the Croatian Philosophical Society bioethics also became a part of curricula of students of philosophy at the faculties of philosophy in Zagreb, Rijeka, Split, Osijek, and Zadar (Zagorac & Jurić, 2008; Čović, Gosić, & Tomašević, 2009).

At the Catholic Theological Faculty of the University of Zagreb bioethics also became an important feature, at first in the works of Professor Marijan Valković

who wrote one of the first reports on bioethics in Croatia (Valković, 1997). In addition, his successor Professor Tonči Matulić contributed significantly to bioethics, especially through his work entitled *Bioethics*, which is written from a theological and philosophical perspective (Matulić, 2001). Early on other Catholic Theological Faculties in Đakovo and Split also introduced subjects connected with ethical issues in medicine.

Another pioneer in bioethics was Professor Valentin Pozaić, a Jesuit scholar (Pozaić, 1992) who with Professor Marijan Valković, was one of the main theological scholars involved in this subject. His work is also very significant. He published numerous publications related to different topics in bioethics. Later, he became a professor at Faculty of Philosophy of the Society of Jesus where he founded the *Centre for Bioethics*, which is a member of the European Association of Centres of Medical Ethics (EACME), and the *Centre for Business Ethics* at the Philosophical and Theological Institute of the Society of Jesus. Both centers have significant collections of relevant literature in the fields of bioethics and business ethics.

The legal profession also contributed to the development of bioethics. In the 1980s and 1990s, Professor Zvonimir Šaparović and Professor Ksenija Turković, experts in criminal law at Zagreb Faculty of Law, wrote several papers on ethics issues in medicine. Furthermore, Professor Vjekoslav Miličić, an expert in the field of general theory of the law and the state at Zagreb Faculty of Law, wrote a book on deontology of the medical profession. Professor Mira Alinčić and later Professor Dubravka Hrabar, experts in family law at Zagreb Faculty of Law, wrote several papers in connection to the issues of artificial procreation and were also involved in drafting several proposals for laws covering this field. In 2009, the *Unit for Bioethics and Law* was founded at the Faculty of Law, University of Zagreb, as a local unit of the UNESCO Chair established in Haifa, Israel. Professor Nenad Hlača, an expert in family law at Faculty of Law at the University of Rijeka, was together with Dr. Dubravka Šimonović the first to translate the Oviedo Convention in Croatian. He also wrote several papers on different bioethics issues. Other faculties of law in Split and Osijek also made contributions to the field of bioethics. The Faculty of Law at the University of Split, for example, founded the *Centre for Medical Law*. In 2009, they started a postgraduate specialist course *Medical Law*, where a variety of bioethics issues are discussed and taught.

Dr. Dubravka Šimonović, an expert in family law and human rights issues, gave probably the most important international contribution to the field of bioethics. She was vice-president and later president of the *Steering Committee on Bioethics of the Council of Europe (CDBI)*, where she was actively involved in drafting several important legal instruments (Šimonović & Borovečki, 2009).

In conclusion, the development of bioethics in Croatia took many roots and approaches making the foundation of the new discipline an interesting journey for everyone involved in this field.

Current Bioethics Infrastructure

Teaching Bioethics

Currently, bioethics courses are taught at all four Schools of Medicine in Zagreb, Rijeka, Osijek, and Split on an undergraduate and postgraduate level. At nursing schools, bioethics courses are also taught at undergraduate level. Bioethics courses are taught at the catholic theological faculties in Croatia in Zagreb, Split, and Đakovo as a part of the course in ethics and moral theology or as separate bioethics courses on an undergraduate and postgraduate level. At the Philosophical Faculty of the Society of Jesus in Zagreb, which organizes its teaching in cooperation with the Faculty of Croatian Studies, the number of bioethics courses on undergraduate and postgraduate level, are also part of curriculum. Bioethics courses are taught at protestant theological faculties in Zagreb and Osijek. At the faculties of humanities and social sciences at Zagreb, Rijeka, Osijek, Zadar, and Split bioethics courses are part of the curriculum on an undergraduate level. Finally, law schools in Zagreb, Rijeka, Split, and Osijek are also actively involved in bioethics education on an undergraduate and postgraduate level.

Ethics Committees

In Croatia, as mentioned above, the first steps toward bioethics institutionalization of ethics committees began in the 1970s with the creation of the so-called "commissions for drugs," which were established for the purpose of joint Croatian-international clinical research projects.

In the 1990s, ethics committees became required by law, with articles 51 and 52 of the 1997 Law on Health Protection devoted to setting the framework for their duties. According to this law, each healthcare institution in Croatia should have an ethics committee consisting of five members, two of whom should be from outside the medical field. Committee functions include:

- Following the implementation of ethical principles of the medical profession
- Approving research activities (protocols) within the health institution
- Overseeing drug and medical device trials
- Overseeing organ procurement
- Solving other ethical issues in the health institution

From this description it is clear that at that time, Croatia had a mixed type of ethics committees in healthcare institutions. Ethics committees performed functions of both Institutional Review Boards (IRBs) and Healthcare Ethics Committees (HECs).

In 2001, the National Bioethics Committee for Medicine of the Government of the Republic of Croatia was founded. This independent advisory and multidisciplinary body is involved in policymaking, education, and debates on ethical issues on the national level. This committee consists of 20 members having different fields of expertise and coming from a variety of institutions. So far the membership of the National Bioethics Committee for Medicine of the Government

of the Republic of Croatia had changed twice. The presence of the committee in public debates and its activities varied depending on the activity and interests of its members.

In 2002, the National Bioethics Committee conducted research on the functioning of Croatian ethics committees. Of particular interest were the number of members, the structure of membership, themes discussed during meetings, reports drafted, the number of meetings to date, policies, and guidelines. Excluding pharmacies and homecare institutions, 241 healthcare institutions took part in the study. Of the participating healthcare institutions, 111 reported having an ethics committee. The response rate was between 100 % and 75 %, depending on the type of the institution (100 % response rate for clinical hospitals, 91 % for regional and local general hospitals, 80 % for clinics and polyclinics, 75 % for medical faculties, and approximately 77 % for all other healthcare institutions, including public health institutes, primary care facilities, and ER facilities). Ethics committees tend to have five to ten members as required by law (though two did not state the number of members, four only have three members, and two have four members). All committees have physicians as members, and 34 committees include a nurse. Only one committee had a philosopher. Almost all committees stated that reviewing research protocols was their main task, though some dealt with other issues as well, mainly concerning "the promotion of the ethical values in their institutions." In 19 institutions, a "commission for drugs" also reviewed clinical protocols, which created additional confusion about the tasks of ethics committees.

In 2003, a new version of the Law on drugs was implemented. This meant significant changes in the work of ethics committees. According to this law, the review of research protocols for clinical trials has now been transferred to the independent central research ethics committee at the *Croatian Agency for Drugs and Medical Devices*. However, the new versions of the Law on Healthcare Protection in 2008 did not significantly change the work of ethics committees in healthcare institutions. They still have the following functions:

- Monitoring implementation of ethical and deontological principles of healthcare profession in the everyday work of healthcare institution
- Approving research activities (protocols) within the health institution
- Overseeing organ procurement of parts of human body after dissection for medical, research, and teaching purpose
- Solving other ethical issues in the health institution

However, the new Law on Healthcare Protection from 2008 introduced the balance between sexes in the membership structure. The membership now has to have 40 % of the members of ethics committee of the opposite sex.

In 2007, with the implementation of the new Law on drugs, the central research ethics committee became responsible for issuing opinions on non-interventional trials as well. This centralization of the review of research protocols in Croatia made the process of review more expedient. Moreover, this prevented having several committees on the local level concurrently reviewing the same research protocol and giving different opinions about it. Furthermore, this centralized approach fosters impartiality and avoids local pressure groups influencing the

review process. Finally, this approach helps to bring together the best experts in one committee, which is especially important in smaller countries, like Croatia.

The majority of the faculties in Croatia now have an ethics committee. These committees are in charge of the review of proposed research projects at these institutions and they also deal with the issues of academic integrity. Ethics committees at the Croatian Medical Chamber and the Croatian Medical Association, the Croatian Dental Chamber, the Croatian Pharmacists' Chamber, and the Croatian Chamber of Biochemists and some other professional associations, deal primarily with deontological values and issues of the specific professions they represent. They do not function in a research oversight capacity (Borovečki, ten Have, & Orešković, 2009).

Expert Bodies/Centers

One of important centers in the field of bioethics in Croatia is the *Centre for Bioethics* at Philosophical and Theological Institute of the Society of Jesus in Zagreb. The center is member of EACME (the European Association of Centres of Medical Ethics). There is also the *Centre for Business Ethics* at the Philosophical and Theological Institute of the Society of Jesus in Zagreb. It has a significant collection of literature from the field of bioethics and is involved in organizing meetings and publication of the books from the field of bioethics.

At Medical School, University of Zagreb, a new *Centre for Communication Skills, Palliative Medicine and Medical Ethics* has been established in 2010. The Centre is also actively involved in the organization of different meetings and educational workshop and plans to publish books for the three fields covered in its work.

At the Faculty of Law University of Zagreb there is the *Unit for Bioethics and Law*. The unit is part of chain of units connected to the UNESCO Chair in Bioethics in Haifa, Israel which is dedicated to bioethics education. Its main work is connected to the organization of symposia and translation of the UNESCO Chair in Bioethics' publications into the Croatian language.

The *Referral Centre for Bioethics in South East Europe*, Faculty of Social Sciences and Humanities, University of Zagreb was established in cooperation with partners in Bonn, Bochum, and Eichstätt in Germany. It has a significant collection of publications from the field of bioethics from the countries of South East Europe and is involved in organization of several important annual meeting and events.

At the Faculty of Law, University of Split there is the *Centre for Medical Law* which has a significant collection of publication from the fields of medical law and bioethics.

Relevant Legislation

The *Code of Medical Ethics and Deontology of the Croatian Medical Association, Croatian Medical Chamber, and Croatian Dental Chamber* (Kodeks medicinske etike i deontologije Hrvatske liječničke komore, Hrvatske stomatološke komore i,

Hrvatskog liječničkog zbora) is an important document for all members of the medical and dental professions in Croatia. There used to be separate ethical codes issued by the Croatian Medical Association, by the Croatian Medical Chamber, and by the Croatian Dental Chamber. Their content was basically the same. In 2006, the three organizations decided to have a joint code.

The *Law on Medical Profession* (Zakon o liječništvu, 2003) regulates the major interprofessional relationships of medical profession and the relationship between the physicians and society.

The *Law on the Protection of Patients' Rights* (Zakon o zaštiti prava pacijenata, 2004) regulates the relationship between physician and patients and promotes implementation and protection of patients' rights.

The *Law on Procurement and Transplantation of Human Body Parts for the Purpose of Therapeutic Procedures* (Zakon o uzimanju i presađivanju dijelova ljudskog tijela u svrhu liječenja, 2004) regulates the field of transplantation of organs and human tissues in Croatia. Croatia has an opt-out system. Those who do not want to be donors have to inform the GPs about it and the GPs then send this information to a central registry.

The *Law on the Ratification of the Convention on the Protection of Human Rights and Dignity of Human Being with regard to the Application of Biology and Medicine*: *Convention on Human Rights and Medicine* (Zakon o potvrđivanju Konvencije o zaštiti ljudskih prava i dostojanstva ljudskog bića u pogledu primjene biologije i medicine: Konvencije o ljudskim pravima i biomedicine, 2003). The law represents the ratification of the Oviedo convention by Croatian parliament thus introducing the Convention into the legal system of Croatia. The Oviedo Convention has become a legal instrument that is above all Croatian laws; all laws had to be adjusted to comply with the Convention.

The *Law on the Protection of Persons with Mental Disorders* (Zakon o zaštiti osoba s duševnim smetnjama, 1997) regulates the rights of persons with mental disorders and the procedures for involuntary hospitalization.

The *Law on Drugs* (Zakon o lijekovima, 2007) regulates the fields of clinical trials, drug production, and marketing policies. *The Guidelines on Clinical Trials and Good Clinical Practice* (Pravilnik o kliničkim ispitivanjima i dobroj kliničkoj praksi, 2007) is a bylaw of the Law on Drugs that elaborates in details clinical trials approval, execution, and monitoring.

The *Law on Animal Protection* (Zakon o zaštiti životinja, 2006) deals with animal protection in general but has several paragraphs dedicated to the protection of animals used for experimentation.

The *Law on Healthcare Protection* (Zakon o zdravstvenoj zaštiti, 2008) deals with the organization of healthcare in Croatia, but also has several paragraphs dedicated to the patient information procedures and establishment of ethics committees in healthcare institutions.

The *Criminal Law* (Kazneni zakon, 2005) has several paragraphs dedicated to the issues of medical laibility, prohibition of active and passive euthanasia, infanticide, and prevention of deliberate spread of dangerous infectious diseases.

The *Law on Health Measures for the Promotion of the Right on Freedom and Decision-making about Birth*, (Zakon o zdravstvenim mjerama za ostvarivanje prava na slobodu i odlučivanje o rađanju djece, 1978) regulates the contraception measures and abortion in Croatia. The abortion is allowed until the 10th week of pregnancy. After the 10th week of pregnancy all abortion requests are evaluated by special commissions. The abortion can be also performed upon the request of minor not younger than 16 years of age.

The *Ethical Code for the Research on Children* (Etički kodeks istraživanja s djecom, Ajduković & Kolesar, 2003) gives basic ethical guidelines for research on children.

The *Law on the Protection of Personal Data* (Zakon o zaštiti osobnih podataka, 2008) deals with protection of all personal data thus also with the protection of medical data.

The *Law on Protection against Discrimination* (Zakon o suzbijanju diskriminacije, 2008) deals with protection against of all sorts of discrimination including the discrimination based on one's genetic heritage.

The *Law on Medical Procreation* (Zakon o medicinski pomognutoj oplodnji, 2012) regulates the field of artificial procreation in Croatia.

Public Debate Activities

Public debate activities are done through public lectures often held in public libraries, symposia organized by Croatian Medical Association, Croatian Medical Chamber, Croatian Philosophical Society, Croatian Bioethical Society, Croatian Catholic Medical Society, among others, different students' organizations, religious organization, political parties' media. Special radio programs and special TV programs are also made to encourage public debate on different bioethical issues and to educate general public. Those are done usually in collaboration with academia as a part of educational programs. The members of the National Bioethics Committee for Medicine of the Government of the Republic of Croatia sometimes participate in public debates but this is very rare.

Other

The following journals publish contributions from the field of bioethics:

The *Croatian Medical Journal* is a Current Contents (CC) indexed journal published six times a year. CMJ owners are four Croatian Medical Schools (University Osijek, Rijeka, Split, and Zagreb). The journal was founded in 1953 as Acta Facultatis Medicae Zagrabiensis and later changed its name to Croatian Medical Journal. It is the official journal of the World Association of Croatian Physicians (WACP), Academy of Medical Sciences of Croatia (AMSC), Forum for Public Health in South Eastern Europe (EPH-SEE), International Society for Applied Biological Sciences (ISABS), and Croatian Centre for Global Health. It publishes papers from all fields of medicine including bioethics and medical humanities.

Synthesis Philosophica is a CC indexed journal published twice a year by the Croatian Philosophic Society. The journal publishes papers from different fields of philosophy including ethics and bioethics.

Društvena Istraživanja is a journal for general social issues, embracing complete thematic and disciplinary openness. It publishes four times a year papers in different social disciplines (sociology, psychology, political science, psychiatry, history, law, economics, demography, linguistics, etc.). In addition, it publishes work that transcends the frontiers of individual disciplines. Papers are subject to anonymous review procedures. The journal is indexed in Current Contents – Social and Behavioral Sciences, Social Sciences.

Prolegomena is a journal published two times a year by the Society for the Promotion of Philosophy. It regularly publishes papers from different fields of philosophy including ethics and bioethics. The journal is cited in Arts & Humanities Citation Index, Current Contents/Arts & Humanities, Dietrich's Index Philosophicus, Humanities International Index, International Bibliography of Book Reviews of Scholarly Literature in the Humanities and Social Sciences, International Bibliography of Periodical Literature in the Humanities and Social Sciences, The Philosopher's Index, Scopus.

Bogoslovska smotra is a journal published four times a year by the Catholic Theological Faculty, University of Zagreb. This is one of the oldest scientific journals in Croatia. It publishes papers on different theological and philosophical issues including the issues from the field of Bioethics. It is indexed in Religious and Theological Abstracts (Myerstown, USA), Elenchus of Biblical Bibliography (Rim, Italy), Ephemerides Theologicae Lovanienses (Louvain, Belgium).

Liječnički vjesnik is a journal of the Croatian Medical Association indexed in MEDLINE/Index Medicus, EMBASE/EXCERPTA MEDICA. It publishes four issues a year. This journal publishes papers from all fields of medical ethics on regular basis including bioethics.

Filozofska istraživanja is a journal cited in Arts and Humanities Citation Index and The Philosopher's Index. The journal is published four times a year by the Croatian Philosophic Society. It regularly publishes papers from different fields of philosophy including ethics and bioethics.

JAHR (*Annual of Department of Social Sciences and Medical Humanities at University of Rijeka Faculty of Medicine*) is published twice a year by the Department for Social and Humanistic Studies, School of Medicine, University of Rijeka. The journal contributions come from the fields of ethics, bioethics, history and philosophy of sciences, sociology, cultural anthropology, theology, law.

Croatian Journal of Philosophy is a peer-reviewed journal with a primary focus on original philosophical work in analytic philosophy in Central Europe. It was established in 2001 and has a particular strength in the philosophy of linguistics. Articles and reviews from Croatia, Slovenia, Hungary, and other countries are published along with contributions from Western Europe and the USA. The journal is published three times per year in Croatia by KruZak and from time to time publishes papers dealing with bioethical issues.

European Journal of Analytic Philosophy is published four times a year by Faculty of Philosophy, University of Rijeka. It regularly publishes papers from different fields of philosophy including ethics and bioethics.

Socijalna ekologija is a journal published three times a year. It publishes theoretical, empirical, and methodological papers within the scope of social ecology, as well as other scientific disciplines related to the area of environmental sociology. The journal is scientific in nature and publishes papers acceptable to variety of readership including papers dealing with bioethical issues.

Zbornik Pravnog fakulteta Sveučilišta u Rijeci is a journal published twice a year by the Faculty of Law, University of Rijeka. The journal publishes papers from the field of law including medical law and bioethics.

Zbornik Pravnog fakulteta Sveučilišta u Splitu is a journal published four times a year by the Faculty of Law, University of Split. The journal is indexed in Current Legal Theory, Index to Foreign Legal Periodicals. The journal publishes papers from the field of law including medical law and bioethics.

Zbornik Pravnog fakulteta Sveučilišta u Zagreb is a journal published six times a year by the Faculty of Law, University of Zagreb. The journal is indexed in Index to foreign legal periodicals, Drant – Droits antiques, Kriminologija in kazensko pravosodje – CRIM, Scopus, and Worldwide Political Science Abstracts. The journal publishes papers from the field of law including medical law and bioethics.

Major Bioethics Issues and Discussions

The debate concerning DNR orders emerges from time to time in professional circles. There are still no clear guidelines in Croatia for the implementation of DNR orders. Since do-not-resuscitate decision making is left to the individual physician, families are seldom involved in decision making. The Croatian Society of Intensive Care medicine has been discussing the issue of the introduction of DNR orders and was trying to find appropriate ways for their introduction. The discussion is only done among their members and with other physicians without the introduction of the problem to general public.

Patients' rights are also widely discussed. The most outspoken about the issue are different NGOs that deal with the protection of the patients' rights. In Croatia, there are several important patients' rights NGOs. The most outspoken about the issue are *Croatian Association for the Promotion of Patients' Rights* (*Hrvatska udruga za promicanje prava pacijenata*) from Split and *Patient Today* (*Pacijent danas*) from Rijeka. The NGOs are not satisfied with the current Law on the protection of patients' rights especially with the extremely complicated procedure for patients' complaints. For the sake of realizing, protecting, and promoting patients' rights, Article 30 of this Act prescribes the obligation of founding a commission to protect patients' rights in each unit of regional self-government (county commissions), while at a state level, Article 38, paragraph 1 prescribes the obligation of the ministry responsible for health care to found a National Commission to protect and promote patients' rights (the Commission of the

Ministry of Health and Social Welfare of the Republic of Croatia). The county commissions, which have five members who are patients, NGOs and experts in the field of protection of patients' rights (Article 32), carry out the following work. They monitor violations of individual patients' rights and propose measures to protect and promote patients' rights in their area, that is, their county, report without delay to the Commission of the Ministry of Health and Social Welfare on cases of serious violations of patients' rights, report to the public on violations of patients' rights, and submit an annual report on their work to the county assembly (Article 33), while at a state level, Article 38, paragraph 1 prescribes the obligation of the ministry responsible for health care to found a National Commission to protect and promote patients' rights (the Commission of the Ministry of Health and Social Welfare of the Republic of Croatia). The procedure of protection of patients' rights before a county commission begins with a complaint by a patient who believes that one of his/her rights as established by this Act has been violated. The patient may express the complaint verbally or in writing to the head of the health institution which offered the specific health service. If the head of the health institution does not inform the patient of measures taken following the complaint within 8 days or if he/she is not satisfied with the measures taken, the patient has the right to file a complaint with the competent county commission. This commission is obliged to inform the patient within no more than 15 days of all the measures taken following his/her complaint. The county commission also has the right of access to premises where health care is provided and the right to inspect how patients' rights are being realized in individual health institutions. The commission is obliged to write a report about the inspections it undertakes, which it must send within no more than 8 days to the competent inspection service (health or sanitary), or the body that supervises the work of health workers, that is the bodies of individual vocational chambers in the health service (the Croatian Medical Chamber, the Croatian Dental Chamber, the Croatian Chamber of Nurses, the Croatian Chamber of Pharmacists and the Croatian Chamber of Medical Biochemists). These bodies are obliged to report within 3 days of receiving the report, and in urgent cases without delay, to the commission on the action taken. If the competent body (inspection service or chamber) on the basis of the procedure undertaken has a reasonable suspicion that a misdemeanor or criminal offense has been committed by the violation of the patient's right, it is obliged to file a misdemeanor or criminal report, without delay and no later than within 30 days, and report to the commission on the outcome of the procedure. The commission will inform the patient about the outcome within 8 days. This procedure is extremely complicated and many complaints are not properly addressed. Possible changes that could establish, for example, an ombudsman system would be more appropriate for the Croatian situation according to the views of some NGOs and some legal experts who undertook the studies of the implementation of the Law. Moreover, a study performed into the work of county commissions found out that their members are often confused about the tasks of commission. The commissions themselves are not really sure what their role is, so they frequently deal with the complaints of the patients related to health insurance rights instead of patients' rights. Even more confusing is the issue of

patient decision making. Article 16 of the Law on the Protection of Patients' Rights from 2004 states that the patient can refuse medical treatment except when such refusal can jeopardize either the patient's health and life or other peoples' health and life. However, in article 22 of the Law on the Health Protection from 2008 one can refuse medical treatment and medical examinations except when such refusal can jeopardize the life and health of other people. Therefore, even if the refusal can jeopardize one's own life or health one can refuse a medical treatment. Here, we have two different approaches to the same issues that are part of two different laws. These discrepancies should be corrected (Borovecki et al., 2011).

In 2009, Croatia implemented the Law on Medical Fertilization (Zakon o medicinskoj oplodnji, 2009). This law stirred a significant public debate, since it was one of the most restrictive in Europe. The law allowed the freezing of female egg cells but not the freezing of embryos. This meant that in vitro fertilization was performed with defrosted female egg cells and then only three embryos were implanted and created. Some of the medical circles were not happy with this solution arguing that such a procedure has no proven efficacy and that the implantation of defrosted embryos is a better procedure. This was supported by a number of NGOs. However, other medical professionals who were performing the procedures according to this law claim that the success rate of such procedures was rather good. The Law did not allow surrogate motherhood, heterologous donation of gametes of both parents or embryo donation. It allowed in vitro fertilization for heterosexual common law couples and legally married couples. It did not allow the creation of embryos for research purposes. A child conceived by medical procreation did have a right to know the donor of eggs or sperm, if the latter had given their consent that their identity could be revealed. Before this law Croatia had no law on medical procreation. Thus, a huge number of surplus embryos had been created in this period for artificial procreation purposes that had been frozen. It is not clear what will become of these embryos.

At the end of 2011, new general elections were held in Croatia and there was a change of government. The new government decided in 2012 to create a new law that would regulate the field of artificial procreation called the Law on Medically Assisted Fertilization (Zakon o medicinski pomognutoj oplodnji, 2012). There has been a huge public debate on this law that was of short duration since the government was pressing the issue and wanted to bring changes to the field of artificial procreation as soon as possible. The new law now allows the freezing of embryos instead of freezing of eggs; medical procreation is also allowed to single women and not only to couples. All religious communities and a number of NGOs were against the implementation of this law. There were calls for a referendum on the law but the government did not want to organize a referendum on this issue.

Croatia is extremely successful in organ donation and transplantation. It has an opt-out system of organ donation and it is a member of Eurotransplant. Croatia is the third country in the world in the number of organ donors. Nowadays, there are not many ethical issues that are being discussed in this field.

Palliative care and palliative care institutions although a part of healthcare legal provisions are still not yet implemented into Croatian healthcare system.

Although palliative care institutions are to be implemented on primary healthcare level, so far there is only one established in Zagreb. The palliative movement in Croatia has a long history. It was started by the efforts of Professor Anica Jušić, a neurologist (Jušić, 1999). Several palliative care workshops and courses are held every year. There is a discussion on the need to extend and improve palliative care services and introduce a palliative care education on undergraduate and postgraduate level. Although there is a constant lack of financial resources in the healthcare system the advocates for the improvement of palliative care are trying hard to bring about the changes within the existing healthcare structures. So far there is the initiative coming from the Catholic Church that is now being involved in building hospices.

Croatia has a long tradition of medical research and recently a good legislation governing this field (see the section on "Ethics Committees"). However, there are still several issues that need to be legally solved. Genetic research is not well addressed in existing legal provisions, as well as the issue of bio-banking. Creating changes that can facilitate the establishment of bio-banks have been made in the Law on Procurement and Transplantation of Human Body Parts for the Purpose of Therapeutic Procedures. However, further efforts are needed in this direction. There is currently a debate among medical researchers regarding the use of archived medical data and tissues in medical research. In Croatia there is no specific regulation regarding this area and the majority of the material archived was collected during medical procedures in hospitals without obtaining the explicit consent of the patients for their use in research purpose. Now, one tries to resolve this situation by the introduction of new informed consent practices that will involve also asking of the patient for consent that his/her medical material collected for health purposes can be used for research purposes since Croatia is now more and more participating in the EU projects. It is clear that special attention needs to be paid to genetic research on archived medical material.

The protection of persons with mental disorders is governed by the Law on the Protection of Persons with Mental Disorders. Involuntary hospitalization is permitted but patients can only be held in a hospital without court procedure for no more than 72 h. After the court decision of involuntarily commitment the case of the patient should be reevaluated within 30 days. After that period the commitment can be extended up to 6 months and then reevaluated. A lot has been done in relation to the de-stigmatization of persons with mental disorders. However, there are still some high profile publicized cases involving psychiatric patients who have been either released and committed crimes or held in psychiatric hospitals without clear diagnostic evidence and public is often discussing whether existing legal provisions could be improved to avoid such situations in the future.

Within the healthcare setting except for the better implementation of the Law on the Protection of Patients' Rights, special attention has recently been placed on the issue of transparency and length of waiting lists. There have been several efforts to shorten the waiting lists. The issue of the rising costs of drugs was also addressed and the government has made several changes to lower the drug prices and to make more transparent the relationship between physicians and drug industry. Some propositions

made by the government in debates over this issue involve the establishment of funds for physicians' education in order to avoid the direct payment of medical conference participation to physicians who often do not even actively participate. The idea is to send with this money only those physicians who have a poster or oral presentation at a scientific conference and to make the process transparent.

Future Challenges

There is a need for further development of bioethics education especially on the postgraduate level. Some of the existing legal provisions will have to be amended, especially the Law on the Protection of Patients' Rights, because its current implementation is causing many problems. The issues of genetic testing, research, and bio-banks need to be further looked into with a view to the development of additional legal frameworks that might cover these issues.

Conclusion

The development of bioethics has gone a long way in Croatia. However, there are still some challenges ahead. Nevertheless, one can conclude that the state of the development of the field of bioethics is on a satisfactory level. Other countries who share a somewhat similar path of history and development can learn a lot and the Croatian experience can help others in their development of the field of bioethics.

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Denmark

61

Linda Nielsen and Berit Faber

Introduction

This chapter about bioethics in Denmark focuses on specific Danish characteristics. These are the early start of a bioethics debate, legislation, and councils; the independence of the councils and the parliamentarians voting on ethical issues; the introduction and extraordinary importance of laymen as part of the bioethical debate and decisions; and the strong focus on debate and educational tools.

L. Nielsen (✉)
Faculty of Law, Copenhagen University, Copenhagen, Denmark
e-mail: linda.nielsen@jur.ku.dk

B. Faber
Faber Advisors Aps, Copenhagen, Denmark
e-mail: berit@faber.net; bf@faberadvisors.dk

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In the following the development of bioethics, the bioethics infrastructure, major bioethics issues at the moment, and the challenges for the future are outlined followed by a conclusion.

Development of Danish Bioethics

Denmark has a history of being one of the "first movers" on the agenda of bioethics, encouraged by important persons advocating for introducing bioethics in a number of ways.

The *Scientific Ethical Committee System* in Denmark was introduced on a voluntary basis as an initiative of biomedical researchers, among whom Professor Povl Riis was the main initiator. It is the responsibility of the committee system on biomedical health research ethics to ensure that from a research ethical point of view, biomedical health research projects are carried out in a responsible manner and that the rights, safety, and well-being of trial subjects participating in such biomedical research projects are protected, while at the same time possibilities are being created for the development of new, valuable knowledge. The basis of the Danish system was the Nuremberg Code and the Declaration of Helsinki, and the first committees were set up in the late 1970s and the early 1980s. Since 1980 Denmark has had a coherent, nationwide committee system with common guidelines and statutes. The scientific ethical committees are examples of an outcome of a democratic dialogue and cooperation between experts and the rest of society.

In order to assess the need for legislation in the area of bioethics,the Danish Ministry of Interior Affairs established two commissions: The Commission for Gene Technology in 1983 and in 1984 the Commission on Ethical Problems regarding in vitro fertilization, artificial insemination, and fetal diagnostics. The commissions were given the task to investigate the need for regulation of safety issues and of ethical issues.

At this time an intense debate in the media about the rapid development in the field of reproductive technologies captured the public. In October 1984 the Committee on Ethical Problems regarding in vitro fertilization, artificial insemination, and fetal diagnostics submitted its report: "The Price of Progress" in which it suggested that a central ethical council for the health services should be created by law. A large majority in the Danish Parliament passed the bill on the establishment of ethics council and the regulation of certain biomedical trials in June 1987. The purpose of the act was to secure that advice and information concerning ethical problems arisen from the development in artificial procreation in the health service and in the biomedical field was given to the Danish Parliament, the government, and the public in general. The result of these deliberations was the establishment of *the Danish Council of Ethics*. In 1987 a special committee in the Danish Parliament was set up with the sole purpose of safeguarding the close relations between the Danish Parliament and the Council of Ethics. The parliamentary committee has a certain influence on the composition of the Council of Ethics and appoints

a certain number of its members. Furthermore, the parliamentary committee follows the work of the council and can also ask the council to treat certain topics within its terms of reference.

The Danish Technology Board was set up as a statutory body in 1986. The purpose was to disseminate knowledge about technology, its possibilities, and its effects on people, on society, and on the environment. The *Danish Board of Technology* was established as an independent body by the Danish Parliament in 1995 and is the successor of the Technology Board.

The issue of artificial reproduction was subject to intense scientific, ethical, political, and public debate in the 1990s, and assisted reproduction is still subject to debate in Denmark. In 1984 the report "The Price of Progress" from the Ministry of Interior Affairs the Committee on Ethical Problems regarding in vitro fertilization, artificial insemination, and fetal diagnostics had drawn the conclusion that no specific legislation measures were needed in the area, but recommended that an independent ethical council for health care services would be established.

But the ethical dilemmas in connection with the research and the use of artificial reproduction grew stronger. In 1997 the first *Act on Artificial Reproduction* was adopted in Denmark. One of the more controversial areas of debate was and is the access to assisted reproduction of single and lesbian women. This is an issue that is still a very controversial one. In the deliberations on the ethical, scientific, and health-care-related questions to assisted reproduction, the Danish Council of Ethics has played and still plays an important role.

The *Danish Committees on Scientific Dishonesty (DCSD)* were set up in the fall of 1992, initially for a 3-year trial period. Back in the 1950s there was a controversial case of scientific dishonesty in a medical doctor's thesis. This case among some of the cases from the USA made a huge impression on quite a few of the newly educated medical doctors from that generation. Over the years the need for establishing a system for dealing with cases of scientific dishonesty grew. In 1992 a working group with prominent Danish medical researchers as Povl Riis, Daniel Andersen, Torben Clausen, and Niels Axelsen among its members issued a report on scientific dishonesty. (Professor Dr. Med. Povl Riis and former deputy chairman Daniel Andersen have in the annual report from 1996 of the Danish Committees on Scientific Dishonesty given a layout of the historic background for creating the first Danish committee for scientific dishonesty). The conclusion was that Denmark could benefit from a central committee based on a voluntary initiative from medical researchers in order to ensure scientific integrity. In order to ensure the legal rights of the parties involved, it was deemed essential to make a qualified judge the chairman of the committee. The committees' mandate comprised only the area of human medical research. In 1995 it was decided to establish the committee on a permanent basis, and in 1998 the decision was taken to broaden the scope beyond the medical field, including natural sciences, social sciences, and humanities, thus establishing 3 committees on scientific dishonesty.

The Danish Committees on Scientific Dishonesty (DCSD) deal with complaints regarding dishonesty in research.

A case can be brought to the committees as a complaint. It is also possible to have a case processed in order to be cleared of accusations of scientific dishonesty.

Each of the three committees comprises one chair and six members.

The members are recognized researchers who have been officially appointed by the Danish Minister for Science, Technology and Innovation after hearings conducted by the Danish Council for Independent Research.

The joint chair for the three committees is a high court judge who is appointed by the minister.

Current Danish Bioethics Infrastructure

The Danish Council of Ethics

The Danish Council of Ethics was set up in 1988. The council's main functions today are to give advice to legislators and the government and to create public debate on issues pertaining to biotechnology, which affect human life, nature, the environment, and food. The council also covers all ethical issues related to the health care sector.

The Danish Council of Ethics has contributed in developing the public debate by setting up public consultations and debates about ethical questions relating to new technologies within medicine. The council aims at communicating ethical dilemmas relating to biotechnology, the use of natural resources, environmental issues and the area of human health to Parliament, the government, and the health care sector, and to lay people.

According to the current law (Act No. 440 of June 9, 2004), the Danish Council of Ethics consists of 17 members chosen from a mixture of specialists and lay people. Nine members are chosen by a parliamentary committee whose task is to follow the work of the council. In addition, 4 members are chosen by the Minister for Health; 1 member is chosen by the Minister for Environmental Affairs; 1 member is chosen by the Minister for Food, Agriculture and Fisheries; 1 member is chosen by the Minister for Science, Technology and Development; and 1 member is chosen by the Minister for Business.

When the Minister for Health appoints the members, the minister must ensure that lay people as well as experts are represented in the council and that there is equal representation of men and women in the council leaving the possibility for either 9 men and 8 women or 9 women and 8 men as members.

The chairman of the council is chosen by the parliamentary committee and is appointed by the Minister for Health. Members and chairman are appointed for a 3-year period and can be reelected for one more period.

The government has no instructional powers toward the Danish Council of Ethics, and likewise the government has no obligation to follow the recommendations of the council. The funding is provided by government, but the council chooses the topics itself and works independently. The council is providing advice but has no competence to make any forms of binding decisions.

The Danish Board of Technology

The task of the Danish Board of Technology is to promote the ongoing discussion about technology, to evaluate technology, and to advise the Danish Parliament and other governmental bodies in matters pertaining to technology.

One of the "inventions" of the Danish Board of Technology was the "consensus conferences," where a number of lay people are "informed and educated" regarding a specific topic, having an opportunity to ask a number of presentations and questions to experts. Based on this, they form an opinion, which is presented to the politicians and the public.

Every year, after a specific stipulation in the nation's "Finance Law," the Danish Board of Technology receives an annual subsidy of around 10 million Danish kroner. The Ministry of Research is the supervising authority for the board, and the Parliament's Research Committee is the board's steady liaison to the parliament. Once a year, an annual report is submitted to the parliament and the government.

On November 15, 2011, it was announced that a bill is prepared in order to close down the board due to a set of really difficult negotiations on the national budget for research and innovation next year. In this connection the public funding of the Board of Technology of 10 mio. Danish kr. is to be withdrawn in order to reach an agreement on a 1 billion DKK (140 million €) extra research budget. Currently a bill has been drafted in order to terminate the Board of Technology. From Wednesday the 20th June 2012 and onwords the Board of Tehcnology has been restructured into a foundation. The Danish Board of Technology Foundation will be a new, non-profit organization that will continue the work of the Danish Board of Technology. At this moment it is not known whether the Board of Technology will be closed down, or whether the activities of the board will be carried on in a different setting.

The Danish Committees on Health Research Ethics

In Denmark research projects involving human beings or any kind of human tissue, and cells need authorization from a regional ethics committee. See the present Danish Act (Act No. 593 of June 14, 2011, on Research Ethics Review of Health Research Projects). According to the newest English translation of the law from the Danish Ministry of Health, the Danish Scientific Ethical Committees are now translated the Committees on Health Research Ethics. The law implements the principles from the EU directive 21/2001.

The Danish Scientific Ethical Committees are characterized by a high representation of lay members.

The *appointment* procedure is as follows: A regional county council appoints the regional health research ethics committees for a 4-year period. The county council can appoint one or more regional health research ethics committees within its geographical area. A regional health research ethics committee shall consist of at least 7 members and at most 11 members. Three to five members must be active in

the area of biomedical science, and the rest of the members of the committee must be lay members. The members can be reappointed for 2–4-year periods.

The National Committee on Health Research Ethics consists of 13 members: The chairman is appointed by the Minister for Health. Two members are appointed by the Minister for Health after joint recommendation from the board of the Danish Council for Strategic Research and the Danish Council for Independent Research. Five members are appointed by the Minister for Health in collaboration with the Minister for Science, Technology and Development after a public call for candidates. Five members are appointed after recommendation from the county regions. When recommending candidates for the committee, an equal number of men and women must be recommended. When the committee is appointed, an equal representation of men and women must be ensured – so because the uneven number of members you can either have is 7 women and 6 men as members, or 7 men and 6 women as members. The committee must consist of members representing both biomedical health research areas and lay members. The chairman must represent public research interests and public educational activities, health research ethics, and general cultural or social interests that are important for the committee's work. The members cannot hold a seat in the parliament or in a county council. The members are appointed for a period of 4 years and can be reappointed for 2 terms.

According to the act, the medical researcher is responsible for the scientific and bioethical quality of the research project. The medical researcher in charge of the trial must apply for authorization from the regional health research ethics committee in the area in which the investigator is operating. The application should conform with the "Guidelines about notification etc. of a biomedical research project to the committee system on biomedical research ethics." According to Act No. 593 of June 14, 2011, on Research Ethics Review of Health Research Projects, the medical researcher responsible for the research project applying for authorization must send the application to the regional health research ethics committee in the area in which the investigator is operating.

It is the responsibility of the Scientific Ethical Committee System to ensure that research projects are carried out in a responsible manner in accordance with the ethical principles of biomedical research and to ensure that the rights, safety, and well-being of trial subjects participating in biomedical research projects are protected. At the same time research projects should provide possibilities for the development of new, valuable knowledge or the deepening and evaluation of existing biomedical knowledge.

The Danish Act on the Scientific Ethical Committee System lays down the legal framework for the scientific ethical assessment of research projects in overall terms. The requirement of informed consent is entirely fundamental to the rules governing the scientific ethical assessment of research projects and to the committee system.

In June 2011 the Danish Parliament adopted a new act amending the act on the Scientific Research Ethics Committee System (Act No. 593 of June 14, 2011, on Research Ethics Review of Health Research Projects entering into force on January 1, 2012). The act lays down new rules for the composition of the committees,

the collaboration between the regional committees, and the national committee. Furthermore, new regulations for the mandate of the ethics committees are stipulated in the areas of inspection of biomedical research trials, quality, and evaluation. The internal collaboration among the research ethics committees and the external collaboration with other stakeholders such as universities, researchers, hospitals, and governmental and regional stakeholders have been elaborated in the act. The other amendments are mostly elaborations and precisions to regulations of the previous act.

The Danish Committees on Scientific Dishonesty

The task of the Danish Committees on Scientific Dishonesty is to make binding decisions. Therefore, it is important that the academic requirements of members and the chairmanship satisfy the need for both trained decisions makers and experts in the fields of biomedical research in question.

One chairperson, who must be a high court judge, chairs the Committees on Scientific Dishonesty.

In addition to the chairperson, each committee consists of six members and the same number of alternates who may only deputize on any member's absence and only for the full consideration of a case. The members shall all be recognized researchers, who between them cover all areas of scientific research. The alternates are appointed after the same criteria as the members.

The chairperson is appointed by the Minister for Science, Technology and Innovation. The members and the alternates are appointed by the minister in their personal capacities following a hearing conducted by the Danish Council for Independent Research. The chairperson, the members, and the alternates are appointed for a period of 4 years and are eligible for reappointment for a period of no more than 2 years.

Based on the experience from the area of medical research, it was in 1998 decided to create three committees on scientific dishonesty covering a broader range of the scientific fields: In the Danish Executive Order No. 933 of 15 December 1998, the Board of the Danish Research Councils was given the mandate to create three committees on scientific dishonesty within Danish research:

1. A committee for research in natural science, agricultural and veterinary science, and technical science
2. A committee for research in health and medical science
3. A committee for research in social science and the humanities

The committees shall jointly determine the remit of each of the three committees set out in the executive order. The demarcation lines are specified in committees' rules of procedure.

To the committees was appointed a joint chairperson – a judge – one of whose tasks was to ensure uniformity in the statements made across the different fields of research.

In the Act from 2003 (Danish Act No. 405 of 28 May 2003 on Research Advice), it was stated that a revision should take place in the 2007–2008 session of the Danish Parliament on the basis of an evaluation of the advice provided by the

research advisory system concerning support for research training. The revision process was planned to take place in the first part of 2008. The Danish Agency for Science, Technology and Innovation and the Danish Ministry for Science, Technology and Innovation prepared the bill.

Major Bioethics Issues and Discussions at the Moment

The Danish Council of Ethics

The council has two main functions: (1) To offer advice to the Danish Parliament and the Ministry of Health and Interior Affairs on ethical problems arising from the development of new technologies and treatments in health care and (2) to inform the public and to promote public debate and public dialogue on ethical issues in the field of human health. The original wording of Section 1 in the act, stating that the council should "carry out its work on the basis of the assumption that human life takes it beginning at the moment of fertilization" (Section 1 of the Act of the Danish Council of Ethics (440/2004)), was changed by the government in the revision of the act in 2004 to the following wording: "Respect for the integrity and dignity of the human being also encompasses the early phases of human life, including fertilized human eggs and embryos" (reference). Thus, the debate on when life begins has changed. It is still being debated from time to time, but is not as controversial as it was in the beginning and as it is in many other countries.

The Danish Council of Ethics has among other themes dealt with the following issues:

- Priority setting in health service
- Medical euthanasia
- Health science information banks
- Treatment of psychiatric patients
- Prenatal diagnostics; examination of fetuses and fertilized ova for disposition to illness
- Organ transplantation
- Priority setting in biomedical research
- Legal aspects concerning the problems of demented patients
- Man or mouse? – ethical implications of stem cell research
- Microinsemination and preimplantation genetic diagnosis
- Medical enhancement
- Utility, ethics, and belief in connection with the release of genetically modified plants

The Danish Regulation on Assisted Reproduction

The Danish Council of Ethics, the Scientific Ethical Committees, and the Danish Board of Technology have dealt with the ethical issues of assisted reproduction in

several reports and conferences during the 1990s. In 1996 the bill on artificial fertilization was introduced in the Danish Parliament. Because the bill dealt with ethical issues, the members of parliament were allowed to vote in accordance with their conscience and were not subjected to the otherwise strict party discipline. This resulted in a fairly big amount of questions to the Minister of Health and amendments to the bill. As a result the bill was not passed in the Danish Parliament before May 1997.

The present act from 2006 (Act No 923/2006) which is the newest revision of the former act stipulates that the act is applicable for medicinal treatment, diagnostics, and research that is conducted by a medical doctor or under the responsibility of a medical doctor, where a pregnancy is induced in a woman in other ways than between sexual intercourse between a woman and a man. The act restricts the offer of medically assisted artificial reproduction to single women with no children and couples with no children of their own. There is though a possibility to be treated in order to have more children within a period of 5 years if the woman/couple has stored frozen fertilized eggs (Section 15).

Prohibitions against treatment are set out in a number of situations:

1. Assisted reproduction cannot take place unless it is with the view of uniting a genetically unmodified ovum with a genetically unmodified sperm cell.
2. It is prohibited to implant identical unfertilized or fertilized ova in one or more women with the view of inducing pregnancy.
3. A pregnancy must not be induced unless the ovum stems from the woman who is giving birth to the child or the sperm stems from her partner.
4. Assisted reproduction must not take place in the case where the woman giving birth to the child is older than 45 years.
5. The fertilized egg's further development cannot take place outside the uterus of a woman.
6. It is prohibited to use ovaries from aborted female embryos, stillborn baby girls, or deceased women.
7. It is prohibited to transplant ovaries to a woman with the aim of curing infertility.
8. It is prohibited to sell, promote commercialization, or in any other way to participate in the commercialization of unfertilized and fertilized human ova.
9. It is prohibited to perform a treatment of assisted reproduction in the case of surrogacy.
10. It is not permitted to export a fertilized ovum.

The act also lays down *restrictions* in the following cases:

1. It is prohibited to apply new treatments of assisted reproduction before the Minister for Health has authorized them. Before authorizing a new treatment, ethical and health care issues shall be taken into account.
2. Choosing the child's sex can only be permitted, if it is done in order to prevent a serious hereditary disease.
3. Genetic diagnostic techniques can only be performed on fertilized eggs in cases where there is a known and substantially heightened risk that the child will develop a serious hereditary disease.

4. Preimplantation diagnostics can be allowed by the heath authorities in the case, where consideration for a child with a serious hereditary illness in the family requires this.
5. Assisted reproduction with human sperm cells that have been manipulated can only be carried out under the supervision of a medical doctor.

If the medical doctor responsible for the treatment deems it likely that there is clear doubt as to whether the woman/couple is capable of taking care of the child after birth, the doctor shall reject treatment of the woman/couple. If the doctor deems it likely that there is reason to doubt the ability of the woman/couple to take care of the child after birth, the doctor shall get a second opinion seeking competent evaluation of the situation if the woman/couple agrees to this. If the woman/couple do not agree, the doctor shall refuse treatment.

The following types of *research* are *prohibited*:

1. Research with the aim of producing genetic identical individuals
2. Research with the aim of producing individuals by merging genetic different embryos or parts of embryos before they are implanted in the uterus
3. Research with the aim of producing chimeras
4. Research with the aim of developing a human individual in a nonhuman uterus

Only certain types of research on assisted reproduction can be carried out and only after authorization from a Scientific Ethical Committee:

1. Research with the aim of improving IVF techniques
2. Research with the aim of improving techniques of preimplantation diagnosis in order to ascertain a serious hereditary disease
3. Research on fertilized eggs and stem cells with the aim of gaining new knowledge in order to better the treatment of illnesses in human beings

The Danish Medicines Agency and the committee system coordinated by the Danish Central Scientific Ethical Committee operate a parallel procedure for authorization of biomedical research projects involving clinical trials of non-approved medicinal products. The Danish Medicines Agency grants the final permission for such projects. According to this system of bipartite decision-making competency, it is the Danish Medicines Agency that makes the final decision on any authorization to commence trials on medicinal products involving human subjects. The Agency's decisions must be made on the basis of a recommendation from the committee system. Given that it is the committee system that has the sole authority to conduct a scientifically based ethical evaluation of a prospective biomedical trial, the committee's recommendation is in effect binding on the Medicines Agency as regards the scientific component of ethical evaluations.

This bipartite decision-making mandate entails liaison, and this takes the form of a coordinating committee of representatives from each of the two bodies. In recent years cooperation between the two bodies has been devoted largely to the EU draft directive on good clinical practice (GCP Directive), in which representatives of both the Danish Medicines Agency and the Danish Central Scientific Ethical Committee participated in the EU talks.

Collaboration in *gene* therapy has been on the agenda. In 1999 there was a case in the county of Aarhus concerning a research project involving gene therapy on human subjects as part of a study of the treatment of patients suffering from hepatic cancer.

The Danish Committees on Health Research Ethics

The main tasks of the Scientific Ethical Committee System are as follows:

1. The protection of the trial subjects: their integrity, rights, and safety
2. The establishing and maintaining of ethical criteria for high-quality biomedical research
3. The control function with regard to monitoring the approved trials
4. The task of maintaining the dialogue on research ethics in the field of biomedicine with researchers, other stakeholders, and the public

Regard for the individual always precedes regard for the advancement of scientific knowledge. That is an internationally recognized basic principle. The main aim of the Danish system of Scientific Ethics Committees is to apply these two seemingly incongruent principles in their work of evaluating biomedical research projects.

Another aspect of the committees' work is the follow-up control on research projects. The executive order and guideline on biomedical trials cover all phases of biomedical research, including regulation of those projects approved. Researchers should basically be self-regulating, in ethical terms, providing a guarantee in terms of ethical revue. Formalized control by the committees will have a preventive effect. Overall, the Scientific Ethical Committees operate in the cross field between research and ethics.

The committees act as gatekeepers and safeguards, so the process of gaining new scientific ground within biomedical research will not get off track. Respect for the individual always weighs more heavily than regard for science. Thus, the Danish legislation on biomedical research authorization covers a wide spectrum, from planning to implementing and completing a biomedical research project.

Informed consent is the cornerstone of the protection and must meet specific criteria: The trial subjects' participation must be absolutely voluntary. Informed consent must be given in writing. Trial subjects' consent must be explicit.

Trials with legally incompetent trial subjects and other vulnerable groups such as trial subjects who because of age or reduced physical or mental abilities due to depression, age, mental deficiencies, or similar conditions are incapable of giving informed consent to participation in a research project require special precautions.

The persons participating in the research project must be informed of the following: the aim of the trial, all possible side effects, all known risks associated with the trial, and drawbacks and inconveniences that participation is voluntary and that they can always withdraw from the trial again, at any time. A special layman's résumé of the research project must always be written.

Scientific Dishonesty

The *provisions* regarding the Danish Committees on Scientific Dishonesty (DCSD) are now laid down in regulation from 2010 (Pursuant to Chapter 7, Section 31–34 of the Danish Act No.1064 of September 14, 2010). According to the Act on Research Advice, the Minister for Science, Technology and Innovation is given the mandate to establish the Danish Committees on Scientific Dishonesty. The scope of the committees is to ensure the scientific integrity of Danish research. The task of the Danish Committees on Scientific Dishonesty is to consider cases involving complaints of scientific dishonesty in cases of public research or research projects receiving public financial grants.

The *definition* that determines the committees' remit is as follows:

By the term "scientific dishonesty" is meant intentional or grossly negligent conduct in the form of falsification, plagiarism, nondisclosure, or any similar conduct involving undue misrepresentation of a person's own scientific work and/or scientific results. This includes the following:

1. Undisclosed fabrication and construction of data or substitution with fictitious data
2. Undisclosed selective or surreptitious discarding of the person's own undesired results
3. Undisclosed unusual and misleading use of statistical methods
4. Undisclosed biased or distorted interpretation of the person's own results and conclusions
5. Plagiarism of other persons' results or publications
6. A false credit given to the author or authors, misrepresentation of title or workplace
7. Submission of incorrect information about scientific qualifications

The committees are however not entitled to consider cases involving the validity or truth of scientific theories or cases involving the research quality of a scientific product.

The mandate of the committees is specified in the regulation. According to this, DCSD can only deal with cases in which the defendant has been scientifically trained. The executive order does not give a definition of the implications of this training requirement in detail. Furthermore, the committees will not be able to deal with cases in which a researcher deals with fields of research other than his or her own. The researcher must either have had the scientific product published in Denmark, have compiled the product in connection with employment/commercial activities in Denmark, have received or applied for a subsidy from the Danish public authorities to compile the product, or be associated closely to Denmark in other ways.

DCSD is only to deal with cases where the person filing a complaint can be regarded as a party to the case under the rules of the Danish Public Administration Act. As a result, only persons with a substantial individual interest in the outcome of the case can file a complaint.

The committees have an opportunity to take up cases by their own initiative, if they are of social interest or of importance to human or animal health, and there is a justified assumption of scientific dishonesty.

The *types of* cases that the Committees on Scientific Dishonesty may consider are cases involving complaints about individuals or groups of individuals. In cases involving complaints about groups of individuals, however, the committees may only use their authority to employ sanctions, if the clarification of the case leads to clarification of who is responsible for the conduct. The committees may also consider cases involving complaints about an application filed with a view to applying for a grant from public research funds.

The *sanctions* include a variety of reactions. In cases where scientific dishonesty is ascertained by the Committees on Scientific Dishonesty, the committees shall make a statement expressing criticism. At the same time, the committees may do the following:

1. Inform the defendant's employer if the party in question is employed as a researcher.
2. Recommend that the scientific project concerned be withdrawn.
3. Inform the relevant public authority supervising the area.
4. Make out a police report where a punishable offense is involved.
5. At the special request of an employing authority, state their views on the degree of scientific dishonesty.

The committees shall state their views on the degree of scientific dishonesty ascertained and on its importance to the scientific message in the scientific product concerned.

The committees may shelve cases under subsection hereof if the committees find the scientific dishonesty ascertained only to be of little importance to the scientific message in the product.

Challenges for the Years to Come

It is well known that it may be difficult to foresee future developments in research. Some 10 years ago the most difficult ethical dilemmas were thought to be found in the area of xenotransplantation. There was a heated debate on the issue, and there was also raising concerns about the risks for spreading diseases between animals and humans. Now, 10 years later, xenotransplantation does not seem to be the area of main concern from a bioethical viewpoint, maybe because the technology has not evolved as quickly as first expected or maybe the ethical qualms that were voiced by the public but a halt to the interest of the scientists' motivation in moving forward. It is very difficult to assess what factors have played the decisive part in determining the fate of the advancement or decline of a technology.

In the future development of bioethics, one of the areas that might raise new questions could very well be the issue of enhancement of the human body and brain. Another yet equally important focus of attention is the areas of risk assessment, risk

evaluation, and risk communication that might prove to be areas that need further development and deliberation in bioethics. Likewise converging technologies combining nanotechnology, biotechnology, ICT, and cognitive science can be expected to raise new questions on how to deal with the ethical issues these new possibilities will raise. These trends are not specific for the Danish situation and will not be explored further here.

In the following some challenges regarding the setup of bioethical bodies are reflected upon, including the need for cooperation between the different councils, the need for independence and autonomy of the bioethics committees, the pros and cons of the efforts to reach consensus in the ethics committees, and the role of lay people.

Cooperation Between the Different Councils and Boards

There has been a need to establish cooperation among the various Danish administrative units assigned to address ethical concerns. The following gives examples of such cooperation between some of the councils and boards dealing with bioethical issues in Denmark.

In Denmark closer cooperation and coordination has been implemented between councils and boards working with questions of bioethics as related to human health, animals, and biotechnology. This cooperation was for a period centralized in BIOSAM, which was a joint body of representatives from the Central Scientific Ethical Committee, the Council of Ethics, the Danish Board of Technology, the Animal Ethics Council, and the Animal Experimentation Inspectorate and which liaises on ethical issues associated with biotechnology research and the application of biotechnology, including cloning and the genetic transformation of mammals. BIOSAM also contributed to making the parliament and the public aware of new developments in research in, and the application of, biotechnology.

Two councils, *the Danish Council of Ethics and the Animal Ethics Council*, have similarly, over recent years, cooperated more closely, by holding joint information meetings. Additionally, a particular joint focus has been directed at the question of cloning. Thus, in 2000, the Danish Council of Ethics published a discussion paper, dealing principally with issues concerning technologies for tissue and organ propagation and the future potential for the genetic manipulation of humans and animals.

In accordance with the Act on the Scientific Ethics Committee System and the Act on the Danish Council of Ethics, the *Central Scientific Ethical Committee and the Danish Council of Ethics* are required jointly to address the more fundamental ethical issues concerning biomedicine. Over the past decade or so, the cooperation between the two bodies has resulted in the holding of information meetings in which representatives of the two bodies have exchanged information about the work. Furthermore, in recent years, there has been closer cooperation between the Central Scientific Ethical Committee and the Danish Council of Ethics, which, among other things, has given rise to joint events, in which both bodies have planned and implemented the joint initiatives.

According to this system of bipartite decision-making competency, it is the Danish Medicines Agency that makes the final decision on any authorization to commence trials on medicinal products involving human subjects. The agency's decisions must be made on the basis of a recommendation from the committee system. Given that it is the committee system that has the sole authority to conduct a scientifically based ethical evaluation of a prospective biomedical trial, the committee's recommendation is in effect binding on the Medicines Agency as regards the scientific component of ethical evaluations. This bipartite decision-making mandate entails liaison, and this takes the form of a coordinating committee of representatives from each of the two bodies.

The "Aarhus Case" revealed the need to establish interdisciplinary collaboration among the authorities mandated to grant authorizations for clinical trials involving gene therapy. Trials of gene therapy involving human subjects involve major environmental, epidemiological, and ethical aspects. In response to this sequence of events, a coordinating committee was appointed by the Danish Medicines Agency for the purpose of promoting dialogue among the authorities responsible for granting the various authorizations. The coordinating committee, made up of representatives from the Danish National Board of Health, the Danish Medicines Agency, the Danish Central Scientific Ethical Committee, the Danish Forest and Nature Agency, and the Danish Labour Inspectorate, attends to the authorization of human clinical trials involving gene therapy.

Regarding the local committees on biomedical research, there is an aim to ensure that there is minimal inconsistency within a single area and between one area and the next. The same issue may arise among regional authorization bodies, for example, meaning that practices may vary in different national regions. This coherency would seem appropriate in the light of the fact that local variation should be acknowledged, whereas in terms of equality this may appear less reasonable. One essential concern is to avoid any dispute over authority among the various bodies appointed and prevent overlap and the duplication of effort this might give rise to. In this respect it is important to establish actively cooperating bodies. This need also emerges from the fact that many of the ethical issues addressed touch on multiple concerns that may need to be addressed by separate committees. The need for interdisciplinarity and cooperation is therefore pronounced in the Danish system. The challenge is finding the right balance between the different committees, to avoid overlap, to secure exchange of information and experiences, and to use their expertise – jointly regarding bioethics and separately regarding their specific topics.

Independence and Autonomy of the Bioethics Committees

It is often emphasized that it is of the utmost importance for ethics committees to be independent. Only in this way can they meet the need for information and debate in a way that comprises an objective stance on current regulation and prevailing opinion, even when this is at odds with the position held by government and parliament, for example.

It has been the Danish policy to establish independent bodies of this nature – at the national level – and to furnish them with sufficient financial resources to allow them to act in an advisory and debate-promoting capacity.

The challenge is to make sure that the crucial independence and autonomy is maintained and secured – and to furnish them with sufficient financial resources to allow them to act in an advisory and debate – promoting capacity.

Is Consensus a Requirement for Ethical Deliberation?

The Danish Council of Ethics has often been confronted with the demand for consensus. The difference between the desire to achieve consensus or not is based on a weighing of advantages and drawbacks.

The advantages of consensus would appear to be that the greater the level of agreement presented by a given ethics committee, the greater will be its prospects of bringing influence to bear on the regulators.

The drawbacks are that such a committee will thereby forfeit much of its impetus, since controversial issues and/or principles are usually the very aspects that make consensus difficult to achieve. It may therefore be more helpful to furnish the decision makers with detailed information as to where any dispute might arise and which ethical principles may be assessed and weighed differently such that the decision makers will have the best possible basis of information at their disposal to assist their deliberations. The Danish Council of Ethics will usually choose the latter strategy in formulating its opinions and advice.

The Composition of the Bioethics Committees: Especially Lay People

Expert representation comprises groups of expert delegates representing the disciplines concerned, for example, biotechnology, biomedicine, philosophy and ethics, law, sociology, and psychology along with other disciplines as required.

The advantages of having such representation are a means of securing comprehensive and well-founded academic expertise for the advisory and decision-making services rendered by the various committees. In this context *interdisciplinarity* is crucial, since under this concept the representatives of different disciplines can meet and discuss ethical issues as a means of familiarizing themselves with each other's terminology, culture, and scientific traditions. This then serves to promote mutual understanding among different scientific domains.

It is essential that the concept of expert representation is not defined too narrowly and that careful consideration is given to which experts will be the most appropriate, especially with regard to the need to include sociologists, anthropologists, psychologists, and other social scientists.

The drawbacks of establishing forums comprised exclusively of experts are that they may have a tendency to become somewhat introverted in their choice of issues and mode of discourse. Communication with the public and decision makers

may be hampered by the fact that many academics have no particular tradition for opening their debates up so as to make them accessible and comprehensible to the general public.

Lay representation involves delegations made up as "counterweights" to (academic) experts. The reflection and knowledge possessed by lay people serves to complement the more abstract and generalizing insights of academic experts and thereby contributes to a more balanced foundation for decision-making than if all decisions were made solely by such experts.. The findings of consensus conferences have been that ordinary, motivated citizens are capable of acquiring and analyzing complex scientific information and of drawing their own, independent conclusions. In the consensus conference model, the use of lay people may be understood as drawing a parallel with jury service in the administration of justice. The experts could be compared to the witnesses summoned before a court; the panel with the jurors, who, after hearing the expert testimonies, withdraw to formulate their collective response to the conference issues, informed by the presentations of the experts and their own common sense.

Denmark maintains a large body of lay people in its ethics committees. The involvement of lay people is already a time-honored component of the Danish judicial system, the purpose of which is to ensure that the public's sense of justice is reflected in criminal procedure. In addition, the involvement of lay people occurs in public governance, for example, in central tax administration in Scandinavia. The "worldly wisdom" possessed by lay people serves to complement the more abstract and generalizing insights of academic experts and thereby contributes to a more balanced foundation for decision-making than if all decisions were made solely by such experts.

The *advantages* of drawing on the services of lay people are, among other things, that they have a confidence-building function, whereby the link with general public opinion and common sense may be sustained. Lay people thus serve to contribute an element of "wisdom," which ensures that account is taken of the opinions and convictions that exist as implicit tenets in the values embraced by a population. This should also be considered in the light of the fact that lay people are perfectly capable of acquiring objective and valid insights and that scientific experts are just as susceptible as lay people to subjectivity and personal factors. Moreover, the involvement of lay people serves a democratic function in that it exercises the principle of autonomy and counteracts the formation of unintended power bases. This serves to establish what might be termed a "bottom-up" element in decision-making processes, just as it ensures dialogue on the issues that the public finds to be important, and ensures that the concerns deliberated are communicated to the public in a way that is comprehensible to the "man on the street," and which thereby contributes to social and democratic learning processes. The subjective and personal factors brought into play by lay delegates will thus be incorporated in consultations on the issues that present themselves for discussion.

The *drawbacks* of retaining the services of lay people include the risk that they may become "overqualified" in connection with their involvement and

representative services to expert bodies. A failure to take special account of the fact that the role of lay people is precisely to provide the originally intended safeguards and to approach the issues from new angles might mean that the values and culture of the academic experts might come to dominate the agenda such that the lay element is at risk of being "held hostage" by expert opinion. It should therefore be ensured that the views held by lay representatives are allowed to evolve freely and that "down-to-earth" opinions are not compromised. Further problems may arise if extensive lay participation displaces the volume of experts deemed necessary without excessively swelling the ranks of the organization.

Political participation in debate-generating activities will often be useful; the problem being that politicians tend to be reluctant to get involved at an early stage in issues that may be regarded as "dangerous" or "awkward" to take a public stance on. In relation to ethics committees, one purpose of which is to serve as an advisory function, it is doubtful whether political participation would be of value.

The advantages are that this ensures a "direct line" to the political domain, which in turn ensures that the advisory element dominates and that the political domain becomes accustomed to discussing difficult ethical issues in greater depth.

The drawbacks may be that politicians run the risk of backing a given opinion prematurely, which again may pose further problems. The risk is also that the political level engages too early in the process, when it may be more helpful if the debate can proceed in the absence of political interests.

The retention of lay services is often endorsed in relation to debate models proper, which refer to public debate in various forums, etc. However, it is important that the lay contingent and generalized debate are also employed in relation to scientific ethical committee systems in which actual authorization of biomedical research projects is effected, since these committees do not necessarily consider broader ethical implications involving general societal concerns and regard for future generations. Such aspects may play an important role in connection with deliberations on research projects seeking to employ technologies such as xeno-transplantation, stem cell research, and cloning of human cells. Deliberations on the broader ethical implications of such projects should therefore be ensured by retaining the services of lay people in scientific ethical committee systems and by incorporation of the debate model proper.

The question of the term in which lay people should serve has also been debated. The fact that it takes time for lay people to familiarize themselves with complex issues speaks in favor of an extended period of service. In contrast, the fact that it may be necessary at times to "inject" fresh opinions and new participants into the debate speaks in favor of a rather more limited period of service. The latter argument would seem to be the more persuasive.

Conclusion

In Denmark bioethics has been on the agenda for many years, and the Danish Councils of Ethics and other ethical bodies have obtained considerable knowledge

and experience. The strategy of having a two-pronged approach to debating and solving bioethical dilemmas has been prevalent for the last 20 years.

Four basic principles are playing important roles in the content of the ethical debate:

1. The ethical principle of *economic and qualitative benefit* is occasionally comprised by preconditions dictating the balancing of the risks against the benefits of carrying out a given bio-project.
2. *The principles of autonomy, dignity, integrity, and vulnerability* are assured in the scientifically based ethical authorization system in the shape of the requirement concerning informed consent.
3. *Just distribution of benefits and burdens* is also an important principle
4. *Codetermination and openness* form the basis for the debate models in the various formats.

The involvement of lay people in the decision-making process on developing ethical principles and in the authorization of biomedical trials on humans has shown the Danish affinity for incorporating input from "bottom-up processes" like consensus conferences as well as the "top-down processes" from expert groups and committees in the legislation process. A guess based on the growing user-generated input into societal deliberation on bioethical issues will be that the influence from bottom-up processes will be even more prevalent in the future. It is encouraging to find that these principles are becoming more widespread all the time and have now also been identified with great emphasis by the EU in the form of a drive for "proactive civic responsibility." The principles of openness and codetermination are procedural requirements in which there seems to be a growing need for implementation in the legislation process.

One *conclusion* on the views presented here might be that it is vital to ensure broad interdisciplinary expert representation – possibly complemented by a panel of academic advisers who may be consulted on specific matters – but that there may equally be a need to ensure lay representation, both in the democratization instruments designed to generate debate and in ethics committees, whether these serve an advisory or controlling function. This ensures an open, transparent system, as well as a counterweight, to prevent medico-professional and research-based interests from dominating in relation to the mechanisms for protection that may be deemed equally important. At the same time this promotes valuable dialogue between experts and lay people. In this context it is important that lay people are provided with sufficient, readily comprehensible information such that they may render their services on a sufficiently well-informed basis, being appraised of the technical data.

A more *general conclusion* may be that compared to the global picture the expectation would be that Denmark represents a country with a quite exhaustive bioethical infrastructure and bioethical regulations and that some experiences can be drawn from this period. One of the crucial aspects is the securing of an independent and autonomous bioethics council, which can initiate and secure thorough public debate with information and outspoken opinions from a number of people with different backgrounds and different views, presenting decision makers with a solid ground for their important decisions in the matters of bioethics and biolaw.

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Danish Health Research Ethics Committees. http://www.cvk.sum.dk/CVK/Home/English.aspx
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Dominican Republic

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Andres Peralta-Cornielle

Introduction

Personal experience has taught me that for the development of the discipline of bioethics, there are important factors that must converge. Those are:

- Involvement of people attuned to their moral principles
- Understanding that a sustainable future of humanity requires the well-being of society
- Creating organizational and institutional structures to guarantee permanence

A. Peralta-Cornielle
Professor Medical Ethics, O&M Dominican University, Medical School, Santo Domingo, Dominican Republic
e-mail: iorcancer@yahoo.com; iorcancer@hotmail.com

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- Providing adequate academic capacity, in both the epistemological and hermeneutic perspectives of bioethics, to those responsible of teaching its fundamentals
- Designing an agenda to promote harmonious coexistence, in mutual respect, for all strata of society
- Implementing programs to teach moral values at all school levels
- Involving of all levels of government in every step of development or implementation
- Ensuring interinstitutional relationships to expand its field of influence
- Promoting international collaboration in the search of multicultural understanding for its implementation
- Educating the population about its fundamental principles to make this new knowledge available to every citizen

On writing this chapter, the above factors are used as a guide since all of them are essential to the development of bioethics in every human environment or activity.

Development of Bioethics

Activities to promote the discipline of bioethics in the Dominican Republic started on July 1988, with the collaboration of the Pan-American Health Organization (PAHO/WHO) and the consultancy of Dr. Eduardo Del Caño, who promoted a series of meetings with physicians, lawyers, nurses, public health specialists, ecologists, and university faculty. During a second consultancy in November 1991, a second multidisciplinary workgroup was formed with faculty from five different universities and the country's Association of Catholic Physicians.

The organizational work culminated in March 1992 with the workshop *Ethics in Health and Quality of Life* held at Universidad Nacional Pedro Henriquez Ureña with 200 professionals in attendance.

Simultaneously the Association of Catholic Physicians, together with two catholic universities, promoted a series of talks and conferences and organized the First National Bioethics conference in May 1992.

The CNB was founded in March 1992. In order to promote bioethics, the newly formed organization set as its first objective to offer seminars in universities, governmental institutions, and physicians' associations. To that end, eight seminars were held from June to November 1992.

In September 1993, the *First National Symposium in Medical Ethics* for the Dominican Medical Association was organized, and in October 1998, the CNB was included in UNESCO's International Directory of Bioethics Organizations. In July 1999, the CNB subscribed to the Panama Declaration, in adherence to the principles of the International Federation of Global Bioethics created by V. R. Potter.

Peralta, A. E. (2011) described the *Beginnings and Development of Bioethics in Dominican Republic* at a conference presented at the VII Congress of the Latin American and Caribbean Federation of Bioethics Institutions (FELAIBE) at Viñas del Mar, Chile, in June 2011.

Major Actors in the Development of Bioethics

The attendance and participation of members and directors of the CNB in activities and events in the field of bioethics held by international organizations, especially in Latin America and the Caribbean, significantly contributed to the development of bioethics in the country. Four organizations have played a fundamental role in that process.

The Regional Program in Bioethics of the Pan-American Health Organization (PAHO/WHO) is among the regional entities that contributed greatly to that development, especially in the sphere of undergraduate and postgraduate education.

Directors of the CNB participated in the seminar/workshop *Bioethics in Latin America and the Caribbean*, held in the University of Santiago de Chile in November 1994 and in 1995 in the workshop for Central America and the Caribbean *Analysis of the Bioethical Aspects of Health Research* at the Victoria de Girón Basic and Pre-Clinical Sciences Institute in Havana, Cuba, both organized by the Regional Bioethics Program of PAHO/WHO.

In July 1997 CNB, with help from the Regional Bioethics Program of PAHO/WHO and with accreditation by the Universidad Nacional Pedro Henriquez Ureña, organized the seminar *Foundation of Bioethics*, taught by Dr. Juan Carlos Tealdi, director of the Latin-American School of Bioethics in Argentina. In February 2000, the workshop for the *Guidance for the Teaching of Bioethics* was held with the sponsorship of the Regional Bioethics Program of PAHO/WHO and the Instituto Tecnológico de Santo Domingo (INTEC), with the attendance of 30 professors from 10 different Dominican universities.

In August 1999, the NBC backed the application of INTEC University to become the site of the Master's Program in Bioethics of the Regional Bioethics Program of PAHO/WHO, which was started in 2001.

The Latin American Federation of Bioethics Institutions (FELAIBE) has been another one of the organizations that contributed to the development of bioethics in the country. Directors of the NBC participated in the *First Congress of Bioethics in Latin America and the Caribbean* and in the *Fifth FELAIBE Meeting* in Sao Paulo, Brazil, in 1995. During the latter, the CNB became an institutional member of FELAIBE.

Members of the CNB have participated and given talks in the congresses of FELAIBE in Brazil, Ecuador, Colombia, Panama, and Chile.

The Latin American Forum of Health Research Ethics Committees (FLACEIS) was founded in Mexico City in October 2000. In the founding assembly, the president of the CNB was elected vice-president of FLACEIS.

In March 2002, the commission organized the course/workshop Interpretation and Implementation of the Helsinki Declaration at the Universidad Católica de Santo Domingo, under the auspices of FLACEIS. The Ministry of Public Health and Social Assistance and its National Commission of Bioethics in Health (CONABIOS), the Executive Commission for Health Sector Reform (CERSS), and the Pan-American Health Organization (PAHO/WHO) participated in this event that brought together both governmental and private sector Health Research Ethics Committees, as well as hospitals' committees of healthcare ethics,

universities' health sciences faculties, and researchers from Mexico, Uruguay, Cuba, Haiti, Puerto Rico, and the Dominican Republic. At the closing of the event, the Dominican chapter of FLACEIS was formed.

UNESCO's Latin America and the Caribbean Bioethics Network

Since its inception up until today, this organization has contributed to the advance of bioethics in Dominican Republic.

In September 2004, the president of the CNB was elected member of the board of directors of RedBioetica during its second Workshop of Bioethics for Latin America and the Caribbean in Havana, Cuba. In October of the same year, he participated in the regional seminar on bioethics titled *An International Challenge*: *Towards a Universal Declaration of Bioethical Norms*, organized by RedBioetica, which took place in the Ministry of Justice and Human Rights in Buenos Aires, Argentina. During this last event, the Letter of Buenos Aires was signed, in which the countries of Latin America stated their position concerning the inclusion of social bioethics topics in the *Universal Declaration on Bioethics and Human Rights of UNESCO* (Peralta 2004).

Since 2004, members of the CNB have participated and presented works in seminars organized by Redbioética in Cuba, Uruguay, Argentina, Colombia, and Trinidad and Tobago.

In September 2007, within the activities to promote principles and postulates of UNESCO's Universal Declaration on Bioethics and Human Rights, with the collaboration of the CNB and on the initiative of the Dominican ambassador to UNESCO, the international seminar *Towards a Sub-Regional Convention of Bioethics* was organized, with the participation of bioethics organizations from Costa Rica, Cuba, El Salvador, Guatemala, Honduras, Nicaragua, Panama, Brazil, Argentina, Chile, Uruguay, Bolivia, Colombia, Haiti, and Dominican Republic.

At the end of the seminar, the representatives of Central America and the Caribbean signed the Declaration of Santo Domingo, in which they committed to promote in their respective countries the implementation of the postulates of the Universal Declaration on Bioethics and Human Rights of UNESCO (National Commission of Bioethics of Dominican Republic [CNB], 2011).

Major Concerns Over Time

The National Commission of Bioethics (CNB) is a not-for-profit, nongovernmental, and autonomous organization with 45 members since 1999. Members include journalists, linguists, lawyers, physicists, environmentalists, psychologists, forest engineers, ecologists, architects, nurses, bioanalysts, physicians, sexologists, biomedical researchers, oncologists, and bioethicists.

On April 24, 1997, by executive decree, the government recognized the National Bioethics Commission as an "autonomous organization and advisor of the

executive branch in ethical matters, as a way of preserving and promoting the ethical values that influence the attainment of a dignified life with quality, equity, justice and liberty, by every inhabitant of the Dominican Republic" (CNB, 2011).

The Dominican Bioethics Consulting Council UNESCO (CCDBU) was created in July 29, 2009, allied to the Dominican National Commission to UNESCO with a 15-member board of directors. A work project has been designed along four areas: bioethics education, bioethics and health, bioethics and media, and bioethics and politics.

In October 2009, the CCDBU held a first seminar on *Bioethics Legislation* for the nation's congress with the participation of the Latin America and the Caribbean Bioethics Network of UNESCO (RedBioetica). In February 2010, the executive council started a program of teleconferences aimed at university students. Among the topics addressed were Informed Consent in Healthcare, Reach of the Universal Declaration on Bioethics and Human Rights UNESCO, and Role of Ethics in Health Research (Dominican Bioethics Consulting Council UNESCO [CCDBU], 2009).

Competence Building in Bioethics

In order to train its members and with the collaboration of the Regional Bioethics Program of the PAHO/WHO, the National Bioethics Commission (CNB) organized in July 1997 the seminar Foundations of Bioethics at the Universidad Nacional Pedro Henriquez Ureña. It was attended by 20 professionals in diverse areas of expertise.

Competence building has continued with congresses, seminars, workshops, and conferences with presentations by members of the CNB. In February 2006, with the collaboration of the National Commission for State Reform (CONARE), Adela Cortina and Jesús Conill, two distinguished Spanish bioethics professors, were invited to give a series of talks on the topics: Ethics and Enterprise, Ethics in Economy, Ethics and the Law, Participative Democracy, Bioethical Aspects of Assisted Reproduction, Ethics and Politics, Ethics and Citizenship, Relationship between State and Civil Society, and Humanization of Health Services.

In September 2000, the course *Ethics in Research*: *The View From the South* was offered at the Center for Maternal-Infant Research (CENISMI) taught by Dr. Olga Rodriguez of the National Center of Clinical Studies in Cuba.

The seminar *Bioethics and Genetically Modified Organisms* was held in February 2001 at the Universidad Católica de Santo Domingo.

Diffusion of Bioethics

The CNB has struggled to spread the principles of bioethics among wide sectors of the education community, professional societies, and scientific, business, and governmental organizations. More than 90 talks have been given throughout the country in congresses, seminars, workshops, courses, and presentations to the media.

From its inception, the CNB was structured as a nongovernmental and autonomous organization without ties to academic institutions or professional organizations. This has allowed it to act independently and to maintain an open and frank dialogue with respect among its participants. Work meetings are promoted in universities, healthcare centers, biomedical research centers, governmental and nongovernmental organizations, academy of sciences, environmental organizations, and medical associations to which its members belong, always maintaining freedom of opinion.

The CNB subcommissions have made significant progress in the areas of education in bioethics, the environment, biomedical research, and the promotion of the creation of bioethics committees in hospitals. Some advances were also made in human rights and behavioral science (CNB, 2011).

Relationships with International Organizations and Institutions

In June 1993, the National Commission of Bioethics was affiliated with the Latin American and Caribbean Federation of Bioethics Institutions (FELAIBE), and on November 1994, it was included in the Directory of Bioethics Centers and Institutions of the Regional Bioethics Program of PAHO/WHO.

In addition, the CNB maintains collaborative relationships with bioethics centers and institutions in Latin America. In December 1995, the CNB created, together with bioethics centers from Cuba and Puerto Rico, the Caribbean Confederation of Bioethics. This confederation elaborated an *Agenda for Bioethics in the Caribbean*, giving priority to fields of work such as bioethics foundation, research in bioethics, human resources formation in bioethics, biomedical research, clinical bioethics, and hospital bioethics committees.

Members of the CNB have participated over the last 20 years as exponents in 34 congresses, 20 workshops, 9 lectures, 8 seminars, 5 symposia, and 5 panels, giving a total of 190 talks in international bioethics organizations in 18 different countries.

In July 2001, Van Rensselaer Potter proposed the creation of a Global Bioethics Network with a group of 10 professors from the USA, Canada, Italy, and Japan as members of the Global Bioethics Core Group. In Potter's opinion, this was necessary because of the strong convictions about what this concept really means, without being obligated to support the evolution of the points of view of the original proponent.

In addition to this group, several scholars from Latin America and other 26 countries who had actively supported the perspective of the original bioethics and the idea of an *International Council on Global Bioethics* were included in the Global Bioethics Network. Some of them have developed educational programs; others are editors, founders, presidents, or authors in the field. Among those scholars, Potter included two members of the National Bioethics Commission of the Dominican Republic.

In April 2005, the then president of the CNB was invited to speak at the Extraordinary Meeting of the International Committee of Bioethics UNESCO

held in Paris, France, where he presented the talk entitled *Towards a Universal Bioethics Norms Declaration*. In March 2006, the president of the CNB was invited by the director general of UNESCO to join that organization as a member, and he will remain a member until December 2013 (CNB, 2011).

Human Resources for Bioethics Teaching

At the start of activities by the CNB in 1992, the country had no professionals with a formal background in bioethics. In 1999, one of the founding members received the title of *Master of Bioethics* in the course Regional Program of Bioethics of the PAHO/WHO that was taught in the Universidad de Santiago de Chile with the collaboration of the Universidad Complutense de Madrid. Another member obtained the title of *Diplomate in Bioethics* at the Lateranense University in Rome. A third one participated in the course of Specialization in Bioethics for university teachers at the Bioethics Summer Institute financed by the National Endowment for the Humanities and held at the Center for Humanistic Studies and Bioethics of the University of Puerto Rico in 1998, 1999, and 2000. In 1997, the CNB held a survey about the teaching of Medical Ethics at the university level in 24 centers of high education. Only eight of the universities returned the survey stating that they taught ethics at the professional level in all of them and at the technical level in one of them, under the names Professional Ethics, Medical Ethics, Ethics of Values and Norms, and Moral Systems.

Faced with that fact, in July 1999, the Workgroup on Education of the CNB organized the workshop *Curricular Structure for the Teaching of Bioethics* at the Universidad Nacional Pedro Henriquez Ureña, which was attended by 20 professionals of 10 national universities. The workshop was taught by Dr. Elena Lugo, of the Mayaguez Campus of the University of Puerto Rico, and members of the CNB.

In February 2000, the workshop Didactics in Bioethics was organized with the backing of the Regional Bioethics Program of the PAHO/WHO at INTEC, which was attended by 30 professors from 10 Dominican universities.

In August 1999, the CNB supported the petition to the Regional Bioethics Program of the PAHO/WHO, which proposed INTEC University as the candidate site for the Master's Program in Bioethics to start in 2001. The university continued the negotiations and INTEC was awarded the site.

During 2000 and 2001, INTEC taught the master's course with the academic validation of the Universidad Complutense de Madrid, Spain, under the directorship of Dr. Diego Gracia. Twenty-eight (28) professionals from several Latin American countries, including seven from the Dominican Republic, completed the course.

In 2003, INTEC started its own Master's Program in Bioethics of 2-year duration, attended by several professionals from the fields of health, psychology, and law. To date, it has graduated 110 masters, 30 % of them Dominican.

In 2000, the Instituto Tecnológico de Santo Domingo (INTEC) created the first University Center of Bioethics with undergraduate and postgraduate academic programs in Clinical Bioethics and Social Ethics. It is important to mention the INTEC Forums of Bioethics, organized and developed by the undergraduate students of the school of medicine. To date, they have held 31 such forums.

Other universities have created bioethics committees in their faculties of health sciences and jurisprudence science.

In 2004, the Universidad Autónoma de Santo Domingo (UASD) and in 2009 the Universidad Católica Nordestana (UCND) started to implement programs Diplomate and Specialization in Bioethics, which have not continued in a regular manner.

A survey done in 2010 for a master's thesis in bioethics in INTEC analyzed the curricular content of the programs in bioethics of 10 Dominican schools of medicine. The survey showed that, with the exception of one sole program, the topics included did not follow a logical sequence of the ethical dilemmas that arise during the life cycle of human beings from conception to death. The study showed that in seven of the ten schools, the class is called bioethics; in one it is called medical ethics and in another one deontology and bioethics (CNB, 2011).

Collaboration with Governmental, Legislative, and Educational Organizations

The promotion of the CNB of the implementation of the principles of bioethics has yielded recommendations to universities and public and private institutions.

The Dominican Medical College, with the counsel of the CNB, updated its ethical code in 1993. Other professional associations have designed codes of ethics with the assistance of the CNB, such as the Dominican College of Psychologists and the Dominican College of Engineers, Architects and Surveyors (CODIA).

In 2001 the Universidad Tecnológica de Santiago (UTESA) created the *Master Lecture in Bioethics Andres Peralta Cornielle*, in honor of the then president of the CNB. Yearly until 2005, a guest lecturer from a roster of Latin American and Dominican professors was invited to teach this master class. With the accreditation of the CNB, each guest lecturer would give conferences in bioethics in each of the campuses of UTESA throughout the country, in other national universities, and in the Dominican Medical College.

In 2008, there was an environmental crisis in the country caused by the clandestine importation of rock ash refuse. The Environmental Subcommission of the CNB oriented the community concerning the negative health effects caused by rock ash refuse. Later, the Environmental Subcommission organized the conference *Environmental Ethics* with the participation of over a hundred citizens and community leaders from different parts of the country.

Also in 2008, the CNB and INTEC University signed a contract with the Metropolitan Transportation Authority of Santo Domingo to teach civil ethics to 50 traffic agents during a 16-h-long workshop and course.

In May 2008, the aspects concerning research on human subjects of Article 33 of the General Law in Health (No 42–01) were debated at the Dominican Academy of Medicine (CNB, 2011).

Commission on Public Ethics

In the master's program developed at the INTEC University, professionals from different areas have been trained to serve as consultants and advisors in bioethics, including public ethics. INTEC, in its center of bioethics and in collaboration with the CNB, wrote a project proposal aimed at the ethical duties of civil servants. To that end, in November 2004, a public ethics workshop was offered, which included talks on the historical/philosophical framework of ethics, its relationship with public and private places, and the development of an ethically responsible citizenry. Several lines of action have been proposed to promote ethics, education in values, ethics in public administration, and creation of public ethics committees. Promotion, education, and prevention were assumed as the main tasks.

In FELAIBE's congress in Puerto Rico, in September 2003, a member and ex-president of the CNB gave the talk *Ethics and Civil Society in Dominican Republic* (Suazo, 2004).

Collaboration with Professional Organizations in Latin America

In October 1999, bibliographical references requested by the College of Physicians and Surgeons of Costa Rica were submitted. To disseminate the principles and postulates of bioethics in Haiti, in 1999 the president of the CNB gave the talk *Anthropological Foundation of Medical Bioethics* at the Haitian Society of Oncology, in Port-au-Prince.

The Haitian Bioethics Society was later founded, and its representatives have participated in activities of the CNB and have applied for membership in Latin American and Caribbean bioethics organizations.

In 2007, the CNB participated in the creation of the National Committee of Bioethics in El Salvador. The president of the CNB gave the talks *Evolution of Legislation to Regulate Clinical Research in Latin America* and *Philosophical Context of the Universal Declaration on Bioethics and Human Rights UNESCO*.

Members of the CNB participated as speakers in bioethics events in Cuba, Argentina, Puerto Rico, México, Haiti, Panama, South Africa, Brazil, Costa Rica, Nicaragua, France, Colombia, Ecuador, Canada, Trinidad and Tobago, El Salvador, and Chile.

At present, a distinguished member and ex-president of the CNB with a Masters in Bioethics is part of the faculty of the Certificate in Bioethics of the Hostosian

Institute of Bioethics of the University of Puerto Rico since 2009. He has also been invited to bring bioethics workshops to the Salvadorian Institute of Social Security and been guest faculty for the Law Doctorate at the Catholic University of Panama.

Congresses and Conferences

Since its foundation, the CNB has organized 3 congresses, 103 conferences, 9 workshops and seminars, and 5 panel discussions in the country. The first meeting of the commission with the scientific and academic community was held at the Universidad Nacional Pedro Henriquez Ureña (UNPHU) in March 1992, during the workshop/seminar *Ethics in Health and Quality of Life*, in which relevant aspects of clinical and environmental ethics were debated.

In its first congress, held at the Pontificia Universidad Católica Madre y Maestra (PUCMM) in November 1994, titled *Bioethics*: *Science of Survival*, participants analyzed the foundations of bioethics.

Its second congress, at the Universidad Nacional Pedro Henriquez Ureña in November 1997, was built around the topic Education in Bioethics. During this congress, the basis and strategies to promote the formation of Dominican university professors in the discipline were defined.

The third congress, with the topic *Bioethics, Poverty and Human Rights*, took place February 24–26 in 2000, jointly with the Third Congress of the Caribbean Federation of Bioethics, at INTEC, with the participation of speakers from Cuba, Puerto Rico, and Venezuela (CNB, 2011).

Resources Developed

Societies

The Puerto Rican Federation of Bioethics, the Cuban Commission of Bioethics, and the National Bioethics Commission of Dominican Republic created the Caribbean Federation of Bioethics in December 1995. In September 2002, the 41-member Dominican chapter of FLACEIS was created.

In October 2011, a member of the CNB participated in an event in Havana, Cuba, where the first steps were taken for the creation of Central American and Spanish-speaking Caribbean Bioethics Network, with help from the Latin America and the Caribbean Bioethics Network of UNESCO.

Books and Journal Publications

The following is a selective list of books published by members of the CNB nationally and internationally:

Rodríguez, J.E.:*Living in Society*. 1997.

Pichardo, A.: *Civic and Penal Responsibilities of the Physician*. 1999.

Pichardo, A., Reynoso, J.: *Organ Donation and Transplantation: Ethical and Legal Considerations*. 1999.
Pichardo, A. *Forensic Medicine*. 1999.
Suazo, M.: *Bioethics for the New Ones*. 2002
Pichardo, A.: *Euthanasia: Ethic-Legal Viewpoint*. 2002.
Pichardo, A.: *Bioethics*. 2002.
Silié, J.A." *Ethics of University Faculty*. 2003.

Internet

In March 2000, the UNPHU University webpage was set up at http://unphu.edu.do. The page has a section on bioethics that can be used freely to search or publish information on bioethics by contacting the address egarcia@unphu.edu.do.

Teleconferences

Throughout 2010, the Dominican Bioethics Consulting Council (CCDBU) organized a series of teleconferences on diverse topics from the field of bioethics, aimed at university students.

Media Publications

An ex-president of the CNB wrote for several years a section on bioethics for the national newspaper *Hoy*. In addition, he published articles on bioethics for the monthlies *Revista Ahora*, *Amigo del Hogar*, *Respuesta*, *FUNGLODE*, *Revista UNESCO*, *Acta Bioetica/OPS*, and *Revista Voces*. The National Council on State Reform (CONARE) publishes the latter, which includes articles such as *Bioethical Aspects of the New Social Security Laws* and *Why We Must Study Bioethics*.

Another ex-president of the CNB published articles in the regional newspaper *La Informacion*, among them *Bioethical Aspects of Cloning*, *Ethical Aspects of Culturing Human Embryonic Cells*.

Bulletin

The first issue of the Informational Bulletin of the CNB was published in June 1994, and it continued a biannual run until 2001 (CNB, 2011).

Current Bioethics Infrastructure

To accelerate its programs, in 1996, the CNB created several working subcommissions in the areas of education in bioethics, social bioethics, hospital ethics

committees, research ethics committees, bioethics and religion, medical ethics, bioethics and the environment, bioethics and human rights, bioethics and mental health, and bioethics and the media.

Subcommission for Research Ethics

In September 1992, the subcommission organized the seminar/workshop *Ethics and Health Research* at the Universidad Central del Este.

Because there were no official organizations to regulate biomedical research – with the exception of the Maternal-Infant Research Center of the Health Ministry, which only evaluated protocols from governmental health institutions – and in the interest of promoting the establishment of ethical norms for said research, the CNB decided in 1995 to create inside its own infrastructure the Research Ethics Subcommission. Over the period of 5 years, it evaluated 15 research protocols for their design, methodology, and ethical implications. From July 1994 to December 1999, the Research Subcommission of the CNB received, reviewed, and decided about 15 research protocols.

In January 2000, on the suggestion and efforts of the CNB, in order to regulate biomedical research, the Ministry of Health created the National Council of Bioethics in Health (CONABIOS), which initiated its activities with the conference *Importance of the Research on Human Subjects Ethics Committees*.

In July 1998, several members of CNB participated as speakers in the Second Caribbean Bioethics Congress, held in the Mayaguez campus of the University of Puerto Rico, on the topic *Research in Health*.

At present, there are 10 research ethics committees in the country, with members graduated from the Master's Program in Bioethics. The CNB has actively collaborated to create some of these committees.

Subcommission for Hospital Ethics Committees

In 1995, a workshop was held concerning the importance of hospital ethics committees, together with INTEC University, one of the most recognized and solid higher education institutions in the country.

In 1998, workshops were brought to hospital in the northern region of the country, with the collaboration of the Mayaguez campus of the University of Puerto Rico and UTESA University. Similar workshops were held at the Health Plaza General Hospital, the main public hospital in the country's capital, in 1999, and eventually successfully established their first hospital ethics committee.

In June 1999, the CNB developed guidelines for the implementation of hospital ethics committees in the Dominican public health system. Once the Ministry of Health approved the project, 25 hospitals were selected, most in the capital and 3 in other regional hospitals.

Since 1997, members of the CNB have served as advisors for the creation of hospital ethics committees in several public and private institutions.

Subcommission for Environmental Ethics

The radio programs *No More Violence*: *Respect for Human life and Dignity* were begun in April 1997. In July 1999, the monographic symposium *Bioethics and Biodiversity* was published. In October 1999, a talk was given for employees of the natural reserve Parque Mirador del Norte. In 2000, Nasseb Dajani, a representative of the Swiss organization Global Harmony Foundation, taught the course *Community, Environment and Lifestyle for the 21st Century*. In November 2000, at the UTESA University School of Medicine, the talk *Global Bioethics* was given, and the Code of Ethics of the Explosives Chapter of the Dominican College of Engineers and Surveyors was evaluated.

Bioethics Committees and Centers

Presently there are two university centers of bioethics, one in INTEC led by an ex-president of the CNB and the other at the Universidad Católica Nordestana led by the current president of the CNB. The CNB also participated in the creation of the ethics committee of the Faculty of Judicial and Political Sciences of the Universidad Autónoma de Santo Domingo (UASD) in March 2001.

Policies and Legislation

By decree number 751–03, dated August 12, 2003, the president of the Dominican Republic officially named the CNB as an advisory organization to the executive in bioethics matters. This decree widened the future field of action of the commission since it offered a legal framework for its intervention in the analysis of specific ethical problems submitted to the executive branch of government and/or public institutions, which would facilitate the goal of safeguarding the values that influence the attainment of a dignified life with freedom and justice for the citizens.

In October 2003, the Environment Subcommission of the CNB referred its response to the request of the directorate of wildlife and environment to put into effect the Project of Development of a National Framework for Biosecurity in Dominican Republic. The project's objective was to establish the guidelines to guarantee the safe use of biotechnology and genetically modified organisms in our country.

In October 2009, the Dominican Bioethics Consulting Council UNESCO (CCDBU) organized a seminar on *Legislation on Bioethics in the National Legislature*, with the participation of the Latin America and the Caribbean Bioethics Network UNESCO and exponents from Argentina, Uruguay, and the Dominican Republic. Among other topics presented to the congressmen were the legislative perspective and judicial precedents relating to the strategic importance of bioethics and the creation, by law, of a National Council or Committee of Bioethics in the Dominican Republic.

In September 2011, the Consulting Council of Bioethics UNESCO sent their response to the request made by the Ministry of Health to analyze the proposed law on sanitary career before submitting it to congress.

Public Debate Activities

Public debates have been held in congresses, seminars, workshops, and in the activities of the subcommissions (CNB, 2011).

Major Bioethics Issues and Discussions

By initiative from the National Commission of Bioethics (CNB), over the last 20 years, most ethical dilemmas that present throughout the life cycle of human beings, the practice of medicine, and the protection of the environment were analyzed in congresses, seminars, and workshops.

1. Beginning of Life
   Since 1992, topics such as Abortion, Cloning, In Vitro Fertilization, and the Use of Stem Cells have been discussed. Every program of Medical Ethics and Bioethics of university medical schools includes topics concerning ethical issues of the beginning of life.
2. End of Life
   The topics of Euthanasia and Assisted Suicide were debated in workshops and talks organized by the CNB and with the participation of its members. Publications in books and journals by members of the CNB approach such subjects as the terminal patient, pain and human suffering, palliative medicine, euthanasia, and assisted suicide.
3. Health and Disease
   In congresses, workshops, and roundtable discussions organized by different specialized medical professional associations, it is more and more frequent to invite members of the CNB and the Dominican Consulting Council of Experts in Bioethics UNESCO to discuss bioethics topics related to the ethics of medical practice, patient's rights, and the promotion and defense of the postulates and principles of bioethics.
4. Healthcare System and Access to Healthcare
   In the Third Congress of Bioethics of the CNB and Third Congress of the Caribbean Confederation of Bioethics, in February 2000, the central topic chosen was Bioethics, Poverty and Human Rights. The topics Bioethics and Healthcare in the Dominican Republic, Bioethics in the Context of Poverty and Human Rights, How Philosophical is Bioethics?, Efficiency Without Justice?, Ethics and the Care of Humans, and Bioethical Implications of Economic Globalization were discussed in other conferences.

   In September 1999, during the workshop Consultation of Inter-Institutional Governmental Commission on Public Sector Hospital Reform, the CNB stated its position in promoting efficiency in healthcare.

In April 2000, representatives of the CNB were invited by the Minister of Health to participate as speakers in the First National Forum on Quality of Healthcare.

5. Genetics
   Ethical issues related to genetics have been discussed in conferences given in national universities and the Dominican Medical College. For example, in March 1995, at the Pontificia Universidad Católica Madre y Maestra (PUCMM), a conference was taught on Ethical Challenges of Advances in Human Genetics, and in March 1997, the symposium Ethical Aspects of Cloning and Organ Transplantation at the Dominican Medical College.
6. Reproductive Medicine
   Topics concerning the ethics of reproductive medicine were analyzed in conferences held at the APEC Institute of Sexual Education (INSAPEC), during the seminar Ethics and Sexuality and Ethics and AIDS. In the seminar organized in March 2001 as part of the Fourth Forum of the Center of Bioethics of INTEC University, the Bioethical Implications of In Vitro Fertilization was presented.
7. Medical Research
   Various activities related to the ethical aspects of research on human beings have been promoted by the CNB in congresses, seminars, and workshops nationally and internationally. Among the topics covered in several conferences by members of the CNB are Current State of Biomedical Research in the Dominican Republic, Ethics in Biomedical Research, Implementation of Standardized Operational Procedures in the Ethical Review of Health Research, Implementation of the WHO Operating Guidelines, Structure for Ethical Evaluation of Research in Health in Dominican Republic, Interpretation and Implementation of the Helsinki Declaration, Challenges of Ethical Evaluation in Health Research, Principles and Criteria of Ethics in Health Research, Structure and Functions of Health Research Ethics Committees, Balance and Perspectives of Ethical Evaluation of Health Research in Latin America and the Caribbean, Theoretical Framework of Research on Human Beings, Capacity Creation and Ethical Evaluation of Research on Human Beings, Reach of the International Conference on Harmonization of Health Research, Ethics of Investigations on Human Beings: A Global Perspective, Ethical Analysis of AIDS Research Protocols, Role and Perspective of Health Regulatory Agencies at the National and Regional Level, Consent and Clinical Research in Latin America and the Caribbean, Informed Consent in Clinical Research Studies, Ethics of Biomedical Research in the Context of the Universal Declaration on Bioethics and Human Rights, Limits Among Clinical Practice and Clinical Research, and Importance of Programs of Continuing Education for Members of Research Ethics Committees.
8. Public Health
   The Environment Subcommission organized the seminar Ethics and Environment at the Universidad Nacional Pedro Henriquez Ureña in October 1992 and, in September 1994, the project Green Belt for the North Zone of Santo

Domingo, to improve the environmental conditions with an educational program and ethical orientations to the community. In March 1995, a meeting was held with community concerning air quality for a healthy colonial city.

A past president of the CNB was invited to give the conference Research Ethics and Human Rights: International Legal Framework, presented in the Caribbean Conference on Bioethics, hosted by the Trinidad and Tobago National Commission for UNESCO, and organized by the RedBioética UNESCO, in Port of Spain, Trinidad and Tobago, in 2006, and the lecture Overview of the Regulation Research Review in Latin America: a Comparative International Workshop for the Regulation Research Review, hosted by the faculty of law, Toronto University, Canada, in 2005.

9. Infectious Diseases
   Members of the CNB gave talks in the conference Bio-Psycho-Social Aspects of Sexually Transmitted Diseases and AIDS, organized by Dominican Foundation for Health (FDS), in July 1992 and in February 2000 in the conference Human Rights of Immigrants with AIDS in Dominican Bateyes.
10. Transplantation Medicine and Organ Donation
    In September 1999, the conference Current State of Liver Transplants was presented, given by Dr. Juan Madarriaga, professor of the University of Pittsburg Transplant Institute. The conference was organized by the CNB and the Universidad Católica de Santo Domingo.

    An ex-president of the CNB gave the conference Ethical Aspects of Organ Donation and Transplants at the Dominican Medical College and the speech Therapeutic Equivalences: Immune-suppressors in Organ Transplantation, at the National University of Costa Rica in 2008.
11. Emerging Technologies
    In October 1992, the seminar Ethics in Health and Technological Novelties was held at the Dominican Institute of Industrial Technology (INDOTEC), and in July 1994, Father Alfonso Llano Escobar, from Javeriana University in Colombia, gave the talk Bioethics for a Technological Culture.

    In February 2000, the CNB organized the conference Biotechnologies and Power in the Third Millennium given by Dr. Jose Acosta Sariego from Cuba. An ex-president of the CNB gave the talk Role of Bioethics in Scientific Development at the Santo Tomas de Aquino Major Seminary, in 2002, in Santo Domingo.
12. Palliative Care
    In April 2002, an ex-president of the CNB gave the Master Class Pain and Cancer: Bioethical Considerations, at the First Dominican Congress on Pain.
13. Care of the Elderly
    Members of the CNB gave talks in national congresses of the Dominican Geriatrics Society, on care of the elderly, and also held national seminars with the topics Growing Old and Bioethics: The View from Clinical Practice, Ethical Principles for Clinical and Epidemiological research on the Elderly, Bioethical Aspects of Oncology in the Elderly, and Bioethical Considerations in the Elderly Patient.

14. Chronic Diseases
    Topics related to chronic diseases presented in seminars, and roundtable discussions by members of the CNB have focused mostly on the oncologic patient.
15. Psychiatric Care
    The CNB participated in the seminar/workshop Duties, Human Rights and Ethics in Mental Health in August 1992 at the Dominican Medical College.

    In October 2000, during the Second Northern Regional Psychology Congress, a member of the CNB presented the conference Humanity: From Suffering to Hope.
16. Pediatric Care
    The symposium Research in Children: Some Ethical Questions, organized by the National Commission of Bioethics (CNB) and the National Maternal-Infant Research Center (CENISMI), took place in July 1995. Members of the CNB also participated as speakers in courses organized by CENISMI.
17. Emergency Care
    In October 2000, an ex-president of the CNB gave the talk Principles of Bioethics in the Practice of Surgery to the surgery residents of the Cabral y Baez Hospital.
18. General Practice
    The CNB has organized several events directed at general practice in medicine, promoting the creation of hospital ethics committees and organizing seminars, workshops, and conferences with the purpose of contributing to the modernization and humanization of healthcare at different levels through the creation of ethics committees in public and private health institutions. The First National Symposium of Medical Ethics was held in September 1993, in collaboration with the Dominican Medical Association.
19. Health Promotion and Education
    In the area of health promotion and education, the members of the CNB have spoken on several topics in congresses and seminars in the country and internationally: Bioethics and Communication in Health, Education in Bioethics, Universal Ethical Values vs. Cultural Relativism in Global Bioethics, Bioethics and Medical Deontology: Present and Future, Anthropological Fundamentals of Medical Bioethics, Values in the Formation of Health Personnel, Role of the University in Education Health Personnel, Why Teach Bioethics?, and Universal Declaration of Bioethics Norms and Human Rights UNESCO.
20. Scientific and Professional Integrity
    Members of the CNB in conferences given in the country and internationally have discussed the concepts of personal integrity, conflict of interest, and corruption.

    An ex-president of the CNB was invited by the World Medical Association to give the conference Examining Conflicts of Interest and Research Incentives, at the University of Pretoria, South Africa.

21. Relations with Industry and Donors/Sponsors
    So far, the relationship with industry and promoters of multicenter research on human beings has been infrequent and limited. Some conferences and workshops developed in the country have been financed by the pharmaceutical industry (CNB, 2011).

Future Challenges

There is no legislation to regulate research on human beings in the Dominican Republic. The National Council on Health Bioethics (CONABIOS) of the Ministry of Health only has an administrative order to supervise biomedical research. There is also no actualized registry of research studies on human beings taking place in the country. Legislative and administrative directives to regulate, monitor, supervise, and accredit research ethics committees and hospital ethics committees are also nonexistent.

The Ministry of Education, to date, lacks projects or programs to promote education in bioethics in primary, intermediate, or high school levels. The Ministry of Higher Education, Science and Technology has not elaborated programs to promote education in bioethics in any university departments. There is no governmental or private organization in the country dedicated to a thorough analysis of the bioethical aspects of new biomedical technologies. Recently, a stem-cell bank was established in the Dominican Republic, although the Ministry of Health has no legal or administrative regulation of such installations. Foreign companies, staffed by foreign professionals, with the assistance of Dominican physicians, have been performing treatments with stem cells for years, in the absence of any type of governmental regulation. These companies advertise on the Internet and offer "health packages" that include airfare, hotel lodging, and performance of the treatment procedures in private medical institutions.

There is an urgent need for performing studies to diagnose the state of knowledge of the principles and postulates of bioethics by professors at all levels of education in the country. Based on the results of such studies, strategies and programs may be designed to further the knowledge and promote the principles of bioethics.

Conclusion

Bioethics in the Dominican Republic is still in development. Despite the country having signed the Universal Declaration on Bioethics and Human Rights UNESCO, there still has not been a concrete governmental initiative to promote the implementation of its principles and postulates.

There also is no governmental support for bioethics organizations, like the National Commission of Bioethics (CNB), which for two decades has been dedicated to promoting bioethics in different fields in the country, despite the existence of an executive decree from April 1997 designating the CNB as an autonomous advising organization to the executive branch of government in matters relating to ethics.

The Ministries of Education, Higher Education, Science and Technology, Environment, and Public Health should promote programs and processes to implement the principles and postulates of the Universal Declaration on Bioethics and Human Rights UNESCO, with counseling from the two organizations with experts in bioethics in the country: the Consulting Council of Experts in Bioethics of the Dominican National Commission in UNESCO and the National Commission of Bioethics.

It is worrisome that despite the diffusion of bioethics having started in the Dominican Republic in 1988 and after two decades of activities promoted by the two organizations mentioned above, the Dominican legislature still has not generated a law promoting the principles of discipline in the health, education, research, or environmental sectors.

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Egypt

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Ahmed Ragaa A. Ragab

Bioethics Development

When and How Bioethics Started?

The Beginning of Bioethics in Egypt: Moral and ethical codes have a long history and they were dealt with in several philosophical and medical traditions. In all cultures, from the inception of humanity, medical practice was regulated by codes of ethics. Medical practice in both developing and developed countries is shaped by the level of growth in general and that of science and technology in particular.

A.R.A. Ragab
International Islamic Center for Population Studies and Research, Al-Azhar University, Cairo, Egypt
e-mail: arragab@yahoo.com

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Spectacular advances in medicine have increased patient expectations and put pressure on medical society (Serour, 1994).

The beginning of Egyptian bioethics dated back to the times of the Pharaohs, where there are many historical evidences that ethical and moral codes were proposed and instructions were given to respect them in the well-known Papyrus documents. Among the first principles of what is now called bioethics were those conceived in Pharaonic Egypt the Goddess MAAT, which represents the concept of truth, justice, righteousness, balance, and order, dates back to 4000–3500 BC. It calls for individual responsibility for the community – including health, no fear of death, and for those who are wealthy and powerful to use these advantages not to exploit those less fortunate but rather to help them (Karenga, 2003).

Known collectively as the Coffin Texts, the spells contain the earliest known body of Egyptian teaching on ethics.

The Coffin Texts are well-known literature for death. They were given to the dead to take along on their trip into the underworld. The earlier but better-known Pyramid Texts, which were written on the monumental tombs built for pharaohs in the latter part of the Old Kingdom (2980–2275 BC), contain the first known written record that man believed in a life after death. The Coffin Texts, which were composed for the tombs of noblemen rather than kings, express a more complicated insight: that man in the next world will be rewarded for his good acts and punished for evil ones.

Smith Papyrus (1,700 years BC, third dynasty Egypt) shows the first medical ethics guidelines (1,300 years before Hippocrates: Have an expectant attitude and trust nature's healing. Be observant of the patient's condition (Sleem, Elkamary & Silverman, 2008).

However, more constructed guidelines were developed later, history tells that different oaths were proposed for treating physicians, among them are (Source: Serour & Omran, 1992).

Moses Maimonides Oath

Moses Maimonides, who was an Egyptian Jewish scholar, and the private physician to Salah El Din the Great (AD 1135–1204) developed an oath and prayers. His oath clearly stated the two principles of beneficence and non-maleficence: "I shall use my professional skills to help in achieving the objectives of all living creatures to live in peace and him to perfect his ego. I swear to fight through my work so as to reduce danger, noise, attempts at impairment of purity of earth, air, and water pollution and fight destruction of natural beauty, mineral elements and wildlife" (Serour & Omran, 1992: 53). The oath extended the two principles of beneficence and non-maleficence to the environment and did not restrict it to human beings.

Abil Hassan Ibn Radwan Oath

Abil Hassan Ibn Radwan who was an Egyptian scientist and a doctor more than 500 years ago, advised that a physician should distinguish himself with seven virtues:

1. Be impeccable in behavior, physically fit, intelligent, good looking, appreciative, studious, and cal.
2. Be well dressed, good smelling, clean in hands, and clothing.
3. Be secure on patient secrets, and never to divulge anything pertaining to their disease.
4. His drive to cure his patient should be stronger than his desire to obtain payment. His desire to treat the poor should be greater than his desire to treat the rich.
5. Be keen on learning and on rendering help to people.
6. Be good hearted, endowed with chastity, and honest in his speech. Whatever he sees, women and riches, while visiting homes of his patients, he should hold in respect and refrain from taking advantage of them.
7. Be trustful, and never to prescribe a deadly medicine or to inform others about it or to prescribe a drug which aborts a fetus. He should treat his enemy with good intention just as he would do with a friend (Serour & Omran, 1992: 54).

Cairo Medical School Oath

The medical oath which was adopted on the occasion of the opening the medical school in Cairo during the reign of the founder of the Modern Egypt, Mohamed Aly Pasha (AD 1806–1848) included the three principles of beneficence, non-maleficence, and justice.

It stated that:

1. The physician should be keen to preserve the conditions of honor, help and doing good in his practice (Beneficence).
2. The physician should serve the poor free of charge and should not overcharge his patients (Justice).
3. The physician should not use his profession in doing harm, should never prescribe a poison, a harmful or an abortion-inducing drug to a pregnant woman (Non-maleficence).

The Egyptian Medical Oath

The Egyptian Medical Syndicate for example developed an oath, which the physicians swear before they start their medical practice (the seventh year). The oath observes three ethical principles: justice, beneficence, and non-maleficence. It states that the physician will protect human life in all its stages and in all conditions and circumstances. He will do his utmost to rescue it from death, disease, pain, and anxiety (beneficence). He will strive in the pursuit of knowledge and harness it for the benefit of mankind and not for his/her harm (non-maleficence). He will extend his medical care to the near and the far, to the virtuous and the sinner and to friend and enemy (justice).

The Oath of the Muslim Doctor (1981)

Adopted by the first International Conference on Islamic Medicine held in Kuwait in 1981 and published by the Islamic Organization of Medical Sciences, Kuwait, in 1982, then adopted by the current Egyptian medical syndicate, it included the main four ethical principles.

It stated that the physician will respect people's dignity and their privacy, and will not disclose their secrets (autonomy). It also indicated beneficence, non-maleficence, and justice as the other oaths.

Formal Bioethics Development

With the increasing demand for observing ethical values and with the observed increasing trend of violation of ethical values by researchers conducted in Egypt, a grant was made available by the Ford Foundation (FF) to the International Islamic Center for Population Studies and Research, Al-Azhar University to fund a working group of medical, legal, and religious scholars to develop a code of bioethics for reproductive health research in Egypt and to support a conference to discuss and ratify the code and plan for its implementation at the beginning of 1 January 1991. The working group met bimonthly during the first 6 months of the grant, then monthly for 3 months preceding the conference. The conference was conducted during the period 11–13th of December 1991. The date was chosen to coincide with the yearly meeting of the Ethics Committee of the International Federation of Gynecology and Obstetrics (FIGO) which was held in Cairo during this period. By choosing that date, the members of FIGO who are internationally recognized scholars in reproductive bioethics were able to participate in the conference. The conference was held under the patronage of the highest religious authority in Egypt, the Grand Sheikh of Al-Azhar and attended by the most eminent scholars and experts from Egypt and abroad. As a result of the conference, the first committee of bioethics ever formed was approved by the Rector of Al-Azhar University. This was the seed for a long way to disseminate widely the concept of bioethics, the proceeding and the guidelines for ethical research were published and due to the high demand for it, it was published repeatedly for several times (Ragab, 2009).

The bioethics curriculum was developed in early 2000 to be introduced to the faculty of medicine, Al-Azhar University. The curriculum was developed and tested and it is currently being taught to the medical students of the fourth year. Eventually with the progress in the field, this curriculum needs to be, continuously updated. In the year 2012, the updating process has started and is expected to be finalized soon.

Who Have Been the Major Actors/Forces?

The International Islamic Centre for Population Studies and Research, Al-Azhar University has a long history of introducing ethics into the Muslim countries. The first initiative in this regard was an international conference on "Bioethics in Human Reproduction Research in the Muslim World," which was organized by the Center in Cairo, December 1991 as mentioned above. From there, bioethics became institutionalized in the center's activities and in cooperation with other funders, conferences and workshops were organized and books on bioethics published.

Maryland University (USA) in collaboration with Ain-Shams University promoted Bioethics Education and Research Ethical Committees in Egypt since the last decade.

UNESCO and ISESCO supported many bioethics activities in Egypt as in many places of the world. The Ford Foundation contributed to building capacities, for example, supporting individuals to participate in the European Master of Bioethics program.

What Have Been the Major Concerns over Time?

In the 1990s, Sandra Lane, a program officer of the Ford Foundation at that time, observed major violations of bioethics in some studies that include giving children fatal experimental drugs, while safe drugs were available in addition to administration of intravenous fluids to premature infants in a manner that diverted greatly from generally accepted guidelines for parenteral therapy and endangered their lives. In fact, many of the observers commented on that and highlighted the need for establishing research committees (Lane, 1994).

In a study of Wazaify, Khalil, and Silverman (2009) the therapeutic misconception was analyzed. The majority of research participants expressed inaccurate beliefs regarding the degree with which individualized care will be maintained in the research setting.

Khalil, Silverman, Rafaat, El-Kamary, and El-Setouhy (2007) examined the attitude, understanding, and concerns regarding medical research among Egyptians through a qualitative study. The study participants recognized the value of medical research and have a great deal of trust regarding medical research and their participation in research. There were, however, concerns with the level of research risks associated with several types of medical research. Many of the participants demonstrated confusion in regard to research methodologies. The publication recommended enhancing educational efforts regarding general research concepts to enhance the validity of informed consent.

While efforts to establish research ethics committees (RECs) in countries of the Middle East, including Egypt, have recently increased, the quality and consistency of ethical review remain unclear (Sleem, El-Kamary, & Silverman, 2010). In general, commentators have voiced concerns that RECs might not be able to promote high standards of human subject protection due to inadequate financial and material resources, lack of adequately trained REC members, insufficient diversity of membership, lack of REC independence and inability to monitor approved protocols. In order to overcome the problem of the little data that are available regarding processes of ethics review, member composition, training members, workload and resource needs of RECs, and challenges that RECs encounter in the region, Sleem et al. (2010) designed a study that revealed variability among respondent RECs in many of the structural and operating processes, including member composition, existence of written standards of practice and conflict of interest policies, access to adequate financial and material resources, and protocol review.

What Resources Have Been Developed (e.g., Books, Programs, Media, Networks, Societies)?

The International Islamic Center for Population Studies and Research, Al-Azhar University published several books:

- The proceedings of the first international conference on "Bioethics in Human Reproduction Research in the Muslim World." Due to the increasing demand on this particular book, it was reprinted for the second time (in the year 2008).
- The Ethical Guidelines for Human Reproduction Research in the Muslim World, 1992.
- The proceedings of a workshop in collaboration with ISESCO on "Ethical Implication of Assisted Use Reproductive Technology for the Treatment of Human Infertility," Cairo, 1997.
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- The proceedings of a conference, in collaboration with the Ford Foundation on "Ethics of Medical Information and Medical Advertisement," Cairo, 2003.

All these activities created awareness of medical ethics in Egypt and paved the way for acceptance of the need to introduce bioethics in the medical curriculum and to establish Ethics Committees.

The Regional Resource Center for Bioethics that was established in the year 2010 with the support of UNESCO started some activities and collaborated with other bodies. Another body was formed with the assistance of UNESCO, is the Arab Network of Women's Health in 2011. The Regional Resource Center and the Arab Network of Women Health organized a regional conference in Cairo, 7–8 December 2011 to examine bioethical aspects of women's health. It was a good opportunity to network between experts.

Current Bioethics Infrastructure

(a) Teaching of bioethics at university and other levels: A master program had been started in the USA that includes 12 months of courses at Maryland Baltimore Campus and another year for a research project in Egypt. Opportunities for PhD are available, but outside Egypt. Members of research committees had the chance to participate in other certificate programs that are available for the Egyptians through the program with Maryland University, however, this program, as all donor's dependent programs, is lacking sustainability.

On the undergraduate level, bioethics, for a long time has been a part of Forensic Medicine teaching, it is only recently introduced as a separate subject, but to the undergraduate students only. Al-Azhar University is the only one that has produced a curriculum of Bioethics. The curriculum links between basic

ethics and Islamic teachings. It affirms that all the ethical principles have roots in Islam texts.

It should be stated here that there is no separate department for Bioethical Studies and there are no PhD studies in the discipline in Egypt. However, with the growing number of bioethics Master holders, it is expected that separate bioethics programs will be established in the near future.

(b) Bioethics committees: Al-Azhar University Bioethics Committee was the first committee to be established in the year 1992. The national bioethics committee started in 1996 by a Ministerial decree of the Ministry of Higher Education and Scientific Research. Starting from the year 2002, many ethical committees have been established in response to the funding agencies' requirements. Currently, there are 13 ethical research committees federally approved to review researches funded by USA. However, not much have been done regarding hospital ethics committees, what routinely done is review of some cases during different departments, meeting. There is an obvious need to promote hospital ethics committees.

The first meeting for the Egyptian Ethics committees was held in Ain Sokhna, a beautiful sea side city in Egypt during 16–18 October 2008. Since then many activities were carried, among them, forming a network and developing guidelines. Till now, there are no National Guidelines developed.

(c) Expert bodies/centers: The International Islamic Center for population studies and research was the first and it took about three decades to have more centers, currently the main universities in Egypt (Cairo, Ain-Shams, Alexandria, Assiut, and Mansoura) have expert bodies. A resource center was needed and with support of UNESCO, the center is now established at the Egyptian Academy of Sciences.

(d) Relevant legislation: The first national committee for reviewing researches was developed after a Ministerial Decree of Higher Education and Scientific Research in 1996. However, Al-Azhar University had established its committee before that date (1992). The Medical Syndicate has its own legalization and committee that examine the misconduct of the medical doctors after a complaint of a patient or a referral from the court.

(e) Public debate activities: The public is concerned with the increase of medical misconduct either technically or in behavior. Recently, media reported on many of the mistakes and misconduct of some medical doctors, although few, but this has percussion on the public. Some incidents of harassment of clients and recording video tapes secretly without consent were discovered.

Public debate was raised, and still, on issues concerning organ donation and the definition of death since there is a close link. This debate has been influenced much by theological perspectives. Theologians needed a clear medical opinion on these issues from trusted medical experts, which was lacking as the medical experts were in conflict regarding the definition of death.

Another debate, which is peculiar of Egypt and some parts of Africa, is the medicalization of female genital cutting/mutilation (FGC/M). Nearly 75 % of the practice, which is a traditional one that involves cutting some of the external

genitalia of girls (clitoris and labia minora), is conducted by medical doctors. Although the practice is criminalized by a recent law in Egypt, still many of the FGC/M practices are conducted as many believe wrongly that it is required by Islam (Fahmy et al., 2010).

(f) Other: Recently, with the increasing of the influence of Islamists in the educational system and other governmental bodies, it is expected to have more debates on gender issues, human rights, reproductive and sexual health. Consequently, bioethics scholars and activists should be ready to clarify the ethical and moral aspects of such issues.

Major Bioethics Issues and Discussions

(a) Beginning of life: at what stage during the pregnancy does the fetus become a human being? Answering this question is central to the debate. Some believe that it is after 120 days, others believe that it is 42 days, depending on the Quran and the traditions and sayings of the prophet Mohammed (peace be upon him). However, there is an emergent medical opinion which is accepted by the theologians that the crucial point is at 14 days from conception. Any of these definitions allow embryo and stem cell research and allow for early abortion, provided that there is a medically justified cause, however, it should never exceed 120 days of pregnancy.

(b) End of life: The common belief among the public and the theologians is that the end of life is a divine decision and should not be taken by humans. Consequently, there is no much debate about the issue currently.

(c) Health and disease: The fatalistic attitude of the majority of the public shapes the perception of health and diseases that they are from GOD. However, seeking treatment is a following of Islamic Teachings, according to the Prophet (PBUH): "God did not create a disease without creating its treatment; some knew it and some do not." In this regard, Muslim Scholars believe HIV/AIDS have treatment, but no one know it, currently.

(d) Health care system, access to health care
In Egypt, where resources are limited and a major part of the national budget goes to the military, available basic health service is well below accepted standards in the public sector. Urban bias exists, since big and well equipped health facilities are there, while in rural areas even basic services either do not exist or lack the necessary equipment and/or personnel. Health insurance for all is a promise of all governments of Egypt, but never fulfilled. In the private sector, very expensive centers that are well equipped and having the best staff do exist. However, the expensive centers would only be able to offer service to a relatively small sector of the society. This should not be at the expenses of providing basic health care service to the major sector of their population.

(e) Traditional medicine: Traditional medicine does exist side by side with the modern medicine; however, there are major concerns about it, as there is no body that controls its use. Advertisements that give wrong information and

magnify the impact of certain herbal extracts abound on different private satellite channels. It should be mentioned here, that most of these products are advertised as aphrodisiacs.

(f) Genetics: Genetic engineering and gene therapy were discussed widely among Muslim scholars. Hathout (2006) argued that genetic engineering involving the introduction of the genes of one species to another is not permissible except as a means of treating illness and alleviating suffering. Nontherapeutic manipulations are controversial and the majority of scholars are cautious regarding its implications on the society level and the universe as whole (Bayaumi & Ali, 2001). Gad El-Hak (1992) argued that human gene therapy should be restricted only to therapeutic indications. Somatic cell gene therapy is encouraged as it involves remedy and alleviation of human suffering. However, enhancement genetic engineering or eugenic genetic engineering would involve change of Allah's creation which may lead to imbalance of the whole universe and should be prohibited. Gene therapy to manipulate hereditary traits such as stature, beauty, intelligence is a serious attempt as it might imbalance the life of man (Serour, 2001).

Hathout (2006) and many other scholars, are of the opinion that, stem cell research on the preimplantation embryo may be justified if the aim is to save actual patients suffering from serious illness, on the basis of the juridical rule of choice of the lesser of two evils. Stem cells derived from adults gain acceptance of the vast majority of Muslim scholars.

Islamic scholars differentiate between PGD for medical purposes which is currently a routine practice offered to high-risk parents, to help them having healthy children, and the controversial preimplantation genetic manipulation which is aiming at enhancement. As a result of PGD, gender selection whether for medical or social purposes has been debated and there are conflicting views. While the vast majority of Islamic scholars approve gender selection for therapeutic purposes or in selected cases for social reasons, where there is a need for a fetus of the selected gender (Serour, 2001). The minority approves gender selection for social reasons without any restrictions.

(g) Reproductive medicine: Regarding human cloning a distinction must be made between reproductive cloning aimed at the birth of identical individuals and nonreproductive cloning limited to the in vitro phase. Hathout (2006) argued that cloning is outside the bounds of religious permission if used for production. Its use for purely research purposes may be permissible during the very early stages before body systems are formed (Hathout, 2006; Serour, 1995).

Regarding assisted reproductive techniques, adoption is not allowed in Islam, however, there are many verses in Quran that indicate that sponsoring orphans is encouraged and rewarded. In this regard, treating infertility and assisted reproductive techniques are welcomed and encouraged by Muslim religious leaders. From the early days on, scholars supported assisted reproductive techniques, using different modalities, provided that there is no third party like surrogacy, egg or semen donation, and the technique should be

carried out during the validity of marriage contract, not for divorced women or a widow (Gad El-Hak, 1992; Serour, 1995).

(h) Medical research: medical research was discussed extensively by participants of the International Conference of Bioethics in 1991. The participants came to consensus on the following:
   1. Evidence should be available to indicate that the proposed therapy or procedure can be superior to currently available alternatives.
   2. Adequate data must be available from animal studies and from studies on a small number of human subjects to confirm safety and to suggest effectiveness. The ethically acceptable practice is to do clinical trials in three successive phases, I, II, and III, and only to move to the next phase after the successful completion of the previous phase.
   3. It is unjustifiable to do clinical trials with drugs that are unlikely to become available to people in the country or community. For example, drugs that are likely to be non-affordable or non-marketable should not be tested in a given population. This applies in particular to industrial and international research.
   4. Research should only be done by investigators who are fully aware of the scientific literature on the subject, who are well qualified and who have the necessary facilities.
   5. The research should not conflict with the society's cultural, moral, religious and legal values.

(i) Public health: Although preventive medicine is at the heart of public health, lacking health education is affecting it negatively. Bilharzia is an endemic disease that is transmitted through Nile water, which is essential for the farmers for irrigation and they cannot stop using it. However, with health education, these risks can be minimized. Also anemia is a problem for women in reproductive age and can be corrected with proper health knowledge. Health, especially reproductive and sexual health, are lacking and affecting much the public health.

(j) Infectious diseases: The ministry of health has strong and up to date standards and protocols for infection control; they are not applied in many settings. There are concerns of lack of infection control in health delivery points in villages and in remote and slum areas.

(k) Transplantation medicine and organ donation: The Sharia allows organ donation from a healthy person to another sick person to save his/her life provided that the donor is not seriously harmed from this donation and the involved benefits exceed or overweight the potential risks. Organs may be transplanted according to medical norms provided the donor does not need the organ he/she gives or will be harmed by this donation. The free informed consent must be obtained without pressure, coercion or exploitation (Serour, 1994).

Information emerged recently through media about gangs that target street children and the poor to buy their kidneys. The operations are usually done in poor settings with many complications.

(l) Emerging technologies (nanotechnology, information technology): Since Egypt is a developing country with limited health resources, expensive nanotechnology and new technology do not exist and they are not welcomed by the ethics community as they believe that, resources should be properly allocated with ultimate justice.
(m) Intensive care: Intensive care units are available, but they are not sufficient to accommodate the increasing demand. However, for the public, the fatalistic attitude prevents many of using it. It is not surprising, that many persons who need to be admitted do not do that because of the rejection of their families.
(n) Palliative care: Palliative care is accepted and welcomed by the public and by the providers; however, it is a private practice mainly. Only few public clinics do exist and mostly exist within cancer treating centers.
(o) Care for the elderly: The tradition in Egypt is that families are responsible of taking care of the elderly. However with the decline of the extended families, the growth of the aging population as a result of improving health, and the emerging trend of small nuclear families as a result of the family planning program, family support is lacking. This compounded by the limited number of elderly homes, the available homes are expensive. Consequently, unless the government of Egypt takes action, the problem, that care for the elderly is increasingly inadequate, will continue to exist.
(p) Chronic diseases: Diabetes and hypertension are increasing in the country, while some educational programs exist but they do not reach the public. Leprosy patients usually are isolated in certain camps. The HIV/AIDS incidence is very low; people living with HIV/AIDS used to be isolated in fever hospitals, however, currently, only those who develop symptoms are isolated. Stigma, expelling from work, divorce are facing people living with HIV/AIDS.
(q) Psychiatric care: For a long time, chronic mentally ill patients were isolated in specialized hospitals, might be for life. However, currently, there is a trend to treat them in public hospitals.
(r) Pediatric care: Because children are valued parents seek care as early as possible even in the private sector. However, in certain parts of the country, the preference for male children is so clear that, when a son becomes ill, the parents seek care immediately, while for a girl, they may seek advice from a neighbor or a pharmacist.
(s) Emergency care: It is a complex issue, as the decision to seek care is in the hands of the head of the family, and if the decision would be taken, the traffic jam in Cairo or the lack of transport in rural areas, or the lack of personnel and equipment in the health facility to deal with the emergency will be obstacles.
(t) General practice: The Ministry of Health is promoting family health doctors and health insurance for all; however, due to economic constraints and political instability, these efforts did not succeed.
(u) Health promotion and education: The country lacks health promotion and education, especially in his field of reproductive/sexual health. However, there are many attempts to deal with the issue.

(v) Scientific and professional integrity, conflict of interest, corruption: The scientific and professional integrity is promoted widely by different Universities and the National Research Academy; however, still, there are many incidents where false results of research were presented and copying other researchers' work without acknowledging.
(w) Relations with industry and donors/sponsors: Before the start of the efforts to promote bioethics in the country, Egypt was the place of many research projects sponsored by the industry; many drugs were tested without informed consent.

Future Challenges

(a) In the field of bioethics infrastructures.
There is a need for national guidelines and there is need for more ethics committees. The ethics committees should be independent and protected. Legalization should be proposed to organize the ethical committees work and to empower them.
(b) In the field of new and emerging issues.
The new emerging issues are always discussed at large by the concerned experts and theologians who usually come to an opinion that takes into consideration the teaching of Islam and the needs and welfare of the people. However, with increasing number and influence of conservative Islamists after 25 of January revolution, there are greater risks of more conservative attitudes toward issues like organ transplantation, contraception, young age at marriage, and female genital mutilation.
(c) After the revolutionary events of 25 January 2011, conservative Islamists became a powerful force in the country. However Islamists are not unified. While the majority is moderate, there are some fundamentalists that have a great number of followers and have a strong voice. Any ethical debate should take into consideration the Islamic point of view.

Summary Conclusion

The current study dealt with the development of bioethics to date, the current bioethics infrastructure, the major bioethics issues and discussions at the moment and the challenges for the years to come.

It is hard to identify the beginning of bioethics in Egypt as the recorded history is full what are considered to be ethical guidelines. Different oaths were recorded that contain what are now called ethics principles. Islam is the religion of the vast majority of the population. Consequently bioethics guidelines were driven from its teachings.

The first Biomedical Research Committee was established at Al-Azhar University and the first National Committee was established in the year 1996. About the year 2002, many bioethics committees were established in nearly all 17 University

in the country and a network was established and coordination strengthened but, till now, although there are some attempts, no approved national guidelines were promoted.

After the 25 January 2011 revolution, the country is polarized into two positions: the majority are Islamists and they are obeying the teaching of Islam, which in its ideal level is consistent with ethical and moral values; the minority is more liberal and views human rights as the central issue that should not be bounded by any constraints. This could be one of the challenges, as the Islamists are not unified and there are a growing number of conservatives that might harm efforts to promote bioethics.

The debate on ethical issues, so far, is driven by Islamic teachings which are rich and full of supporting evidence on all issues that needs ethical reflection. Providing the theologians with the medical facts will be necessary so that they will come with the ethical guidelines concerning relevant issues.

Thus, bioethics activists should work hard to promote the discipline and to work on developing National Guidelines and to network, not only among themselves, but also with different stakeholders, mainly religious leaders, legislators, and health policy makers.

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Ethiopia

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Adamu Addissie and Markos Tesfaye

Bioethics Development in Ethiopia

The development of bioethics in Ethiopia can be traced back to around the introduction of biomedicine in to Ethiopia. Hence, it becomes relevant to discuss the development of biomedical science and modern medicine and health care in the country.

A. Addissie (✉)
School of Public Health, Department of Preventive Medicine, Addis Ababa University, Addis Ababa, Ethiopia
e-mail: adamuaddis@yahoo.com

M. Tesfaye
Department of Psychiatry, College of Public Health and Medical Sciences, Jimma University, Jimma, Ethiopia
e-mail: tesmarkos@yahoo.com

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Country Background

Ethiopia is located in the eastern part of Africa, often called the "Horn of Africa." It is the second most populous country in sub-Saharan Africa, with increasingly promising economic development. The oldest human fossils in human history so far are found in Ethiopia, and hence, it is considered as "Cradle of Mankind." Unique to other African countries, Ethiopia is the oldest independent nation in the continent and an icon of freedom as it has never been colonized, with the exception of a short-lived Italian occupation from 1936 to 1941 which was accompanied by continued freedom fighting. Ethiopia is the tenth largest country in Africa with great geographical diversity with a variety of contrasts ranging from high peaks of 4,550 m above sea level to very low depression of 110 m below sea level. Ethiopia is a home to mosaic nations, nationalities, and peoples with more than 80 different spoken languages. The country is among the least-urbanized countries in the world with more than 80 % living in rural areas. And its population is predominantly a young population.

The major health problems of the country remain largely preventable communicable diseases and nutritional disorders. Despite major recent progresses, the country still faces a high rate of morbidity and mortality and a low health status with life expectancy of 54 years (53.4 years for male and 55.4 for female), infant mortality rate of 77/1,000, under-five mortality rate of 101/1,000, and maternal mortality ratio of 590/100,000 (CSA, 2012). In addition to relatively inadequate availability of services, cultural norms and societal emotional support bestowed to mothers, distance to functioning health centers, and financial barrier were found to be the major determinant factors.

Ethiopia is a Federal Democratic Republic, composed of nine regional states, having their own regional governments and two city administrations including the capital Addis Ababa. The country's economy is mainly dependent on agriculture. The regular droughts combined with poor cultivation practices make Ethiopia's economy vulnerable to climatic changes, and the country has suffered from various natural calamities until the recent past. Despite being one of the poorest economies in the world, there are very impressive and obvious changes and economic progress in the past decade to the level of meeting the Millennium Development Goal targets in certain areas such as education and health care.

The Federal Ministry of Health of Ethiopia takes the main responsibility for medical services in Ethiopia. The private medical service is emerging and mainly urban centered. The Ethiopian health policy of 1993 is focused more on public health interventions and primary health care. The ministry has formulated and implemented a number of policies and strategies that afforded an effective framework for improving health in the country. The main objective of Ethiopia's health services policy is to provide a comprehensive and integrated primary health care in health institutions at the community level.

History of Modern Medicine in Ethiopia

The Ethiopian health system has been in constant change corresponding to the socioeconomic and political changes that took place during the last century. There have been rapid developments in the last two decades in terms of new health policies and programs and growth of the private sector in the context of the global paradigm of health sector reform. Even though modern medicine began to be practiced in Ethiopia only at the beginning of the twentieth century, its introduction and utilization date back to the start of the sixteenth century.

Western modern medicine was introduced to the country by foreigners such as religious and diplomatic missions to travelers, traders, invaders, and warriors. Further progress in the development of modern medicine was made during the reign of Emperor Menelik II (1889–1913). The Russian mission established the first hospital in the country (the Russian Red Cross Hospital) in 1897 and subsequently few Ethiopians were sent abroad for medical training.

As signatory to the 1978 Alma Ata charter, Ethiopia has adopted the 1979 declaration of "Health For All by the year 2000" using the PHC strategy and it is one of the pioneering countries in implementing the basic health services approach with its "Health Center Team Training Program," launched in 1954 with new cadre of health professionals (health officers, community nurses, and sanitarians) assigned to render services at the district level to perform mainly community-oriented health activities. The main strategic and policy focus of the national health program is on preventive and promotive aspects. Since 2002, the country has launched a massive community-based health program "The Health Extension Service" with more than 30,000 community-based health extension workers (Haile Mariam & Kloos, 2005).

Ethiopia has a long tradition of indigenous medical practice, which deserves an important place in the country's social and cultural history as Ethiopians have been familiar with a wide range of diseases and medical complaints for which they had long-established names, both in their ancient classical language, *Ge'ez*, and in other indigenous tongues of the country (Pankhurst, 1990).

History of Health Research and Research Ethics in Ethiopia

Health Research in Ethiopia is more than a century old. The first publication was on "Abyssinia in Its Sanitary and Medical Aspects" in *The Lancet* (1868). Abyssinia is the old name for Ethiopia. However, output in terms of quality and quantity remains low as the total number of publications is still fewer in number. In Ethiopia, the agenda of health research ethics is a recent phenomenon. Despite the attention given to the issue, the knowledge and practice of standardized regulations and follow-ups remain shallow. The health department

of the then Ethiopian Science and Technology Commission in collaboration with the National Health Science and Technology Council embarked to address health research ethics issues in the country. Accordingly, in 1994, the commission officially launched the National Health Science and Technology Policy and established a broad-based body at a level of a council with a function to advise the federal government on health science and technology issues in general and research and development in particular. One of the standing committees of the council was the National Health Research Ethics Review Committee which is given the responsibility to review health research ethics issues, fundamental principles of health research ethics, and their applications in the Ethiopian context. The first health research ethics guideline was developed by the commission in 1995 and has been revised twice, in 1997 and 2004 (ESTC, 2005). With the expansion of postgraduate programs in Addis Ababa University and other immerging universities and with the availability of funding related to HIV/AIDS and other diseases of public health importance, the number of research projects with human subjects on yearly basis is progressively increasing. This clearly puts demand on the current system to be more effective and efficient.

Health research ethics review committees have been established at three levels: national, regional, and institutional. The National Research Ethics Committee is responsible for the final approval of all clinical trials, research on very sensitive issues, multicentered and collaborative research projects, research financed or carried out by external donors, research to be conducted in more than one region of the country, and projects that require sample transfer (ESTC, 2005). Regional ethics review committee is responsible for the ethical review of projects involving more than one institution in the region and can review projects other than those mentioned under the mandate of National Research Ethics Committee. Institutional ethics review committees review all health research proposals of an institute and are responsible for reviewing and deciding upon all proposals of the institute which do not come under the mandates of either the national or regional committees. Accreditation and recognition of ethics committees are mainly done by National Research Ethics Committee. All regional and institutional committees need to be registered at the secretariat of National Research Ethics Committee, to be renewed every 2 years.

Major Actors of Bioethics in Ethiopia

The major actors for bioethics (for both medical ethics and research ethics) in Ethiopia include academic institutions, hospitals, government offices, and professional associations. Below are some of the prominent actors. These entities have played major roles in the initiation and development of a system for ethics in biomedical research and medical issues in Ethiopia. The contributions of each could vary but all have put significant contributions and remain to be both potential and major stakeholders.

Addis Ababa University

Established in 1950, Addis Ababa University (http://www.aau.edu.et/) is the oldest and largest higher education institution in Ethiopia, which has made a remarkable contribution to the country through provision of trained manpower, research, and community services.

One of its main campuses is the College of Health Sciences, which for many years used to be the Medical Faculty having the country's oldest and biggest specialized teaching hospital, the Tikur Anbessa [in Amharic Black Lion] Specialized Hospital. The college incorporates School of Public Health, School of Medicine, School of Pharmacy, School of Allied Health Sciences, and the teaching hospital integrated to form one administration center which envisions to be the center of excellence in health-related issues.

The university has contributed as spearhead in higher education and research in Ethiopia and beyond. It has helped a lot in the establishment of national system for biomedical research ethical review under the Ministry of Science and Technology. Most of the national steering and standing committee members were and are from the Medical Faculty of Addis Ababa University. The then Faculty of Medicine and current College of Health Sciences run an IRB, which is the first African IRB to receive Strategic Initiative for Developing Capacity in Ethical Review (http://www.sidcer.org) recognition from WHO. The IRB serves in capacity building for the national research ethics review in collaboration with partners, i.e., professional associations and donors. In addition to research ethics, the university is expected to lead in the development of bioethics in Ethiopia. There have been efforts to establish Medical Ethics committees in the university's teaching hospital, i.e., Tikur Anbessa Hospital. Yet, the progress so far is nor remarkable.

Armauer Hansen Research Institute (AHRI)

Armauer Hansen's Research Institute (http://www. eaccr.org/sites/ahri/) is a biomedical research and capacity-building and training institute in Ethiopia. It is involved in conducting research with relevance to disease control, particularly in tuberculosis, leprosy, leishmaniasis, and other diseases of public health importance including malaria and HIV. The institute was founded in 1969 through the initiative of the Norwegian and Swedish Save the Children organizations seconded by the Ministry of Health of Ethiopia. More than 350 papers in peer-reviewed journals have been published from AHRI and it has produced a substantial number of theses and dissertations from international and Ethiopian scholars in biomedical research. It has played a key role in institutionalizing Bioethics and is the home office for Pan-African Bioethics Initiative (PABIN). Its ongoing projects, among others, include Establishing an African Coordinating Office for Ethics through PABIN (EDCTP) and Ethics Review Committee Establishment in the Universities in Ethiopia (with ETBIN).

Ethiopian Health and Nutrition Research Institute (EHNRI)

Ethiopian Health and Nutrition Research Institute is the result of the merger of three institutes: National Research Institute of Health, Ethiopian Nutrition Institute, and

Departments of Traditional Medicine, under the Federal Ministry of Health of Ethiopia (http://www.fmoh.gov.et). The main objectives of the institute are to: contribute to the development of health science and technology; provide referral medical laboratory services relating to the causes, prevention and diagnosis of major diseases of public health importance; and establish and support National Laboratory Quality Assurance Programs and systems.

Being a national research institute on public health and biomedical science, EHNRI has contributed a lot on the development of health research ethics in the country. The institute is one of the network members of the Ethiopian Bioethics Initiative and continues to help in capacity-building and ethical trainings. The institute owns its own IRB and its staff serve in various national ethics committees. The institute also runs capacity-building trainings and seminars on research ethics for medical researchers.

Ethiopian Medical Association (EMA)

The Ethiopian Medical Association was founded in 1961 under the patronage of the then Emperor of Ethiopia (http://www.emaethiopia.org/). The association exists to promote professional excellence of Ethiopian medics in both preventive and curative medicine through medical research, annual and special conferences, and publications. It provides professional and technical advice to the Ministry of Health and other concerned organizations and the exchange of clinical knowledge and research information at the local and international levels. EMA runs continuing medical education sessions on ethics. It also runs various trainings on ethics for medical doctors, researchers, and editors. It has developed and published a guideline on "professional code of practice for physicians in Ethiopia." EMA is one of the standing members of the Health Professional Ethics Committee at EFMHACA. These values allowed EMA to maintain a standard of behavior that is always humane and rational, for dealing with lives of people.

Ethiopian Public Health Association (EPHA)

Ethiopian Public Health Association (http://www.etpha.org/) is an association of public health professionals of varying categories and levels of training which envisions the attainment of an optimal standard of health for the people of Ethiopia, through promotion and advocacy for better health services and high professional standards, professional competence, relevant policies, and effective networking. The association stands for professional development of its members without prejudice as regards gender, religious, or ethnic affiliation. Like the Ethiopian Medical Association, it also serves as member of the national networks in medical ethics and runs various capacity-building sessions through continuing medical educations and trainings. It also runs regular trainings on "Research Methods and Ethics" for its members in different locations in the country. In addition, it owns an independent IRB which reviews proposals on health research. EPHA also contributes to the national dialogues in ethics.

Food, Medicine and Health Care Administration and Control Authority (FMHACA)

Food, Medicine and Health Care Administration and Control Authority (http://www.fmhaca.gov.et/) is one of the wings under the Federal Ministry of health. Like the Federal Food and Drug Administration in the USA, it is responsible for the accessibility of quality health service to all citizens throughout the country. Accordingly, health and health-related services and products quality regulation core process are redesigned in the purpose of protecting the public from any emerging health risks. One of its major objectives is to standardize health services and protect the public from unqualified and unethical professionals and substandard health institutions. The authority is responsible for ensuring professional ethics. Its Professional Ethics Committee looks into medicolegal issues and does case-based deliberations and advises the legislative body on medical malpractice. In addition, all drug clinical trials need to be further registered, approved, and regulated by FMHACA. For this, a guideline had been developed incorporating Good Clinical Practice and made publicly available.

Ministry of Science and Technology (MOST)

Ministry of Science and Technology (http://www.most.gov.et), which used to be Ethiopian Science and Technology Commission (ESTC), is a governmental institution established with the mission to create a technology transfer framework that enables the building of national capacities in technological learning, adaptation, and utilization through searching, selecting, and importing effective foreign technologies in manufacturing and service-providing enterprises. The ministry has the powers and duties to forward recommendations based on studies for adopting and revising polices, strategies, laws, and directives on the development of science, technology, and innovation activities that support the realization of the country's socioeconomic development objectives. As is mentioned under the section "development of research ethics in Ethiopia," the then commission in collaboration with the National Health Science and Technology Council (NHSTC) embarked the first organized national initiative to address health research ethics issues in the country. The National Health Research Ethics Review Committee under the ministry is endowed with the responsibility of reviewing health research ethics issues at a national level and setting principles and standards on health research ethics and their applications in the Ethiopian context. ESTC launched three versions and revisions of the national research ethics guideline (1995, 1997, and 2004) (ESTC, 2005). The ministry is responsible for licensing and regulation of Research Ethics Committees at national, regional, and institutions levels. Its National Committee is composed of various independent stakeholder members responsible for reviewing proposals that need to be reviewed at national level.

Ethiopian Bioethics Initiative (ETBIN)

The Ethiopian Bioethics Initiative is a country chapter of the Pan-African Bioethics Initiative (PABIN) which aims to build capacity in ethical clearance of health research in the country. Established in 2002, its secretariat is based at AHRI,

which is a founding member institution and itself important stakeholder in bioethics in Ethiopia. ETBIN hosted the Third PABIN Conference in Addis Ababa in 2006. ETBIN helped in implementing the initiation of capacity-building program that aimed at supporting other institutions establish Ethics Review Committees and to strengthen existing committees. The national network provides a forum for regular meeting and discussion on bioethics in Ethiopia in order to preserve and promote Ethiopian traditions in ethics and bioethics. It also aims to improve communication among ethics committees in reviewing biomedical research (health, behavioral, and social science) in Ethiopia. It assists in fostering education in bioethics and the trainings, promoting and assisting the development of ethical committees, acting as an Ethiopian collaborating center for fostering ethical review, organizing national meetings and symposia, and assisting with the implementation of standard operating procedures for ethical review in the country. ETBIN is in the UNESCO Bioethics databases and receives project support from EDCTP (European and Developing Countries Clinical Trials Partnership).

Resources Available and Steps Taken for Bioethics in Ethiopia

There are some regulations and guidelines in Ethiopia made available to provide guidance on the ethical conduct of health professionals. These guidelines are developed by the government and by professional associations.

The revised 2005 version of Criminal Code of the country (Proclamation 414/2004), which is based on the country's Constitution, has addressed issues in the medical practice. Article "271 of the penal code" states as follows:

> (1) Whoever, in the circumstances defined above [i.e., in time of war, armed conflict or occupation . . . and in violation of the rules of public international law and of international humanitarian conventions] organizes, orders or engages in: . . .(c) compelling persons engaged in medical . . . activities to perform acts or to carry out work contrary to or to refrain from acts required by their . . . professional rules and ethics or other rules designed for the benefit of the wounded, sick or civilian population, is punishable in accordance with [rigorous imprisonment from five years to twenty-five years, or, in more serious cases, with life imprisonment or death]. (FDRE, 2004, Ethiopian Criminal code - FDRE, the Criminal Code of Ethiopia; Proclamation No. 404/2003).

There are also a number of professional codes of conduct by respective professional associations. "Medical Ethics for Physicians in Ethiopia" has been published by the Ethiopian Medical Association twice so far (EMA, 2010). Other resources include an introductory text on Professional Nursing and Ethics, which is a textbook and reference material for mainly nursing professionals (Cherie, Mekonen, & Shimelse, 2005); "Professional Code of Ethics and Conduct for Midwives" by the Ethiopian Midwives Association (EMWA, 2011); and Code of Ethics For Medical Laboratory Technologists Practicing In Ethiopia by the Ethiopian Medical Laboratory Association (EMLA, 2008). The federal ministry of health has developed a module for health extension workers on health management, ethics, and research, as a blended learning module for the Health Extension Program, for health

extension workers, and as a guidance for research in primary health care (FMOH, 2011). The Ethiopian Society of Obstetricians and Gynecologists (http://www.esog.org.et) also has developed Sexual and Reproductive Health Ethical Guidelines for Ethiopia, which is available on the web. There are also curricula on general ethics for undergraduate students. However, the courses are more on civics than bioethics. There are very few or less available resources in Public Health Ethics and much is integrated to the public health systems and ethics is not treated separate such as tobacco proclamation and guideline.

Several guidelines on research ethics exist in Ethiopia. The Ministry of Science Technology (MOST) has training modules on research ethics for the Ethiopian context and National Research Ethics Guideline on how the national research ethics review system should work at the national level which are made available (http://www.most.gov.et/). The Ethiopian Public Health Association (EPHA) has also developed a course on Research Methods and Ethics for its members and other public health professionals (http://www.etpha.org). EFMHACA has guidelines available on the web on the applications of Good Clinical Practice (http://www.fmhaca.gov.et/). In addition, most IRBs (such as Addis Ababa University) have their own SOPs and guidelines published in book formats available for applicants, reviewers, and IRB members.

Current Bioethics Infrastructure

As explained under the section "Research Ethics System in Ethiopia," there is a very good structure available for research ethics review. The public media also frequently hosts and broadcasts public debates and panel discussions on various topics on Bioethics.

Teaching of Bioethics at University and Other Levels

Regarding training in bioethics, for very long, there have not been medical ethics courses in the medical curriculum. Recently, medical ethics is included as a course in undergraduate medical trainings in the medical school. The course is given for other health professionals such as nursing and medical laboratory technology. So far, there are no independent academic courses in research ethics. This is addressed under research methods trainings for postgraduate students. Professional associations such as EMA and other partners give various trainings on "research ethics." But these are not very structured as such. Still, there are no full-blown graduating programs in bioethics.

Bioethics Committees

Even though there are no bioethics committees in the hospitals, almost throughout the country, there are functional research ethics committees both at national,

regional, and institutional levels. These are generally research ethics committees, but not bioethics committees dealing with clinical ethics and case deliberations. Tikur Anbessa Specialized Teaching Hospital is the first one to have a bioethics committee which is functioning below its capacity. The main reasons for the retarded progress in the clinical aspect of bioethics have to do with less awareness, less expertise, and existence of few ethical dilemmas, compared to much advanced countries.

Legislations

The main legislation guiding medical ethics in Ethiopia is the Ethiopian Civil Code; there is a Professional Ethics Proclamation under review and a number of national guidelines available (see section on resources and guidelines above).

Public Debate Activities

Media and panel discussions have taken place mainly in the areas of medical professional ethics organized by media groups, professional associations and agencies such as Ethics and Anticorruption Commission.

Major Bioethics Issues and Discussions

Contemporary major bioethics issues in the Ethiopian context are dictated by the current socioeconomic and medical developments in the country and the sociocultural context. Below are issues pertinent to the Ethiopian context. The list is not exhaustive by any standard but demonstrates some of the major highlights.

End of Life

There are few places which provide modern palliative care in Ethiopia. Many persons with terminal illness are treated in general wards or even at home. According to the Ethiopian code of medical ethics, physicians are not permitted to advocate or practice euthanasia (Nwafor, 2010; EMA website). There is no published data regarding public opinion about issues of end of life in Ethiopia.

Autonomy and Disclosure

Decision-making in medical care and health research at an individual level is determined by ethno-cultural factors existent in the country. These factors vary

according to the specific location and tribe. As in many other traditional societies, individual autonomy is not absolute in the Ethiopian context. In the Ethiopian society, individual decisions are not made on an autonomous basis; consensus from the public and the community elders is unusually sought in major community undertakings such as community-based interventions and research undertakings. The extended family is the most important institution. In the medical practice, direct and frank disclosure of certain medical information such as diagnoses and prognoses of grave illness or death of a family member is considered as inappropriate and insensitive. Therefore, in these conditions, doctors would communicate little information to patients and usually tell the bad news to a family member first. During illness and crisis, Ethiopians rely heavily on family members to help them cope. In the Ethiopian culture, the patient-healer relationship is paternalistic and protective, and trust is a major component of this relationship. Physicians and nurses therefore need to take time to understand and pay attention to such paradigms which could take different shape across ethnic differences in this multicultural country (Beyene, 1992). Confidentiality (keeping medical secrets) is more one sided with a patient telling his medical secret to a doctor in confidence. Sharing something in confidence would mean the issues to remain only between a certain group of individuals and not to be shared outside those boundaries. The more traditional the culture, there is less truth telling regarding the patient's condition. (Blackhall et al. 1995; honesty is the most highly valued character trait in the Ethiopian culture and truth is socially defined. However, confidentiality is not very well maintained in medical care practice in Ethiopia). Existing national medical codes and guidelines affirm the importance of this principle; however, its application needs to be carefully laid out (EMA, 2010).

Health-Care System and Access to Health Care

The Ethiopian health-care system is mainly a public health system. However, there are discrepancies between and within societies, regarding responsibility, decision-making, risk sharing, and fair distribution of resources. For instance, urban-rural discrepancies are documented in various surveys (CSA, 2012) as there appears an urban bias in the distribution of health facilities even though great majority of the country's population resides in the rural areas. Current estimates put the coverage by the modern health system at about 50 %, which is merely geographic coverage of health services, disregarding actual utilization of services. Many residing in the catchment area of health facilities may not be utilizing any of the services for reasons of lack of awareness, cultural barriers, economic problems, and difficulty of physical access. Thus, the proportion of the population benefiting from the modern health sector is much less than the one calculated based on the geographic coverage. Furthermore, resources required for health care are very scarce. Compared with other policy sectors, the health sector has not been given due priority as evidenced by the very low MOH expenditure per capita per annum (Haile Mariam & Kloos, 2005).

Reproductive Health

According to the Ethiopian Society of Gynecologists and Obstetricians, there are a number of considerations for Ethiopia in relation to reproductive health. Reproductive health workers are expected to be instrumental in addressing ethical issues in gender and reproductive health. Gender inequality is a long-standing problem in Ethiopia, which is demonstrated via access to basic medical and social services, such as education and job opportunities. Traditional reproductive health practices such as female genital mutilation are common. Gender-based violence is a common phenomenon. Modern advancements in infertility treatment such as artificial reproductive technologies are still not well developed as average options for Ethiopians, and the ethical dilemmas associated with them are rare at this stage. Sexuality is a socially defined issue in Ethiopian society, which is considered very conservative compared to other countries even in Africa. Sex before marriage and abortion are taboo but the study indicates it is becoming common for minors and unmarried women (Alemu, 2010). A big area of debate is abortion, which will be discussed further later.

Traditional Medicine

Another area of moral dilemma in the medical practice in Ethiopia is traditional medicine. For modern health professionals, traditional medical practices are considered wrong and inappropriate, while most Ethiopians do visit traditional practitioners, and there are at times conflicts between the two areas. Traditional Ethiopian practitioners possessed a wide variety of cures. Many of these came from medicinal plants. Much knowledge about traditional Ethiopian medicine is preserved in the folk memory of Ethiopians in many parts of the country.

There are a number of traditional medicinal practices that reflect the diversity of Ethiopian cultures which are concerned not only with the curing of diseases but also with the protection and promotion of human physical, spiritual, social, mental, and material well-being. The health and drug policies of the Ethiopian Ministry of Health recognize the important role traditional health systems play in health care. However, little has been done to enhance and develop the beneficial aspects of traditional medicine including its possible integration into modern medicine (Kassaye et al., 2006). In some cases, traditional medicine is generally prescribed for mental illnesses and chronic conditions as the modern medical care is believed to not to help (Birhan, Giday, & Teklehaimanot, 2011). As there are beneficial practices, there also are a number of traditional medical practices which are harmful and are associated with immediate and long-term complications. False health beliefs and ineffective treatment caused delays in the treatment at modern health services of infectious and noninfectious diseases (Kloos & Kaba, 2005).

There is always the possibility that traditional Ethiopian medicine possesses valuable ingredients for use in modern medicine. Most patients do visit traditional practitioners and continue to do so together with seeking modern health care. It is

always good to explore and address such issues and use them positively and provide comprehensive awareness (Pankhurst, 1990).

Cultural Issues in Medical Research

Especially in the rural areas, there is little understanding of research, which is often misinterpreted as treatment. The concept and even the terminology of research are nonexistent in most of the local languages. This therapeutic misconception is a challenge for proper consent processes in biomedical research. In addition, consent and decision-making mechanism are influenced by a number of cultural and social issues such as stigma and discrimination. Rural patients are afraid of participation in a genetic study, fearing that the study might aggravate stigmatization by publicizing the familial nature of the disease. That genetic study should be approved at family level before prospective participants are approached for consent (Tekola et al., 2009a). Like in other developing and traditional countries, there is increasing recognition of the need for research in developing countries where the burden of disease is high. Understanding the role of local factors is important for undertaking ethical research in developing countries. It is recommended that researchers should evaluate the effectiveness of consent processes in providing appropriate information in a comprehensible manner and in supporting voluntary decision-making on a study-by-study basis (Tekola et al., 2009b).

Disclosure and Data Ownership Issues in Public Health

There are circumstances when the public health system has been very protective of public health data. Good communication policy and strategy are equally important in guiding response and creating a responsibly and trustworthy atmosphere. Ethiopia is one of the signatories of the new revised International Health Regulation (IHR) (WHO, 2008), which was ratified in the World Health Assembly (WHA) in 2005 and fully enforced starting from 2007 and has clearly established the importance of national and international responsibilities in epidemics by stating codes of conduct in reporting and notification. Irrespective of the impacts it might have, it is an ethical mandate of the public health system to be just and transparent in providing early notification to the country's public and also to the international community in cases of travel-related risks and cross-border phenomenon. To this effect it is high time to reconsider the policy of nondisclosure of such outbreaks to the public and beyond. The moral laws of autonomy and justice would otherwise be violated (Addissie, 2009). It is to be understood that a country needs to have its own policies on how data should be shared and utilized, but this should not impede and get in conflict with the international regulations and agreed up on treaties like IHR (WHO, 2008). Recently, there are very useful movements implementing a data-sharing policy in major research centers, for example, in EHNRI and the AAU Butajira Health Project.

Medical Issues in Ethiopian Black Jews

The Black Jews who lived for centuries in Ethiopia, as part of the exodus of Jews, are resettling back to Israel. Though the origins of the Ethiopian, Jews are obscure; they traditionally relate to the lost tribe of Dan. These Black Jews have faced different levels of stigma and discrimination in various forms including discarding blood donated for transfusion and involuntary forced contraceptive administration. In 1996, the Israeli government dumped hundreds of units of blood with the reason that the Ethiopian Jews could have HIV/AIDS. This instigated a fierce reaction from the public and from the Ethiopian Jews themselves (Weinstein, 1996). In addition, recent news in Israeli and other international media revealed the administration of involuntary contraceptives to the settlers by health professionals (Nesher, 2013).

Malpractice: Medical Professional Ethics

Professional ethics among medical practitioners is a growing concern of the Ethiopian public and the media and panel discussions mention a lot about it. The medicolegal discipline is not developed in Ethiopia and currently falls under the digression of courts and the media. Medical malpractice is becoming a public concern and there is not a clear system. Yet, codes of practice exist. A study done by the School of Law (Simachew, 2011) revealed that medical malpractice claims in Ethiopia fall within the general ambit of private law. Medical malpractice claims might be raised based on the law of contract or extra-contractual liability. Generally, a claim for medical malpractice in Ethiopia is adjudicated based on the determination of fault which caused the injury.

Ethics of Public Health and Medical Emergencies

Ethiopia is known to be affected by repeated public health disasters. Thus, dilemmas arise about how to respond to such emergencies. Public Health Emergency Management (PHEM) is a directorate under the FMOH, mandated to respond to public health emergencies and health-related disasters at national and regional levels. The PHEM guideline mentions of standard procedures to follow during such events but the ethical issues are not well explored (PHEM, 2012). Issues often raised include the need of ethical approval of such investigations and the consent from individuals as well as the ethical mandates of response. Even though it is taken for granted that there is no need for ethical appraisal of such investigations, there is no clear guideline available. The same analogy applies to clinical emergency care in Ethiopia. Issues arise concerning consent and mandates to responding to medical emergencies in the clinical setting. Emergency medicine is yet undergoing developments and there is a need to address the associated ethical issues (Germa, 2011). Another issue is the availability of resources and the dilemma of discontinuing some supportive interventions such as artificial ventilation.

Abortion

Another very controversial issue in Ethiopia is abortion and termination of pregnancy. Abortion has been illegal until 2004 when the Ethiopian Parliament voted to approve a new, progressive law. Though the new Criminal Code of the Federal Republic of Ethiopia (2005) maintains the legal prohibition of abortion, it stipulates that abortion is allowed by law in the following conditions: when the pregnancy results from rape or incest, when continuation of the pregnancy endangers the health or life of the woman or the fetus, in cases of fetal abnormalities, for women with physical or mental disabilities, for minors who are physically or psychologically unprepared to raise a child, and in the case of grave and imminent danger that can be averted only through immediate pregnancy termination.

The revised law establishes that poverty and other social factors may be grounds for reducing the criminal penalty for abortion, and that in cases of rape or incest, no proof is required beyond the woman's statement that it has occurred. However, the law does not allow abortion for economic and social indications and abortion is not available just on request (Wada, 2008). By allowing abortion for minors who are unprepared to raise a child, the law also marks a significant change for Ethiopia, where adolescents make up more than 45 % of those seeking abortions.

In contemporary Ethiopia, abortion decision-making is a challenging process involving moral and religious dilemmas, as well as considerations of health and safety. Amidst widespread condemnation of female premarital sex and clear moral sanction against induced abortion, young Ethiopian women are nevertheless sexually active, and induced abortions are still sought and performed, with the potential for grave physical harm and social stigmatization (Kebede, Hilden, & Middelthon, 2012). The Ethiopian public is predominantly conservative and religious, and this makes it difficult to implement the law in uniformity. While there are health-care providers whose personal values do not conform to the new law. Others rather might abuse the system.

The majority of unwanted pregnancies of minors are ended in abortion, which are undertaken without medical professional intervention (self-induced or with traditional medication and in illegal places). Most girls who undertook abortion feel ashamed and guilty of committed sin and crime; hence, they have no internal peace. Minors who are from relatively lower income families mostly go to traditional abortionists. The major religious institutions in Ethiopia have no official stand on the use of contraceptives by married women and leave the choice to individuals. However, the institutions highly condemn sex before marriage (Alemu, 2010).

HIV and AIDS

Being located the sub-Saharan region, Ethiopia is one of the countries affected by HIV/AIDS. Currently, the burden and rate of infection is said to be decreasing. However, there are a number of moral dilemmas associated with HIV and AIDS.

Examples include disclosure of HIV testing information to partners when the client is not ready to disclose, religion and condom issues, when to disclose serostatus for children, and treatment adherence issues. Another criticism is about the rationing of treatments: ART treatment guidelines developed using methods that do not fully satisfy the requirements of fair processes (Johansson et al., 2008).

Medical Tourism

Due to the lack of medical advancement in Ethiopia, it has now become a common trend to refer patients for unavailable medical services to foreign countries. The list of countries where patients often visit includes Kenya, South Africa, Thailand, and India, while some patients travel to Europe and the USA. Especially the Thai and Indian markets are very appealing to most Ethiopian patients. The major reasons for such medical trips are malignancies, cardiac surgeries, and transplants. Reports have indicated that nearly 95 % of African citizens are travelling to countries like Thailand, Singapore, South Korea, and India for better treatment in orthopedics, cardiology, pediatrics, and internal medicine. Patients need an official referral from the government. Important issues concern the costs. But there are also brokers and agents who claim to facilitate. The question is whether they are genuine or looking for business. In general, post-trip follow-up is not often available in the country and one would ask the ultimate benefits of the clients.

Psychiatric Care

Two major ethical issues exist within the psychiatric care system in Ethiopia. The first issue is the lack of resources for psychiatric care including infrastructure, trained manpower, and availability of effective psychotropic medications (WHO, 2006). For many years, modern psychiatric care was only available at a few centers located in the Capital, Addis Ababa (Alem, 2001). Among persons with severe mental illness living in rural Ethiopia, only less than 10 % had visited modern psychiatric care (Negash et al., 2005). Most families take their sick relatives to traditional treatment places (Girma and Tesfaye, 2011) and the treatments are applied against the patients' will that are often shackled (Alem, 2000). In those treatment centers, there are no checks for the rights of patients. Many families keep their sick relatives restrained at home until they are no more violent (Alem, 2000). It is not uncommon to see patients presenting to psychiatric facilities with wounds from tight chains around their arms and legs. The second issue is the fact that there is no mental health legislation in Ethiopia (Girma and Tesfaye, 2011; WHO, 2006). It means that mental health professionals rely on the general ethical codes. In practice, clinicians only need informed consent of persons who escorted the patients for involuntary admission and treatment (Alem, 2001). It has been found that mental health professionals in Ethiopia are more likely to recommend involuntary hospitalization, inform the spouse against the patient's wishes, and apply restraints

compared to professionals in other countries. Also, there is a tendency to withhold information about side effects of medications when professionals thought that the patient might refuse to take the prescribed medications (Alem et al., 2002). The problems in the breach of ethics and patients' rights in the context of psychiatric care in Ethiopia could be much worse as the reports might be affected by social desirability bias. In addition, Ethiopia does not have separate human rights body with authority to oversee mental health institutions and to ensure rights of patients (WHO, 2006). Consequently, none of the mental health institutions and residential facilities have been inspected or reviewed by an independent human rights body in the past (WHO, 2006).

Brain Drain

Ethiopia has an inadequate number of health professionals of all categories. On top of this, many doctors migrate to the USA, Europe, Middle East, and Southern Africa for greener pastures. The Ethiopian government is determined to fight against brain drain and the quest for skilled nationals should be armed with enthusiasm. Others regard this as a positive phenomenon since doctors in the Diaspora continue to contribute to the country directly and indirectly. The American Health Professionals Association (ENAHPA) is making extreme efforts to the realization contributing back to the country and people by the Ethiopian medics practicing currently in North America. Ethiopia should do all it can to mitigate brain drain and make a maximum use of its skilled manpower in the Diaspora. Others argue that the disadvantages of brain drain are more significant than the advantages in the case of Ethiopia where manpower training is markedly under-subscribed. The country should formulate a government policy sooner than later to facilitate retention of skilled manpower and to serve as a springboard for moving forward in the development endeavor and catch up with the tempo of the rest of the world (Mengesha & Kebede, 2005). In response, Ethiopia is now planning for a flood of medical doctors within "three to four years," an influx meant to save a public health system that has been losing doctors and specialists to internal and external migration. Some argue the quality of training is compromised with a rapid intake of medical students; for others, quality is relative and the number of professionals reflects also quality.

Summary and Future Challenges

Ethiopia being a country with diverse social and cultural identities, the issue of bioethics is also diverse and dictated by context-specific realities. The country has tried to address bioethics issues in different ways; however, this is yet to be strengthened. There are a number of issues related to building bioethics capacity in the country using more indigenous and local experts and resources in the area.

Having a supporting infrastructure and system is vital for the development of bioethics in Ethiopia. One of the challenges is the enforcement of existing laws and legislations. More attention needs to be paid to this issue. At times, there is confusion regarding the standard operating procedures for the implementation of the existing procedures. The same is true for the existing policies. Due to the lack of national standards, the governance of professional and research ethics is not very well defined by decree and a research act does not exist. Legislation needs to be in place to address emerging issues such as artificial reproductive technologies and genetic research.

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Iceland

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Vilhjálmur Árnason

V. Árnason
Department of Philosophy and Centre for Ethics, Department of History and Philosophy, School of Humanities, University of Iceland, Reykjavik, Iceland
e-mail: vilhjarn@hi.is

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Bioethics Development

When and How Has Bioethics Started?

Bioethics in Iceland started in relation to the teaching of ethics to students of the health professions, especially nursing in the late 1970s. The Centre for Ethics at the University of Iceland, which has been the main forum for research and publications in the field, was founded in 1988.

Who Have Been the Major Actors/Forces?

A pioneer in bioethics teaching in Iceland was Arnór Hannibalsson, professor of philosophy at the University of Iceland, who prepared some teaching material in courses he taught at a private continuing education nursing school during the 1970s. He later taught an introductory course in philosophy for nurses at the University of Iceland in the early 1980s where he introduced topics in health care ethics. Another pioneer in this field is Örn Bjarnason, MD, who initiated discussion about issues in medical ethics in medical circles, not least through his position as editor of *The Icelandic Medical Journal* in the 1970s. Dr. Bjarnason also taught some medical ethics to medical students at the University of Iceland. A third pioneer in bioethics in Iceland, Dr. Björn Björnsson, professor of social ethics at the Faculty of Theology (1969–2002), developed a course on topics in medical ethics from a Christian perspective and advised students who wrote their thesis in theology on bioethical themes.

A major actor in the field since the late 1980s is Vilhjálmur Árnason, professor of philosophy and chair of the board of the Centre for Ethics at the University of Iceland. Árnason wrote the first comprehensive monograph in Icelandic on ethical issues in medicine and health care. Since then he has been an active participant in the field of bioethics through teaching, research, public lecturing, writing, and international cooperation.

What Have Been the Major Concerns Over Time?

In the early days, the main concerns were issues at the beginning and the end of life, such as questions related to euthanasia, abortion, and IVF, occasioned both by new technology and by increasing demands for self-determination in the population. Attention was also paid to analysis of the codes of ethics for the health professions and the patient-professional relationship. In recent years, the focus has been more on issues in research ethics, particularly genetic research and population databases. A primary reason for this is that one of the major genetic research companies in the world, deCODE genetics, is located in Iceland (Árnason, 2010a). The company went through financial difficulties, but is presently fully financed and its research is thriving.

What Resources Have Been Developed (e.g., Books, Programs, Media, Networks, Societies)?

In relation to his teaching, Prof. Hannibalsson (1982) produced a collection of chapters on major themes in ethics of the health professions which was the first writing in Icelandic where the classical big issues of bioethics, such as euthanasia, abortion, and justice, in health care were discussed in one place. This material was only used for teaching and not published.

In 1991, Dr. Bjarnason published a book on some themes in the ethics of medicine (*Siðfræði og siðamál lækna*). The largest part of the book is a collection of ethical codes for the profession both in English and in Icelandic translation by Dr. Bjarnason who also writes an introduction (Bjarnason, 1991). Much of this material had previously appeared in *The Icelandic Medical Journal*. Two other books about philosophy of medicine in Bjarnason's translation accompanied his book: *Philosophy of Medicine* by Henrik Wulff, Stig Andur Pedersen, and Raben Rosenberg and *Rational diagnosis and treatment* by Henrik Wulff.

Among the first publications of the Centre for Ethics was a book on ethical codes for the professions (Kristinsson, 1991). In 1933, Vilhjálmur Árnason published a book, *Siðfræði lífs og dauða* (Árnason, 1993). *Erfiðar ákvarðanir í heilbrigðisþjónustu* (*Ethics of Life and Death, Difficult Decisions in Health Care*), which had grown out of his teaching for nursing students and active involvement in professional ethics and biomedical issues generally (Árnason, 2011). The book deals with all the major topics in bioethics, but the main emphasis is on various issues concerning the everyday interaction of patients and professionals. It is the main textbook in bioethical education in the country, has been used widely by health care professionals, and was also well received by the general public. The book has been reprinted several times and appeared in a new and revised Icelandic edition (2003). The second edition was translated into German as *Dialog und Menschenwürde. Ethik im Gesundheitswesen* (Árnason, 2005).

In the last decade, three books about genetics from the viewpoints of science criticism (Erlingsson, 2002), biology (Eggertsson, 2005), and anthropology (Pálsson, 2007) have been published by Icelandic scholars. All these authors discuss topics relevant to bioethics and also partly address explicitly bioethical questions.

Icelandic readings in bioethics consist otherwise of single articles and book chapters by various authors in the fields of medicine, philosophy, law, nursing, and theology. In the last 2 years, two medical doctors who have education in philosophy, Ástríður Stefánsdóttir and Stefán Hjörleifsson, have edited a regular ethics section in *The Icelandic Medical Journal*. In this section, cases are briefly presented and analyzed from an ethical perspective.

No society or networks for bioethics have been created in Iceland. The Centre for Ethics has been part of a Nordic Network for Philosophy of Medicine and Medical Ethics, funded by NordForsk, which is a venue for cooperation between Nordic and Baltic scholars in the field of bioethics. No Icelandic media resource or specific programs on bioethics have been made. The Centre for Ethics has led

international research networks, most notably ELSAGEN, funded by the EC 2002–2004 (Häyry, Chadwick, Árnason, & Árnason, 2007).

Current Bioethics Infrastructure

Teaching of Bioethics at University and Other Levels

Bioethics has been taught in several departments of the University of Iceland, usually at the initiative of the professors of philosophy (Árnason, 2002). Among the first Icelandic articles in the field were written by professors of philosophy, Páll Skúlason ("Medicine and the Moral Sciences," 1977) and Thorsteinn Gylfason ("On Euthanasia," 1981). Since the University of Iceland was founded in 1911, most students have been expected to take an introductory course about the philosophical foundations of the sciences or "philosophicum." The main objective of the philosophicum is to motivate students to think critically about science in general and about their particular field of study. Since the early 1980s, the course has been optional and designed for each department. This provided a good opportunity to introduce bioethical issues to the students of the health sciences.

Since the philosophicum became optional in the early 1980s, it has not been taught for medical students at the University of Iceland. However, since 2004, a course in ethics for first- and second-year medical students has been developed, dealing mainly with topics related to the doctor-patient relationship but also with issues such as prioritization and end of life questions. In the fourth year, an effort is made to improve and consolidate the ethical education provided in clinical courses in cooperation with senior clinicians in different specialities. Medical ethics is also taught as part of an extensive program in medical communication and clinical skills, medical professionalism, and confidentiality.

In the program of public health, there is an introductory course where a philosopher has given three lectures on the ethical issues in public health.

Students in the Department of Physical Therapy take a course in their third year of study which has a considerable emphasis on various themes in health care ethics, such as the patient-professional interaction and just health care. Graduate students of physical therapy also attend a half-day seminar on research ethics with medical students.

Since nursing became a university discipline in the late 1970s, there has been a heavy emphasis on the philosophicum oriented toward the ethics of nursing, medicine, and health care. The specific objective of this course is to enable students to perceive and tackle the ethical problems that arise in the nursing profession. Within the Department of Nursing, there is a special program of midwifery, where ethical issues related to the discipline are discussed.

Students of dentistry have been obliged to take a small philosophicum course in the spring semester of their second year of study, emphasizing issues in health care ethics.

Within the Faculty of Theology, students have had the option to take a course on ethical issues that may arise at the beginning and at the end of life. In cooperation

with the Centre for Ethics, the faculty has run a continuing education MA program in pastoral care with considerable emphasis on ethics at the end of life.

Selected bioethical themes are dealt with by professors of law, for example, abortion, euthanasia, and privacy. Occasionally, students take interest in these issues, and then they are able to write their thesis under the supervision of these professors.

Some teaching on the topics of bioethics has been taken up as small parts of other courses in the Department of Biology, but not regularly except in a course on human genetics where a discussion about the ethical implications of human genetics is included at the end of the course.

Until recently, there was no systematic teaching of bioethics within the Department of Philosophy. Occasional seminars were taught on issues in applied ethics with emphasis on bioethics, and special seminars have been devoted to the ethics of the life sciences and genetics. These seminars were mostly attended by students of philosophy but also from other departments, such as biology, medicine, and theology.

In 2002, a 1-year program in professional and practical ethics started within the Department of Philosophy in cooperation with the Centre for Ethics. This program has now been developed into a full master study of applied ethics where students can choose a program in bioethics. A doctoral study in applied ethics has recently been established at the Department of Philosophy.

The Department of Philosophy also offers a course in English for graduate students in all fields of study on the ethics of science and research.

In the School of Education, an ethics course has been designed for social educators which largely includes bioethical themes. In particular, the course deals with ethical issues relating to disability, such as prenatal diagnosis, the rights of the disabled, and professional ethics.

At the University of Akureyri, a one-semester ethics course is taught in the fall in the Department of Nursing and Occupational Therapy. Approximately half of this course is devoted to bioethics.

For several years, an introductory course on ethics was taught to lab technicians and X-ray technicians at the College of Technology. Special emphasis was placed on research ethics and on some aspects of the professional-patient relationship.

Ármúli High School has a special health line where students who intend to work as assistant nurses, medical secretaries, dental assistants, pharmacy technicians, and masseurs are expected to take a course in ethics with an emphasis on the issues concerning the patient-professional relationship. Although Ármúli High School is the best example, bioethics is taught as a part of health education in other Icelandic high schools around the country.

The Institute of Continuing Education at the University of Iceland offers a variety of courses in the area of health care, some of which have bioethical themes. A recurring course has been held for administrators in health care institutions where professional duties and patient's rights have, for example, been discussed. Special courses have been held on bioethical topics such as genetics, ethics of life and death, just health care, and autonomy of the elderly.

There is no systematic teaching of bioethics or medical ethics at the National Hospital, but in the 1990s, short courses for health professionals devoted to some special topics within health care ethics and a postgraduate course in medical ethics for young doctors were offered at the hospital.

The individual health care professions sometimes sponsor their own special lectures or even seminars on bioethical issues. There has been especially strong emphasis on continuing education for nurses, partly because nursing has only been a university subject since the late 1970s and those with older education needed to upgrade it. Health care ethics seminars have also been offered for physical therapists and occupational therapists.

Bioethics Committees

The Icelandic National Bioethics Committee was founded in 1997 as part of the law on the rights of patients. The main objective of the committee is to evaluate applications for research proposals on health-related issues involving human subjects. Such proposals include genetic research on human diseases, drug trials, or experimental treatment aiming to alleviate pain and cure diseases, as well as studies involving the collection and interpretation of health-related information or data provided through questionnaires by participants themselves. The members of the National Bioethics Committee were initially nominated by professional organizations and academic institutes. In the summer of 1999, in the midst of the heated debate about a Central Health Sector Database, the Minister of Health ousted the National Bioethics Committee (Abbot, 1999; Árnason, 2004). For a few years, the committee members were nominated exclusively by the government. The nomination has now been changed again; four members are appointed by ministries, two by the Directorate of Health, and one by the Centre for Ethics at the University of Iceland.

Expert Bodies/Centers

The main expert body for bioethics is the Centre for Ethics at the University of Iceland. The center was founded in 1988 and started as a joint project of the University of Iceland and the Icelandic Church. Since 1998, there has been no official relation to the church although the church council still appoints one member to a board of five. The other members are appointed by the Department of Philosophy (chair), the Department of Theology, the School of Education, and the University Council. Until 2008, the center was among few other interdisciplinary centers directly under the university council but is now formally a part of the Institute for Humanities.

The center is a forum for research, education, and service, and its main tasks are (1) to strengthen research in ethics at the university; (2) to cooperate with other universities in the field of ethics; (3) to publish books, educational material, and

research results; (4) to give information and council about matters of ethics; (5) to coordinate interdisciplinary education in ethics; and (6) to hold courses and public lectures about ethics.

The Centre for Ethics has hosted several workshops, seminars, and conferences. In 2004, the center hosted in cooperation with the European Society for Philosophy of Medicine and Health Care an international conference on genetics and health care (Árnason, Nordal, & Árnason, 2004).

Prof. Páll Skúlason was the founder and the first chairman of the Centre for Ethics at the University of Iceland. The current chairman since 1997 is Prof. Vilhjálmur Árnason, and Salvör Nordal, MPhil, is the director of the center since 2001.

Relevant Legislation

The relevant legislation is mentioned in discussion of the main topics as appropriate. See http://eng.velferdarraduneyti.is/legislation/.

Public Debate Activities

Although it is officially among the roles of the National Bioethics Committee to participate in public debate about bioethics and publish recommendations about matters in its sphere of activity, it has in practice limited its role mostly to research review. Unlike in other Nordic countries, there is no national ethical council in Iceland which has the main task of raising public debate about bioethical developments and policy like, for example, the Danish Ethics Council or the Norwegian Biotechnology Advisory Board. For many years, there was an Ethical Council of the National Directorate of Health which functioned both as a review and policy committee. After the National Bioethics Committee was founded in 1997, the Directorate Council focused on issues of policy and social debate. It was active in both the initiation of the act on the rights of patients and of the act on biobanks and worked on guidelines for informed consent in medicine. In 2000, the Directorate of Health could no longer finance the council and started working on the idea of establishing a national ethical council. It soon became clear, however, that the political environment was not fertile for this idea, and it was aborted.

In the absence of a national ethical council, there is no structure to the public debate activities on bioethical issues in Iceland. To take one example, the societal debate on stem cell research in Iceland was exclusively initiated and sponsored by independent professional societies and research centers, such as the Icelandic Association of Health Care Professionals, the National Bioethics Committee in cooperation with the Icelandic society of biologists, and the Centre for Ethics at the University of Iceland in cooperation with the National Director of Health (NordForsk, 2007). The Icelandic Research Foundation facilitated a dialogue between a geneticist and a moral philosopher as part of its popular series “Science Café” in 2005.

Although the Centre for Ethics or professional organizations try to put bioethical issues on the agenda, they do not have legal mandate to facilitate public dialogue with the aim of informing the legislator about public concerns and principled positions.

Major Bioethics Issues and Discussions

Beginning of Life

Ethical issues at the beginning of life were among the first discussed in this field when the abortion debate entered the national scene in the early 1970s. The discussion of abortion was closely related to the battle of women for increased self-determination and focused on the legal right to have abortion. The first scholarly article on the topic appeared in 1974 in *The Lawyers' Journal* (*Tímarit lögfræðinga*) by a young lawyer who had also studied philosophy of law at Oxford.

Abortion has been legal for both social and medical reasons in Iceland since 1975. The abortion should preferably take place before the 12th week, and after the 16th week, abortion is not legal unless there are strong medical reasons for it. A special committee must permit such exceptions. In all cases, a woman who requests an abortion must go through counseling.

Although abortion has not been discussed much in the last two decades, it has been indirectly on the agenda through an ongoing debate about prenatal screening. The debate on this issue in Iceland started in the mid-1980s, but ultrasound examination around 18–19 weeks of pregnancy became a standard procedure in antenatal care in 1984–1986 (Gottfreðsdóttir & Árnason, 2011). In 1991, nuchal translucency screening was introduced for women over 35 years of age in order to reduce the use of amniocentesis. Since 2005, nuchal translucency screening for Down's syndrome and other trisomies during the first trimester of pregnancy has been a routine part of antenatal care in Iceland. In the capital area, where screening is easily accessible, 84 % of pregnant women opted for screening in 2005 (Gottfredsdóttir, Sandall, & Björnsdóttir, 2008).

The Icelandic Medical Journal in 2001 devoted a special issue to this topic: "Systematic search for genetic defects in early pregnancy. Scientific knowledge and humane positions." The guest editor was Jóhann Ágúst Sigurðsson, professor of family medicine at the University of Iceland, and the contributors are from the fields of medicine, ethics, nursing, disability studies and organizations, midwifery, theology, and literature (Sigurðsson, 2000). The debate has mainly been about the decision-making process; the policy is justified by reference to autonomy and responsibility of the expecting parents, while the complexity and uncertainty of the information makes it hard for people to make an informed decision. It is also debated whether it is justifiable to offer this kind of screening to all pregnant women since the benefits do not clearly outweigh the risk of harm. Moreover, the issue

of genetic discrimination has been discussed. Statistics for 2004 and 2005, for example, show that all fetuses identified with Down's syndrome following screening were aborted (Gottfreðsdóttir, 2009). This has raised questions of eugenics, and the history of eugenic practices in Iceland in the 1920s and 1930s has been brought to the fore.

End of Life

Issues at the end of life were also among the first discussed in Icelandic medical ethics discourse. Again, one of the first scholarly publications appeared in a journal of the students of law in 1976 where the topic of euthanasia was discussed from the perspectives of law, Christian ethics, and medicine. In 1989, *The Icelandic Medical Journal* published the Appleton Consensus, international guidelines for decisions to forgo medical treatment at the end of life followed by a round-table discussion on the ethical questions involved with participants from medicine, theology, and philosophy.

In 1987, the Icelandic Cancer Society initiated hospice service for terminally ill patients, and in relation to that, an advisory interdisciplinary group was set up. Ethics was among the expertise represented in this group which organized well-attended conferences on ethical questions at the end of life. *On Death and Dying* by Elisabeth Kübler-Ross in Icelandic translation was published in 1983.

End of life issues have never been hotly debated in Iceland. Spokesmen for active euthanasia have been few, and they have not gained ground in the discussion. At regular intervals, there has been public discussion about care at the end of life and death with dignity. Two documents have been issued on these topics by the National Directorate on Health in Iceland. First, in 1996 the Directorate Council of Ethics issued "Guidelines for limiting treatment at the end of life." It is emphasized in these guidelines that health care professionals should preferably discuss with their patients, and their relatives if the patient so wishes, the options that may arise in the terminal phase of their treatment. The options are divided into (1) full treatment, (2) full treatment up to resuscitation, and (3) palliative care only. The Directorate Council of Ethics based these guidelines on older guidelines initiated by Pálmi Jónsson, MD, Chief of Geriatrics. Landspitali University Hospital (Jónsson, 1989). In 2005, the Directorate issued a living will or advance directives for treatment at the end of life. In this directive, it is also possible to declare a willingness to donate an organ.

In 1995, a medical student presented a questionnaire about limiting treatment at the end of life for physicians and nurses working in Iceland. The general result was that these health care professionals found it important to respect patients' wishes to deny life-prolonging measures. Under certain conditions, 5 % of the physicians and 11 % of the nurses found it justifiable to perform euthanasia. Another medical student repeated this study in 2010. The results now showed that 18 % of physicians and 20 % of nurses found euthanasia justifiable, while only 3 % were willing to comply with such a wish of a patient.

Health and Disease

There has not been much bioethical discussion of health and disease in Iceland. In 1982, however, the society of psychology students at the University of Iceland published proceedings from a conference on the concept of disease, its meaning, use, and limitations in psychiatry and psychology (Hjaltason, Wiedman, & Sturluson, 1982). Specialists from philosophy, sociology, law, and psychology contributed, and the position of the psychiatrist T. S. Szasz is summarized. One of the most controversial parts of Árnason's book (1993) was his argument against a wide definition of health involving a social dimension. Árnason's argument is that a clear distinction needs to be made between the concept of health on the one hand and the determinants of health and recovery on the other hand where the social dimension is crucial.

The phenomenon of medicalization has received some attention. In a report on the future prospects of the health care system published in 1987, a chapter was devoted to the criticism of the prevailing paradigm in medicine by Ivan Illich, Ian Kennedy, and Thomas McKeown. In 2004, The Centre for Ethics at the University of Iceland published a collection of articles on medicalization (Jónsson & Jónsdóttir, 2004). Among the authors in that book is Sigurðsson, professor of family medicine, who has been a critic of overtreatment in medicine, particularly in the form of overuse of SSRI drugs for anxiety, depression, and related disorders. The use of these kinds of drugs is pervasive in Iceland and much more than in the neighbor countries. Prof. Sigurðsson has been part of a Nordic research group that has written about medicalization in many forms, such as pregnancy, population screening, and treatment of coronary disease and hypertension (Getz, Kirkengen, Hetlevik, Romundstad, & Sigurdsson, 2004). Another author, Stefán Hjörleifsson, has written widely about medicalization (Hjörleifsson, 2008), largely in the spirit of Illich, and its kinship with the processes of geneticization (Árnason & Hjörleifsson, 2007).

Related to this critique of medicine, an interdisciplinary group of Nordic scholars focusing on the conditions for a more humanistic medicine was formed at a meeting in Skálholt, Iceland, in May 2001. In the following years, this group held several seminars in Rosendal, Norway, stimulating reflection on themes such as moral responsibility in medicine and the nature of the biomedical paradigm in medicine and its limitations (Getz, 2009). The Rosendal group, as it came to be called, has had considerable impact in medical circles, particularly in family medicine in Norway (Trondheim and Bergen) but also in Iceland.

Health Care System, Access to Health Care

In 1996, the Icelandic Minister of Health set up a working group which had the task to formulate guidelines for prioritization in health care. Two members of this working group had education in bioethics. The group took into account similar reports that had been published in other Nordic countries, the Netherlands, New Zealand, and the state of Oregon, USA. The working group agreed that the

main objectives should be the following: (1) The health service shall be fair, based on a mutual responsibility shared by all citizens and mainly financed by public funds; (2) access to health care shall be easy and as equal as possible for everyone; and (3) those in greatest need of health care shall be given priority (Ministry of Health, 1998; Árnason, 2009a). The recent economic collapse in Iceland has made the issue of prioritization in health care even more pressing than before and will present challenges in the future.

Traditional Medicine

Traditional medicine has not entered the discourse on bioethics in Iceland. Icelanders have an interesting history of widespread interest in spiritual healing. A recent study shows that Icelanders use complementary and alternative medicine to a considerable degree and increasingly in recent years. Most users of this type of treatments seem to use them as a supplement to the care received in the general health care system (Helgadóttir, Vilhjálmsson, & Gunnarsdóttir, 2009).

Genetics

A plan to construct a central databank of the population's medical records came as a bomb on the Icelandic bioethical scene in 1998. This plan was part of a larger project by deCODE genetics, a private company, for human population genetics research (Rose, 2001). The act from 1998 has the following definition: "Health sector database [HSD]: A collection of data containing information on health and other related information, recorded in a standardized fashion on a single centralized database, intended for processing and as a source of information." These data were to be extracted from medical records of those Icelandic citizens who did not explicitly opt out. In order to opt out, people were to notify the Directorate of Health that data on them should not be transferred into the HSD. The act also authorizes the licensee to connect data from the HSD to data from two other databases: a database with genealogical information that have been processed from public genealogical records and a database of genetic information that is processed from biological samples obtained with explicit consent for research by physicians cooperating with deCODE genetics.

The debate about the HSD centered largely about the issues of consent and privacy (Árnason, 2004). In the first bill, consent was not even mentioned, and only after fierce protests was an opt-out clause put in. To many, this was far from meeting the moral requirements of consent to participation in research of the kind planned by deCODE genetics. Some argued for an informed consent for each research project, while others argued for a more general authorization for conditions of use that would be more appropriate for population database research where secondary uses of samples are unforeseeable at the time of collection. Defenders of the presumed consent policy argued that explicit consent would obstruct the

gathering of information and the scientific utility of the database would be diminished. The personally nonidentifiable data would mainly be used for epidemiological research and statistical analysis useful for public health policy. They also pointed to overwhelming support for the project shown in opinion polls (Gulcher & Stefánsson, 2000).

Critics responded that it was highly controversial whether the data are personally identifiable or not, and it should not be used as an argument for waiving consent. When health care data are connected to genealogical and to genetic information, there is a considerable risk in a small society that individuals can be identified, even though the data obtainable for research and inquiries from the HSD were only to be in statistical form and never about fewer than a group of ten (Árnason, E., 2002). While an opting-out policy might be suited for competent informed adults, it neglected the interests of vulnerable groups who need special protection. They also pointed out that the overwhelming public support could be used as an argument for obtaining explicit consent. Polls indicated that people were ill informed about the project. A group of scientists, doctors, and concerned citizens was formed – Mannvernd, Association for Ethics in Science and Medicine in Iceland – and its members actively opposed to the HSD project. They argued that the bill violated internationally sanctioned norms of biomedical practice and encouraged citizens to opt out of the database (Sigurdsson, 2003).

A young woman who had opted out of the database brought the privacy issue to court. Data about her deceased father were in the database, and she argued that the combination of medical and lifestyle, genealogical and genetic information could be used to identify her and thus pose a violation to her privacy. The Icelandic high court agreed. Three things stand out in the high court ruling no. 151/2003: first, that it was not unreasonable to expect that the woman could be indirectly identified by the information about her deceased father; second, that the access to information to the database was open to many others than health care professionals without explicit consent of the individual concerned; and third, that the stipulations concerning privacy are not clear in the law but are left to the regulatory agencies. Consequently, the court argued, constitutional right to privacy is not sufficiently protected in the HSD law.

The high court ruling implies that the policy of presumed consent requires stricter privacy protection than a policy of presumed nonconsent, especially when parties outside of the health care setting can have access to the information. This had been a major argument of the Icelandic Medical Association. As guardians of information that had been collected in confidential interaction with patients, physicians reacted strongly to a policy which required them to hand over medical records to third parties, not involved in the patients' care, without their patients' explicit consent.

It is implicit in the high court ruling, as well as in the position of the Icelandic Medical Association, that the situation would have been quite different had HSD been within the public domain of the Icelandic national health care system. In that case, a policy of presumed consent could have been substantiated by an appeal to

reciprocity and common benefit. However, when the information has become a commodity of a for-profit commercial firm, it is in a very different ethos. But this has not been particularly disturbing to the majority of the Icelandic public who decided to trust the company, although it may have been a major reason why over 20.000 people, approximately 7 % of the population, decided to opt out of the HSD.

As a consequence of the high court ruling and some other factors, the HSD project was aborted (Helgason & Gibbons, 2008). Nevertheless, deCODE genetics has been a thriving research company which has built up large population databases as a resource for its research. This has come about in an ongoing large-scale research of many diseases, frequently in cooperation with physicians working at the National Hospital. Participants provide a blood sample, and an interview is taken about their medical history. They can also allow physicians to provide information from their medical records. The company performs a genealogical analysis of the list of participants which provides a basis for exploring interactions between genes, genealogy, lifestyle, environmental factors, and health/diseases.

It has been argued that with the exception of the HSD case, human genetic research and its potential effect on health and society has not been much discussed. The author is especially critical of the Icelandic media coverage which has left highly relevant questions unattended (Hjörleifsson, 2008). The study demonstrates that news briefs from deCODE about their successes are uncritically taken up by the media which even leaves out the company's own reservations. In this way, the scientific and health care benefits of the research are treated as being beyond reasonable doubt, while uncertainty about financial issues is predominant (Hjörleifsson, Árnason, & Schei, 2008).

This media study squares well with the main features of the public debate around HSD. The discussion was very polarized and often personalized, and in so far as it was about ethical issues, it was narrowly framed. The focus was on legal and technical problems, such as legal technicality about identifiability and coding techniques, while larger societal issues, such as the geneticization of health care, were neglected. Besides, both the parliamentary debate and the public debate in the Icelandic society suffered from the fact that public and private interests were mixed throughout the process (Árnason & Árnason, 2004). The Icelandic government has been very favorable to the company, probably in the belief that it would bring great benefits to the Icelandic economy. Similar attitudes have been reflected in the media discussion.

The pervasive genetic research in Iceland has presented some challenging tasks for the regulatory agencies. The National Bioethics Committee has developed guidelines for consent for participation in database research involving biosamples. Participants are given options to sign one of three consent forms with more or less restricted consent. For samples stored in biobank with wider consent, NBC decides in each case whether new consent shall be obtained for further use and cross-matching of samples for additional research.

Reproductive Medicine

When the Act on Artificial Fertilisation was in the works in 1996, the most debated issue was about the right of the individual, who is conceived by ART with a donor sperm, to know about his or her origin (Árnason, 2005). The act prioritizes the right of donor to anonymity and leaves it to him to decide whether it should be lifted or not. Only when the donor has not requested anonymity can the individual at 18 years of age get information about identity of the donor or the other biological parent. A committee that was asked by the parliament to review the law in 1998 recommended that the individual at 18 years of age should have a right to have access to genetic information about the donor because of relevance for susceptibility to genetic diseases. This was not observed.

In the 1996 act, only a woman in marriage, in civil partnership, or who had been living together with her partner for 3 years or longer could have access to the services. In 2006, a few articles in the law were changed to make it clear that the partner of a woman could be another woman. Very little public debate took place around this change of access to ART which came as a part of major changes in the legal status of homosexuals in Iceland. The current act also permits single women to access ART, and as a consequence, this act conflicts with an article in the law on the rights of children to have paternity (Nordal, 2010).

The ART act prohibits surrogacy, and this issue had hardly been discussed at all in Iceland until an interview appeared in 2007 in one of the newspapers with a couple who is unable to have a child unless by the help of a surrogate mother. Another case in the media was about a couple who had a child with help of a surrogate mother in India. This has stirred a debate in the media, where some insisted on the right of people to have children and the corresponding duty to provide the help needed, while others focus on the interests of the child and the surrogate mother. A bill has been introduced in the parliament where it is proposed that altruistic surrogacy be legalized in Iceland. Almost all professional organizations that have commented on the bill have been opposed to it. A committee, consisting of two lawyers and a moral philosopher, has now been appointed to work on a proposal on the legal text on this matter.

The surrogacy issue demonstrates very clearly how much the national debate suffers from the lack of a National Ethics Council responsible for facilitating public debate and informed policy making. This also partly accounts for the unusually liberal ART legislation which can probably also be explained by the fact that the population is relatively homogenous, pronatalist, and with little diversity in religious views. Also, there is wide trust in science in the population which has never encountered any scientific scandal or serious misconduct in its history.

In the act from 1996, research on embryos was prohibited unless it was part of an in vitro fertilization treatment or intended to advance such treatment (Ministry of Health, 2008). The new Act, however, allows stem cell nuclear transfer technology (SCNT) to create human stem cell lines for medical purposes if the same objectives cannot be reached by research on adult stem cells or stem cells procured from surplus embryos. It is emphasized that while an "ordinary embryo" has genetic material from

two parents like human beings, the cloned blastocyst has genetic material only from one human being. The Icelandic term for embryo, "fósturvísir," implies that the human fetus is about to be formed and is not used for the cloned blastocyst. The act does not allow creation of "ordinary embryos" for the sole purpose of using them for the procurement of stem cells. This is regarded as a much larger and more debatable step to take, because it implies that human embryos would be produced merely as a resource to exploit even though it would be for beneficial purpose.

In 2003, a paper reporting a survey of the views of medical doctors, Lutheran ministers, and lawyers on the use of human embryos for clinical medicine was published (Óskarsson, Guðmundsson, Sigurðsson, Getz, & Árnason, 2003). The results showed quite liberal views among these professions, which seems also to be the case among the general public.

Medical Research

Considerable attention has been paid to ethics of medical research in Icelandic bioethics. Árnason (1993/2003) includes a chapter on the topic, and a special handbook on the methodology of research in the health sciences has been published by the University of Akureyri (Kristinsson, 2003) with chapters on the ethics of research. The main international ethical guidelines for medical and nursing research have been published in professional journals.

The regulation of medical research in Iceland is mainly in the hands of two agencies: the National Bioethics Committee (NBC) and the Data Protection Agency (DPA). NBC is responsible for the evaluation of applications for research proposals which concern health issues and involve participation of human subjects, such as genetic research, drug trials, and studies comprising the collection and/or interpretation of health-related information (www.visindasidanefnd.is). The role of DPA is the protection of individuals with regard to the processing of personal data and the free movement of such data (www.personuvernd.is). In Icelandic law and regulations on scientific research, there is considerable leeway for these agencies to interpret the general letter of the law, without these agencies being furnished with clear and lawful parameters on which to base their evaluations. This has often created tension between researchers and the regulatory agencies and feelings of frustration in the scientific community.

The Centre for Ethics at the University of Iceland conducted research with focus groups of stakeholder representatives discussing these issues and how they can be improved. In 2008, the center sponsored a meeting between the Ministry of Health, the National Directorate of Health, members of NBC and DPA, and representatives from the scientific community, for example, from deCODE genetics, the Cancer Registry, and the Icelandic Heart Association. The unanimous conclusion of the meeting was that there was an urgent need to set up a working group to prepare a new bill on scientific research. The main aim of this new law would be to differentiate more clearly what is done in the current legislation between various types of research, for example, clinical research and database research where the

nature of participation is very different. Also, the aim is to state clearly in the law the parameters on which regulatory agencies are to base their evaluations. In 2009, the Ministry of Health set up a working group which is still working on a comprehensive bill regarding research in medicine and health care. The working group has had close and extensive consultation with the main stakeholders in the field.

Among the changes of ethical relevance in the new bill is that a wide consent can be obtained from participants in database research. In that case, the participants must be enabled to follow the course of the research and have the possibility to opt out of particular research projects. It will be an interesting challenge to create a framework for implementing this practice which moves away from an exclusive emphasis on the initial consent to a more dynamic process which is intended to keep alive the option of withdrawing data from research. This is regarded as preserving the ethos of voluntariness without insisting on informed consent for each particular research project. An argument has also been put forth that this will contribute to more active citizenship by raising awareness in society about population database research (Árnason, 2009b). Sigurður Kristinsson (2007) has argued that the prevailing association of informed consent and individual autonomy is mistaken and the argument for informed consent should rather be based on respect for persons in the Kantian sense.

Public Health

Awareness about public health has been on the increase in Iceland since the Public Health Institute was established in 2003. The institute merged with the National Directorate of Health in 2011. The issue of public health has not entered much into the bioethical discussion. In 2005, the 8th Nordic Public Health Conference was held in Iceland and the opening lecture was given by a philosopher on ethical issues in public health. In 2010, the Nordic Bioethics Committee held a 2-day conference in Reykjavík on ethical issues in public health (Soini, 2011). Some philosophical discussion has taken place about addiction and the right to restrict individual liberty, both in *The Icelandic Medical Journal* and in handbooks for students and parents about prevention of addiction.

Another topic that has received some attention in the bioethical discourse on public health is obesity. Ástríður Stefánsdóttir (2011), physician and associate professor of ethics at the School of Education at the University of Iceland, has argued that it is largely mistaken to conceive of obesity primarily as a medical problem which concerns the obese individual and the health care professional. This conception, she argues, identifies the problem in a wrong way and leads us to respond to it by ineffective means. She suggests that obesity should primarily be seen as a social problem since its main reasons lie in the fact that people are living in an environment which makes difficult for them to lead healthy lives. By regarding obesity as a social and even as a political issue, the primary responsibility is put on politicians and others who have the power to shape society and not the individuals concerned.

This emphasis on the collective responsibility for obesity is indicative of a trend in Icelandic bioethics in recent years to intertwine bioethics and biopolitics.

Árnason and Hjörleifsson have argued that bioethics can take on a legitimating role by focusing too narrowly on particular ethical questions at the neglect of the larger social implications (Árnason & Hjörleifsson, 2007). Bioethical analyses tend to focus on questions concerning a particular set of issues relating to basic human interests, such as privacy and consent and risk of harm or discrimination. If there are good reasons to believe that these interests can be protected, a particular bioethical technology could legitimately be introduced. For example, the introduction of genetic testing could be discussed primarily in terms of whether the practice would duly meet the requirements for informed consent of patients undergoing the tests; whether the test would put the person at considerable risk, for example, relating to knowledge of nontreatable disease; and whether privacy of information would be protected so that the patient would not be in danger of being discriminated against on the basis of his genetic susceptibility for certain diseases. The question concerning the effects of introducing pervasive genetic testing upon health care services, public health, and the practice of medicine might not, however, be taken into account. Such a narrow ethical discourse is ideological in the sense that it implicitly covers up important moral aspects of the effects of biotechnology while claiming to analyze its main ethical implications. This is a major reason why increasing attention needs to be paid to social and political issues and bioethics must not be distinguished sharply from biopolitics (Árnason, 2008).

Infectious Diseases

Stefánsdóttir (2006) has discussed ethical issues relating to infectious diseases in an article about health services for immigrants in Iceland.

Transplantation Medicine and Organ Donation

In 1991, two important bills for this discussion were passed in the Icelandic parliament. The first was a bill about determination of death and the second a bill about removal of organs and autopsy. In 1989, the general assembly of Icelandic Lutheran Church decided to commission a report from the Centre for Ethics at the University of Iceland about the moral questions raised by these two bills. The Centre for Ethics set up an interdisciplinary working group consisting of two philosophers, a theologian and a medical doctor. The working group produced a report or position paper on the definition of death and the removal of organs which was published as a pamphlet (Árnason, Ásmundsson, Björnsson, & Karlsson, 1990). The working group supported the brain death criteria introduced in the first bill and the policy of presumed nonconsent for removal of organs. This policy has worked without complications in Iceland, but recently, voices have been raised to the effect that the policy for organ retrieval from dead donors should be changed from presumed nonconsent to presumed consent.

Emerging Technologies (Nanotechnology, Information Technology, etc.)

In the beginning, the main arguments used by the spokesmen of deCODE genetics for compiling a comprehensive collection of population data were that it would enable researchers to identify key genes linked to common diseases and to the regulation of drug response. The argument was that this could play a crucial role in delivering personalized medicine (Hákonarson, Gulcher, & Stefánsson, 2003). In 2007, deCODE genetics launched an online direct to consumer service, deCODEme, which offers a comprehensive genome scan and online analysis of individuals' DNA profile by scanning one million variants in their genome. Users are to learn how scientific knowledge about ancestry, disease risk, and the inheritance of physical traits applies to them. This has generated some bioethical debate in *The Icelandic Medical Journal* and in the media. There has also been a discussion in the Icelandic parliament about the need for regulation of this kind of service.

The ethics council of the Icelandic Medical Association has discussed the matter and written a quite critical evaluation report. It is argued that because of the nature of the service, it should be categorized as health care, but then it would have to meet several conditions that it presently fails to meet, such as the following: (1) Because no professional agent acts as an intermediary between the company and the individual, there is no way to know whether the sample which is sent to the company comes from the individual who sent it or not. (2) For the same reason, there is no one to help the individual to interpret and analyze the information she receives from the company and to give appropriate genetic counseling. The statistical information about susceptibility to several diseases can be quite difficult to interpret. (3) The information is also inaccurate, especially because the relationship between the statistical results about risk for diseases and their clinical penetration is not well substantiated. (4) If this information is regarded as health care information, the company is violating important articles in the Icelandic physicians' Code of Ethics, such as articles about providing patients with accurate information and avoiding giving information which can create unnecessary fear for the patient. (5) This unmediated online service can create unintended burdens for the public health care system since people are likely to bring their genome scan analysis to their family doctor for interpretation. This would increase the cost of public health care for services that are not likely to have beneficial consequences for public health (Stefánsdóttir, 2010).

The spokesmen of deCODEme have argued that the information is not to be regarded as health care information which is seen by critics as strategically motivated to avoid regulatory action. The company's CEO has defined the service as "health promotion," and the information should be understood as "my map to better understanding of my future health" (Stefánsson, 2007). The main moral justification for this is to enhance peoples' self-knowledge and individual autonomy. The accusation of incurring unnecessary anxiety is seen as paternalistic.

In a recent ethics seminar of the Icelandic Medical Association, it was argued that Icelanders might become the first nation where whole-genome sequencing could be used to predict susceptibility for diseases in an entire population. It is

a major challenge to translate the research findings by scientists at deCODE genetics into more targeted therapeutic and preventive strategies for genetically defined groups and individuals based on predictions of genetic susceptibility to diseases. Such a project would raise major challenges for bioethics in Iceland, not only concerning the effects that introduction of genetic testing may have on individuals, but also on health services and society at large (Árnason, 2012).

Intensive Care

Intensive care has only entered the bioethical discussion insofar as it relates to treatment at the end of life.

Palliative Care

See discussion above about issues at the end of life and on chronic diseases below.

Care for the Elderly

In 1995, three people working in bioethics formed a research group about self-determination of the elderly in Iceland. With funding from the Icelandic Elderly Council, a questionnaire was formed and inhabitants of five nursing homes in Iceland participated in a study where they were asked about their everyday life. A book with the results was published in 2004 with a philosophical discussion of autonomy and the elderly and critical analysis of the law on the elderly. The book stirred much discussion and controversy about the elderly in nursing homes (Stefánsdóttir & Árnason, 2004). Based on the empirical study, the authors demonstrated how the self-determination of the elderly in nursing homes concerning their daily life was radically restricted. This restriction comes about by a combination of factors, such as the routine of the service provided, the frailty of the people concerned, and their own attitudes toward self-determination once they have moved to nursing homes. The authors argue that the official vision of nursing home as a home rather than an institution does not stand to scrutiny. The authors held several meetings with nursing home staff and professional organizations to discuss their findings. The media showed unusually much interest in the study which is the clearest example of empirical bioethics done in Iceland.

Chronic Diseases

The Icelandic association for the study of pain has held a couple of meetings where philosophical and ethical issues of living with pain and the treatment of chronic pain have been discussed. But no specific attention has been given to chronic diseases from a moral point of view.

Psychiatric Care

The little discussion that has taken place in Iceland about ethics in relation to psychiatric care has centered around involuntary institutionalization. A study conducted in 1989 of the feelings and attitudes of patients admitted against their will to the Department of Psychiatry of the National University Hospital, Reykjavik, Iceland, concluded that involuntary admissions should be prepared more thoroughly in cooperation with the patient and more emphasis should be placed on giving the patient clear information about his/her legal rights (Guðmundsson & Stefánsson, 1989).

In the wake of the collapse of the Icelandic banks in 2008 (Árnason, 2010b), some discussion has taken place in *The Icelandic Medical Journal* and the media about psychopaths in corporations and their impact in the financial sector which has created fertile soil for ruthless, risk-seeking individuals (Briem, 2010).

Pediatric Care

As in many Western countries, complex ethical questions arose when new technology enabled health care professionals in neonatal care to save the lives of children with serious conditions which in earlier time would have resulted in early death. Some meetings were held in the 1990s where these issues were discussed among health care professionals and moral philosophers. Árnason (1993, 2003) has a chapter on ethical issues in neonatal care and argues for a "best interests of the child" approach to selective nontreatment in the spirit of Weir (1984).

Emergency Care

No particular publication has been produced on this topic in the Icelandic bioethical literature.

General Practice

No particular publication has been produced on this topic in the Icelandic bioethical literature, but members of the above mentioned Rosendal group come from general practice (Getz, 2009).

Health Promotion and Education

Considerable interests in and discussion about this topic has taken place on Iceland, especially among nurses, but it has not entered the bioethical discourse.

Scientific and Professional Integrity, Conflict of Interest, Corruption

Icelandic universities have ethical guidelines concerning good practices in research and education. Since 2010, the Icelandic Research Council has been working on comprehensive guidelines about good scientific practice and research integrity for the Icelandic scientific community. Two philosophers working in bioethics have been part of an interdisciplinary team drafting these guidelines which are modeled by the guidelines of the national advisory board of ethics in Finland. A committee will be established to oversee that good practices are observed. One of the tasks of that committee will be to formulate guidelines about conflict of interests.

Relations with Industry and Donors/Sponsors

Along with increasing and closer relationship between industry and research and education, the issue of conflict of interest has been raised. This issue has been discussed at seminars within the University of Iceland and has been one of the topics addressed in the ethics section in *The Icelandic Medical Journal*. It still remains a challenge for the scientific and research community in Iceland to adopt a strong policy on the conflicts of interests. This is one of many issues that have been increasingly on the agenda in the wake of the collapse of the Icelandic banks. A working group on ethics that was part of a parliamentary commission looking into the cause of the collapse of the Icelandic banks pointed out that the relationship between the academic community and the financial sector was too close.

Future Challenges

In the Field of Bioethics Infrastructures (Need for Legislation, Ethics Committees, Ethics Education, etc.)?

There is a need for a National Ethics Council in Iceland, a body that would have a role similar to that of the Danish Ethics Council to facilitate public debate about bioethical issues and help to prepare responsible public policy on these issues. The Centre for Ethics at the University of Iceland has proposed to the Icelandic parliament to establish such a committee, and the issue is being discussed in the parliament. A bill has been introduced in the parliament to increase education in ethics and critical thinking in the Icelandic school system, and the University of Iceland has introduced a new policy with increased emphasis on teaching of ethics.

In the Field of New and Emerging Issues?

The genetic research that is being carried out at deCODE genetics will present complex ethical issues relating to whole-genome sequencing and personalized

medicine. Discussions are already taking place between the National University Hospital and deCODE genetics about how results from genome-wide association studies can be translated into medical practice. These plans will not only raise particular ethical questions of consent, privacy, and risk of harm but also about the effects upon our health services and society. These developments are likely to provide future challenges for bioethics in Iceland.

Summary Conclusion

Bioethics in Iceland is in many ways typical in the sense that it has dealt with the major questions thrust upon us by new technology and changed mentality in the last decades. One distinguishing characteristic comes from the fact that in such a small nation, the contribution of very few individuals, such as that of the present author, becomes relatively large. Another distinctive characteristic is the pervasive influence that deCODE genetics, one of the major research companies in the world, has upon the bioethical discourse. In all likelihood, that influence will continue since there are major challenges ahead concerning how to translate the genetic knowledge that is the fruit of the research into therapeutic and preventive benefits.

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Augustine Pamplany

A. Pamplany
Institute of Science and Religion, Little Flower Seminary, Aluva, Kerala, India
e-mail: apamplany@gmail.com

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Introduction

Almost a population of 1.2 billion substantively permeated with an inbuilt ethical consciousness traditionally inherited from almost the dawn of the human civilization but poorly professionalized at the applied level; this formulation might absorb the paradoxical reality of the Indian bioethical scenario. The following comment by Chattopadhyay, barring its extreme tone, is a rather realistic representation of bioethics in India: "Bioethics in India is, to say the least, a complex and difficult terrain where even angels may fear to tread. Any discussion of US-born-Western-bioethics-headquartered-at-Paris in the Indian scenario may open up a 'Pandora's box' of intricate issues – some of which remain unresolved, others inadequately addressed, and a few even untouched. Worse, attempts to address these issues run the risk of generating more heat than light" (Chattopadhyay, 2011, p. 20).

Bioethics in its modern Western sense made its presence in India in the 1980s. It is still to take a definite structure and shape at the theoretical and infrastructural levels. Perhaps, this is due to historical reasons linked to the age-old ethical consciousness of the country. Not that India did not encounter bioethical issues in modern times, rather, given the deeply inbuilt ethical and spiritual consciousness of the country, many of the active problems in bioethics in the Western world tended to be pseudo-problems for India. For instance, many in the country still consider it an anathema to hold public debate on euthanasia since there are foregone conclusions for the Indian mind-set in such regards.

India is the world's second most populated country with an estimated population of 1.2 billion. India is a union of 28 states and 7 union territories. India is a nation that is characterized in its constitution as a sovereign socialist secular democratic republic. Like the United States, India has had a federal form of government. However, the central government in India has greater power in relation to its states, and its central government is patterned after the British parliamentary system. India is the world's largest democracy in terms of citizenry. The president of India is the head of the state, and the prime minister of India is the head of the government. Executive power is exercised by the president and is independent of the legislature. Legislative power is vested in both the government and the two chambers of the parliament of India, the Lok Sabha and the Rajya Sabha. Federal and state elections generally take place within a multiparty system. The judiciary is independent of the executive and the legislature, the highest national court being the Supreme Court of India.

Under the constitution, parliament has the power to make laws for the whole of or any part of the territory of India. The state legislatures have the power to make laws for the states. Parliament has the exclusive right to legislate in respect of items such as defense, foreign affairs, currency, income tax, excise duty, railways, shipping, and posts and telegraphs. state legislatures have the exclusive power to make laws in relation to items such as public order, police, public health, communications, agriculture, lotteries, taxes on entertainment and wealth, and sales tax. Both parliament and the state legislatures have the power to legislate in items

appearing in the "concurrent list." This list includes items like electricity, newspapers, criminal law, marriage and divorce, stamp duties, trade unions, and price controls. Health care in India is mostly a concern of the state governments. Public health pertains to the "state list" of items upon which the state governments have the exclusive powers to make legislation.

India inhabits enormous cultural, linguistic, and genetic diversity. A journey across this nation will enable one to encounter almost a series of "countries" with different cultures, life-styles, and habits in every 300 mile utmost, typically underscoring the catchword of the Indian nation, unity in diversity. As per the 2011 census, the country is home to 1.2 billion people with diverse languages, groups, religious faiths, and cultures. India has been the cradle of contrasting diversities, varying from the highest forms of the mystical traditions through the atheistic and materialistic traditions of *Charvaka* to the nonviolent political ideology of Mahatma Gandhi in recent times. Though India habitats the largest religious festival, the *Kumbh Mela*, it is not ironical that it was in Kerala, the southern state of India, that the communist-Marxist party was voted to power through democratic means for the first time in the world. India also holds the paradoxical record of the growing number of millionaires and the largest number of poor people in the world. While a significant percentage of the population has access only to the primary health centers, medical tourism even from Europe and America has been gaining momentum in the country for over a decade. The paradoxical setting of bioethics in the Indian context has to be understood within this paradoxical social and economic reality in which the nation is placed at large.

This chapter attempts to give a bird's-eye view of the bioethics activities in India, at various levels. Starting with the history of bioethics, it dwells on the current issues, legislations, and future challenges pertinent to bioethics in India. Some directions for the future course of developments for bioethics in India in particular are made, and some areas of engagement between the Indian and the Western bioethics in general are also proposed.

Bioethics in India: Development and Current Infrastructure

The origin and development of bioethics in India has been closely associated with the Indian Council for Medical Research (ICMR), "the apex body in India for the formulation, coordination, and promotion of biomedical research" (http://icmr.nic.in/human_ethics.htm). It has been assigned with the additional task of formulating ethical guidelines for biomedical research, bioethics training, providing ethics consultation, as well as maintaining a database and coordinating international collaboration on bioethics. As stated on the website, the mission of ICMR is "...building capacity in bioethics which is relevant to Indian ethos, with special emphasis on research ethics related to genetics, drug development (including traditional medicine), public health ethics and social sciences, and international research ethics" (http://icmr.nic.in/human_ethics.htm).

Indian Council of Medical Research (ICMR) Ethical Guidelines

In 1980, ICMR drafted its ethical guidelines concerning ethics committees; informed consent; clinical trials; and clinical and medical practices involving the vulnerable sections of the society like children, the mentally disadvantaged, and those with diminished autonomy. The revised guidelines incorporating the modern challenges were formulated in 2000. However, a serious loophole with the Indian bioethics system is that the ethical guidelines are not adequately imposed by corresponding legislation or it has been weakened by delayed legislation. However, some of these guidelines were effectively incorporated in the amendments to the *Medical Council of India Act, 1956* of 11 March 2002 and the *Drugs and Cosmetics Act*, *1940* on 20 February 2005 (Kumar, 2006).

The revised ICMR guidelines also serve as a sort of template for guidelines on stem cell research, on radiopharmaceuticals, or on bioterrorism as it carries 12 general principles. There are also specific principles articulated on issues pertaining to clinical research on human genetics and organ transplantation, including fetal tissue transplantation, and stem cell research including embryonic tissue, epidemiology, and assisted reproductive technology. A draft of the guidelines for the *ethical issues surrounding genetically modified food* and *stem cell research and therapy* is jointly formulated by ICMR and the Department of Biotechnology, a government funding agency for biotechnology. This draft was originally prepared in 2006 and revised in 2008. The lack of consensus among political parties and policy makers has delayed its introduction in the parliament as a bill, though the recent controversy in the country over the Bt-brinjal has revived the discussions on the same. ICMR has a bioethics page on its website, which includes the institutional ethics committee survey questionnaire, a model format for submission of applications by principal investigators to the ethics committee, and a format for reviewers on what points they look for in approving a proposal. It also gives guidelines for preparing standard operating procedures for ethics committees.

The policy statement of the ICMR *ethical guidelines for biomedical research on human participants* was submitted to the Ministry of Health and Family Welfare for empowerment with legislation in 2006 (Ministry of Health & Family Welfare, 2011).

Bioethics Training Programs

ICMR hosts a studentship program, the appeal of which is doubling every year. ICMR has found it an imperative to offer courses and training programs in bioethics in the country. Though with no concordance, some universities in India offer bioethics courses. There is a clear instruction from the Medical Council of India to make bioethics as part of its general syllabus in the various medical colleges across the country. St. John's Medical College in Bangalore tops the list of the institutions with a strong ethical sensitivity in its medical curriculum with a legacy of over 45 years of teaching ethics. Though the instruction of the Medical Council is not binding on the medical colleges, many universities and medical colleges are

making genuine efforts to introduce medical ethics in the curriculum. Rajiv Gandhi University in Karnataka, MGR University in Tamil Nadu, Maharashtra Medical University in Maharashtra, and Father Muller Medical College in Mangalore are some other front runners in this regard. As of now, the nation does not have a uniform curriculum for training in biomedical ethics though many health institutions have launched their own programs. ICMR has also initiated measures to rectify this issue by drafting a uniform core curriculum. This process is still on and expected to be completed by the beginning of 2013. Subsequently, there is the possibility of Medical Council of India adopting this syllabus. If Medical Council of India makes medical ethics a separate subject in its syllabus, all the medical colleges and universities in the country will implement it. There is a strong call from bioethicists in the country to make medical ethics a compulsory course with requisite attendance for the award of medical degrees. Making ethics an optional course in medical colleges does not serve its purpose In India.

The training program of the ICMR has a three-pronged strategy. The first, the sensitization program, covers the undergraduate, postgraduate medical students, nonmedical students, institution ethics committee members, researchers, and faculty members. The first of its international workshops was held on 6–10 February 2006. An informal teaching module via distance education is planned with the help of the Indira Gandhi National Open University. The short-term training for the trainers forms the second component, targeting the faculty and researchers. In the long-term course which constitutes the third component, the trainees undergo training at various places and institutions. ICMR hosts joint workshops with the World Health Organization in alternative years where a common module is designed and used at health science universities and institutions in a number of states. This helps the medical and nonmedical participants to be introduced to the essential principles and practices of ethics in biomedical research. It is lamented that even those universities, which included medical ethics in their syllabus, have not made it mandatory to be part of the syllabus for examination (Kumar, 2006).

The document on "Ethical Policies on the Human Genome, Genetic Research and Services," (Tandon, 2005) issued by the National Bioethics Committee, established by the Department of Biotechnology, Govt. of India, was a follow-up to the recommendations of the "International Bioethics Symposium on Human Genome Research: Emerging Ethical, Legal Social and Economic Issues" organized by the National Academy of Sciences in India in 1998. However, these initiatives do not offer an adequate platform for the rapid progress of the ethics projects in the country (Eubios Ethics Institute 1998).

Ethics Committees

The overall state of affairs with the IECs in India is disheartening. A survey by ICMR in 2000 disclosed the surprising facts that many important institutions in the country are unaware of the ICMR guidelines. Still worse, there was no legal expert in most of the committees. "Appointment procedures were unethical and there was

lobbying for appointment as members. Decision-making was either by consensus or by majority opinion. The number of proposals reviewed varied from 2 to 60 in a meeting. The institution which had 60 at that time now has more than 100 and they are reviewed in half a day!" (Kumar, 2006, p. 62). The survey also showed that the prevalence of ethical committees is relatively better in the states of Maharashtra in central India, Andhra Pradesh in the southeast, and Karnataka in the southwest. This factor is at their lowest ebb in the northeastern states like Sikkim and Tripura. Set up in 2000, the Forum for Ethical Review Committees in Asia and the Western Pacific (FERCAP) had a joint workshop with ICMR in 2002 for developing standard operating procedures for institutional ethics committees. The chapter for India was launched in 2002 in FERCAP.

Clinical Trials Registry

Yet another creative and important initiative taken by ICMR is the clinical trial registry. This was conceived in the context of the outsourcing of the clinical trials to the country. The regulatory bodies had no adequate mechanism to handle this situation as the multinational agencies and clinical research organizations flooded into India. ICMR organized a number of workshops where multiple stakeholders were involved and the result was the planning of the clinical trials registry.

ICMR also networks with the World Health Organization, National Institutes of Health, the Wellcome Trust, the Bill and Melinda Gates Foundation, and the Ford Foundation in its bioethics campaign. On the whole, though ICMR has made a significant impact upon the bioethics map of India, it still has a long way to go by developing more sensitization programs and seeking international collaboration for capacity building.

A major milestone in the progressive bioethics campaign in the country is the launching of the South India Unit of UNESCO Chair in Bioethics at Father Muller Medical College in Mangalore in the southern state of Karnataka in January 2012. The UNESCO Chair in Bioethics, established at the University of Haifa in Israel, inaugurated a unit at Father Muller Medical College. This unit runs parallel to similar units in Malaysia, Singapore, Indonesia, Pakistan, Sri Lanka, and Japan as part of the Asia Pacific Network to address the issues in bioethics education in medical and allied health care education and research in South India and the Asia Pacific region. The unit aims at achieving excellence in health care through bioethical principles.

The objectives of the unit include imparting and empowering health care professionals in Father Muller Medical College with bioethical principles, collaborating with medical schools across South India and Asia Pacific Network in promoting bioethical concepts, and acting in concert with the Chair of the Asia Pacific Network and the UNESCO Bioethics Chair in Haifa in implementing relevant and appropriate projects and programs. In achieving its mission and objectives, the unit has designed a three-pronged activity framework consisting of an information bank, education and training programs, and research. The unit also envisages

networking with human rights infrastructure in the country and seeks to take the lead role in representing bioethics and human rights at the governmental and nongovernmental levels in South India.

With no financial commitment, the UNESCO Chair in Israel provides the technical know-how, online books, and online curriculum template to this unit and facilitates contacts with other units. So far, the unit has created ethical awareness and sensitization among nurses and doctors at the said medical college through public lectures. They have also been organizing regular training programs for their future faculty in teaching ethics with expertise by the bioethics professionals from the various parts of the country and abroad. The unit has also initiated the measures toward establishing a master's level medical ethics course at the Father Muller Medical College.

Traditional Indian Medical Ethics

Bioethical discussions in India inevitably find themselves within the conceptual and philosophical matrix of the Indian philosophy and spirituality in general. Unlike the philosophical frameworks of the Western ethical discussion, Indian ethical deliberations cannot delink themselves from the perennial perspectives of India on life, humans, cosmos, and God. Hence, a short recourse to the general ethical framework of India is necessary at this point.

There are very strong theoretical principles incorporated from science, ethics, and philosophy in Indian medical ethics which act effectively in solving practical ethical issues. Many Indian doctors practicing in foreign countries have reported that they are intuitively helped by their tradition and upbringing when faced with ethical dilemmas. Traditional Hindu medical ethics uses the theoretical principles such as the sanctity of all life, nonviolence (*ahimsa*), transmigration (cycle of death and rebirth), and a willingness to accept life situations as defined by one's *karma* (actions in life). There is a holistic unity and interconnectedness to realities of universe and life therein. The foundation of ethics is the unity of existence, not merely of human being alone, but extending to all other beings. Hinduism emphasizes the relative nature of dharma (moral righteousness) and does not recognize absolute good or evil; evil may be described as what is less good. One cannot stipulate what is absolutely good or evil for all men at all times.

What India can boast of in biomedical forums is its historicity pertinent to medicine and medical ethics dating back to several centuries before Christ. Unlike the Western system, in India, bioethics has not emerged itself as an independent branch of ethics though the mainstream ethical thinking in India and the ancient literature on Indian medical tradition are rich with bioethical principles and practices.

Dhanvantari is the father of the traditional Indian medicine of *ayurveda*. He looms in immemorial past. Indian historians claim that Dhanvantari's descendants, Charaka and Sushruta, lived prior to Hippocrates (460–370 BC). *Charaka Samhita*, the ancient treatise on medicine formulated by sage Charaka, defines *ayurveda* as

follows: "That is named *Ayurveda* wherein is laid down the good and bad life, happy and unhappy life, and what is wholesome and what is unwholesome in relation to life and also the span of life" *(Charaka Samhitha – Sutra Sthana, 1:41)*. The *Siddha Vaidya* branch of Indian medicine, which deals with pharmaceutical chemistry, is an independent branch, and later, it was incorporated into *ayurveda*.

Charaka advocated a departure from faith-based approach to medicine and emphasized a reason-based approach. Charaka seems to criticize fatalism and passivity that is pervasive among millions of people even today and asserts the procedural nature of a good life. "Good conduct, in his view, implied the avoidance of the overuse, underuse and misuse of the senses and the mind" (Valiathan, 2003, p. 178.). By emphasizing reason-based approach to medicine, Charaka has placed the responsibility of creating optimal conditions for a good life squarely on the individual and the community. The ethical outlook advocated by *ayurveda*, as it is explicated in various ayurvedic texts, is based on the conception of a comprehensive philosophy of life. Ancient Indian medical manuals have prescribed strict ethical codes for discouraging and penalizing medical malpractices and unethical procedures. There are ample references in the Indian epics such as the *Mahabharata* (Hopkins, 1993) and secular texts like the *Arthashastra* (Kangle, 2006) of Kautilya about the desired conduct of physicians. This shows the importance of public accountability of the medical professionals. Charaka, for instance, asserts that a physician should invariably seek the happiness of all beings. He ought to heal the sick with his whole heart and should not do it for money alone (Sen, 1917). Indian medical tradition stresses certain characteristics for the patient too. According to Charaka, good memory, willingness to follow the instructions of the physician, fearlessness, and not hiding any relevant information about his symptoms and disease are the four qualities of a good patient.

In India, medical practice has been traditionally paternalistic. The doctor-patient relationship is paternalistic in *ayurveda* also. In the medical practice of *ayurveda*, such a transition from paternalism to informed consent is least noticeable as paternalism or ethics of trust still holds good here. Sushruta holds that a physician must not reveal the secrets of the household or the patient nor spread broadcast the demerits of the family. He must therefore never expose the patient and must honor the confidence the patient has in him.

Major Bioethics Issues

Beginning of Life

Hindus have clear prohibition for abortion except to save the life of the mother. It is considered as against the universal order and a sinful act against the moral law of *dharma* fraught with karmic repercussion. Hindu ethics does not justify abortion because of the actual or potential deformity or mental retardation as each birth has a divine purpose.

Medical Termination of Pregnancy (MTP)

MTP is a legalized procedure in India and is widely practiced. The Medical Termination of Pregnancy Act was enacted by the Indian parliament in 1971 and was brought into force from 01 April 1972. The MTP act was revised in 1975 and further in 2002. Despite the clear prohibition of abortion in traditional Hinduism, the Indian MTP act is very liberal in itself.

One of the reasons for this liberal approach could be the strong requirement of the country to address the issue of the growing population. The liberal policy of the country favoring abortion to address the specific interest of the growing population and not addressing the life-long mental stress of the women conceding to abortion is a major ethical dilemma that is conveniently neglected.

The liberal attitude toward the medical termination of pregnancy has not alleviated India's woes with newborn and maternal deaths. India records 26 million births every year which is 54 % of the total births worldwide. 23 % of the babies born have low weight (below 2.5 kg), and India is among the world's five countries that account for more than half the world's 3.3 million newborn deaths. Almost 45 in every 1,000 births are born to mothers aged between 15 and 19. As regards maternal deaths, India sees the highest number of women dying during childbirth. In India, one woman dies every 8 min due to pregnancy-related complications.

Female Feticide

Many abortions in the Indian context are done as female feticide. India has a skewed sex ratio in favor of males. In 2011, indicating a continuing preference for boys in society, the child sex ratio in India has dropped to 914 females against 1,000 males. The ICMR guidelines have very specifically put forward that prenatal diagnosis (PND) should be limited to detect the fetal abnormalities or genetic disorders as per PND technique and not for sex determination of the fetus. In 1994, India banned the use of technology to determine the sex of fetuses and abortion on the basis of gender, but still sex determination is commonly practiced. The country has made it mandatory that all ultrasonography centers should be registered to get the license and should explicitly mention the fact that no ultrasonography will be done for sex determination. The law was implemented in 1994, but still the sex ratio is not in favor for girls.

The Women's Code 2011

The Commission on Rights and Welfare of Women and Children in the Kerala state in its proposed Women's Code Bill 2011 recommended that a fine of Rs. 10,000 or 3 months simple imprisonment deserves to be slapped on the expectant father of a third child. The proposed bill maintains that violation of family norms will be deemed a legal disqualification and parents will not be eligible to receive any benefits from government. It insists on that religious and political outfits should not be allowed to discourage population planning and no person or institution shall use religion, region, sect, cast, cult, or other ulterior inducements for the bearing of more children. Medically safe contraceptives and instructive literature are suggested to be made available free at the time of marriage. Safe abortion should

be made free and through hospitals and health care centers in both private and government sector. These recommendations have already sparked off much hue and cry in the state.

End of Life Issues

In India, especially in the Hindu tradition, people generally wish to embrace a natural death. Unnatural hastening or delaying is not appreciated in the country. In circumstances where treatment cannot assure the patient a certain quality of life, it is considered better to forego treatment beyond palliative measures. Given the belief in the predetermined timing of death, Hindus do not strain to gain a few months. For some traditional sects, sustaining life on life support machine is tantamount to torturing the soul. Hindu scriptures do discuss nourishment related to life support and allow the termination of food and water at the request of the terminally ill. Hindu philosophy does not support assisted suicide leading to the death of a patient at the patient's own request. In the Hindu worldview, such measures only reinforce the *karma* (cycle of death-rebirth) which one wishes to escape.

In India, in general, the life-shortening actions near the end of life like withholding treatment, stopping treatment, treatment of symptoms accompanied by shortening of life, and actions terminating life - in the strict sense, administering lethal drugs - is not practiced in general. Euthanasia was neither practiced nor legalized in the country till recently. In modern times, all available aggressive treatments are carried out to the end of life. Such a support is a natural expectation from the patients and the relatives, though the physician may not share this view as it is medically futile to treat the condition. The concept of medical futility does not seem to be appealing to the general public. The medical practice in India when it concerns end of life is very much culturally conditioned (Puri, 2005).

Passive Euthanasia

However, a landmark ruling by the Supreme Court of India on March 7, 2011, changed forever India's approach to the contentious issue of euthanasia. The court ruled for the first time that life support can be removed for some terminally ill patients in "exceptional circumstances" – for example, when a patient is kept alive purely mechanically and when he or she is only able to sustain involuntary functioning through advanced medical technology. All mercy killing pleas should be heard by a two-member bench of the appropriate High Court, and decisions may be taken only after seeking medical opinion from three empanelled doctors, who must examine the patient, his or her medical records, and also get the views of the hospital staff. Decisions will be case-by-case and made by high courts after hearing the opinion of the family and a medical panel. The ruling came in the petition for Ms. Aruna Shanbaug, a former nurse, who has been lying in a vegetative state for 37 years following a sexual attack. However, the same ruling declined euthanasia for Ms. Aruna given her medical conditions. And till parliament introduces new laws on euthanasia, it is Ms. Shanbaug's case that is to be used as a point of reference by other courts.

Advance Directive

An advance directive is the formulation of a competent patient's moral and legal right to refuse treatment in the post competent period based on the principle of respect for autonomy and individual self-determination. In India, the practice of advance directives hardly exists. There is no indication in the bioethics literature that this aspect has trickled down to ethical discussions on end of life issues. The nonexistence of an advance directive in India is possibly the result of specific cultural values and age-old social and religious philosophies.

Hospital-Patient Protection Law

In 1992, India expanded the purview of the Consumer Protection Act of 1986 to cover the paid medical service against medical malpractice. The greed of the medical establishments in the country to some extent has disfigured the pristine values of the medical profession in the country, which has resulted in instances where people attack hospitals, doctors, etc., a negative trend which has been on the rise in the nation for over a decade. It has forced a number of state governments to draft doctor-patient protection act. Such laws are already enacted by the states of Andhra Pradesh and Karnataka. The Kerala Health Services Persons and Healthcare Service Institutions (Prevention of Violence and Damage to Property) Ordinance issued by the state government, which also includes provisions to ensure patients' rights, proposes that all violent acts committed against a hospital and its staff be made a cognizable and non-bailable offense. It also proposes that the rights of patients to receive complete information about the medical treatment received at the respective hospitals be ensured and that the patients' right to redress of any grievances regarding any lapse in medical treatment or service provided by a hospital be ensured.

Drug Development Ethics

India produces synthetic, genomic, and plant-based drugs with investment from the public and private sectors. Although genomic drugs are well regulated in the country by regulatory committees, such regulation is not adequate in the field of plant-based and synthetic drugs. The guidelines followed in this regard are the ICMR ethical guidelines and the Indian good clinical practice guidelines. The 1982 amendment of the *Drugs and Cosmetics Act*, *1940* now covers the traditional medicine too with independent clauses (Section 33-C) for *ayurveda*, *siddha*, and *unani* medicines with recommendations for quality control of the formulations, the appointment of a drug technical advisory board and a drug consultative committee, provision for government inspectors and analysts, etc. The amendments of January 2006 of the same act imposed mandatory compliance with good manufacturing practice and mandatory testing for heavy metals in export formulations. When it concerns drug trial approval, it is mandatory in India that the chairman of the institution ethics committee is from outside the institution. Biotech recombinant

products have to get the approval from three bodies at the federal level, that is, Biosafety Committee, the Review Committee for Genetic Modification, and the Genetic Engineering Approval Committee, though efforts are on now to promulgate a single window for clearance.

Health and Disease

The Indian mind-set has a philosophical way of looking at health and disease, traditionally conceived from the ancient Indian medical legacy of ayurveda. Ayurveda, the science of positive health, has three goals: achievement of positive health for the individual, protection of health of the masses, and obtaining ultimate liberation. Health is defined as the inseparable combination of the body, sense organs, mind, and soul. As such, the emphasis on wholeness in the WHO definition of health is inbuilt in the Indian view with more spiritual and metaphysical grounding. The body is the synchronized conglomeration of the five great elements (*pancha mahabhutas*), namely, earth, water, fire, air, and space. Two types of substances are essential for creation – material and immaterial. There must be an immaterial essence and material form in every living organism. When the variations and combinations of *pancha mahabhutas* are well balanced, the body is intact. Therefore, health is the harmony of the body within itself and with the cosmos and the divine. This also tells what disease is. Bharadwaj, an ayurvedic physician in 600 BCE, had stated that the root cause of all illness is the loss of faith in the divine. It suffices to state that in ancient India, physical and mental health were never considered separate from sane living.

The impact of the traditional belief system of the concept of rebirth is still evident in modern times too where some people are inclined to look at disease as the result of one's wrong actions in the previous birth. In the traditional Hindu belief, development of disease is not considered to be caused by external agents or injury but a result of the *karma*, the fruit of the past actions of the individuals in his/her past life. These belief systems need to be critically redressed for a relevant and practical ethical discussion. Fatalism, the view that one's life is predetermined by fate, is still dormant and operative in the minds of many when it concerns disease and sickness. However, the modern Western scientific and rational approach toward health and disease is permeating the Indian mind-set in general in modern times.

The traditional medicine of *ayurveda* and the *unani* medicine from Persia also form part of the medical system in India. Another traditional system, *siddha*, has its roots in India centuries ago. These classical traditional systems are still recognized by the government though there have been some moves toward disapproving some of the alternative medicines in recent years.

Health Care

Health in India is mostly a subject of state governments. According to the Medical Council of India, the allopathic doctor-population ratio works out to 1:1722,

in May 2007. The patient-nurse ratio depends on various factors like type of patient care provided and nature of specialization and varies from 5:1 to 19:1. India had been somewhat successful in meeting health parameters since independence in 1947, such as increase in life expectancy and eradication of some endemic diseases. In 2009, India has 271 medical colleges throughout the country out of which about 31,000 medical students graduate every year. According to estimates by the Planning Commission, India is short of 600,000 doctors and one million nurses. The low doctor-patient ratio does not make medical care affordable. This shortage is all the more pronounced in India's rural communities as the majority of the doctors live and practice in cities. The 11th five-year plan, therefore, aims at establishing 60 medical colleges and 225 new nursing and other colleges in deficit states. India needs many more doctors and many more medical institutions. Augmentation of medical institutions in the country is one of the important first steps to overcome shortages. The public sector spending on health accounts for 25 % of aggregate expenditure. The balance 75 % is the expenditure incurred by patients to private practitioners of various hues. Public spending on health in India has itself declined after economic liberalization in 1990s from 1.3 % of GDP in 1990 to 0.9 % in 1999. Central budget allocations for health have stagnated at 1.3% to total central budget. In the states, it has declined from 7.0 % to 5.5 % of state health budget (Srinivisan, 2011).

Genetics

Though in its infancy, India is venturing into the relatively new field of genetics research. As research in this area invades into the previously untouched concerns of ethics and morality, the Department of Biotechnology of the Government of India has set up a National Bioethics Committee to prepare guidelines for research in genomics, as part of its new human genome initiative. The committee has been set up to fulfill obligations under the UNESCO Declaration on the Human Genome and Human Rights, to which India is a signatory. Ethical Review Committee set up by the Indian Council of Medical Research (ICMR) has finalized a comprehensive set of ethical guidelines to regulate biomedical research involving human participants. There are no specific laws governing the processes of human genetic modification at any stage. Human cloning is prohibited by the ethical guidelines. Respect for embryos in the context of genetic research, by ethically regulating conditions of research and safeguarding the commercialization of embryos, is upheld. It also prohibits the generation of embryos for the sole purpose of obtaining stem cells and gene therapy for enhancement of genetic characteristics and eugenic genetic engineering.

The leading centers for genetic research in the country are the Genetics Unit, Department of Pediatrics, All India Institute of Medical Sciences, New Delhi; the Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGI), Department of Medical Genetics, Lucknow, which offers a Medical Genetics course; Genetics Cell, Sri Ramachandra Medical College (SRMC) Porur, Chennai; and Surendra Genetics Laboratory, Royapettah, Chennai, India.

Genetic research initiatives in India need to make genetic tests feasible to the common man in India, especially of the genetic diseases common to the general Indian population. Lack of accessibility and exposure to the genetic knowledge and lack of well-equipped lab infrastructure are the challenges that India faces today. Social disparity of the poor and the rich plays a major role in accessing knowledge and treatment of genetic disorders. One important field with great potential in the Indian genetic context is the genetic exploration of the causes of the diversity of the Indian populace. Governmental initiatives are minimal in the genetic field in India.

Reproductive Medicine

India has been considered a highly fertile country. Therefore, governmental initiatives started with the issue of contraception and fertility control. India's engagement with contraceptive medicines started as early as in the late 1950s (Unnithan, 2010). This, in fact, did not give justice to the numerous problems related to fertility, sexually transmitted diseases, and the particular Indian social context and poor quality of health care provisions during pregnancy, delivery, and post pregnancy. Popular reproductive techniques in India include the different variants of IVF, intrauterine insemination, intracytoplasmic sperm injection, and surrogate motherhood. Surrogate motherhood is more of an arrangement than a technique. In India, the first baby conceived through in vitro fertilization (IVF) techniques, Harsha, was born in 1986. Surrogacy became popular in India after the 1990s. Commercial surrogacy is legal in India as it is recognized by the Supreme Court of India in the year 2002. The Assisted Reproductive Technologies Regulation Bill of 2010 puts up some important guidelines in the Indian context. This draft bill highlights the regulations for the clinics performing ARTs and the rights and duties of patients, donors, surrogates, and children and the punishable offenses in this regard (Ministry of Health and Family Welfare, 2010).

What India needs today is a contextually based ethics which goes beyond the biomedical framework in the case of ARTs. Context plays an important role in the ethically important concepts like choice, consent, and assent. In India, infertility is ritually highly stigmatizing, and often, women are held responsible for not having children. With the ARTs, there are growing tendencies of commodification by compromising the health, well-being, and personhood of women. Over 13–15 million couples were estimated as being infertile in India in 2005, and a majority are women who suffer from secondary sterility. There is also a higher rate of exploitation of poor and rural Indian women. Low success rates of technological interventions are yet another concern.

Medical Research

Medical research in India is a very well-established field with its cheap cost of medical trials, trained staff, and well-equipped lab settings. Besides, India is a hub

of infectious diseases specific to the Indian general public. The Indian Council of Medical Research is the highest body in India to conduct, regulate, and promote biomedical research. ICMR undertakes and supports basic, applied, epidemiological, and operational research in the area of public health. It lobbies for certain methodologies which need to be used to carry out high-quality research. In 2006, ICMR issued the *ethical guidelines for biomedical research on human participants*. Medical research and trials are governed by the Drugs and Cosmetics Act of 1940 and the ethical guidelines provided by the Indian Council of Medical Research (Indian Council of Medical Research 1980, 2000). The last amendment to this act was in the year 2010. Besides these, the Drugs Controller General of India and the Medical Council of India are the major surveillance bodies for conducting medical research and clinical trials of drugs in India.

Sponsors of clinical research in the first world move clinical trials to less costly countries, and India is one of the hotspots for such trials (Glickman et al. 2009). Therefore, most of the trials conducted in India are solutions to the health problems of the affluent countries, and remedies specific to the Indian medical scenario are not aptly sponsored and researched. Lack of stringent laws monitoring medical research in which people are participants and lack of clarity with regard to the guidelines for research related to genetics and the inefficacy of already existing regulatory bodies vouch for the unethical practices and corruption in India in the area of medical research. The president of the Medical Council of India and some colleagues were arrested by the Central Bureau of Investigation in India for their alleged roles in a 440,000 dollars bribery case, in April 2010. The practice of illegal payment to medical practitioners, wherein a certain percentage of salary in cash could be given to them without having to remit income tax on the said portion, is a common practice. Moreover, disparities with regard to wealth, education, gender, and class in India do endanger the interests of the research participants (Thatte & Bavdekar, 2008).

Public Health

The Constitution of India makes it mandatory for the government to ensure fulfillment of the right to health for all without any discrimination under Articles 14, 15, and 21 (rights to life, equality, and nondiscrimination). Health constitutionally is an issue of the state (The National Health Bill, 2009). The central government can interfere to assist the state governments in issues related to public health. Being densely populated, India is highly vulnerable to public health issues. For instance, India was plague free from 1966 to 1994. But, in 1994, a total of 693 suspected bubonic or pneumonic plague cases were reported to WHO by Government of India, a grave stigma on the public health map of India. Water and land sanitation, pollution, poverty, class and gender disparities, environmental problems and overpopulation are major concerns of the public health department. The Indian Government has taken major initiatives in eradicating or containing some of the endemics like kala-azar, malaria, filariasis, polio, tuberculosis, cancer, and

HIV/AIDS. The National Rural Health Mission established in 2005 assists in marginally bringing down the public health issues.

Union Health Minister Ghulam Nabi Azad announced on February 25, 2012, during the inaugural session of the two-day Polio Summit, that India is finally off World Health Organization's list of polio endemic countries. This means that no new polio case has come up in the country in the last one year and also all laboratory samples collected during this period have tested negative for the virus. According to the emergency preparedness and response plan put in place for polio, any new case will now be declared as a public health emergency. If India remains free of any new polio cases over the next two years, it would finally be declared polio free in 2014.

India is easily susceptible to zoonoses (diseases transmitted from animals to humans) due to the close contact with animals especially in the rural areas. Many diseases, which authorities claimed to have been eradicated, reemerge after a period of quiescence. The administrative responsibility of public health care is shared by central and state governments. Spread of major infectious diseases like HIV/AIDS, polio, and leprosy is monitored and controlled by central government. From the late 1990s, the Indian Council of Medical Research has stepped up its funding in the field of research on infectious diseases, especially the emerging diseases (Kant, 2008). The Government of India uses two-pronged action strategies in combating infectious diseases. It uses special programs for monitoring and controlling selected infectious diseases. The National Tuberculosis Control Programme, the National AIDS Control Programme, and the National Leprosy Eradication Programme are some of the examples. It also helps state governments upon demand for the control and eradication of regionally significant infectious diseases (John et al., 2011). India has a Public Health Act (1897), and most of the programs for the control and eradication of infectious diseases are funded by the WHO.

Public health issues are not easily addressed in India. Poor pandemic management and geographical inaccessibility are some of the hurdles that India faces in the public health management. Pollution of food, water, land, and air; changing life-styles; and poverty are the main causes of poor public health status of India. Inadequate public health centers and lack of facilities and human resources worsen the public health situation in India. The growing scale of chronic diseases is a clear indicator of the public health situation of India. Creating of public health cadres to work for prevention of disease, ensuring that every village has access to safe drinking water, and accelerating efforts to providing hassle-free and cashless outpatient care in the public hospitals are some of the recommendations of the high-level expert group setup by the Planning Commission on Universal Health Coverage.

Transplantation Medicine and Organ Donation

Organ donation and transplantation in India today transcend mere medico-pharmaceutical needs. In India, organ transplantation is regulated by the Transplantation of Human Organs (THO) Act of 1994, which has legalized the concept of brain death. The first successful cadaver kidney transplantation was done in KEM

Hospital, Mumbai, in I967. The first successful heart transplant was done at AIIMS, New Delhi, in 1994, and the first successful multiorgan transplant was done at Apollo Hospital, Chennai, in 1995. Today, many hospitals have set up the Organ Donation Registry with the purpose of encouraging organ donations.

In India, only a very few patients can really afford transplantation of human organs. Lack of proper awareness among the common public, the shortage of related organ donors, and the failure in collecting cadaver organs lead to illegal organ trafficking in India. Statistics show that annually for over 100,000 patients with end-stage renal disease, only 3,000 receive kidneys in India. In India, the number of actual organ donors per million is 0.08, and it does not account even for the 10 % of the demand. There is also the middle man between the potential donor and the patient who earns heavily from the deal (Prakash, 2008). Besides, religious and cultural background of India with belief in rebirth also restricts the possibility of cadaver organ donation and transplantation. Poverty and illiteracy also come into play in organ transplantation and donation. There have been numerous instances of medical practitioners fraudulently removing kidneys of poor people during a surgery.

Intensive Care

Intensive care in India is only on its way to a full-fledged medical service. Critical care initiatives began in the Indian medical context in the early half of 1970. The Indian Society of Critical Care Medicine was formed in the year 1992. Community hospitals which are run by government, private hospitals, and nursing homes are the major sectors, through which intensive care is provided in India (Prayag, 2002). The number of ICU beds available is disproportionately low both in private as well as public sector hospitals in India. Many hospitals in India are not adequately equipped and duly staffed with regard to intensive care. Intensive care units in the private sector are very expensive. Therefore, the majority of Indians cannot afford this service. Future challenges in critical care include the development of guidelines, the consolidation of training activities, and research on the outcome of critical tropical problems which are peculiar to India.

Palliative Care

India, a nation known for its virtues, has got a very ancient history of administering to the needs of the dying. It is said that Emperor Ashoka (304–232 BCE) established a *mukthi bhavan* (salvation home) on the banks of river Ganges for the people to take refuge during their last days. However, palliative care, as a branch of medicine, traces back to the 1980s in India. Most of the legal pronouncements in this regard, whether constitutional or judiciary, refers to the cure of the patient, and very less is referred to the concept of alleviating the pain of the suffering. The Delhi High Court in 1998 ruled that patients who suffer moderate and severe pain have the right to be administered medicines that can assuage their pain (Amon, 2009). Indian palliative

care facilities do not suffice to the demand of the number of patients with incurable diseases. There is a very serious dearth of palliative care units. Only less than 10 % of patients with incurable diseases receive palliative care in India. The delayed access to the palliative care units due to sparse distribution of such units at the national level is yet another problem in India.

Care for the Elderly

With its rich cultural heritage, Indian younger generation has been showing respect and care for the elderly. Elderly people were in general looked after in a homely ambience and died in the presence of the near and dear ones. However, cultural variations like industrialization, urbanization, modernization, and the changing understanding of family and relationship affected very critically the way Indians look at the elderly. In India, the Ministry of Social Justice and Empowerment looks after the welfare of the aged. This ministry is ably assisted by the National Council for Older Persons for the execution of policies related to the well-being of the elderly. The Indian government had issued a National Policy on Older Persons in the year 1999, which provides the framework for the social, economic, and constitutional security for the elderly citizens of the country. Old-age pension, widow pension, and income tax rebate for the elderly are some of the benefits that the Government of India provides for its senior citizens. State and central governments give concessions to senior citizens for conveyance by bus, train, and planes. The older population of India, which was 56.7 million in 1991, is 72 million in 2001 and is expected to grow to 137 million by 2021. The Indian Gerontological Association (www.gerontologyindia.com) was established in the year 1968 which is devoted to the well-being of the aged and promotes research on aging.

Economic issues, cultural diversity, changing definitions of family and relationship, and changing views of suffering and life after death critically altered the way young Indian generation look at the elderly today. With the predominance of nuclear families, senior citizens do not get their due with regard to respect and care from their own families. Therefore, the number of the elderly left to themselves is increasing day by day. However, the number of old-age homes does not reciprocate the number of senior citizens left alone by family members. One statistics has it that there are only a little over 700 age-old homes in India, out of which 125 are in the southern state of Kerala. Many of the Indian old-age homes do no admit senior citizens with dementia. The problems of elderly widows are still more complex. Besides, disputes about the property and poor economic conditions of the elderly are stresses that the senior citizens of India are subjected to.

Chronic Diseases

India has been known for its serene life-style, closeness to environment, and a majority of people with vegetarian food habits. However, with changes in culture

and life-style, India is becoming easily vulnerable to a variety of chronic diseases. There are governmental and nongovernmental agencies formed for control and awareness programs. The Centre for Chronic Disease Control based in New Delhi is a nonprofit research organization for the control, generation, and transmission of knowledge of chronic diseases which now accounts for 53 % of deaths in India. The major chronic diseases that India faces today are diabetics, cancer, stroke, heart, and respiratory diseases. India has the dubious first in terms of losing potential productive years due to cardiovascular diseases.

According to a recent joint study by WHO and World Economic Forum, India will lose a whooping US $ 235 billion by the year 2015 because of the occurrence of the chronic diseases among the working class. Awareness programs on healthy diet and life-style have to be conducted all throughout the country. Trained and qualified counselors for stress and depression management are to be deployed nationwide. India also lacks a governmental policy development with regard to the control of the spread of the chronic diseases.

Psychiatric Care

Indian culture has always looked at the holistic well-being of the person. Traditional Indian medical systems like *ayurveda*, *unani*, and *siddha* give illustrations of psychiatric disorders and its remedies. Mandu Hospital opened by Mahmood Khilji (1436–1469) at Dhar in the present state of Madhya Pradesh was the first Indian mental asylum. Bombay asylum was the first lunatic asylum in modern India, and it was built approximately 1750 AD. The famous central mental hospital, Yerwada, Pune, was opened in 1889. The first asylum for insane soldiers was established at Monghyr, Bihar, in the year 1975. The Bhore All India Institute of Mental Health was set up at Bangalore, in the year 1954, which later came to be known as National Institute of Mental Health and Neurosciences. The National Mental Health Programme was initiated in the year 1982 for earmarking vulnerable populations, causes, and the effects of the mental disorders in various regions of the country (Parker et al., 2001). The Government of India has passed the Mental Health Act in the year 1987.

The situation of mental health in India is very complex. Changing patterns of life-styles, family setup, work stress, competition, and relationship affect the psychological health of the Indian population. Scarcities of trained and qualified psychological counselors and failure of governmental initiatives to reach the rural areas are some of the major problems in solving the problems of mental disorders. Social stigma and alienation add to the agony of the patients and their families. Treatment of mental illness does need a multidisciplinary approach which combines clinical psychological treatments, counseling, spirituality, and sociology. This kind of holistic approach to mental health in India is rare. Preservation of the basic human rights of the mentally sick person is another challenge that India faces today. Many patients live in subhuman conditions.

Emergency Care

Emergency care in India is gaining significance due to the amount of road accidents, natural disasters, and the outbreak of infectious diseases. Every year, nearly a million deaths occur due to road traffic injuries, falls, burns, poisoning, drowning, suicide, work place/occupational injuries, disasters, and violence. In a significant ruling in 2007, the Supreme Court has ruled that all injured persons especially in the case of road traffic accidents, and assaults when brought to a hospital/medical center, have to be offered first aid, stabilized, and shifted to a higher center/government center if required. It is only after this that the hospital can demand payment or complete police formalities. Failure to administer emergency care in the wake of an accident or disaster amounts to the violation of the constitutional "right to life." Emergency care in the military with well-equipped staff has been functioning in India since the 1960s. The first emergency department at the private sector, modeled after the American system of emergency medical care, was established in Chennai at Sundaram Medical in the 1990s. In the year 2009, the Medical Council of India recognized emergency medicine as the 30th specialty of medical curriculum.

Emergency care and the trauma relief system in India are very sparse, and sometimes, it is totally absent in the rural areas. The ignorance of common people to administer first aid in case of emergency in India is another problem that has to be immediately sorted out. Emergency services in India are not systematically networked, and therefore, a lot valuable time is lost before the patient has being admitted to the best suitable place. Emergency care coupled with better rehabilitation programs for the injured is the need of the time in India. Trained professionals, better equipments, and creating mass awareness can produce better care during emergency cases. A policy-based injury control and trauma relief system would do great help for the proper functioning of the emergency care in India (Subhan & Jain, 2010).

General Practice

In the past, the upper and the rich class of Indian society had access to *vaidyas* (physicians), and the people who belonged to the lowest rung of the society depended mainly on household remedies. India did not have a well-established public health system before the arrival of the British. They established medical colleges and hospitals mainly centered in cities. This pattern led to a hospital-centered urban medical care for the patients contrary to the context of India. The 1930s witnessed the arrival of general practice in India in Mumbai (Pingle, 2002). General practitioners had a cordial relationship with the patients and were generally humane in their approach. Changing cultural patterns, greed for money, competition, breakage of traditional familial concepts, and the trend of specialization led to alterations in the general practice and more importantly changed the way a patient related with the doctor.

Prevalence of unethical practices is common in general practice today. India is known for general practitioners who are inexperienced or even unqualified.

Commercialization of medical care is another factor that affects Indian general practitioners. Malnutrition, illiteracy, and poverty are some other factors that challenge the general medical situation. Pregnancy-related deaths are very common in rural India. Another area of concern of the general practitioners in India is the medical condition of the tribal population. Modern medicine is very technical in its approach, and this is contrary to the traditional Indian medical context. Generally, the traditional Indian medical context is communitarian, holistic, and eco-friendly. General practitioners today have the Herculean task of coupling effectively Indian traditional value-based medical ethos with modern medicine for the holistic well-being of the patients.

Nanotechnology and Information Technology

India is slowly catching up to the immense possibilities that nanotechnology offers in the field of medicine. In India, the Department of Science and Technology of the central government is overseeing the development and promotion of nanotechnology. The Nano Mission Council, the highest advisorial policy-making body for nanotechnology in India, is under this department; it also includes two other advisory groups, namely, Nano Applications and Technology Advisory Group and the Nano Science and Advisory Group. The main nanotechnological research bodies in India in the field of medicine are the Indian Council of Medical Research, the Council for Scientific and Industrial Research, and Indian National Science Academy. The Department of Science and Technology and the University Grants Commission (UGC) now fund nanotechnological research initiatives in India.

Today, information technology in India is making revolutionary inroads in all aspects of life. With its rich and large pool of IT professionals and English-speaking young generation, India is fast becoming the hot spot for the IT revolution. For the first world countries, India is one of the favorites for outsourcing because of its cheap but efficient labor. The Information Technology (IT) Act was passed in the year 2000 and invited major amendments in the form of the Information Technology Amendment Act of 2008. The Information Technology Action Plan of 1998 and recommendations of the National Association of Software and Service Companies (NASSCOM) help the Department of Telecommunications to draw out policies which will safeguard the security of the nation and the rights and duties of its citizens in the cyber world.

Infrastructural and knowledge constraints limit the growth of nanotechnology in India. The problem of the absence of a clear-cut patent policy is another drawback. Nanotechnological initiatives could go any farther ethically by invading the private space of an individual with "nano-implants." In this regard, who manages it would be a very important question. It could be manipulative in the hands of the powerful; this is very true in the context of Indian social setup. In India it can lead to uneven distribution of knowledge, power and wealth as there is the extreme inequality in all aspects of life (Sharma & Noopur).

Anonymity, the issue of intellectual piracy in the form of documents and software cracks, are already posing threats to the security of the nation. Erosion of the cultural values is one of the issues that India faces today in the field of Information Technology. Health related problems and emotional insecurities plague the young Indian generation who work in the IT field. Information technology has brought in a sort of colonization whereby the talents of the young generation are tapped without adequate remuneration and other work related rights of the professionals. Information technology coupled with nanotechnology can raise unprecedented ethical problems in the context of India. The power generated by knowledge can easily be manipulative in the social setup of India as many live in subhuman situations with evils like social inequalities, gender disparities, and poverty. The plight of the best talents in the country to the IT sector adversely affects the fundamental research in other branches of science.

Emerging Contexts and Future Directions

This section discusses some of the active bioethical issues in the country and the possible challenges that India will have to address in the near future and suggests some directions for the future course of bioethics in India.

Conflict of Interests

India, especially the southern state of Kerala, seems to be at the epicenter of the world's endosulfan debate in recent times. India is the largest manufacturer and exporter of the pesticide and its second largest user. As the debate on endosulfan has been gaining momentum in the Stockholm Convention in Geneva, Kasargod, a district in the state of Kerala, has been highlighted as a classical case of the nightmare with a certain population of brutal victims attributed to the misuse of this pesticide, with the aerial spraying of the same by plantation corporations. Even when most other countries are supporting a ban on endosulfan, the Government of India is opposing a ban against the persistent pressure from the state of Kerala. Settling this open debate in the country will have wider ramifications for the bioethical concerns in the country.

Labeling Laws

The absence of labeling laws in India has been exposed by the hot public debates in recent months on the release of Bt-brinjal, the genetically modified form of the vegetable, in India. The Genetic Engineering Approval Committee is the recommendatory body for clearance of such crops. Though cleared by the GEAC, a series of public consultations organized by the Ministry of Environment led to a moratorium on commercial cultivation of Bt-brinjal.

Toward Justice

A contextual challenge to the bioethicists in India is posed by the inefficient and unjust health care delivery system because of which the benefits are not available to all sections of society. It is unto the bioethical theorists in India to sensitize the Indian doctors to the national efforts to provide quality health care to all, especially in the rural areas.

The Interdisciplinary Pursuit and Networking

The networking between the governmental bodies of the Indian Council of Philosophical Research (ICPR) and ICMR can accelerate the promotion of bioethics in India. Teaching ethics is strong in the faculties of philosophy in the various universities in India but with inadequate integration of the bioethical discussions. Interdisciplinary attention to be paid to the development of the bioethics is all the more crucial in the diverse and polyvalent context of bioethics in India. The current bioethical theorists and champions are not adequately equipped to promote this interdisciplinary exercise. Hence, a serious engagement between the various stakeholders in related fields is important for the effective promotion of bioethics in India.

Engaging the West

The dream project of ICMR like the development of a uniform curriculum for bioethics blending the Western philosophical and theological streams with the noble Indian conceptual and religious traditions which sensitizes the Indian context and Indian reality, if duly materialized, will be a significant contribution to the international project of bioethics with the rare addition of local sensitivity and global responsiveness, a mandate for the international community of bioethics at large. Those engaged in bioethics in India seem to be placed at the polar ends of the uncritical accommodation or blind negation of the Western bioethics in India. Indian thinkers need to learn to engage the West in a more constructive and informed manner.

Legal Enactment

Ethical guidelines in the country often lack the teeth with no legal promulgation. India is a country with poor law enforcement, and the soft-pedaling on ethical guidelines results in almost defeating the very goal. For instance, in the recent ruling on euthanasia, the Supreme Court of India has called for the parliament to build the principles outlined in its ruling into humane legislation.

The Holistic Matrix

The dormant principles in the Indian paradigm of bioethics disclose the cultural, social, religious, and existential embeddedness of the ethical issues. The model of India might call for the deeper issues at stake in an effort to resolve it. The Indian model postulates the wider philosophical and spiritual horizons of decision-making in bioethical issues.

Infrastructure

The bioethical activities in India may be coordinated under a single umbrella by erecting a National Bioethics Commission which addresses ethical problems pertaining to science and society, engages in deliberations, and advises the government and the public.

Conclusion

This chapter discussed firstly the bioethics infrastructure in India elucidating the role of the Indian Council of Medical Research in promoting bioethics in India through workshops, networking with international bodies, establishing ethics committees, formulating guidelines, training programs, and developing a curriculum. Next, the roots of the biomedical ethics in India are explored in reference to the traditional Indian medical system of *ayurveda*. The subsequent part dwells on the bioethics issues and discussions related to beginning of life, end of life, health and disease, health care system, genetics, reproductive medicine, medical research, public health, information technology, and nanotechnology. The current state of affairs with each of these issues in the country at the applied, legislative, academic, and social level was presented, and the concerns about them were expressed. The common strand of perception emerging from these discussions was that though ethical sensitivity is present in all these issues, the need for systematization and infrastructure development with definite shape and mandate are imperatives for the development of bioethics in India. It has also been noted that a systematic and standard approach and an organized way of dealing with ethical issues are missing in the Indian medical setting. Some suggestions for the development of bioethics in India in order to address the future challenges from emerging context are also made.

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Challenges, Changes, Concepts for Future Generations

Soenarto Sastrowijoto, S. Yati Soenarto, Nur Azid Mahardinata, and Wika Hartanti

Introduction

Values and ethics in medicine have been discussed since ancient times: in Chinese medicine (2838–2698 BCE), in Babylonia (the Code of Hammurabi, 1780 BCE), in Sanskrit documents in India (1500 BCE), and in Greece (the Hippocratic Oath/Corpus, 430–330 BCE). In the following centuries, the teaching of ethics was found in the curriculum in China (AD 618–906), Rome (Galen, AD 700), and

S. Sastrowijoto (✉) • S.Y. Soenarto • N.A. Mahardinata • W. Hartanti
Faculty of Medicine, Center for Bioethics & Medical Humanities, Universitas Gadjah Mada (UGM), Yogyakarta, Indonesia
e-mail: Cmhpe_fkugm@yahoo.com; Bioetika_2007@yahoo.com

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Arabia (al-Ruhani and Ibn Sina, Canon of Medicine, AD 900–1200). During the seventeenth century, the teaching of ethics was included in the curriculum in European medical education (Paris, Padua, Vienna, Leiden), and in the following centuries, America lead the way in medical education (Calman, 2007).

Since the 1960s, the emergence of the field of bioethics has been closely related to rapid progress in science and technology in the biological and biomedical sciences. The term *bioethics* was first used by Aldo Leopold (1949), a land ethicist and conservationist, and by Van Rensselaer Potter (1970), a cancer specialist. Bioethics can represent a radical transformation of ancient and traditional medical ethics (Callahan, 1995; Widdows, 2011).

Medical and health education in Indonesia was begun by the Dutch government in 1894 in Batavia/ Jakarta and Surabaya, 1913. After Indonesian independence in 1945, the Faculty of Medicine at Universitas Gadjah Mada (UGM) Yogyakarta was established by the government of the Republic of Indonesia as a public university. In 2012, there were 72 medical schools in Indonesia, located in various provinces. Ethics education for medical students in Indonesia has been improving, particularly since in 2000, when each school of medicine developed a unit or team of Ethics or Bioethics and Medical Humanities. The term *bioethics* was first formally used in Indonesia at the School of Medicine UGM (1997) in developing the Bioethics and Medical Humanities Team, chaired by Prof. S. Yati Soenarto, Ph.D. After a conference titled, "The Bioethics 2000: An International Exchange," organized by the School of Medicine UGM in collaboration with the Harvard School of Medicine, each medical institution developed a unit or team of Ethics or Bioethics, appropriate to their own situation or condition.

Here, the development of ethics, bioethics, and global bioethics, particularly in schools of medicine in Indonesia, will be clarified and discussed as it relates to education, research, health and medical care. Nationally and internationally, networking, partnerships, and collaboration among health and medical institutions and professional organizations will be briefly reported.

Organizational Development of Bioethics in Indonesia

The term *bioethics* was used at the national level in developing the Indonesian National Bioethics Commission, or Komisi Bioetika Nasional (KBN, 2004).[3] Before the KBN, the term *bioethics* was used at the School of Medicine UGM in developing the Bioethics and Medical Humanities Team (1997) and in a scientific meeting, "Bioethics 2000: An International Exchange." This successful scientific meeting was carried out at the School of Medicine UGM in partnership with Harvard Medical School and was followed by the development of the Indonesian Health Bioethics and Humanities Network, or Jaringan Bioetika dan Humaniora Kesehatan Indonesia, and their first national conference (JBHKI, 2000).[4] JBHKI holds periodical bi-annual meetings and the School of Medicine UGM is the permanent secretariat office. These meetings have been held in Yogyakarta (2000), Bandung (2002), Jakarta (2004),

Surabaya (2006), Medan (2009), and Semarang (2011); in 2013 the meeting will be held in Padang. Most schools of medicine in Indonesia has developed a team, unit, division, center, or department of Bioethics and Medical Humanities.

Ethical commissions related to medical and health research have been established, such as the "Komisi Nasional Etika Penelitian Kesehatan" (KNEPK, 2005), or the National Commission of Health Research Ethics, to develop various national guidelines of ethics in medical and health research. At the institutional level (schools of medicine or hospitals), there is the "Komisi Etik Penelitian Kesehatan Institusi" (KEPKI), or Institutional Review Board (IRB). At the national level of the Indonesian Medical Association there are committees related to ethical, disciplinary, and legal issues in the practice of medicine. Ethics committees related to education, particularly at the higher education institutions, have been developed and are quickly growing. At the schools of medicine, these committees for medical students, faculty members, and nonacademic or support staff have been established in some universities.

Internationally, Indonesia, in partnership with the other countries (Taiwan, NTU and TMU; Malaysia, USM; USA, University of Washington at Seattle, Harvard; The Netherlands, AMC; and Australia, Monash University), developed "UBHEN" (University Bioethics and Humanities Education Network). This network plans partnerships in teaching bioethics, particularly in master's programs in bioethics, collaborative research or studies, and conferences in bioethics.

Bioethics in Medical Health Education

The teaching of bioethics is still developing in Indonesia, especially in the face of global progress in science and technology. The medical curriculum developed in the first generation was science based, and in the second generation it was problem based, focusing on innovation and values; the third generation (system based) includes leadership (Frenk et al., 2010). Bioethics/values and innovation was implemented in Indonesia in 1997, and the Indonesian Medical Council approved national standards in basic medical education and postgraduate medical education, particularly in specialty training. Currently, medical education in Indonesia uses competence-based curriculum (CBC) to produce professional medical doctors, meaning that medical students must be trained and pass examinations in knowledge, skills, and behavioral competencies (WFME, 2003; KKI, 2004). Among 72 schools of medicine, if we ask who teach bioethics the responses of each school are various. This is our challenge, and it might also be the case in the other countries.

Teaching Bioethics in CBC Medical Education

Based on the International Standards in Medical Education (WFME, 2003), medical education as a continuum of education consists of basic medical education

(undergraduate and graduate) standards, postgraduate medical education (master's and doctoral degree programs and specialist–subspecialist training programs) standards, and standards of continuing professional development (CPD) program. All of these programs should be carried out through CBC, consisting of cognitive, psychomotor, and affective domains competencies. The teaching and learning process should be carried out in the school setting, clinical setting (primary, secondary, and tertiary care), community setting, laboratory setting, and any other setting in the practice of medicine. The methods of education should be innovative and include problem-based and integrated teaching and case discussion.

The teaching of bioethics should be integrated into all activities of medical students (lectures, tutorials, laboratory practice in biomedical sciences, clinical, bioethics/humanities, community, etc.) (Boelen, 1999; Cruess, Cruess, & Streinsert, 2009; Frenk et al., 2010; WFME, 2003). There is a clear relationship between the development of moral ethics, biomedical ethics, bioethics, and global bioethics and a new sense of medical professionalism in practice. These issues may be linked with medical education to avoid a misalignment between the health care system and the medical education system (Castellani & Hafferty, 2010; Frenk et al., 2010; Van Lyuk, 2005; Passi et al., 2010). In developing medical professionalism for future doctors, some issues should be seriously considered, such as curriculum design, student selection, teaching and learning methods, role modeling, and assessment methods (Passi et al., 2010).

There is agreement in Indonesia that teaching bioethics and medical professionalism should be carried out via a continuum process and program, in a conventional or innovative curriculum (Fig. 67.1).

The implementation of the teaching and learning of bioethics and medical professionalism is integrated into all student activities: lectures; tutorials; laboratory practices in biomedical sciences, bioethics and humanities; clinical skills, community health; and interprofessional skills. All activities in undergraduate and clinical rotation, in postgraduate programs (master's degree, doctorate, specialist, subspecialist) and in CPD are carried out in a continuum process.

Student assessment in the CBC program is based on students' competencies in the cognitive (C), psychomotor (P), and affective (A) domains (Fig. 67.2):

All schools of medicine in Indonesia are implementing this national guideline model of teaching bioethics, appropriate with the conditions of each institution. Examples include the following:

1. The Universitas Jendral Soedirman (Purwokerto) adapted the CBC and PBL. Teaching bioethics for medical students in the school of medicine is coordinated by the bioethics team. In 2007, a bioethics subdepartment was established under the Department of Public Health and Community Medicine. Teaching bioethics in a Block of Bioethics and Health Law (BHL) was organized by the subdepartment of Bioethics with five academic staff (two full-time and three part-time). In early 2012, the School of Medicine developed the Department of Bioethics, with seven staff (three full-time and four part-time from the other department's faculties). Bioethics teaching is now organized by the Department

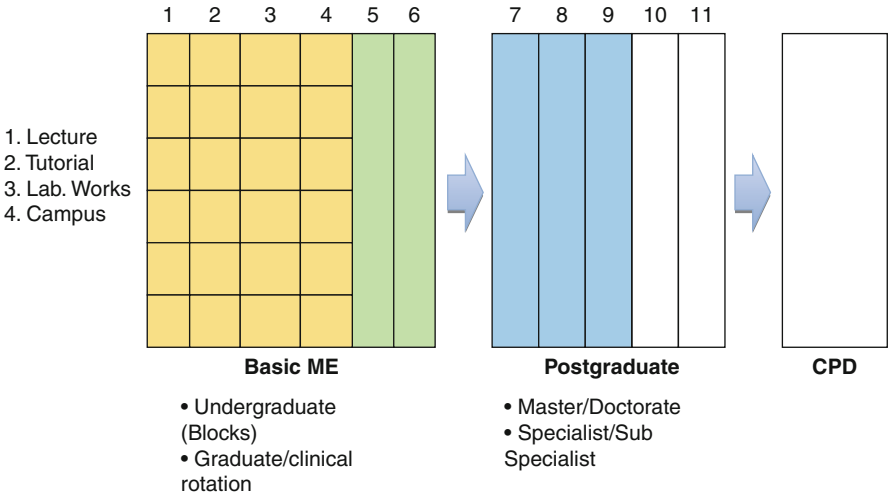

Fig. 67.1 A continuum process of bioethics teaching in medical education (basic, postgraduate, continuing professional development) (Sastrowijoto, 2006)

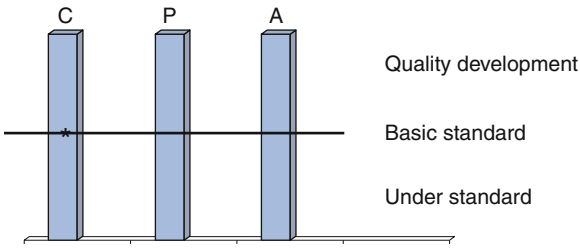

Fig. 67.2 Competence – based – curriculum examination (pass and failure). Minimal standards score of student should be achieved before graduation in all C, P and A competencies (Sastrowijoto, 2006)

of Bioethics, which collaborates with the Bioethics Team from the Faculty of Biology and with the Medical Education Unit.

2. At the Universitas Padjajaran (UNPAD, Bandung), the School of Medicine established the Bioethics and Medical Humanities Unit in 2001 to manage the teaching of bioethics for undergraduate medical students. This unit is supported by faculties from various departments, including obstetrics and gynecology, surgery, psychiatry, forensics, neurology, pediatrics, anesthesiology, internal medicine, and public health. Bioethics teaching is integrated into lecture themes, tutorial case scenarios, and other activities. The UNESCO core curriculum, developed in 2008, influenced the curriculum significantly. The school has used a fully student-centered approach since 2000. Each clinical department develops bioethics teaching related to their field of study and has the responsibility in teaching bioethics in the clinical rotation/clerkship and residential training.

3. At the Universitas Muhamadiyah Jakarta (UMJ), the Team of Bioethics, Medico Legal and Human Rights was established in 2007, and in 2011, related to teaching bioethics to undergraduate medical students, a new team was approved by the dean of the school, the Team of Bioethics–HELP (Humanity, Ethical, Legal and Professionalism). The team is chaired by Dr. dr. H. Anwar Wardy, Neurology and Forensic Medicine, and the secretary of the team is dr. H. Amir Syafruddin. Teaching of bioethics in integrated in various medical student activities in the CBC implementation.
4. At the Universitas Pembangunan Nasional "Veteran" (UPN) Jakarta, bioethics teaching is organized by the Medical Education Unit, in a continuum process for undergraduate medical students, with teaching and learning processes through various student activities such as lectures, card games, mini-seminars, role play, debates (devil's advocate), and workshops. Bioethics and medical humanities modules were developed to support the program, and all are organized by a program coordinator.
5. At the School of Medicine Gadjah Mada (UGM), teaching bioethics formally started in the competence-based curriculum (2002–2007), in a special block of bioethics at the end of first-year undergraduate education, Block VI. After a 5-year program evaluation, the result was that the student perception of this block of bioethics was that of lectures in theory and understanding of bioethics and medical humanities. Students have no experience with the internalization process, implementation in case discussion, or real cases in practice of medicine (the clinical setting); the program had little opportunity for students to mature in their character. With the new CBC (2007–2012), the teaching/learning process was integrated in varies activities of students, such as lectures, tutorials, laboratory practice in the new bioethics and humanities lab, clinical skills lab, community or public health lab, and on campus or in the teaching hospital (inter-professional training). In clinical rotation or clerkship and residential training, teaching bioethics was organized by each clinical department. On the other hand, faculty members (clinicians) should be trained in mentoring students, integrated with the apprenticeship concept, and the positive feedback is very important.

In teaching bioethics, particularly global bioethics in the era of globalization (liberal and free market), the appropriateness to local and national wisdom should be carefully considered, analyzed, and discussed. The concepts of local and national wisdom, tradition, culture, religion, and pluralism should be included in the teaching of bioethics, through small group and panel discussion, stimulated with cases (real or theoretically developed, simulation, etc.). The new sense of global bioethics is the concept of bioethics involving national ideology, philosophy, and wisdom, cultures, traditions, religions, and pluralism. These wisdoms, such as Pancasila (Indonesia), Rukun Negara (Malaysia) Semaul Udong (Korea), Confucianism (China), Hinduism (India), and Buddhism (Thailand), should be implemented to balance the liberal and free market concept of bioethics. In the long run, the balance of Western bioethics and Eastern (Asia) bioethics could minimize or eliminate

global injustice and inequities, particularly for disadvantaged populations worldwide, for the happiness and harmony of individuals, families, and communities in the future (Sastrowijoto, 2010).

Graduate Certificate, Graduate Diploma, and Master's Program in Biomedical Ethics

In responding the needs and demands of bioethics teachers, the development of graduate certificates, graduate diplomas, and master's programs in bioethics should be a priority not only in Indonesia but also in all Asian and Asian Pacific countries. The importance of the program is related to the moral obligation and responsibility of the university to their social mission (Horton, 2010). With the advance of science and technology, social justice needs to be rediscovered; a "remoralization" of health professional education is needed (Frenk et al., 2010) and international standards in medical education (WFME, 2003).

Nationally, graduate certificate, graduate diploma, and master's programs in bioethics have been carried out at the UGM and could be developed at the other universities (e.g., University of Indonesia, University of Airlangga, and University of Padjajaran). Internationally, these four universities have collaborated with University of Washington in Seattle. UGM is also developing partnerships with TMU in Taiwan, USM in Malaysia, and Monash in Australia to have an international master's and PhD program in bioethics and medical humanities, in collaboration with Harvard, UW Seattle, and AMC Amsterdam. The road map of the curriculum could inform the development of the curriculum at USM, TMU, NTU, and Monash, and vice versa.

The road map of the curriculum of the Graduate Diploma and Master Program in Bioethics and Medical Humanities consists of eleven blocks and includes international graduate certificate, diploma, master's, and PhD programs in bioethics and medical humanities. It is a collaboration between UGM, TMU, USM, NTU, and Monash, in partnership with HMS, UW/ Seattle, and AMC (2013) (Table 67.1).

The objective of this master's program in bioethics is:

- To educate the participants with important issues related to bioethics (Humanity, Ethical, Legal, and Professional Behavior aspects, HELP) of local, national, regional, and international health care, research, and education.
- To pay specific attention to the Asian–Asian Pacific national and regional wisdoms, traditions, cultures, and religions, as a pluralism.
- To promote the debate and exchange of experiences and ideas among participants and staff, and the possibilities of developing collaboration or partnership.
- To prepare participants in teaching and training in bioethics at their own institutions, applying bioethical concepts in health care, research, and education.
- To promote the participants in exploring their national wisdom to support the continuing development of the new concept of global bioethics for the future generation to eliminate the global inequities and injustice

Table 67.1 The road map of the curriculum (UGM, 2013)

Out put	Blocks		Contents	Credits
Graduate CERTIFICATE 33 credits	Core	I	Bioethics, General Theory and Methods	4
		II	Bioethics, the Development and Its Applications	3
		III	Bioethics, 'HELP' Aspect Approach (Humanities, Ethics, Legal, Policy/ Professionalism)	3
	Core Specific	IV	Bioethics in Medical – Health Care	5
		V	Bioethics in Medical – Health Research	5
		VI	Bioethics in Medical – Health Education	4
		VII	Bioethics in Global Health System	4
	Optional	VIII	Bioethics 'HELP' Aspect Approach, Case, Discussions and Lectures	5
Graduate DIPLOMA 37 credits	Core	IX	Writing – two case reports – one literature review Inter-university activities (Research, Symposium, Seminar, Video Conference, and Publication)	4
MASTER in Bioethics 45–50 credits		X	Research Methodology and Biostatistics	3
		XI	Thesis for Master in Bioethics	
			– By Course (Research Proposal)	5
			– By Research (Research)	5
				50

The implementation of this program:

- The type and timeline could be part time or full time. The first graduate in the graduate diploma at UGM was part time, due to the fact that most of the participants must follow the regulations of their institution as lecturers and even as managers related to their limited human resources.
- The format of program could be a joint, double, or dual program between UGM, TMU, USM, NTU and Monash.

Bioethics in Medical Health Research

Currently, research in School of Medicine UGM, institutionally, nationally, and internationally is coordinated by the dean's office in inter-country or inter-center collaborative studies. The rapid advanced of science and technology in medicine, clinical trials, and translational research encompasses a complexity of medical professionalism in the social complex system (Campbell, Chin, & Voo, 2010; Castellani & Hafferty, 2010; UNESCO, 2008). In comparing the capacity building of each medical institution, they must develop strong biomedical (biomolecular) studies, clinical studies, and public health studies and improve translational research collaborations and partnerships with various stakeholders. In this case, the A-B-C-F-G partnership – A (Academicians/University), B (Business),

C (Community), F (Funding Agencies/Foundation), and G (Government) – and the possibility of bioethical issues must be seriously considered (Sastrowijoto, 2011).

There are some issues that should be analyzed, clarified, and discussed to improve the quality standards of studies, scientifically and ethically:

1. The ethical and regulatory aspects of health research, e.g., (a) scandals and tragedies in health research, (b) guidelines in health research involving human and animal participants, (c) health research in certain populations (communities, pregnant women, children, captives, those with impairments, etc.).
2. Ethics imperialism, e.g., in international collaborative clinical trial/translational research, from developed to developing countries, usually engaging cross-cultural ethics. Are ethics local or global?
3. Issues of conflict of interest: in international or inter-center studies, before the study will be started, some kinds of agreements should be considered and agreed upon, e.g., material transfer agreement (MTA), the owner of the specimen, data, equipments, the right of researcher(s), sponsor(s), research participants, authorship, patency, product(s) marketing, etc., and all should be based on fair sharing benefit principles.
4. Scientific misconduct, informed consent, report writing, and publication should be seriously considered.
5. The needs of the DMC (Data Monitoring Committee), DSMB (Data and Safety Monitoring Boards), and CIC (Conflict of Interest Committee) should be considered and developed by sponsor(s) and author(s) if necessary.
6. How should the A-B-C-F-G partnership be managed to eliminate or minimize financial conflict of interest and other issues of interest among parties?

In clinical trials/translational research, the clinician is also a researcher, and also a guardian of the patient's health and welfare, including safeguarding the freedom and safety of the patient, who is also the research participant. In gaining informed consent, the following must be seriously considered: Who is to be served of his/her two masters? Indonesia is one of many countries that is a common site of clinical trials. In balancing global bioethics in a global era of corporatization of education, research, and health care, there is a new sense of global bioethics to minimize or eliminate global injustice and inequities, particularly for those who are relatively powerless and who suffer most from these inequities. It is our responsibility to sustain the planet for future generations. They should live in a happy and harmonious world (Campbell et al., 2010; Sastrowijoto, 2010, 2011; Widdows, 2011). See Fig. 67.3.

Activities Related to Bioethics

Some activities related to bioethics at the institutional, national, regional, and international level, such as conferences, symposiums, workshops, courses, and scientific oral or poster presentations, will be briefly reported. National conferences in bioethics have been carried out regularly by JBHKI, regionally by Asian Bioethics Conferences, internationally in IAB World Conference in Bioethics, and by the UNESCO Chair of Bioethics.

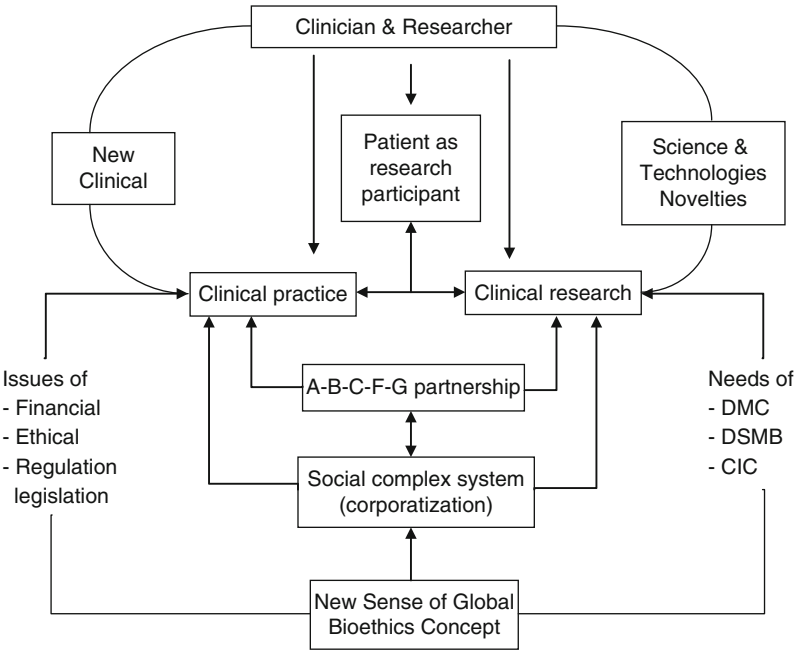

Fig. 67.3 The relationship of clinical trials and A-B-C-F-G partnership and the new sense of global bioethics

Examples from Some Schools of Medicine

1. Activities in Bioethics at the School of Medicine UPN "Veteran" Jakarta
   (a) "Teaching Bioethics and Medical Humanities at UPN "Veteran"." Oral presentation (2008)
   (b) "Role Play as the Instructional Media on Doctor's Professionalism in Teaching Bioethics, at UPN Veteran"
   (c) "Malpractice Victims Gathering as the Instructional Media on Doctor's Professionalism and Patient's Safety in Teaching Bioethics at UPN "Veteran"."
   (d) Fifth JBHKI conference (2009)
   (e) "Building Perspective Principle Based Ethics in Medical Student through Role Play Method." Oral presentation, 10th World Congress of Bioethics, Singapore (2010).
   (f) "Strategies and Instructional Media in Bioethics Teaching." Oral presentation, National Workshop USM (2011).
   (g) "Learning of Understanding in Culture through Game: A Study of Bioethics and Medical Humanities at UPN "Veteran"." Sixth JBHKI conference, Semarang.
   (h) "Devil's Advice as Learning Media on Bioethics and Medical Humanities at UPN "Veteran"." Oral presentation

(i) Poster presentation: "Field Study as a Mean of Developing Student's Responsibility for Their Professional Behavior."
(j) "Clinical Ethics Workshop to Review Medical Student (7th semester) at UPN "Veteran"."

2. School of Medicine UNSOED, Purwokerto
Beginning in 2008, research on "A comparative study on bioethics teaching between students from the previous curriculum (semester credits system) and the new curriculum (competence-based curriculum)." As of 2012, seven studies have been carried out; three have been analyzed and four are ongoing. More students have expressed interest in supporting bioethics studies.
3. School of Medicine UNPAD, Bandung
Some research, survey, and reviews articles, including the following:
(a) Multidisciplinary approach for bioethics education at UNPAD, from curriculum to online journal (2009–2012)
(b) Baby blues syndrome as an infanticide causal factor in the Conundrum of Indonesian justice system (2011)
(c) Implementation of bioethics education in residential trainee program (2011)
(d) Portfolio for assessing professional behavior (2010)
(e) Ethical issues in the case of high-cost public medical school in Indonesia (2010).
(f) The ethics and legal dilemma of clinical supervisory activities (2009)
(g) The Ethics-medico legal aspect of "forcep dismissal" of classical forensic in emergency unit (2009)
(h) Dilemma of the application of DNA paternity testing involving extra-marital children in Muslim society (2009)
(i) Social problem of disaster victim identification in tsunami Pangandaran (2009)
(j) Forensic aspects of the missing in post-conflict and post-disaster scenarios: Indonesian perspective (2007)
(k) Disaster victims identification in cultural and religions perspective (2005)
(l) Can DNA test for kinship determination could be accepted by Muslim law? (2004)

Future research, surveys, review topics may include:
(a) Indonesian perspective on various ethical issues and norm
(b) Education and assessment of professional behavior in residential trainee.

4. School of Medicine UGM, Yogyakarta.

Activities

A. Seminars, workshops, symposia
- 2000
  - Bioethics 2000: An International Exchange (Harvard Medical School – Gadjah Mada Medical School)
- 2007
  - Seminar and workshop: International Exchange on Teaching Bioethics for Medical Students.

- 2009
  - Seminar and workshop: Teaching Bioethics and Medical Humanities in Clinical Setting (AMC and GMC; TMU; USM; UW Seattle, UGM)
- 2010
  - Graduate courses in Bioethics and Medical Humanities (Grad. Certificate and Grad. Diploma) – (AMC, TMU, USM, UW, Harvard, UGM)
  - Will be continued to postgraduate program (master) for bioethics and medical humanities (BMH)
  - TMU suggested/ supported – Regional Master Program
- 2011
  - ABC meeting in Taiwan and visit/collaboration with TMU, NTU, NCKU, NCU, etc.
  - Developing "BEN" (Bioethics and Medical Humanities Education Network) – TMU, USM, AMC, UW, UGM. MEEN/ BMHEN?
    MEEN (Medical Ethics Education Network)
    BMHEN (Bioethics and Medical Humanities Education Network)
  - USM – Meeting: Seminar on Ethics Teaching Common Approaches for Regional Teaching: "Ensuring a Sustainable Tomorrow"
  - Bangkok meeting. Asian Pacific Bioethics/ UNESCO
- 2012
  - Symposium number 42 in 11th World Congress of Bioethics (Rotterdam, June 26– 29 2012) "Thinking Ahead: Bioethics for the future – challenges, changes, concepts"
  - Topic: The Graduate Diploma and Master Program in Bioethics and Medical Humanities: Partnership of UGM-TMU-USM and its Collaboration with UW-Seattle and AMC-Amsterdam.
    A New Sense of Global Bioethics for the future.
    Note: – Courses on Bioethics by WHO–SEARO (New Delhi),
  - UNESCO (Bangkok), NIH (India, Jakarta) etc. UI and UGM
  - UW at Seattle – UI, UNAIR, UNPAD, UGM

B. **Research Activities**

- 2000
  - Similarities and differences of the faculties' and students' perception on teaching bioethics, Harvard/ UGM – Fulbright
- 2003
  - End of life: medical care in Indonesia. Harvard/ UGM – Aminef/ Fulbright
- 2003–2008
  - Tobacco Cessation in Indonesia/ Quit tobacco – Arizona/ 2009–2014 UGM – NIH/ Fogarty
- 2003
  - Field testing "Teaching Guideline and Case Material" for SEARO countries – WHO.

- 2004–2006
  - Health system reform and ethics: Private Practitioners in 2006–2008 Poor Urban Neighborhoods in India, Indonesia & Thailand. DANIDA –Aarhus – AIIMS – DANISH – Naresuan – Gadjah Mada.
- 2005
  - Refinement and Dissemination of the Teaching Guideline and Modules for the Medical School in Indonesia – WHO
- 2006–2007
  - Supporting young children in disaster area/ Aceh. Bernard Van Leer – The Netherland.

Future Studies

1. Pro-life and pro-choice attitudes about **abortion** among religions, gynecologists, women, etc. in Yogyakarta.
2. **Euthanasia** – perception among practitioners, patients, and the family in Yogyakarta.
3. Medical **tourism**, medical practitioners, patients, national policy (authority) perception and action.
4. Exploring local/national wisdom, related to components of **professionalism** in Indonesia (*iman*: faith, belief, creed; *luhur*: noble, nobleness, budiluhur: noble-mind, beriman: faithful).

Other schools of medicine have experienced various degrees of progress depending on their situation and the condition of various available resources and their own school's programs. UI, UNAIR, UNHAS, and USU have various researchers and activities and will likely develop graduate diploma and master programs.

Bioethics in Medical-Health Care

All Indonesian medical and health care institutions, public and private, must appropriately implement in their activities according to the regulations and guidelines developed by the Indonesian Medical Association (Code of Ethics Conduct) and regulations from the central and local government. The Medical Practice Act (2004) requires each medical-health care institution to develop its own local and institutional standard operational procedure (SOP) based on the available resources of human expertise, buildings, laboratories, medical-health equipment, and so on.

Because Indonesia is a large country, a main issue is the allocation of scarce resources. In discussing medical-health care issues, Indonesia is faced with conflicting problems in the health care system. First, health care and the education system must respond to the increasing needs and demands of health care with the highest medical and health technology (e.g., genetic diagnosis and treatment, organ transplantation, etc.). Second, for some rural areas of Indonesian people, even basic health care services is not yet well distributed.

In developing national regulations and guidelines and the institutional SOP, we adapted various available scientific resources, such as the "Clinical Ethics for the Medical House Officer, General Principles and Cases" (Forrow, Zand, & Baden, 1999), "Clinical Ethics" (Jonsen, Siegler, & Winslade, 2010), and "Medical Ethics and Law: The Core Curriculum" (Hope, Savulescu, & Hendrick, 2009), as appropriate with Indonesian national wisdom, cultures, traditions, religions and pluralism.

Global Bioethics Challenges, Changes, and Concepts for the Future

At the beginning of the twenty-first century, we must consider the effects of two different and conflicting processes. First, rapid progress in medical science and technology has made available new and more effective diagnosis and treatment of diseases that were once considered incurable. Second is the global health condition marked by injustice and inequities due to the poverty and the seriously lack of access to health care (UNESCO – IBC, 2009; UNESCO Report, 2010; Frenk et al., 2010). Another condition is the concept of the free market idea in the era of globalization, which is closely related to freedom, liberty, autonomy, individualism, liberalism, capitalism, colonialism, imperialism, and **corporatization** or **commercialization** of health care. Other issues are the implications of the new ways of corporatization, colonialization, capitalization, and imperialization from developed to the developing and from advantaged to disadvantaged groups of populations in a country and among countries; all are emerging challenges to bioethics and must be responded to by changes in the global mindset, developing a new concept of global bioethics in the local and global context.

Bioethics is considered a systematic multi-disciplinary field of study that is closely linked to various science and technological developments and is strongly related to a wide range of issues: politics, economics, humanities, education, environment, tradition, cultures, religions, pluralism, and globalization (Nasim, -). The economic and political positions of developed countries and advantaged population groups are growing stronger. They are exploring natural resources (forestry, mining, etc.) and developing big companies and factories with large capital investments (Ronald Cohan, 2012), employing the disadvantaged group of population without sharing benefits appropriately and sometimes inhumanly. Global warming and climate change may present further natural, political, economic, psychological/mentally, ethical, legal, and human disasters and crises (Nasim, -; UNESCO – IBC, 2009; UGM, 2010).

A global mindset is the ability to perceive, analyze, and decode behaviors and situations in multicultural contexts and to use those insights to build productive relationships and organizations across cultural boundaries.

Why this new concept of bioethics for the future development? First, the rapid progress of science and technology, including biomedical or molecular studies, began in the 1960s and 1970s, followed by the overexploitation of natural resources (oil and wood), which has lead to economic growth. On the other hand, global

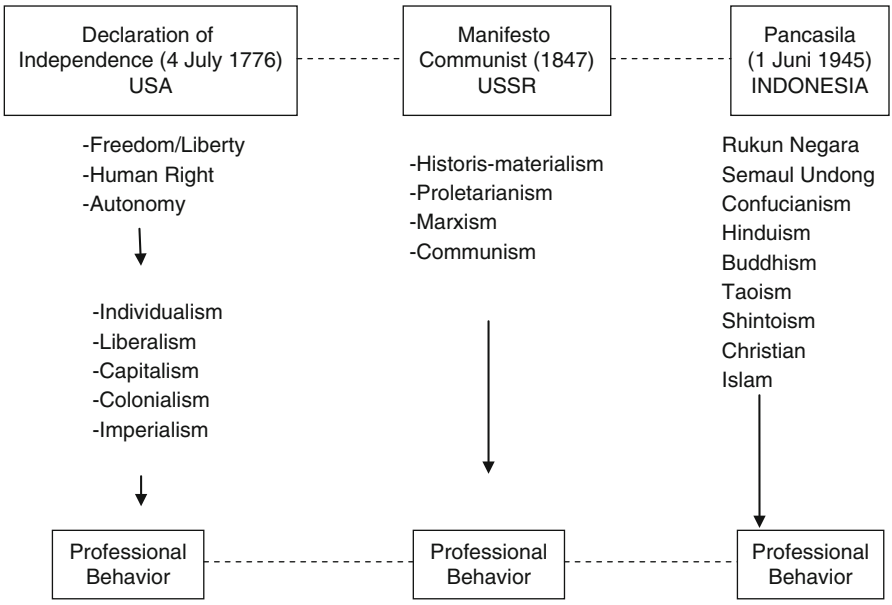

Fig. 67.4 The development of professional behavior based on their own local/national wisdoms. Contribution in social complex system and global professional behavior

climate change and various disasters also resulted. The other result of the overexploitation of natural resources is the fragility of "our one and the only world." We must also consider our moral responsibility for future generations. Another issue is the commitment of universities to the health of the disadvantaged and other underserved people. Have some universities come to do research "on people" rather than "for people"? The goal of the UN in this decade is for better education and health for all, adequate shelter, respect for human rights, rational use of resources, a culture of peace and nonviolence, and international solidarity (Blumental and Boelen, 2001).

The Universal Declaration on Bioethics and Human Rights stresses the need to reinforce international cooperation in the field of bioethics, taking into account, in particular, the special needs of developing countries, indigenous communities, and vulnerable populations.

How should we respond? Serious discussion should involve local or national wisdoms, ideologies, philosophies, cultures, traditions, and religions to develop a new concept of global bioethics. In developing a new concept of global bioethics, one starting point might be to discuss and analyze the differences and similarities between three basic national philosophies: the Declaration of Independence (USA, 1776), the Communist Manifesto (USSR, 1847), and Pancasila (Indonesia, 1945) (Fig. 67.4.). The Declaration of Independence is based on the philosophy of freedom (liberty, human rights, and autonomy); the Communist Manifesto is based on histories of materialism, proletarianism, and communism.

Pancasila, the state ideology of Indonesia, is based on the following five principles:

1. Ketuhanan Yang MahaEsa (Value of divinity or diety or faith)
2. Kemanusiaan yang adildanberadab (Value of humanity)
3. Persatuan Indonesia (Value of unity)
4. Kerakyatan yang dipimpin oleh hikmat kebijaksanaan dalam permusyawaratan perwakilan (Value of deliberated democracy)
5. Keadilan sosial bagi seluruh rakyat Indonesia (Value of social justice for all)

The ideology of *Rukun Negara* (Malaysia) consists of:

1. Kepercayaan kepada Tuhan (Belief in God)
2. Kesetiaan kepada Raja dan Negara (Loyalty or allegiance to king and country)
3. Keluhuran perlembagaan (Grandeur or lofty or uprightness of the institution)
4. Kedaulatan undang-undang (Act's sovereignty)
5. Kesopanan dan Kesusilaan (Good manner and morality)

Semaul Undong (Korea) is the spirit of the Korean people:

1. Change of Korean people's mindset
2. Innovation in every activity
3. Hardworking behavior
4. Honesty
5. Collective spirit

Confucianism (Boyle & Theol, 2004), the origin of morality in China, values: Traditional Chinese thought directed to social, political, educational and moral action – as the ancient Chinese medical ethics. The origin of morality in China are REN, YI, LI, and ZHI.

The contemporary China in facing modern bioethics debate such as moral status of the fetus, abortion, healthy birth and eugenics, physician – patient relationship, death and euthanasia, reproductive technology and genetics, basically the same with the original morality in China (REN, Humaneness, YI- Righteousness, LI-Propriety and ZHI –wisdom) – a virtuous person.

1. REN (humaness: love, humanity)
2. YI (righteousness: rightness, wise, justice)
3. LI (propriety)
4. ZHI (wisdom)

The ideology of *Taoism* (Hsin, Hsin Chen, & Macer, 2004) includes:

1. The importance of "quality of life and quality of death"
2. Letting life and death follow its natural course
3. Seeing death as a return to the nature

The people of Taiwan may adapt ancient the Chinese philosophy of Confucianism, Buddhism, and Taoism as their value system.

Hinduism:

1. Nature as the teacher, enriching human's wisdom.
2. A diverse body of religion, philosophy, and cultural practice native to and predominant in India, characterized by a belief in reincarnation and supreme being many forums and nature, by the view that opposing theories are aspects of one eternal truth, and by a desire for liberation from earthly evil.

Buddhism:
Vertical philosophy of nature:
1. Arupadhatu (wisdom)
2. Rupadhatu (enlightenment, free from carnal desire)
3. Kamadhatu (carnal desire)

Japan:
Shintoism and Buddhism:
1. Meiji government, with the slogan of "a rich country and strong army and navy"
2. Western trades – Christianity (The Netherlands, Russia, England, France, America), in equal treaties.

Christianity:
1. All of the God's creations provide comparable values.
2. The moral excellence or virtue of theology of faith, hope and love or affection.
3. The virtue of Christianity are prudence, justice, temperance, fortitude and excellence.
4. There are Beato and Santo related to miracle of healing.

Islam:
1. Human beings are the crowning creation, as a God's agents are endowed with responsibility in the care and stewardship of others (humans, animals, plants, microbes, and the environment)

These national wisdoms could be globally organized to develop new principles based on **social investment**, called "A New Sense of Global Bioethics." This new concept would balance the old sense of global bioethics, which is based on **capital investment** and the liberal free market.

Professional practitioners must develop clinical and ethical decisions that are scientifically, ethically, legally, and humanly based (Sastrowijoto, 2005). Currently, the ways of practicing medical professionalism have developed into various competing types or clusters and might be influenced by the concept of neo-materialism, neo-individualism, and neo-liberalism in the globalization era through corporatization and commercialization of health care, research, and education (Castellani & Hafferty, 2010). The type of medical practice that could be observed or studied in Indonesia could be predicted to be not much different than what had been studied by Castellani and Hafferty in the US.

The contribution of local and national wisdoms and collaboration could serve as a strong foundation for a new sense of global professional behavior and a new concept of global bioethics in a challenging era in the twenty-first century (Fig. 67.5.).

Discussion

Teaching bioethics and professional behavior should be in a continuum process for the medical profession, using "heart," "head," and "hand," thought and feeling. When students and residents were asked about the teaching of professionalism, they said, "We are being asked to be professional in an unprofessional environment. Faculty should be subjected to the same criteria for assessment as students and

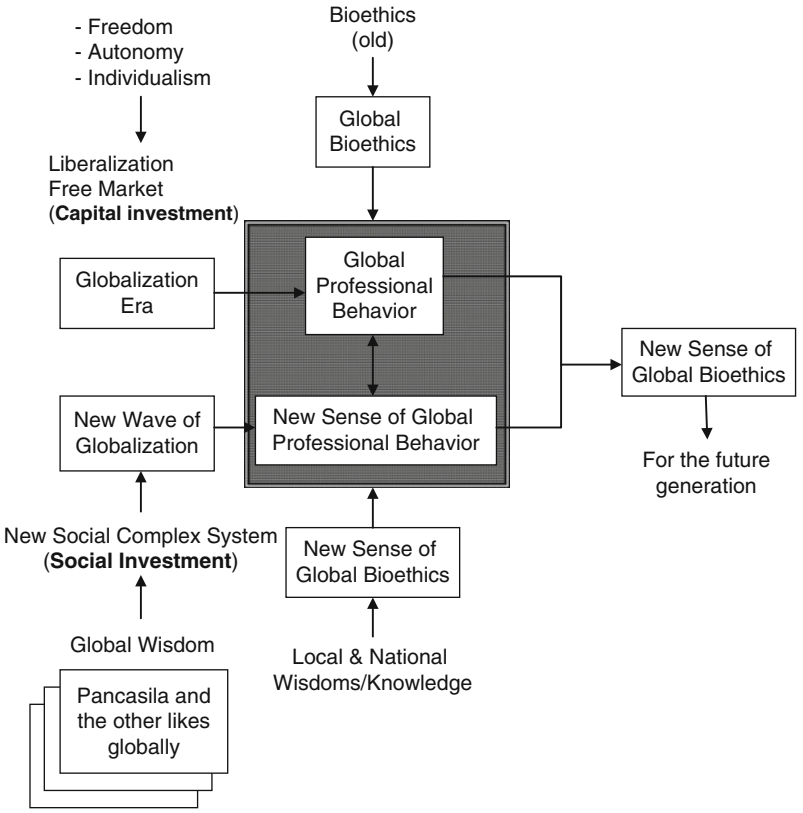

Fig. 67.5 Development of new sense of global bioethics, based on local/national wisdoms from around the world

residents" (Hundert et al., 1996; Hafferty et al., 1994; Sterm, 1998). Related to this issue, discussion of training cases should be carried out not only by the students and residents but also by all faculty members and nonacademic staff. The main goal is to improve institutional professionalism.

Basic concepts of moral/ethical principles (respect for person/autonomy, beneficence and non-maleficence, and justice) are influenced by globalization. One of definition of global bioethics is the ethics or the voice for those who are relatively powerless and who suffer most from global injustice, the poor and vulnerable (Widdows, 2011).

Students had the following views (Stigler et al., 2010) on professionalism in the twenty-first century: (1) students agreed on knowledge, skills, and attitude to be achieved by all doctors before graduation; (2) students should be involved in the entire process; (3) students from low income countries should have the benefit from such an initiative; (4) interprofessional forums should include medicine, nursing, pharmacy, and allied health professionals together; (5) students from all professions

and all countries should be involved in a joint planning mechanism. These students' views are worth including in developing medical professionalism in future doctors. A systematic review is provided by Passi et al. (2010). The development of medical professionalism might include (1) student selection, (2) curriculum design, (3) teaching and learning methods, (4) role modeling, and (5) assessment methods.

The Belmont Report (1979) lists the following basic moral principle of ethics: (1) Respect for person, (2) Beneficence, and (3) Justice. The following concepts (Beachamp TL and Childrens JT, 1979/ 1983/ 1989/ 1994/ 2002) have been put forward as the basic moral principles of biomedical ethics: (1) respect for autonomy, (2) non-maleficence, (3) beneficence, and (4) justice. A concept of biomedical ethics as an abstract "mantra" is empty of normal ingredients of moral concern without grounding in dominant ways of people in their day-to-day lives.

The term *biomedical ethics* developed into *bioethics* (Khushf, 2004). In the global era, *bioethics* became *global bioethics*, with various meanings, perceptions, and perspectives. It is different between West and East, and also between the advantaged and disadvantaged population groups. Today, challenges and changes should be responded to with a new concept, especially for the future generation. The basic moral principles in the twenty-first century may consist of (1) belief in God or faith, (2) respect for others (human, animal, plant, microbes, and environment/nature), (3) beneficence, (4) non-maleficence, and (5) social justice.

Conclusion/Summary

In Indonesia, the development of ethics, biomedical ethics, bioethics, and global bioethics has proactively engaged by the School of Medicine UGM in partnership with others in the face of challenges, changes, and concepts for the future generation.

Global injustice and inequities should be minimized or eliminated through the development of a new sense of global bioethics, involving local and national wisdom, traditions, cultures, religions, and pluralism. This new concept is an appropriate approach to responding the need and demand for qualified teachers, not only in Indonesia but also for other parts of the world.

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Iran, Islamic Republic of

68

Alireza Bagheri

Introduction and Historical Background

The Islamic Republic of Iran is in the Middle East region, with a land area of 1,648,000 km^2 and a total population of 74 million. The per capita gross domestic product (GDP) was about 4,540 USD in 2009 (World Bank, 2009), with health expenditures at 5.5 % of GDP (WHO, 2009) and literacy rate at 76 % in 2002 (National Literacy Policies, 2002).

Like many other countries, there is increasing interest in bioethical issues in Iran. These issues have attracted scholars from different backgrounds, including medicine, biology, law, philosophy, and religion, however, physicians are the leading

A. Bagheri
School of Medicine, Tehran University of Medical Sciences, Tehran, Iran
e-mail: bagheria@tums.ac.ir; bagheria@yahoo.com

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figures in bioethics. Mostly, topics in medical ethics have been discussed in recent years. Based on the importance of Islamic opinions on different bioethical issues, Islamic scholars are involved in the discussion of issues such as abortion, artificial reproductive technologies, brain death, and organ transplantation. They have been called upon in early discussions by specialist physicians who seek their official *fatwa* on the issues. Given the fact that Iran is becoming a leading country in terms of overall growth of science and technology in the region, attention has been called by scientists to the ethical issues posed by recent scientific developments, and ethics experts urge policy makers to seek the necessary infrastructure to address related ethical issues.

This chapter provides a map of bioethics in Iran, including current developments, infrastructure, special issues, and future challenges. Before Islam (625 AD), Iranians were Zoroastrian, and religious teaching emphasized the behavior and character of medical doctors. For example, in a section of *Avesta*, the holy book of the Zoroastrians, entitled "Vendidad," there are explanations about the character of physicians and some ethical issues in medicine (Larijani & Zahedi, 2006). An analysis of the qualities of the ideal physician in the sixth century AD can be found in the Sassanian Persian's encyclopedia, *The Dinkard* (Najmabadi, 1987). After the introduction of Islam, based on moral Islamic teachings that govern all aspects of society, Muslim physicians inspired by religious encouragement put more emphasis on ethical values in their medical practice. The prophet of Islam, *Mohammad* (PUH), announced the perfection of morals as the aim of his appointment. He said, "I have been appointed as the prophet for the completion and perfection of morals" (Al-Mustadrak, Vol. 2, 1002 CE). Going back to the flourishing time of Iranian (Irani) medicine in medieval times, there was great attention paid to the ethical issues in medicine by the Iranian physicians such as Razes (865–925 AD) and Avicenna (Ibn Sina) (980–1038) in their books, teachings and medical practices. For centuries, their medical ethics instructions were dominant in the teaching and practice in medicine, and they were followed by other prominent Muslim physicians. A review of contemporary bioethics in Iran shows that the first academic book on medical ethics was authored by a physician at Tehran Medical School in 1963, *Medical Ethics and Customs*. In this book, Dr. Etemadian discusses ethical issues in medicine such as abortion, privacy, the doctor-patient relationship, confidentiality, and the moral character of physicians (Etemadian, 1963).

Development of Bioethics

Bioethics Activity: Medical ethics, led by physicians and health authorities was the main force behind the bioethical activity in the country. In the 1990s, ethical questions were raised by the application of assisted reproductive technologies (ARTs) and organ transplantation. Hence, the need to address related ethical issues became an emerging issue for the health authority. Therefore, some bioethics initiatives were the starting point to create the necessary infrastructure in biomedical ethics in the country. To this aim, the Center for Study and Research on

Medical Ethics was established by the Ministry of Health in 1993. The center was the first official organization working on ethical issues in medicine. However, it should be noted that the word *bioethics* and its translation into Persian as "Akhlaghe Zisti" appeared in scientific articles in late 1990. With the increasing interest in medical research in 1990s, the National Ethical Codes in Biomedical Research were compiled in 1997 (Farhadi et al., 2000).

In 1998, the National Research Ethics Committee to review research protocols was established by the Ministry of Health, and in the same year via an administrative order, all universities and research centers were instructed to establish an ethics committee for research. Currently, the National Research Ethics Committee is undergoing a major revision in terms of its structure, membership, and working methods. The development of national ethical codes in biomedical research and the establishment of research ethics committees across the country are two important tasks of the Center for Study and Research on Medical Ethics. The first international congress of medical ethics in Iran was held in 1994 and was a step forward towards promoting ethical discussions at the national level. The participation of physicians, lawyers, philosophers, religious scholars, and health policy makers created a platform for a multidisciplinary discussion on various bioethical issues and raised national awareness of bioethical issues.

In 2004, the Research Center for Medical Ethics and History of Medicine was formed by Tehran University of Medical Sciences. This center has played a great role in bioethics education and research. The center developed the national medical ethics strategic plan and bioethics network in the country, with participation of religious scholars, physicians, philosophers, legal experts, and sociologists. The center holds national seminars, workshops, and courses on different bioethical topics. It also has offered a Master of Public Health (MPH) course with a major in medical ethics since 2004, which has been a successful course for mid-career physicians. A PhD course on medical ethics designed for physicians, dentists, and pharmacists was developed by the Ministry of Health in 2008. Currently, there are three universities offering a PhD in medical ethics. The Second International Congress of Medical Ethics in 2008, organized by this center, provided a platform to introduce what had been achieved so far in the country and to promote ethical discussions and awareness. It paved the way for future developments. The establishment of the departments of medical ethics in the universities, national and regional research ethics committees, courses, book publications, and related bioethics associations and committees at university and national level are among the steps that have helped to promote medical ethics in Iran.

Currently, there are 47 public medical schools across the country that offer a two-unit compulsory course on medical ethics for undergraduate students (Ministry of Health, 2011). However, there is no compulsory bioethics education and nursing ethics for nursing students. Currently, the nursing curriculum is under review by the Ministry of Health and Medical Education. One issue is the consideration to add nursing ethics as a compulsory course for students in the faculty of nursing. The Specific National Ethical Guidelines for Biomedical Research were compiled in 2005. They include Ethical Guidelines for Clinical Trial, Ethical Guidelines for

Research on Minors, Ethical Guidelines for Genetic Research, Ethical Guidelines for Gamete and Embryo Research, Ethical Guidelines for Transplantation Research, and Ethical Guidelines for Research on Animals. Along with these initiatives, some other universities, such as Shahid Beheshti Medical University in Tehran, Shiraz Medical University in Shiraz, and Tabriz Medical University, have established a dedicated center working on ethical, legal, and philosophical issues in biomedicine in their universities. Following the UNESCO recommendation to member states, a National Bioethics Committee was established under the UNESCO national commission in 2001 (Zali et al., 2002; National Commission of UNESCO, 2010). In the past few years, the number of institutes and research centers focusing on medical ethics has increased followed by a growing number of academic journals of bioethics. For instance, the *Iranian Journal of Medical Ethics and History of Medicine*, as the first professional journal in medical ethics in Iran, was published in spring 2008. This is an online, bilingual (Farsi and English) journal. There are several scientific journals, including *Hakim*, *Journal of Medical Law*, and *Iranian Journal of Ethics in Science and Technology*, publishing peer-reviewed articles on bioethical issues in Persian. Recently, some active bioethical groups have been organized, including the Iranian Association of Ethics in Science and Technology (http://iranethics.irost.org/) and the Iranian Association for Medical Ethics. The Avicenna Prize for Ethics in Science is an initiative by the Islamic Republic of Iran to acknowledge the importance of ethics in science and technology and to become involved in the international bioethical discussion. The prize consists of a gold medal of Avicenna along with a certificate, the sum of $10,000, and a 1-week academic visit to Iran, which includes the delivery of speeches in the relevant academic gatherings. The prize is awarded every 2 years. It is intended to reward the activities of individuals and groups in the field of ethics in science. The prize owes its name to the renowned eleventh-century Iranian physician and philosopher of medieval Islam Ibn Sina (980–1038), known in Europe as Avicenna. A healer and a humanist, Avicenna developed an exemplary holistic approach that captures the essence of ethics in science (UNESCO, 2011).

Bioethics Infrastructure

In Iran, like many other countries, ethical dilemmas in health care were a starting point for bioethical discussions. However, unlike many other countries, the leading figures were medical doctors and not philosophers, lawyers, or sociologists. This is the reason why, in comparison to other disciplines in bioethics such as environmental ethics, only issues in medical ethics have been discussed in depth, and the infrastructures have been established in medical schools. The dependency of medical ethics on socio-cultural and religious issues has urged policy makers in Iran to take these issues into account and to utilize the rich Iranian-Islamic culture in addressing ethical issues raised in biomedicine.

Bioethics Organizations: In the last two decades, the number of research centers, institutes, and committees dedicated to bioethics has increased dramatically. As mentioned earlier, in the 1990s there was only one research center at the

Ministry of Health focusing on ethical issues in medicine. Now there are several bioethics or medical ethics centers and institutes across the country, and all major universities and research centers have established research ethics committees and/or hospital ethics committees. Therefore, due to the establishment of research ethics committees in all universities and research institutes, there is good coverage of ethical issues in biomedical research. However, when it comes to clinical bioethics there is a lack of infrastructure and programs to address ethical issues at the bedside such as ethics consultation.

Regarding bioethics education, the number of programs has increased and, currently, there is a PhD course on medical ethics at the medical universities of Shiraz, Tehran, and Shaheed Beheshti; a 1-year fellowship program designed for university medical specialists at the Shaheed Beheshti medical university; a master of public health (MPH) with a major in bioethics at the Tehran medical university; and several specialized courses and seminars providing post-graduate training. It should be noted that the two-unit course on medical ethics for undergraduate medical students has recently been revised (Bagheri et al., 2009).

There are several initiatives to translate critical bioethics reference books into Persian to allow more people to use these resources. It should be noted that, although the importance of ethical issues in regard to the environment has been discussed recently, compared with the issues in medical ethics, there is still less representation from environmental ethics in the country.

During the last decades, several initiatives by health authorities have helped the expansion of bioethics centers. For example, the Iranian Academy of Medical Sciences formed a new department of medical ethics in 2006. In 2011, the Ministry of Health established a new organization called the High Council of Medical Ethics in order to monitor medical ethics programs and coordinate bioethics activities with other governmental agencies and ministries as well as national policy making in the field of medical ethics. This council can issue national guidelines on different aspects of medical ethics and undertake the supervision of issues related to medical ethics in the country.

Based on the recommendation of the United Nations Educational, Scientific and Cultural Organization (UNESCO), the UNESCO National Commission in Iran has established a National Bioethics Committee with representation from different related organizations, such as the Ministry of Science, Research and Technology, the Ministry of Health and Medical Education, the Organization for the Protection of the Biological Environment, the Ministry of Agricultural Jihad, and the Legal Medicine Organization. The committee also includes some independent experts. The National Commission also established the National Ethics Committee on Science and Technology in 2003. However, recently, the National Commission has combined these two committees into one, the Iranian National Committee of Bioethics and Ethics in Science and Technology (National Commission of UNESCO, 2010).

Capacity to deal with new bioethical dilemmas: In Islamic jurisprudence, the issues and problems that come along with the progress of human knowledge and technology are considered as newly emerged problems. Islamic regulations are originally expressed as certain general principles and norms that are not expounded

in details. Therefore, for many bioethical issues raised along with new technologies there are no textual ordinances offering explicit guidance. It is a matter that falls within the domain of legal discretion (*ijtihad*). In Iran, in order to deal with newly emerged issues in medicine, scholars of religion and jurists work in collaboration with medical specialists in order to find a solution for such complex questions. For example, the medical specialists first explain the problem of brain death and the patient's state and conditions to a *faqih*. The *faqih* then utilizes authentic sources and documents that include God's Holy Book (the Qur'an), tradition (*Sunnah*), consensus (*Ijma*), and reason to extract the ordinances of the Islamic law. When such a rule is expressed by *faqih*, it is called a "legal opinion" or *fatwa*. Muslim physicians perform their therapeutic duties according to such legal opinions and recommendations. It should be noted that in Islamic law controversy exists not only among different schools of thought such as Shi'at and Sunni but also within each one of these schools. For instance, different ruling *fatwas* on the application of assisted reproductive technologies and also abortion can be seen among Shi'ee scholars and Sunni scholars (Bagheri & Afshar, 2011).

Legislation in the area of bioethics: In the area of bioethics there are several bills that have been passed into law by the parliament. The first was the Brain Death and Organ Transplantation Act (2000), which authorizes organ removal for transplantation from a brain-dead patient. The Act has expanded the donor pool and has increased the number of organs available for transplantation. In 2003, based on the religious approval for embryo donation, the Iranian Parliament ratified the "Act of Embryo Donation to Infertile Spouses." This Act regulates embryo donation to infertile couples under certain conditions. In 2005, the parliament regulated abortion by ratifying the Act on Therapeutic Abortion. According to this Act, a pregnancy can be terminated within the first 4 months of pregnancy if the fetus suffers a congenital abnormality, mentally or physically, or when the mother's life is in danger. It is noteworthy that there are several techniques and methods, especially in the area of ARTs such as surrogate motherhood and sperm donation for which there is religious permission (*fatwa*). However, there is no law or regulation in this area. This poses ethical challenges for healthcare institutions. Thus, more attention and efforts need to be paid in order to regulate these reproductive techniques.

Major Bioethical Issues

Looking back to what has been common practice in dealing with bioethical issues in Iran, one may find that, in many cases, following the emergence of an ethical dilemma raised by the application of a new technology (e.g., ARTs), the responsible authority has formed a panel of experts in order to deal with the issue and provide an ethical guidance for the health system. However, by establishing different ethical bodies, the health authority is trying to deal with these issues in a more structured form. Some of the bioethical issues that have emerged in biomedicine and the responses to the ethical challenges posed by these issues are discussed below.

National Priorities in Medical Ethics

A national survey has recently identified the top ten priorities in medical ethics across the country (Bagheri, 2011). In this survey, scholars who are involved in bioethical discussion, teaching, research, and policy making from different fields have been asked to choose ten priorities among 20 topics in a questionnaire about medical ethics. The issue of patient rights has been chosen as the first priority, followed by doctor-patient relationship, just resource allocation, autonomy and informed consent, fee splitting, hospital ethics committee, public health ethics, capacity building in medical ethics, ethics in medical education, and finally the issue of ethics in research.

Patient Rights

As mentioned above, the issue of patient rights is the top priority in the national survey. Recently, special attention has been given to patient rights by the Ministry of Health and Medical Education. The Iranian patient rights charter was compiled with a novel and comprehensive approach in 2009 and has been adopted by the Ministry of Health. This charter aims to elucidate the rights of recipients of health services as well as to observe ethical standard in medicine. The charter has 5 chapters and 37 articles, including a vision and an explanatory note. The charter's five chapters are (1) the right to receive suitable services, (2) the right to access to desirable and adequate information, (3) the right to choose and to decide freely about receiving health care, (4) the right to privacy and confidentiality, and (5) the right to access an efficient system of dealing with complaints (Parsapoor, Bagheri, & Larijani, 2010). It must be noted that, although adopting the patient rights charter was a step forward to ensuring patient rights, a serious challenge is faced in implementing the charter and bringing it into medical practice within the healthcare system in Iran.

Brain Death and Organ Transplantation

In Iran, the Organ Transplant Act, 2000, allows organ removal from persons declared dead, based on brain function. The significant value placed on saving a life in Islam provided the foundation for this ruling, and religious teachings encourage people to donate their organs for transplantation to save human lives. The living unrelated (LUR) kidney donation program was started in 1997 based on the idea of "rewarded gifting" in which organs are not bought, but rather donors receive a "reward" for the gifted organ. As a result of kidney procurement from LUR donors, the waiting list for kidney transplantation in Iran was eliminated in 1999 (Ghods, 2002). The so-called "sacrifice gift" is given as a reward from the society to compensate the donor's altruistic donation. The acceptance and regulation of LUR kidney donation in 1988 provided the foundation for this initiative.

According to this program, after organ donation, the donor submits several documents, including a certificate from the hospital certifying that the procurement was performed, to a NGO called the Charity Foundation for Special Diseases. The NGO then pays the donor a fixed amount of ten million Rials ($1,000) as the sacrifice gift (Zargooshi, 2001). However, it should be noted that, since the start of this program, the number of living related organ donation has decreased dramatically. A study shows that the living unrelated donor program had an adverse effect on the number of living related donors. In this study, 81 % of the kidney recipients from living unrelated donors had a potential living related donor. In those cases, family members were reluctant to donate because of the availability of living unrelated donors for transplantation (Ghods, Savaj, & Khosravani, 2000).

It was hoped that a LUR kidney transplant program would decrease the waiting list mortality and improve quality of life for patients undergoing dialysis. Before the implementation of LUR donation, only 30 % of patients on the waiting list for transplantation would receive a kidney from a living (related) donor.

However, the program has been criticized because it facilitates the possibility of a private transaction between an organ donor and a recipient because they can get to know each other under the program. The program does not eliminate the possibility of individual kidney sales, and in some cases it may encourage people to offer their kidneys for sale through a private transaction rather than a donation (Bagheri, 2006). In reality, the program is not well designed to prevent donor-recipient monetary relationships. If donors and recipients are known to each other, it is easy for them draw up a contract together for a private transaction. In fact, the program in Iran lacks secure measures to prevent the risk of a direct monetary relationship between donors and recipients, and this is the main ethical problem and loophole of the procurement system in Iran. However, preventing any direct monetary relationship between donors and recipients through a "nondirected living donation" policy can be instrumental in overcoming this ethical problem (Bagheri, 2006).

Assisted Reproductive Technologies

In Iran, on average 10–15 % of couples are infertile and many of them seek assisted reproductive technologies to have their own baby. The first infertility center was established in Yazd Province in the central part of Iran in 1986. Since 1990, when the first test tube baby was born in Iran, there have been major technological achievements in the area of infertility treatment. Currently, infertile couples do not have any legal barriers to taking advantage of these technologies (Abbasi-Shavaz et al., 2006). There are 50 IVF clinics across the country, among the highest numbers in the Middle East. Assisted reproductive technologies have been in practice since 1989 based on the religious authority permission (*fatwa*), and none of the techniques, such as eggs and gamete donation or surrogacy, have been governed by legislation. In the absence of a legal regulatory framework for assisted reproductive technology, however, infertility clinics have been able to practice all forms of gamete donation and surrogacy to benefit their infertile

married couples based on the existence of religious permission (*fatwa*). Although all assisted reproductive techniques such as IVF, surrogacy, and embryo and sperm donation are available in the county, only embryo donation has a legal basis in Iran.

The Act of Embryo Donation to Infertile Spouses was ratified by the parliament in 2003. It noteworthy that, among Islamic countries, Iran is the only one in which assisted reproductive technology using donor embryos is supported by legislation. The Act has five articles. Article 1 of the Act requires that the donors should be legal or canonical spouses. It also states that the donated embryo should be produced from the IVF procedure and written spousal consent is necessary. Article 2 details the prerequisites for receiving the embryo, and Article 3 is about duties and responsibilities of the spouses adopting the embryo. Article 4 mentions the role of the Family Courts and the legal process of embryo donation, and Article 5 obliges the Ministry of Health and the Ministry of Justice to provide a guideline or bylaw for embryo donation after 3 months (The Act, 2003). As a result, the executive bylaw of the Act was passed by the Cabinet Council in March 2005. However, the Act addresses only embryo donation, while there is a lack of legislation on the other forms of gamete donation or surrogacy. The Act of Embryo Donation to Infertile Spouses can be instrumental in helping infertile couples. However, the vagueness of the Act created more confusion and lack of clarity. The Act has been criticized for several reasons. First, it does not restrict the donated embryos to surplus embryos and is silent about the number of embryos that could be transferred. Also, the Act is silent on the issue of heritage, which can be a challenging issue under the anonymity policy in embryo donation (Afshar & Bagheri, 2012). Currently, there is no standard national protocol or guideline to evaluate the prerequisite conditions of the embryo recipients and supervision of the embryo donation. The same problem exists for the application of other assisted reproductive technologies in the country.

Abortion

As in other countries, abortion is a sensitive issue. However, in the conservative Islamic society the issue becomes critical. In Iran, as a Muslim country, the *Shari'a* law, based on Shiite school, is the basis of the ruling *fatwas* on abortion and it influences public attitudes and practice. Based on Islamic jurisprudence, ensoulment takes place at 120 days of pregnancy and after that time a fetus is considered a full human being; thus, abortion is not permitted after ensoulment. Against this backdrop, abortion is permitted before 120 days of pregnancy under very restricted conditions, for example, if the mother's life is endangered. In 2005, the Therapeutic Abortion Act was passed by the parliament and approved by the Guardian Council (which is the responsible body to check all laws passed by the parliament to avoid any contradiction with Islamic *Shari'a*).

The Act reads as follows: "Therapeutic Abortion is permissible with definite diagnosis of three specialist physicians and approval of Legal Medicine Organization for cases in which fetus suffers from congenital anomaly or retardations and causes hardship to mother and also for cases in which mother suffers from a life

threatening disease, before ensoulment (4 months of pregnancy) with consent of mother and there is no penalty for consulting physician. Violators of this act would be punished based on Islamic punishment act" (Therapeutic Abortion Act, 2005). However, critics believe that the Act provides a wide range of maternal as well as fetal indications for abortion that are subject to misuse. The condition of "hardship" as referred by the Act is a vague concept and subject to interpretation (Bagheri & Afshar, 2011).

Stem Cell Research

Ethics in biomedical research was one of the first bioethics issues that attracted the attention of researchers and health policy makers in Iran. As a result, national ethical codes in biomedical research were compiled in 1997. However, stem cell research was not a popular topic at that time. Therefore, the national ethical codes lack any specific reference to stem cell research. In Iran, there is an increasing interest in research on stem cells and, in a recent initiative, a draft of ethical guidelines in stem cell research is under review by the Ministry of Health. These include general ethical guidelines and specific guidelines explaining ethical issues in research on stem cells; a second part deals with ethical issues in stem cell therapy (Nejad Sarvari et al., 2010).

Environmental Ethics

As mentioned earlier, bioethical discussion began with exploring ethical issues in medicine, however, some issues such as environmental ethics are receiving more attention. Nonetheless, public awareness has increased due to air pollution in big cities, and academic discussions on global warming and climate change have caused experts in the field and policy makers to pay more attention to environmental ethics. Many believe that the world faces an environmental crisis and a solution for this crisis can be found by returning to religious tradition (Mohaghegh-Damad, 2000).

Islamic teachings urge Muslims to take care of the environment and animals as Almighty God's creatures. Although, from the religious perspective, the particular attributes of human beings give mankind on a special status compared with other creatures, but at the same time it gives them responsibility toward nature and the environment. Such responsibility demands that the possible consequences for other living organisms not be ignored in decision making regarding the environment (Abedi-Sarvestani & Shahvali, 2008).

In fact, both religion and religious leaders have the potential to encourage people, based on religious teachings, to care more about their surrounding environments. However, this has not been fully exercised in Iran.

There are several universities in Iran that offer undergraduate and post-graduate studies in environmental sciences. Recently, courses in environmental ethics have gained more attention. For instance, environmental engineering programs at the

graduate level have been developed since 1990. However, there is not an environmental ethics course in this program. The addition of several courses to the curriculum of all environmental engineering programs in Iran has been suggested, such as environmental law, environmental economics, and environmental ethics and philosophy (Alavi Moghaddam, Maknoun, & Tahershamsi, 2008). It is noteworthy that the number of NGOs dedicated to preserving the environment is increasing. However, due to the lack of public awareness, except for air pollution, other environmental issues have not yet become topics of public discourse.

Physician-Patient Relationship

The physician-patient relationship in Iran does not operate on a patient-centered model of decision making, as one might find in Western countries. Looking at the four prominent models of physician-patient relationship (paternalistic, collaborative, informative, and technician models), one can find that, currently, the dominant physician-patient relationship in Iran is not a purely paternalistic model, nor is it one of the other models. Two decades ago, the medical system was based on a purely paternalistic model, but due to social changes, public awareness, and changes in medical education, the relationship between physicians and their patients is now in a transitional phase. It is hard to predict which model will become the predominant model of relationship between physicians and patients. More time is needed before the result of these changes can be seen.

Several factors have been claimed as a major force in changing the physician-patient relationship model, including fee splitting, sharing medical fees with professional colleagues for patient referrals (Parsa & Larijani, 2009), as well as direct monetary relationship between physicians and their patients (Bagheri, 2011). Traditionally, there is a relatively high level of trust between patients and their physicians. However, this tradition is threatened by the recent expansion of the practice of fee splitting and under-the-table payment due to unrealistic fee-for-service payments set by the health authority, especially in the private sector. The trust between the medical profession and society is fragile and is in a critical stage. Without constructive intervention by the health authority as well as professional associations, the relationship between healthcare providers and patients will undoubtedly be damaged (Bagheri, 2011).

End-of-Life Decision Making

For many Muslims, religious beliefs are a fundamental part of both personal and social existence in their daily life and a major determinant for healthcare decision making, especially at the end of life. In Islamic teachings, the importance of inter-human as well as human-divine relations are emphasized. Muslims look to these teachings in shaping their relationships with others and with the Almighty God. In this section, some issues related to end-of-life decision making are discussed.

It should be noted that, although Iran has a relatively young population, because of the scarcity of health resources, end-of-life issues are among the important topics in bioethics.

Right to Die: According to the Qur'an, life is a divine trust and cannot be terminated by any form of human intervention. Its term has been fixed by the unalterable divine decree. The Holy Qu'ran reads, "God takes the souls at the time of their death" (Holy Qu'ran 39: 42). Since the decision to end a life is a divine decree, the Islamic *Shari'ah* refuses to recognize individual rights in that matter (Sachedina, 2005). Therefore, the current notion of the right to die is not recognized. Hence, the right to be assisted in dying, whether "passively" or "actively," is also ruled out. The juridical principle of non-maleficence, which states, "No harm shall be inflicted or reciprocated in Islam" (*la darar wa la dirar fi' l-islam*), provides the justification of this ruling. However, it recognizes the possibility of arriving at a collective decision by those involved in providing the health care, including the attending physician and the family to withhold or withdraw life support intervention deemed futile. Instead of contemplating ways to end one's life, either by refusal of life-support treatment or by requesting to die with active assistance, Muslims afflicted with illness are advised to ask God to forgive their sins and pray for an opportunity to have a fresh start with restored health.

When death approaches, close family and friends try to support and comfort the dying person through supplication as well as remembrance of Allah and His will. The purpose is to help the dying person to repeat their commitment to unity of God. The recently developed Iranian Charter of Patient's Rights emphasizes the special needs of a dying patient and urges healthcare providers to be sensitive to these issues (Parsapoor et al., 2010).

Surrogate Decision Making: End-of-life decision making arises precisely at the critical point when a person lacks the capacity for making a decision. What must be done at that point? What are the patient's wishes, and who knows them? In case of minors, one may face the same difficulties in decision making. In Islamic societies, the family has the right to decide on behalf of their loved ones based on his or her best interest, especially if the patient did not express their wishes. For minors, parents are surrogate decision makers for their children. In case of emergencies and unconsciousness, accompanying family members act as surrogates.

Disclosure to the patients/families: In medical practice in Iran, family authority is often more dominant than the patient's autonomy. Many physicians provide the facts to the family members but not to the terminally ill patient. If the family asks physicians not to tell the patient, many physicians will agree to this request, and many patients accept this as standard practice. Therefore, it can be claimed that decision making in healthcare is based on a family-centered model.

Futile Treatment: The end of life should be as calm as possible and any unnecessary intervention or care management that could bring additional suffering to the dying patient or his relatives should never be used. Withholding and withdrawing life support interventions deemed futile is a controversial issue in Iran. In general, life-support withdrawal should be discussed with the family. If the treating physician finds that a certain modality of treatment is useless or will

increase the suffering of the patient, that modality of treatment should not be enforced (Albar, 1999).

Suicide: The Qu'ran is very clear on the subject of suicide: "Do not kill yourselves as God has been to you very merciful" (Holy Qu'ran 4:29). Taking away life should be the domain of the One who gives life. There is pain and suffering at the terminal end of an illness, but, as Quran reminds, there is reward from God for those who patiently persevere in suffering (Holy Qu'ran 39:10 and 31:17).

Future Challenges

Bioethical Challenges

There are several major challenges in bioethics in Iran, which influence the approach taken when dealing with bioethical issues.

The relationship between ethics, law, and Islamic jurisprudence (*fiqh*) is an important challenge. In the scholarly literature there are different approaches toward multidisciplinary discussion in bioethics (Mohaghegh Damad, 2010). Being a religious country, it is important to define the position of Islamic *Shari'a* on the questions raised by an ethical dilemma. In practice, the priority of the religious position is evident by the fact that, in case of any question (permission or prohibition of an act) on the application of a new biotechnology, scientists and physicians are keen to explore what would be the opinion of Islamic scholars (*faqih*) on the issue.

In the last two decades, the approach to an ethical dilemma has been as follows: First, a physician or a group of physicians who face an ethical dilemma in their practice would explain the problem to a *faqih* or to a committee of Islamic scholars in order to obtain the religious opinion on that issue. After approval by the religious authority, the issue would be taken to the health authority for the development of national guidelines or to the parliament for policymaking, if needed. Then ethical deliberation and discussion to explore the ethical dimensions of that issue would begin. For instance, the religious authority first accepted the notion of brain death and organ removal for transplantation from brain-dead cases. Then, based on this acceptance, an act was passed to allow the use of brain-dead cases as a source of organs. When organ procurement became part of medical practice, the ethical issues such as organ sale were then discussed. The same pattern can be seen in the case of abortion. It is interesting to mention that, because of this trend, there are several practices such as sperm donation and surrogate motherhood that are permissible according to the ruling *fatwas*. However, the ethical issues have not been fully discussed and there is no law or regulation governing the procedures.

Another challenge is that, as an Islamic country, there is a great effort in Iran to define principles of biomedical ethics based on Islamic ethics. In an article by Larijani and his colleague, the following principles have been proposed for dealing

with ethical issues based on Islamic Ethics: the principle of "the public interest" (*Maslaha*), the principle of "do no harm" (*La Dharar wa la Dherar*), the principle of "necessity" (*Dharura*), and the principle of "no hardship" (*La Haradj*) (Larijani & Zahedi, 2008). However, there remains a need to initiate a multi-disciplinary project with the participation of all stakeholders, Islamic jurisprudence, ethics, philosophy, medicine, and law to develop Islamic principles of biomedical ethics which are acceptable for the key players in the field.

A third challenge is that existing institutes and research centers have mainly focused on ethical issues in medicine. As a result, there is less attention paid to other topics in bioethics such as environmental ethics. Therefore, capacity building and strengthening the necessary infrastructure to deal with other critical topics in bioethics remain a challenge for the future of bioethics.

The last serious challenge for the development of bioethics is a lack of public discourse about bioethical issues. Given the importance of public discussion in bioethics, especially in policy making as well as implementation, there is a need to enhance public discussion and involvement in bioethical discussions. This, in turn, will bring about better public awareness and participation.

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Italy

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Stefano Semplici

Bioethics Development

Two main factors, from the second half of the 1970s, paved the way in Italy to the development and success of bioethics. The first was the debate about the value and

S. Semplici
Department of Business, Government Philosophy, University of Rome 'Tor Vergata', Rome, Italy
e-mail: semplici@lettere.uniroma2.it

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dignity of human life prompted in the first place, although not exclusively, by the strong political and cultural conflict on abortion. The law that allowed women to terminate a pregnancy was adopted in 1978, but the controversy continued. A proposal to repeal the law was submitted to a national referendum in 1981 and rejected by nearly 68 % of voters, notwithstanding the strong opposition of the Catholic Church. The focus on the beginning of life also encompassed other and new aspects related to scientific development. In 1984, the same year the *Report of the Committee of Inquiry into Human Fertilization and Embryology* was published in Great Britain, a commission (the "Santosuosso Commission" after its chairperson) was established, with the aim of preparing a bill on assisted reproduction. Although the confrontation over these issues did not necessarily imply the reference to "bioethics," the route was thus marked out. In effect, the first person to introduce the word in Italy had been Menico Torchio, a professor of Marine Biology, who had published *Rapporti uomo-natura secondo le principali metafisiche orientali, loro implicazioni bioetiche ed ecologiche* (*The relationships of humankind and nature following the main Oriental Metaphysics, with their bioethical and ecological implications*) in the journal "Natura" in 1973. He relied on the broad, ecological perspective sketched by Potter just 2 years before but had little success. This does not imply that the idea of a "bridge to the future" grounded on the respect for nature and the whole biosphere was simply dismissed, nor that the question of "animal rights" did not receive attention, but Italian bioethics, from its very first steps, gave priority rather to cutting-edge issues stemming from different evaluations of the rights to be recognized and the obligations to be performed when human life is on the threshold of its beginning and end.

The second decisive factor contributing to orientate fledgling bioethics towards the challenges of the biomedical sciences, as well as towards medical rather than environmental ethics, was the impact of new technologies on health care and clinical practice. This impact was strengthened by the shift from the old paternalistic to the new autonomy-centered paradigm of medicine. It was no longer simply about looking for the best "technical" method to apply a treatment or to decide when it had become futile and should therefore be suspended. It was about looking for the best way to involve the patients in this complex process of decision making, enabling them to make their own choice in terms of free and informed consent while ensuring at the same time the concrete availability of the appropriate treatment and a rational allocation of resources, in a context where access to quality health care is guaranteed to everyone as a fundamental constitutional right, regardless, among other things, of economic conditions.

As a consequence, many initiatives and committees were established in the 1980s, both within hospitals and research institutions and via academic bodies and other cultural organizations. For the former, initial experiences arose in Milan (Clinical Institutes for Specialisation, Hospital S. Raffaele with Paolo Cattorini, National Institute for Research and Treatment of Cancer), Genoa (National Institute for Research on Cancer), and Rome (Catholic University of the Sacred Heart). Two different clusters of responsibilities can be easily highlighted. On the one hand, there were the obligations of respect connected to

research on human subjects, starting with the application of the principles already made explicit in many international documents in the wake of the *Nuremberg Code*. On the other hand, it was also necessary to cope appropriately with those conditions of disease which entailed a great deal of suffering, no concrete hope of recovery, and, at the same time, the possibility of tapping more and more powerful means of treatment simply to prolong life. In some cases, the competence to assess the results of the application of the law on pregnancy termination was also explicitly foreseen.

The controversy over the right to life, in its various declinations, is indeed the Ariadne's thread of this first period, even though other issues were considered at the same time. Theologians and philosophers, as well as scientists and jurists, were involved. Relevant documents from the magisterium of the Catholic Church were published rapidly, one after the other. The oldest Italian philosophical journal, the "Rivista di filosofia," that had published an article by Maurizio Mori pointing at the rapid development of bioethics in 1980, devoted a special issue to this topic in 1983. The Catholic Church undoubtedly played a major role. The "Centre for Bioethics" at the Faculty of Medicine of the Catholic University of Rome, where Elio Sgreccia had begun teaching bioethics 2 years before, was inaugurated in 1985. With the support of the journal "Medicina e Morale" (founded in 1950) and one of the greatest specialized libraries, this center imposed itself as the benchmark of a bioethics strictly aligned with the teaching of the Church. Sgreccia himself, who was made cardinal by Pope Benedict XVI in 2010, is probably the most influential representative of this position. His *Manuale di bioetica* (*Handbook of Bioethics*) was printed in several editions and has been translated to many languages. The center, directed since 2006 by Adriano Pessina, is now at the service of the whole Catholic University and its main seat has shifted to Milan, whereas in Rome, the Institute of Bioethics, set up in 1992, continues its work. At the same time the "Lanza Foundation" was established in Padua. A crucial attention to bioethical issues and to the relationship between ethics and medicine – as we can read on the website of the foundation – was assumed as a part of its more encompassing mission to address the challenge "to respond to the compelling scientific and technological progress and massive changes in our economic and social system" on the basis of Christian ethical principles.

Many other initiatives were launched in the 1980s, independently of the Church and often openly opposing it. In 1987, Uberto Scarpelli published in "Biblioteca della libertà" a short essay entitled *La bioetica. Alla ricerca dei principi* (*Bioethics: in search of the principles*), pointing at new ways outside theology and at two fundamental principles: tolerance and dignity. The contribution of secular thought was decisive from the very beginning, as well as that of different interests and sensibilities. The "Centre for Bioethics" established in 1984 at the University of Genoa by Luisella Battaglia tried to renew a broader awareness of human responsibility for all life, with a special focus on the rights of animals as an issue of interspecific justice. The "Italian Society for Bioethics," linked to the Chair of Anthropology of the University of Florence (Brunetto Chiarelli), also aimed, relying on Potter's legacy, to connect the bioethics of medicine with the bioethics of environmental studies and biological sciences:

Potter himself came and gave a lecture in Italy at the invitation of Chiarelli in 1990. The Centre for Research and Education in Politics and Ethics "Politeia," established in Milan in 1983 and with a liberal background, started a section on bioethics, which contributed to boosting open, interdisciplinary debate in 1985. In 1990, Politeia promoted an important congress on *La bioetica: questioni morali e politiche per il futuro dell'uomo* (*Bioethics: moral and political questions for the future of humankind*), inaugurated just 1 day after the formal establishment of the National Bioethics Committee, through a decree signed on March 28 by the president of the Council of Ministers. In 1989, still in Milan, the neurologist Renato Boeri founded the "Council for Bioethics," with the aim of supporting a secular approach to biomedical issues. In Rome, the year before, the "Gramsci Institute" had started a project on life sciences: the congress on *Questioni di vita. Scienza*, *etica e diritto* (*Questions of life: Science*, *Ethics, Law*) was the first initiative of its Centre for Bioethics.

Most of these centers – as well as producing books and other research material – also founded journals, such as "Problemi di bioetica," later renamed "Global Bioethics" (Italian Society for Bioethics, until 2006), and "Bioetica. Rivista interdisciplinare" (Council for Bioethics), that has rapidly become one of the most important references for the debate in Italy. Among the journals published by these institutions devoting special attention to bioethics are "Kos" (San Raffaele Foundation), "Notizie di Politeia," and "Etica per le professioni" (founded in 1999 by the Lanza Foundation). By the beginning of the 1990s, the first pioneer period of bioethics in Italy was over and we entered a new phase of progressive widening and reinforcement that has continued uninterrupted to the present.

Current Bioethics Infrastructure

Academic teaching and research, institutional and other cultural and scientific sites for public debate, and legislation are the most telling indicators of the growing, pervasive relevance of bioethics in the last 20 years. Bioethics is now taught in most Italian universities: in the faculties of medicine, although it has not yet been included as an obligatory part of the curriculum but also in faculties and departments of law and philosophy. The traditional sectors that provided and continue to provide the greatest numbers of bioethicists are legal medicine and history of medicine, philosophy of law, and moral philosophy. As a consequence of these differentiated and interdisciplinary approaches, master's and PhD programs have come to take place within numerous institutional frameworks, often relying on and boosted by the specific competence and commitment of prominent scholars. Many centers for bioethics are either located within universities or promoted by university professors, and it is therefore quite obvious that research and teaching activities are placed side by side. Curricula in bioethics have been proposed at different levels in Turin, Genoa, Milan, Padua, Firenze, Siena, Rome (Catholic University, Lumsa, La Sapienza, Roma 3), Napoli, Bari, Lecce, Palermo, and Messina, among others. The Pontifical University Regina Apostolorum of Rome, which as such does not belong

to the Italian university system, unlike the University of the Sacred Heart and Lumsa (another Catholic university, where Francesco D'Agostino set up a Centre for Biojuridical Studies now directed by Laura Palazzani), has even established an autonomous Faculty of Bioethics, where a UNESCO Chair in Bioethics and Human Rights is also to be found. Other pontifical universities in Rome and many teaching and research institutions of the Catholic Church elsewhere have also started programs in bioethics.

Of course, not all of these initiatives have had the same impact and shown the same capacity to consolidate themselves. Expertise in bioethics is as flexible as it is uncertain in terms of immediate employability, although it still appears to be required in the first place to effectively address the new challenges arising in the domain of biomedical sciences. It was the "Istituto Superiore di Sanità" (National Institute of Health) that launched the SIBIL Project (Sistema Informativo per la Bioetica in linea/Online Bioethics Information System: www.iss.it/sibi) through its documentation service in 2001. The SIBIL Project is an integrated system aiming to provide as complete an overview of bioethics as documents, internet sites, university courses, congresses, and reports from the media (other portals for bioethics are www.biogea.org, established by the Basso Foundation, and www.portaledibioetica.it). As a part of the SIBIL Project, the Italian Bioethics Thesaurus was published in 2006, including over 1,000 terms related to bioethics. In the master's programs, which are often located within faculties of medicine or organized with their decisive contribution, this orientation is more explicit: teachings of moral philosophy, philosophical anthropology, and philosophy of law but also private and international law and sometimes management of health care systems are offered, with a background of genetics and genetic engineering, gynecology and obstetrics, endocrinology, anesthesiology, and epidemiology. The practice of medicine and medical research, as well as the need to regulate unprecedented possibilities and risks in this field, have been and are likely to be in the future the crux of Italian bioethics.

Apart from that within universities and teaching, the infrastructure of public debate, in Italy as in many other countries, is characterized by the presence of an institutional body flanking many initiatives whose number has been steadily increasing over the last decades. The National Bioethics Committee (Comitato Nazionale di Bioetica) is appointed by the president of the Council of Ministers, with the task "of expressing opinions, and also for the purpose of preparing legislative acts, to address the ethical and legal problems that may arise as a result of the progress in scientific research and technological applications on life" (quoted from the website of the committee: www.governo.it/bioetica). In 1992, a National Committee for Biosecurity, Biotechnology and Life Sciences (Comitato Nazionale per la Biosicurezza, le Biotecnologie e le Scienze per la Vita) was also established, with the more specific task of assessing the risks arising from the use of biological agents, developing criteria for the definition of safety standards, and cooperating in drafting regulations from European directives. A joint group of the two committees is entrusted with discussing those issues of shared interest and responsibility, such as, most recently, genetic tests and the collecting of biological samples according to the principle of consent.

The decision to appoint a *national* committee, which should be representative both of different methodological approaches and ethical perspectives and sensibilities, is rooted in an awareness of the special relevance of the problems that bioethics deals with. Constitutional essentials are at stake, starting with the right to life and the right to quality health care. Bioethical controversies may impinge deeply even on the idea of shared citizenship and therefore require the greatest effort to overcome or at least to contain the conflict as far as possible, especially when it comes to legislative action. The committee has been chaired by Adriano Bompiani, Adriano Ossicini, Giovanni Berlinguer, and twice by Francesco D'Agostino. The present president (until December 2012) is Francesco Paolo Casavola, former president of the Italian Constitutional Court.

Notwithstanding the role and important activity of the National Committee, the true "engine" of Italian bioethics is probably still to be found in the many centers and institutions disseminated throughout the territory. Among the initiatives established in the 1990s that make explicit reference to the Catholic tradition, the Sicilian Institute for Bioethics distinguished itself through a specific commitment to developing a Mediterranean bioethics. The institute that published the journal "Bioetica e cultura" and a *Dictionary of Bioethics* (1994) is now called "Istituto di Studi Bioetici Salvatore Privitera" (from the name of its founder), offers a master's degree in Mediterranean Bioethics and publishes the journal "Bioethos." Still in Sicilia, the Laboratory of Bioethics, set up in Messina in 1993, is now a center linked to the Salesian Pontifical University. The "Scienza e Vita" (Science and Life) Association, established in 2005, has undertaken the task of boosting awareness of the intrinsic dignity of every human being in every stage of his or her existence, especially at its beginning or end or when it is burdened with disease, fragility, or disability. The position of the Catholic Church, however, remains just one of the perspectives inspired by religious faith, even in Italy. The Union of the Methodist and Waldensian Churches, for example, established a working group (thereafter a commission) on bioethics in 1992 that has produced documents on pregnancy termination, euthanasia, assisted reproduction, secularism. These documents offer arguments and solutions inspired by a very different set of principles and therefore provide further evidence of the inadequacy of addressing Italian bioethics through the key of a conceptual *passe-partout*, according to which the supporters of the principle of the sanctity of life on the one hand and the supporters of the principles of quality of life and self-determination on the other hand simply clash one against the other.

Needless to say, one of the most urgent challenges remains that of providing conceptual tools and normative guidelines for the new responsibilities that the medical profession is called upon to deal with. The Jano Institute, directed by Sandro Spinsanti, is a telling example. Referring to a divinity endowed with rich symbolic meaning and orientated to the experience of transitions and changes that so deeply characterizes the time we are living in, the Institute aims to reconcile the traditional deontological dimension of medicine (the look at the past) with the unavoidable outcomes of innovation and increased technical power (the look at the future). "Janus" is the journal for this program of integrating knowledge stemming

from the sciences of nature with anthropological questions and social commitment in a more and more multiethnic and pluralistic environment.

In this perspective, the experience of the Ethics Committees established by hospitals or research structures, which had already played a major role in the pioneer phase of bioethics in Italy, is still decisive. They have the specific task, according to European directives and other long-established normative statements concerning research on human subjects, to assess pharmaceutical clinical trials, therefore verifying the relevance of the experimentation, the adequacy of the protocol, the competence and expertise of researchers, the respect of the principle of free and informed consent as well as of all other aspects that should be relevant in order to protect the rights, and the well-being and safety of every individual involved in the trial. According to the register of Ethics Committees, a section of the database of the National Monitoring Centre of Clinical Trials (*OsSC*), there are by now more than 250 Ethics Committees in Italy and their number has continued to increase after the last Ministerial Decree of 2006 that provided the minimum requirements for establishing such committees and the following transposition to regional laws. The composition of these committees guarantees a wide interdisciplinarity and article 3 of the decree explicitly mentions the possibility of also entrusting the committees with a consultative function over ethical questions linked to activities of assistance, quite apart from those of scientific interest. The committees are also entitled to propose initiatives for training and professional education in the field of bioethics. In this way, they are likely to become more and more indispensable when conceptual clarifications and legislative actions arise.

Major Bioethics Issues and Discussions

Looking at the opinions and motions of the National Bioethics Committee, two main features of bioethics in Italy stand out. The first one is the width of debate in the country. Most of the crucial ethical issues that developed societies have now to face as a consequence of a faster and faster scientific development have been addressed, either in connection with traditional arguments over the value and dignity of life or dealing with the many aspects that the respect for such value and dignity now entails, starting with the respect for everyone's autonomy and self-determination, *vis-à-vis* both the new technical possibilities that have been made available in the biomedical domain and the responsibility to allocate limited resources according to the fundamental principles of fairness and justice. The work carried out by the committee – to focus just on the most recent years and to mention just some of the opinions – is actually a reliable summary of the present agenda of bioethics in Italy, ranging from pivotal aspects of research and clinical ethics (conflict of interest in biomedical research and clinical practice, pharmacological and clinical trials, secrecy in drug regulatory system procedures, premature infants, conscious refusal and renunciation of health care in the patient-doctor relationship, criteria for the ascertainment of death, organ donation, use of placebo, conscientious objection) to new versions of the never-ending controversy on the

status of the embryo (the destiny of embryos resulting from medically assisted procreation; chimeras and hybrids, with specific attention to cytoplasmic hybrids) and the most advanced frontiers of research, including its economic fallout (pharmacogenetics and pharmacogenomics, genetic testing and insurance, health and new information technologies, biobanks and research on human biological material, nanosciences and nanotechnologies, neurosciences). The conceptual and normative span of bioethics is broadening, encompassing issues such as minor sexual differentiation disorders, biometrics, ethics, sport, and doping responsibilities toward animals. At the same time, the National Committee is contributing to fostering awareness of the idea that bioethics necessarily relies on and impinges upon a cultural, social, and political context, whose values, rights, and obligations and networks of solidarity are at stake. That is why bioethics must also cope with old and new risks of discrimination (women, elderly people, prisoners, developing countries) and be perceived as a challenge for education, possibly even in schools rather than just at university.

In many cases these opinions, which can also be found in English on the committee website, have been voted for by a large majority of the members. However – and this is the second feature of Italian bioethics that the experience of the committee helps enlighten – it remains true that whenever the discussion approaches the limits of self-determination as applied to the beginning and the end of human life, conflict breaks out once more. There seems to be very little room for consensus, and we are often left with an "on the one hand [. . .] on the other hand" argument. A telling example is to be found in the opinion concerning the conscious refusal and renunciation of health care of 2008: "On the one hand there's the position according to which human life constitutes a good that cannot be disposed of, which must be always protected and preserved, guaranteeing adequate medical care. On the other hand, the position that considers life as a good without question of primary importance and deserving of the outmost protection, but not for this subjugated to a system that totally forbids the disposition of it, having to take into account the value that the individual attributes to it, in light of the principles and of the moral choices that reflect the meaning each person gives to his/her own life" (§ 8).

The legislative actions that define and delimit the disposability of human life at its very beginning have prompted the hardest confrontation among bioethicists and in public opinion. The constitutional court itself, in many judgments, has implemented the "balancing of principles" as a tool to contain the consequences of a disagreement that directly impinges on the first of human rights and obligations, depending on the status that the embryo and fetus are recognized. This is the conceptual background of the law that introduced the right to terminate pregnancy in Italy. The State acknowledges, respects, and protects the self-determination of a woman and her interest in her own health and well-being but reaffirms at the same time the importance of respecting and protecting human life from the very moment of conception. In the unfortunate case of conflict between the two principles, prioritization is unavoidable. However, accepting that the principle "x" overrides the principle "y" in a given situation, where it is impossible to guarantee both of them, does not entail in any way the possibility of simply dismissing "y."

The criterion for prioritization was set by the court in February 1975, in a judgment which has become the cornerstone of all subsequent legislation and jurisprudence. A woman "is already a person." Therefore, her right to health and well-being has to take precedence over the respect even for the life itself of an embryo or a fetus, which are "not yet a person." The law 194/1978 draws on this assumption, aiming at balancing as far as possible this priority with the principle of respect for human life. In Italy, at least *de principio*, abortion is not simply free on request, and the State, although allowing it to be performed free-of-charge in public hospitals or private structures authorized by the regional health authorities, is not simply a spectator. Even during the first 90 days, some *indications* are to be considered and termination is permitted in circumstances that "would seriously endanger" women's physical or mental health, "in view of their state of health, their economic, social, or family circumstances, the circumstances in which conception occurred, or the probability that the child would be born with abnormalities or malformations." There are also *time limits* to be respected: after the first 90 days, voluntary termination of pregnancy may be performed only where the pregnancy or childbirth entails a serious threat to the woman's life or where serious abnormalities or malformations of the fetus, which could constitute a serious threat to the woman's physical or mental health, have been diagnosed. Eventually, where it is possible that the fetus may be viable, the physician may perform the termination only in case of immediate threat for the woman's life and undertaking every action to save the life of the fetus as well. Even though the actual application of the law has largely eluded the provisions made for the first 90 days and abortion is substantially free on request within such a limit, the idea of balance implies that the final goal of the law be that of preventing women from resorting to pregnancy termination, therefore supporting them in the attempt to remove the reasons of this choice. It is worth reminding that there had been two referendums against the law and carried out in 1981: the one promoted by the "pro life" supporters, which I have already mentioned, and another one aiming to eliminate all restrictions, which was rejected by an even larger majority of voters.

The law on assisted reproduction (40/2004) has also been discussed and harshly criticized in terms of balancing of principles. There was widespread agreement that new technologies should not simply be allowed to fulfill all kinds of wishes. However, the law passed by parliament was fiercely contested by the opposition, many experts, and associations because of what they considered a very limiting approach. The most controversial provisions of the law were the prohibition on creating more than three embryos at one time and the obligation to transfer all of them to the maternal womb in order to avoid embryo cryopreservation, the prohibition of using gametes from a third person outside the couple (heterologous fertilization), the prohibition on performing screening for genetic defects, and the prohibition on research on human embryos for purposes other than diagnosis and therapeutic treatment aiming at protecting the health and development of the embryo itself (with the subsequent strict ban on destroying embryos in order to obtain stem cells for the purpose of research). As in the case of abortion, a national referendum was promoted, with the aim of removing these restrictions.

The referendum was carried out in 2005 and did not achieve success due to the rules that regulate it in Italy. In order for a referendum to produce its repealing effects, it is required that more than 50 % of voters go to polls and the percentage of voters remained far below this threshold, although the great majority of those who went to polls expressed themselves against the restrictions.

However, the controversy continued in other forums. The constitutional court gave a judgment by which the prohibition of producing more than three embryos was overcome, together with that of cryopreservation. The argument, once again, pointed at a different balancing of principles, orientated more to the safeguarding of a woman's health than to that of the embryos. The prioritization of the former made it acceptable to resort to cryopreservation in order to avoid repeated cycles of ovarian hyperstimulation and reduce the risks of multiple pregnancies. The debate remains open, as does the confrontation on the use of embryonic stem cells for the purpose of research and experimentation.

Over the last years, end of life issues have also become a major subject of discussion. In this case, we draw on some shared premises. The criteria of death are no longer a matter of controversy, even though new scientific knowledge has triggered a reassessment of procedures (see the Decree of the Ministry of Health of 11 April 2008) in ascertaining "whole brain death," already acknowledged in a law of 1993 as fundamental neurological criterion. This is the assumption the 1999 law on organ transplantation is based on, in Italy as in most other countries. It can also be said that, at least so far, there are very few political actors and associations, as well as bioethicists insisting on the necessity of legitimizing the practice of "active" euthanasia, that is considered, according to article 579 of the Penal Code, a crime (murder at the request of the victim) punishable by imprisonment of between 6 and 15 years. Incitement to suicide and assisted suicide are also illegal, and it is worth underlining that "passive" nonassistance of a person in danger, when the one who omits is legally obliged to intervene, as it is normally the case for a physician, is made equal to an active behavior for penal consequences, according to article 40 of the same code.

Article 32 of the Constitution offers the key to address the fundamental point of confrontation with regard to end of life decisions: "The Republic safeguards health as a fundamental right of the individual and as a collective interest, and guarantees free medical care to the indigent. No one may be obliged to undergo any health treatment except under the provisions of the law. The law may not under any circumstances violate the limits imposed by respect for the human person." Apart from the recognition of access to health care as a fundamental "social" right of citizenship, pointed out as the goal and touchstone of a specific and ineludible political responsibility, the two principles to be balanced are still the protection of human life as "a collective interest" on the one hand and autonomy and self-determination of the individual, who cannot "be obliged to undergo any health treatment," on the other hand. There can be conflict when a patient refuses a treatment which is perfectly adequate and proportionate to the aim either of fully restoring him or her to health or to prolonging his or her life. Jurisprudence and clinical practice, according to the obligations deriving from the shift from the

ancient paradigm of paternalistic medicine to the new one of autonomy and those clearly stated in all relevant international documents about free and informed consent, have long since aligned in Italy with the recognition and acceptance of the patient's word as the last and decisive word to be said, even when such a decision implies, with full awareness, the consequence of renouncing life itself. This is obviously easier to make consistent with the collective interest of safeguarding every individual's health when the treatment which is refused (not even started) or renounced (the patient asks to stop the treatment at some point) could only prolong life in conditions of great suffering without any concrete hope of recovery, as may happen in the case of terminal illness. However, this is to accept in any case, notwithstanding the physician's obligation to advise patients of all the consequences of their decisions and to carry on the effort to persuade them not to give up too hastily, according to the idea of clinical practice as a "therapeutic alliance" between patient and physician.

Two cases have recently reignited the debate, with the consequence of reaffirming this conclusion and focusing on the issue of advanced directives, respectively. In the first, a man who was suffering from a progressive neurological disease and had been living for many years in enforced immobility and attached to a breathing machine asked for the machine to be switched off. This is the case the opinion of the National Committee on the conscious refusal and renunciation of health care that I have mentioned also referred to. In order for a patient to refuse a treatment or to renounce it when it is already in use, no "active" intervention is normally required by a third party: the physician ought simply to abstain, because the patient's will sets an insurmountable limit of privacy and respect in a context where a legal obligation to cure oneself is excluded, even with regard to the physician's general duty to intervene. Does it make a substantial difference if the decision to renounce, given the impossibility for the patient to switch a machine off by himself, requires for its fulfillment someone else's help? Whereas there have been different moral evaluations on this point, the judicial proceeding left no room for further uncertainties. The physician who made it possible for the patient to exercise his right to renounce the treatment was acquitted of any charge.

In the second case, the father of a woman in a vegetative state for many years asked to stop artificial nutrition and hydration and let his daughter die, asserting that she had expressed many times, before the accident that had determined such a condition, her firm will not to accept it. After many judicial rulings, accompanied by a fiery confrontation in public opinion, a court eventually allowed the interruption of the treatment and the woman died in a few days. In this case, however, the debate remained open on the necessity of adopting legislative measures on advanced directives (or statements, according to the title of the bill discussed in parliament for many years and strongly supported by the Catholic Church, which considers this kind of care an unconditional application of the principle of respect for human dignity). The point of immediate and hot disagreement concerned the possibility of stopping artificial nutrition and hydration, on the premise of an advanced directive, in an extreme condition such as a vegetative state that prolongs itself for many years. The more encompassing and difficult challenge that still

needs addressing is that of a fair balance between the collective interest to safeguard life as a good in itself and the right for everyone to maintain the control of his or her own body. The balance is more difficult, and the obligation of the physician to comply with the directives could be perhaps less strict or at least require some process of interpretation when the individual's will cannot be expressed "here and now" and had been anticipated in view of an imagined and not actually experienced condition.

I have mentioned many subjects that Italian bioethics is currently dealing with. This is likely to help reshape and possibly eventually to overcome a currently ongoing polarization. The contraposition between "Catholic" and "secular" bioethics is indeed key to understanding the general framework of debate in Italy. In the *Caritas in veritate*, the encyclical letter given in 2009 by Pope Benedict XVI, the statement is unequivocally made that bioethics is a "crucial battleground in today's cultural struggle between the supremacy of technology and human moral responsibility" and we are therefore presented with a clear *either/or* between two types of reasoning: "reason open to transcendence or reason closed within immanence" (§ 74). In vitro fertilization, embryo research, and the possibility of manufacturing clones and human hybrids are the new frontiers, while systematic eugenic programming of births adds new concerns about "the tragic and widespread scourge of abortion," and a pro-euthanasia mind moves forward.

On the other side, the features of a secular bioethics have been summarized by Giovanni Fornero as follows: humankind as the one and only source of moral values, refusal of a normative concept of "nature," autonomy, disposability of life, knowledge as an instrument of progress, refusal of suffering, different qualitative value of lives, the functionalistic concept of person, pluralism and liberalism, and an antiabsolutistic approach. This polarization, even though underscoring some relevant aspects of the bioethical debate, may result in putting worries of alignment before insight into the complexity and the often overlapping aspects of the questions addressed, especially when it comes to legislative action. It is therefore challenged by those who claim that it is not the religious or irreligious personal choice that can provide and actually provides bioethics with the decisive line of argument.

Future Challenges

The National Committee, in its 2010 opinion on bioethics and education in schools, launched the idea of a "bioethical citizenship," pointing out a double aim. On the one hand, evidence suggests that enhancement of this specific kind of ethical awareness relies on an enhancement of scientific education. Bioethical debates are triggered both by the increasing experience of pluralism of values and spurs stemming from the unprecedented pace of development of biomedical sciences and their applications. Therefore, scientific knowledge "not only *can*, but, in its essential data, *must* be acquired and shared by *all* moral subjects, in order to find an answer to the new ethical questions." On the other hand, communication is also

a decisive challenge. What is at stake is the "public good" of science and its applications. Therefore, public debate on these issues should be improved "regardless of sensationalism and ideological pressures." The possibilities opened up by scientific and technological progress impose choices which "must be the result of free and informed debate between *all* those involved" (§ 1): both active and responsible participation and mature awareness of the new rights and duties involved are required.

Looking at this idea of a bioethical citizenship, there are two challenges. The first is the necessity to strengthen not only scientific education in schools, including those aspects related to the environmental and social determinants which have a direct impact on life and its quality, but also the orientation and habit of recognizing and properly addressing the ethical issues and responsibilities arising thereby. In this perspective, the observation that bioethics has not yet been included as a fundamental teaching in all the curricula of those professionals whose activity is immediately related to life and its safeguard (starting of course with physicians and nursing personnel but also veterinarians) sets a priority that cannot be eluded any further. The second and probably even more relevant challenge, besides toning down the debate and freeing it from its most ideological component, is that of redefining and updating the agenda of bioethics.

This update will probably entail a broader sensibility towards the environment and all other living beings, which are objects of growing attention, partly as a consequence of the awareness of the global risks for humankind determined by unhinged exploitation of resources. Some legislative actions have been undertaken to enforce animal protection, in connection with compulsory European directives, but also beyond that. A new crime of failure to offer assistance to animals of affection or those belonging to protected species involved in accidents, for example, has been introduced in the Road Code and Italian legislation against abandonment and maltreatment of animals is among the most severe. This widening of interests is consistent with maintaining a focus on the bioethical debate which is more directly connected to human life. The confrontation over the concept of dignity of life and the rights and obligations to respect, protect, and fulfill where it begins and ends will carry on. Nonetheless, other issues also require more and more attention as we are at the crossroads of scientific development, economic interest and constraints, political responsibilities, juridical order as a premise, and the guarantee of technological order (D'Avack 2009). Nanotechnologies and genomics, for example, are two issues that the National Committee as well as other centers and institutions have already started dealing with extensively.

The broad "horizontal" impact where nanotechnologies meet bioethics contains some crucial points: consequences for the environment; specific problems of information stemming from the "invisible" nature of nanoparticles, with special regard to the toxicological hazard arising from exposure people could not be aware of; the combination of organic and inorganic molecules; the applications of nanomedicine as a new, powerful instrument of therapy but also of possible enhancement, together with the necessity to draw up guidelines for research and experimentation in this field; the so-called nanodivide, that is, the possible

deepening of faults of inequalities between the developed and the least developed countries. Research on the human genome and genomics was involved with the bioethical debate from the beginning. At first, it focused on differences when compared to other kinds of research on human subjects. There is a need to reconsider the modalities of consent, depending on the fact that research is carried out on a sample and not on an individual and that the consent of the person involved could easily become a sort of "blank check" (the definition was proposed in an opinion of the National Committee of 2006) in relation both to the time limitations for use and the possibility of other uses within projects completely unknown to the subject. Other important issues, also widely discussed at the international level, are the issue of secondary information and/or unexpected findings and that of so-called group consent, that is, the possibility that some individuals, including relatives, could be involved in the outcomes of research.

Nowadays, two other major challenges are imposing themselves with increasing urgency. One is the risk of possible discrimination and stigmatization. Decoding the genetic endowment of individuals implies the possibility that some specific "fragility" could be made accessible to third parties: insurance companies, employers, educational institutions, pharmaceutical companies, or even public systems providing health care. The fundamental question of privacy is manifestly at stake. On the other hand, there is also the new and promising scope of pharmacogenomics and personalized medicine, which is going to deeply reshape clinical practice itself and raises important questions in terms of access and affordability, especially in the framework of a public health care system like the Italian one.

It is exactly this overlap of bioethics with the more general issue of health care that is likely to become a greater priority. Italy is among the countries whose citizens can rely on a longer life expectancy: almost 79 years for the male population and over 84 for the female. However, the scheme of the National Health Plan for the biennium 2011–2013, coordinated by the Ministry of Health, already stresses the urgency of improving appropriate standards with regard both to the introduction and the use of new procedures, drugs, and medical devices. The task to fulfill remains that of marrying "quality" and "sustainability" of health care and also taking advantage of information and communication technology. Among the emerging problems, besides aging of population, there is exactly the problem of access to new technologies. The ministry points out the importance of both personalized medicine and medical genetics and can but acknowledge the existence of deep, growing asymmetries as to the distribution and availability of the most advanced technologies and therefore opportunities of diagnosis and treatment in the different regions of the country. It is from this perspective that the link between bioethics and social and political responsibility looks set to strengthen.

Summary and Conclusion

Bioethics deals essentially with a question of limits and a question of commitment: the question of the limits we ought to accept in the use of biosphere and in

developing our technological grip on the world, as well as those that are to be set as an insurmountable bulwark to protect the dignity of human life; the question of commitment to widening the room for a mutual exercise of freedom and rights and sharing the benefits of scientific progress, especially as far as health and health care are concerned, avoiding digging new faults of inequalities and deepening the old ones. In Italy, the debate over the most controversial issues related to the beginning and the end of human life has long taken priority, particularly in connection with important legislative actions such as those on abortion and assisted reproduction. The National Committee, many other centers for bioethics, and the ethical committees which operate within hospitals and research centers have long since contributed to addressing the relevant ethical issues arising in the biomedical field and the new responsibilities to be met in clinical practice, in a country that provides its citizens with a high standard of health care. The polarization between Catholic and secular bioethics has played and keeps playing a role in public debate, but the new challenges require a less ideological and far more articulated approach.

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Bakhyt Sarymsakova

B. Sarymsakova
Department of Health Policy & Management, Central Asian Bioethics Association (CABA), Kazakhstan School of Public Health, Almaty, Kazakhstan
e-mail: bakhyts@yandex.ru; b.sarymsakova@ksph.kz

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Bioethics Development

Bioethics in Kazakhstan began has developed recently, mainly in the last decade. Representatives of the medical community initiated the establishment of public bioethics committees to promote ethical principles in medicine. The Congress of Physicians in 2002 adopted an oath of a doctor of the Republic of Kazakhstan (thereafter adopted as a code) that contained core ethical principles for health workers' professional activity. An international conference on the topic of good ethical practice in biomedical research was held in the same year under the auspices of the FECCIS/WHO with the support of the Ministry of Health (MoH) of the Republic of Kazakhstan (RK) and several international organizations. This conference played a significant role in the development of ethics in biomedical research in the country. A network of ethics committees was established, proposals to the regulatory and legal framework were made, training was conducted, and international cooperation with international organizations such as WHO/SIDCER, UNESCO, OHRP/DHHS (USA), WMA, FIC (USA), COHRED, and the World Bank was developed. A working group on development of the new Code of People, Health, and the Healthcare System was established in 2006 and included experts in research ethics. A number of articles were included in this code concerning ethics committees' organization, conducting ethical reviews, and the ban on euthanasia, patients' rights in health care, the legal framework for reproductive technologies, organ transplantation, and medical and genetic counseling. The code was approved by decree of the president on September 18, 2009. The Central (National) Ethics Committee (NEC) of the Ministry of Health of the Republic of Kazakhstan was established, along with local committees at research institutes and centers and medical universities.

Bioethics was included in both undergraduate and master's programs in public health in medical universities as a compulsory component in 2009.

Major Actors and Forces

A nongovernmental organization, the Association of Physicians and Pharmacists of the RK (currently the National Medical Association), has played a leading role in the development of bioethics in the domain of health care in Kazakhstan. This organization initiated some of the above-mentioned initiatives, and today the National Medical Association continues to promote bioethics issues in health care through education, legislative initiatives, conferences, and seminars for doctors, lawyers, nurses, and other professionals.

Since the establishment of the NEC of the Ministry of Health, the committee has become a leader in the promotion of ethical principles during research involving human subjects. Significant work is in progress on improvement of the system of ethical review, as well as the methodological, coordinating, and educational role of the NEC Ministry of Health embedded in the Constitution of NEC.

Currently, the NEC Ministry of Health is involved in development of proposals to amend the existing law on science of the RK to extend the scope of application of bioethics general principles for research in biology, genetics, biotechnology, ecology, sociology, psychology, and other fields. The NEC Ministry of Health is a national partner of the National Commission of the RK for UNESCO, and a number of important activities were held under the UNESCO Participation Program with the support of the National Commission and UNESCO Cluster office for Central Asia in Almaty.

The Central Asian Bioethics Association (CABA) was established in 2008 and joined experts in bioethics from Kazakhstan and other Central Asian countries. The secretariat of this Association is located in Astana, Kazakhstan. CABA is one of the most active players in bioethical principals' promotion in the country ensuring international cooperation in this field.

Major Concerns

Priority areas for bioethics development at the initial stage were implementation of ethical principles in medical practice, especially the practice of obtaining informed consent (IC) prior to medical interventions. Currently, this practice is implemented everywhere, the list of medical interventions is defined where written patient consent is required, and forms of IC are approved by the Order of the MoH.

Issues that have been highlighted the last decade include patients' rights, justice, quality, access to health care, fair resource allocation in the healthcare system in a transition economy, and healthcare policy (discussion of reforms and programs to improve population health and public participation in health issues discussion).

Special attention was also paid to the implementation of ethical principles in such areas as mental health services, HIV/AIDS, assisted reproductive technologies in connection with IVF development, and stem cell research.

A working group on stem cells research of the Ministry of Health was established as a result of public discussions concerning the ethics of stem cells research in 2006. A specialist in bioethics was included in this working group.

The result of this commission was an order of the Ministry of Health calling for a temporary suspension of research with the use of embryonic and fetal cells prior to the development of regulations.

Remarkable results have been achieved in the field of assisted reproductive technologies (ART) during the past 15 years. All known ART are applied in Kazakhstan today, and there are 10 centers for IVF. Women have a right to fertility treatment according to the legislation of the Republic of Kazakhstan, including the use of modern assisted reproductive technologies that are permitted in the country: germ cell donation, artificial insemination, in vitro fertilization, and embryo implantation. Men and women of marriageable age have the right to bank germ cells. The law of the Republic of Kazakhstan declared that human cloning is prohibited in the country.

Surrogate motherhood is permitted for medical reasons in the Republic of Kazakhstan and assumes carrying of a pregnancy and childbirth by agreement between the surrogate mother and prospective parents with remuneration payment or without.

When using assisted reproductive methods and technologies, sex selection is not allowed except the in cases where there is possibility of inheritance of a sex-related disease.

The law of Kazakhstan states that a human embryo cannot be obtained for commercial (buy/sell), military, or industrial needs (Lokshin, 2012).

Another priority area is transplantation of organs and tissues. The basic framework for tissue and organ donation regulation has been defined, and the concept of consent presumption was enshrined by the law with respect to posthumous tissues and organs donation. A ban is imposed on buying or selling organs A pronouncement procedure of biological death or irreversible brain death has been established.

Resources

No professionals in Kazakhstan have been involved in bioethics on a permanent professional basis. Training is carried out mainly with books by Russian and foreign authors, and there is no textbook in Kazakh approved by the Ministry of Education and Science that has been adapted to the local cultural and religious conditions.

Training manuals on bioethics, medical ethics, and research ethics were developed and approved at the university level for students of medical universities.

Since 2001, Kazakhstan has actively participated in the SIDCER (Strategic Initiative for Development of Capacity for Ethical Review) initiative supported by WHO/TDR. Through the regional forums for ethics committees (FECCIS), many activities have been implemented to strengthen the capacity for ethical review of biomedical research. Participation in this network has been an important force behind research ethics development in Kazakhstan.

As a result of collaboration between SIDCER/FECCIS and Western Institutional Review Board (WIRB, Olympia, WA, USA), a participant from Kazakhstan took part in a 6-month course on bioethics and ethical review in 2005.

Measures Taken

A working group on development of the new Code of People Health and Healthcare System was established in 2006 and included experts in the bioethics of research. The code was approved by the decree of the president on September 18, 2009. The Central (National) Ethics Commission of the Ministry of Health of the Republic of Kazakhstan was established according to the code, along with local committees at research institutes and centers and medical universities. These committees mainly review biomedical research involving human subjects.

According to the code (Article # 181), the commission is an independent national body, the main objective of which is to protect rights, health, and well-being of research participants and patients and to guarantee their safety.

The commission carries out activity to enhance national legislation on the ethics of science and technology by developing appropriate proposals and recommendations. The commission is also provides an independent ethical and legal review of clinical research materials.

The commission also provides methodological assistance, consultation, education, and contacts to mass-media. The action plan of the commission also includes carrying out of international ethics conferences and publication of articles in the scientific magazines.

The commission was established on an interdisciplinary basis and consists of experts in the field of medicine, biology, pharmacology, law, religion, and representatives from state and public organizations. The commission fulfills a key role of developing guidelines to help frame the ethical protections of the interests of patients. These include:

- The Constitution of the Republic of Kazakhstan;
- The Code of People Health and Healthcare System;
- The Declaration of Helsinki;
- The Order of the Ministry of Health Rules for Carrying Out Clinical Research, Medical and Biological Experiments and Clinical Trials in the Republic of Kazakhstan;
- The Good Clinical Practice (GCP) standards of the Republic of Kazakhstan;
- The Commission Constitution and standard operational procedures.

To create favorable conditions for the development of similar structures in other ministries and agencies, the commission determined principal targets for the near future:

- Coordination of the activity of the local ethical committees in the country;
- Development of a unified approach to requirements and mechanisms of the ethical review process;
- Counseling help for other ethical structures and implementation of different models;
- Help in training of experts;

One directions for future activity is to develop international cooperation in the field of human rights protection while undergoing medical care, and within the framework of research with human subjects, exchange of experience, joint development of training materials and recommendations in ethics, and other projects in collaboration with international organizations (WHO, UNESCO) and other stakeholders.

In addition, public bioethical committees were established at the Academy of Science, at the National Coordinating Council for Healthcare of the Ministry of Health, and at other public organizations. These committees dedicate their activity to education, increasing public awareness, public discussions, and promoting legislative initiatives. A significant achievement was the inclusion of bioethics in educational programs at the undergraduate and postgraduate levels.

Due to new approaches to moral and ethical problems in medicine and science and the emergence of bioethics as a cross-sectoral discipline in recent decades, it is now necessary to review all levels of training programs. Although "bioethics" has not been included in the state standard of higher medical education, issues related to bioethics are included in other programs. For example, issues of biomedical ethics have been introducing within the framework of communication skills at the Department of Introduction to Medicine, General Medicine. A course on research ethics has been suggested as an elective for undergraduate students (General Medicine, Public Health). The issues of bioethics and law are included in the master of public health program (2 years), master's in medicine program (2 years) as a compulsory course, and for the doctorate in public health (3 years) as an elective course. Also, bioethics and legal aspects are offered to physicians doing post-graduate studies.

The Higher School of Public Health (MSPH) has included discussions on ethics of scientific research in health in its training programs since 2001. Starting in 2002, the HSPH participated, together with the Bangladesh Medical Research Council with financial and technical assistance from an international award, in bioethics training and career development at the International Fogarty Center (FIC) and the National Institutes of Health (NIH) in the United States.

Professor Harun Al-Rashid was the Director of the Program, Director of the Bangladesh Medical Research Council (BMRC), and am member and secretary of the Committee on Ethics of this council, which is considered to be the National Committee of the country.

The program consisted of two components: Kazakhstan and Bangladesh. The Kazakhstan consultant for the program is Professor M.K. Kulzhanov, the principal of the HSPH. The coordinator of the program is B.E. Sarymsakova, M.D., Academic Secretary of the HSPH.

The program consists of the following aspects:

1. Development of complete curriculum/program for a bioethics seminar;
2. Training of young scientists (having various areas of expertise) in bioethics of scientific research.

An intensive training seminar on the ethics of scientific research was developed by the Higher School of Public Health in 2002–2003. The program included a seminar, panel discussions, and meetings. About 20 specialists from various scientific and research institutions in the country participated in development of the seminar program. During preparation of the training program, the teaching staff conducted an intensive seminar on the ethics of scientific research in Kazakhstan. The seminar program was approved by a consulting committee that provided general management of the program, its monitoring, and evaluation. This program was translated into English and sent to international consultants for review and to offer any improvements. At the time, pass-fail forms for trainees and general evaluation of the seminar were also developed.

The Seminar is intended for young scientists doing research in various scientific areas. Fifty people total were trained during three seminars over the course of 5 days. The main purpose of the training in scientific research ethics is to improve ethical practice during scientific research, increase awareness of ethical issues

during scientific research involving humans, provide basic and applied knowledge of ethics with an emphasis on its international aspects, and to familiarize trainees with existing ethics guidelines.

Issues of ethics related to international scientific research in the area of health were specifically emphasized at the seminar. The seminar covered such subjects as historical perspective of ethics related to scientific research in health, international declarations and guidance on scientific research involving humans, informed consent, confidentiality, motivation, ethics of clinical studies, ethics of population and demographic research, ethical issues of scientific research on reproductive and children's health, functions of Committees on Ethics; ethical expertise guidelines, conduct of scientific research in developing countries, and religion and culture in ethics.

The teaching staff included key national experts with respective professional and educational experience in philosophy, legislation, public health, epidemiology, reproductive health, and genetics. Professor Harun Al-Rashid was one of the main professors with experience in conducting such seminars and he speaks Russian fluently. In total, 10 professors were invited to conduct this seminar.

Those doing research in biomedicine, clinics, and public health were invited to participate in the seminar. Notices were sent to all medical institutes, universities, state, and non-state medical organizations. Trainees were selected based on recommendations of the institutions themselves. Heads of the institutions selected a few candidates to take part in the seminar based on the selection criteria as set forth in the information letter. The candidates had to demonstrate their involvement in research and have a minimum of 3 years of research experience. This seminar was intended for young professionals under 35 years old. Criteria for selection were offered and approved during development of the training program. Candidates had to send all necessary documents, including references, of the head of their institution and to the Organizing Committee for the Seminar (OCS). Potential participants were selected on a competitive basis at the OCS meeting. The seminar was organized by the management of the Higher School of Public Health (HSPH) Almaty, Kazakhstan. Trainees received certificates signed by the Principal, Academic Secretary of the Public Health School, and the Director of the Program. A total of 50 young scientists from all regions of Kazakhstan were trained under the program.

Bioethics was included in undergraduate and master's programs in public health in medical universities as a compulsory component in 2009.

Current Bioethics Infrastructure

Teaching of Bioethics at University and Other Levels

The basics of bioethics are included in educational programs for students of medical universities at the faculties of public health, nursing, pharmacy, and dentistry in the third course for 36–54 h. Bioethics issues are included under the subject of

"communication skills" at the Faculty of General Medicine in a volume of 36 h. Biomedical research ethics is offered as an elective course for third-year students in the general medicine specialty.

Bioethics as a compulsory component is included in master's programs in medicine and public health for 54 h; foundations of bioethics and biomedical research ethics are found as an elective course in doctoral programs in the specialty of public health.

Foundation courses in bioethics and health law and biomedical research ethics have been proposed for advanced professional training for healthcare providers, ethics committees members, researchers, and other professionals in the faculties of additional medical education.

Bioethics Committees

In Kazakhstan, the system of ethical review of research in the field of health care has only been recently introduced. The basic elements for the functioning of such a system are the legal framework, a network of the ethics committees (EC) at the national and institutional levels, and personnel training. Status and functions of the EC are approved by "The Code of Public Health and Healthcare System of the RK" (2009) and other regulations. Today the EC's work is under way, but in many cases there is a low degree of interaction with authorities and a lack of effective control over the research being conducted.

The system of ethics review of research in the healthcare sector consists of two stages: the Central Ethics Commission under the Ministry of Health of the RK and the Local ethics committees at the level of research institutes/centers of MOH RK. The commission was established as an independent body whose primary purpose is to protect the rights, health, and welfare of the subjects and researchers, and to create guarantees for their safety. The Central Commission for Ethics conducts an independent evaluation of studies at international and national levels.

The Ministry of Health, at a meeting of the Academic Council (2007), recommended establishment of the local ethics committees (LECs) in all research institutions and medical schools. The composition of the LECs and their regulation are approved by an order of the head of the healthcare organization under which the commission has been created. The LECs carry out an independent ethical review of clinical research performed in the establishment and guarantee the rights of patients participating in studies, as well as monitor and control of the interim study after granting permission to conduct.

The commission on ethics may include specialists in healthcare, science, art, and law, along with representatives from religious groups and public associations. The work of the commissions is guided by international instruments, national laws, regulations and statutes, and standard operating procedures (SOPs). SOPs define all of the ECs' activities: the creation and organization of the EC, its composition, procedure for considering an application, documentation, paperwork (application, decision, and report), archiving, and so on.

According to the regulations, ethical review is mandatory at the planning stage of research and is performed by the ethics committees under the research organizations of the Ministry of Health of the RK. In most cases, this work is carried out under the *local* ethics committees under the healthcare organizations accredited as clinical sites for clinical studies/trials (CT) and approved by the Order of the Ministry of Health of the RK.

Procedures for mandatory ethical review of clinical trials have been implemented since 2005, under the order of the Ministry of Health of the RK. This order laid the foundation for the process of accreditation of healthcare organizations for conducting clinical trials and training of professionals involved in clinical trials. An indispensable condition for obtaining the right to conduct clinical trials was the establishment of ethics commissions under the sites to be accredited, as well as availability of specialists with knowledge of the basics of good clinical practice (GCP).

Expert Bodies

The scheme of interaction between the Central and local ethics commissions in considering requests for clinical trials is as follows: application (sponsor-customer) → expert body (the Center for Medicinal Products Expertise under the Ministry of Health of the RK) → Central Commission for Ethics under the Ministry of Health of the RK → expert body → Committee for Medicinal Products Control of the Ministry of Health of the RK → Customer → clinical site (basic researcher) → local ethics commission → conduction of clinical trials.

Without the approval of the ethics commissions, documents on the clinical research or tests cannot be approved by the authorized body (the Ministry of Health of the RK), and the research itself cannot begin.

Relevant Legislation

The basis for legal regulation of biomedical research and its ethical review in the RK is formed by a series of international guidelines and recommendations on research ethics (WMA Declaration of Helsinki, Manual CIOMS, ICH-GCP, the WHO recommendations, etc.). With regard to the domestic system of legal regulation of biomedical research in the RK, it should be noted that detailed regulation exists for clinical studies and trials of medicinal products only.

"The Code on People's Health and the Healthcare System" (2009) regulates the conduct of biomedical experiments, pre-clinical (non-clinical) and clinical studies, use of new methods of diagnosis, treatment, and medical rehabilitation (provision 180).

The State Standard of the RK for "Good Clinical Practice" (65–119 GCP RK) was developed and approved in due course and came into effect in January 2008 (51). This document is a scientific and ethical standard for running clinical studies

and tests, the results of which are scheduled for submission to the authorized bodies. This standard is based on ICH-GCP-Guidelines for Good Clinical Practice of the International Conference on Harmonization.

The principles established in this standard can be applied to other clinical research and tests that may affect the safety and well-being of the subject.

In accordance with Provision 74 of the Code of RK the "Regulations for clinical researches and (or) pharmacological tests of medicinal products, medical devices and medical equipment" (2009) were approved. These regulations for clinical research and (or) pharmacological tests of medicinal products, medical devices, and medical equipment (hereafter, clinical research) in the Republic of Kazakhstan (hereinafter, the Regulations) define how to conduct clinical research in the Republic of Kazakhstan, providing protection of the rights, safety, and health of persons involved in the research, as well as accuracy and precision of information obtained during the clinical research.

Thus, the current system of legal regulation of biomedical research in the Republic of Kazakhstan ensures compliance with generally accepted ethical standards and requirements, especially in the field of clinical research. However, questions of ethical regulation of research not related to medicinal products testing (genetic, sociological, epidemiological, and other biomedical research involving human subjects) require additional legal regulation.

One of the basic problems that was revealed was the absence of unified approaches to the LECs' work organization. It is necessary to develop Unified National Ethic Guidelines on organization and conduct of biomedical research with due account to the international requirements. The most essential element of such guidelines should be a unit devoted to conduct of ethical examinations and organization and examinees' rights protection. In this case, it is necessary to standardize creation procedures and activity of ethic committees/commissions through distribution of standard operational procedures (SOP) approved by the Ministry of Healthcare and the Ministry of Education and Science.

Each LEC should create and follow its own SOP guidelines, whose application and field of influence reflects activity of the LEC and refers to national and international standards for ethic examination in biomedical research.

Future Challenges

In Kazakhstan, a system of ethical review of research in the healthcare sector has been created and in operation, which has a legal, regulatory, and institutional framework (the central and local ethics commissions).

It is worthwhile to develop and implement a clear scheme of cooperation for structural elements of the system and to divide their functions and authorities. This should result in increased efficiency and quality of examination of scientific research with human subjects.

Moreover, it is important to provide conditions for EC functioning (administrative, organizational, and financial support at the institutional level). A key problem

is training LEC members and providing methodological, informational, and resource support for the committees' activities. Creation of an Information and Resource (or Methodological) Center under the Central Committee on Ethics Issues Ministry of Health RK has been suggested. This center is supposed to carry out the following functions:

- Create and update the national database on EC, resources, results of completed ethic examinations within different healthcare organizations (clinical, scientific, training);
- Support permanent system of dialogue between the EC members (annual conference, foundation of the EC association/forum, creation of special website for opinion exchange between the ECs and the exchange framework within an organization, etc.);
- Implementation of the EC experience for teaching medical students, biologists, geneticists, and people in other related specialties.

It is necessary to include discussions of bioethics, research ethics, and ethical review of research projects in the system of continuing professional development of physicians and researchers, experts, and members of the ethics committees, which will increase the level and quality of scientific research in accordance with international standards. The concept of training expert members of the ethics committees has been suggested and included of basic and continuing education. It is crucial to include the subject of bioethics in the state educational standard for undergraduate and postgraduate education based on the UNESCO core curriculum on bioethics.

The system of the ethical review of research involving human subjects in the Republic of Kazakhstan has a legal (the legal framework) and an institutional (the ECs network) basis. The legislation regulates the ethics, mainly, in clinical research, and there is no regulation for other ethical principles of biomedical research involving human subjects.

Implementation of the system of ethical review of research in the Republic of Kazakhstan requires effective support from the government and research organizations: training professionals for the LECs, increasing interaction of local ethics committees, and improving the regulatory framework for biomedical research with regard to their ethical regulation.

According to self-assessment and expert review, the local ethics committees' activity in research institutions of the Ministry of Health of the Republic of Kazakhstan is not yet in line with international recommendations, especially with regard to management of ethics committees and the level of expert committee members' training.

Results of this study have formed the basis of recommendations for further improvement of the system of ethical review of research organizations of the Ministry of Health RK. There have been proposed measures to improve the regulatory framework of ethical review and improve training for the LEC members, providing institutional support to the LEC, and increasing interaction of ethical committees at various levels that will improve the quality of ethical review of research in the health sector, in line with international recommendations.

New and Emerging Issues

Strong measures for development of science and technology are under way in Kazakhstan. Government programs to support scientific and innovative development of the country have been approved, and new universities, research centers, and technology parks have been established. The HSTC (Higher Scientific and Technical Commission) defined national priorities for science development for 2011–2013, which were approved by the protocol resolution №20-55/372 dated April 21, 2011:

1. Energy industry (energy efficiency, ecological cleanness and environmental safety, alternative safety, renewable sources, nuclear and thermo-nuclear power);
2. Advanced processing of raw materials and products (refining of hydrocarbon and mineral raw materials, chemical and mining and smelting technologies, and agricultural products);
3. Information and telecommunication technologies;
4. Life sciences (medical and biomedical research, biotechnologies, ecology, anti-aging, pharmacy, agriculture);
5. State intellectual capacity (basic natural science and humanitarian international level research, exploratory research in promising directions).

The following priorities are defined in the field of medicine for 2011–2015:

1. Environment and health;
2. Active longevity (prolongation of life and rejuvenation);
3. Regenerative medicine (cell technology, artificial organs);
4. Child welfare and reproductive health technologies;
5. Technologies to prevent premature death and disability from disease and injuries;
6. Technologies to prevent and reduce the burden of communicable and socially significant diseases (tuberculosis, HIV/AIDS, viral hepatitis).

The new Nazarbayev University, named after the first president of the country, was opened in 2010 in Kazakhstan. Science and technologies schools and a Center for Life Sciences were opened at this university, where the main focuses are anti-aging, cell technologies, personalized medicine, and genetics research.

Transplantation is being actively developed in the country; a National Coordinating Center for Transplantation was established in 2012, which should develop an organizational, legal, and methodological basis for this service development in the country.

There are some unresolved issues, however, such as lack of donor organs and ethical and legal basis for organs removal. The key issue – the consent for organ and tissue removal – is not regulated and did not accurately determine the presence of intra-vitam refusal from the deceased patient for posthumous tissues and organs donation and did not establish a mechanism for access to the deceased patient's relatives for such a data request or for their opinions. In addition, the issue of brain death as the death criterion is not fully resolved. All this will serve as an impetus for the further bioethics development in the country.

Other Problems and Opportunities

Kazakhstan and other Central Asian countries (Kyrgyzstan, Tajikistan, and Uzbekistan) have well-established historical, social, and linguistic ties, having been part of a single country (the Soviet Union) for more than half a century. However, the region its own unique identity that is evolving and is influenced by the region's strong geopolitical location at the crossroads of two large regions, Asia and Europe. The need to recognize and cultivate a uniquely Central Asian identity has been the impetus for the creation of the Central Asian Bioethics Association (CABA). In Central Asia, this identity represents the convergence of many factors: for example, traditional and modern values, the increasing influence of Islam in many regions, rapid economic development in some sectors, and insufficient resources being dedicated to science and technology, education, and innovation. The region's diverse cultural and religious composition makes development of ties and sharing of information imperative with countries throughout Asia and the Middle East, as well as with the former Soviet bloc.

During the years after the break-up of the USSR, the system of science and education changed drastically, relations between scientists weakened, there was a substantial outflow of qualified specialists, the material and technical base deteriorated, and funding was reduced, etc.

At the same time, the role of scientists who are called on to control disease and improve health has become more important. This research often involves humans, which imposes a special responsibility on a researcher. The advancement of medical and biological research causes concern, as it makes it difficult to predict social and general biological consequences following from the latest scientific discoveries in genetics, stem cell therapy, and other areas. Bioethics, as an interdisciplinary scientific school of thought, tries to answer these challenges.

For Kazakhstan, increasing globalization of science and technology presents new opportunities to build quality and efficiency into research among all actors engaged in promoting best practices in the country: bioethics committees, researchers, research institutions, and universities, as well as those benefiting from scientific and technological achievements, including patients and consumers. Awareness in the country has already been raised regarding the importance of interdisciplinary cooperation in the field of bioethics.

In the course of socioeconomic transformation, there is a necessity for Kazakhstan to develop its science and technology sector and to invent new technologies in medicine and biology. In this regard, there is a growing attention to the importance of ethical principles in scientific and health research National, regional, and international guiding principles are imperative for the effective functioning of ethics expertise. However, international ethical standards are not sufficient to ensure ethical practices, for example, the protection of human research subjects, if information gathering, knowledge dissemination, and educational activities are conducted without systematic approaches at the national level. For Central Asia, the relatively small size of countries in the region means the number of specialists working on bioethics issues is quite small, only a few in each country. Because of this, a regional approach based

on national support mechanisms is necessary to comply with the highest ethical and scientific standards in research practice of the region.

CABA's advantage is its partnership approach and collaboration among experts from the leading institutions of the region and international organizations. This initiative will provide those in Kazakhstan with an opportunity to discuss bioethical problems raised by the application of biotechnology and research at the national, regional, and international level. It is also proposed to create allies with other organizations that are dealing with science, research, and ethics, including research institutes, health facilities, governments, and NGOs. CABA is supporting countries, institutions, and society by providing opportunities to develop ethics and science, contributing to an inclusive ethics-based decision-making process and creation of a legal framework that takes into account the interests of citizens in the region.

Conclusion

Bioethics has developed over the last 10 years in Kazakhstan. Public medical organizations, physicians, and researchers were at the origins of this process. This determined the main vector of bioethics development in the following years; the emphasis mainly was on medical ethics and medical research ethics.

Significant results have been achieved in this field today: legal basis, a network of ethics committees, and training in the basics of bioethics in medical universities. However, due to development of new scientific discoveries and technologies and international cooperation of scientists in the field of basic research, further bioethics development with the involvement of others from outside the medicine sectors is required. For this purpose, it is necessary to establish cross-sectoral structures interested in promotion of bioethics principles in various fields of science, education, and new technologies development. It is necessary to raise the awareness and involvement of the widest social strata in the discussion on urgent bioethics issues, to implement training in bioethics in school and university curricula, and to develop international cooperation.

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Lithuania

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Eimantas Peicius and Vilius Dranseika

Lithuania is a country situated at the northeast part of Europe along the east coast of the Baltic Sea. Currently, Lithuania is a civic democratic society governed by a freely elected parliament (Seimas) and a president, and has been a member of European Union since 2004. With more than three million inhabitants, the country has one of the lowest GDPs in the European Union, comparable to Latvia, Romania, and Bulgaria. In this chapter we are going to discuss development and the main characteristics of Bioethics in Lithuania.

E. Peicius (✉)
Department of Social Sciences and Humanities, Lithuanian University of Health Sciences, Kaunas, Lithuania
e-mail: eimpei@gmail.com; eimantas.peicius@lsmuni.lt

V. Dranseika
Department of Logic and History of Philosophy, Vilnius University, Vilnius, Lithuania
e-mail: vilius.dranseika@fsf.vu.lt

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Bioethics Development

The development of ethical norms related to the field of medicine in Lithuania can be divided into three historical periods: nineteenth to mid-twentieth century discussions on norms governing behavior of medical doctors, Soviet medical ethics, and bioethics since re-establishing the independence of Lithuania. The first two periods were mostly concerned with medical deontology, that is, the duties of medical professionals. The third period witnessed the expansion of the field in terms of establishing new academic and governmental institutions dealing with bioethics, as well as establishing international connections, cooperation, and engagement around a much broader thematic scope of issues.

The first fragmented ethical considerations related to medical activities can be found at the beginning of the nineteenth century in the Faculty of Medicine of Vilnius University, the oldest education center in Lithuania (established in 1579). The departments of hygiene and forensic medicine were established, and the course on social hygiene and forensic medicine was introduced at the Faculty of Medicine, Vilnius University. In the context of those activities, some historical sources indicate academic discussions over physicians' duties to patients in amputation, surgery, and other medical procedures. However, further developments were impeded by the suppression of academic activities in Lithuania by the Russian Tzarist rule. (Most of Lithuania was a part of the Russian Empire from 1795 until World War I). Between 1918 and 1940, Lithuania was an independent state until it became a part of the USSR during World War II. During the independence period, academic activities in the field of what now would be called bioethics were few and mostly concentrated on professional behavior and character traits of medical specialists. Perhaps the most notable example was "On Professional Ethics of Medical Doctors," a small booklet by Petras Avižonis published in 1929 (Avižonis, 1929), which addresses three issues: (a) moral, intellectual, and physical features of a good doctor; (b) duties of doctors towards their colleagues; and (c) their duties towards patients.

The second stage of bioethics development happened during the Soviet period while Lithuania was a part of the Soviet Union (USSR). In general, Soviet medical ethics, usually referred to as medical deontology, was a set of rules mainly based on the Hippocratic Oath. These rules were integrated into the Soviet ideological philosophical teachings based on dogmatic Marxism (e.g., Černeckis, 1971; Žemaitis, 1976). Without going too deep into the political and ideological conditions of Soviet totalitarianism, it would be sufficient to state that, arguably, the development of bioethics in the Soviet Union was nearly impossible and significantly differed from the historical and political circumstances prevalent in Western countries. In such a context, officially prescribed norms and principles that were imposed upon professional activities should rather be distinguished from the ethical norms and values actually accepted and practiced by health care professionals. Consequently, the narrow understanding of medical ethics of the former socialist countries of Eastern Europe and especially the former Soviet Union has usually been identified with the statements taken from "The Oath of Soviet

Physicians." This oath included, for instance, obligations to always take into account the interests of the society, to make sure that "the conduct of all my actions accord[s] to the principles of the Communist morality" (Gefenas, 2009b, p. 469), and to keep in mind the "high responsibility I have to my people and to the Soviet government" (ibid.).

Since the re-establishment of independence in 1990, bioethics has gradually developed both in academic and governmental activities. A number of academic departments conducting research and teaching medical humanities were established in educational institutions across the country. A system of ethical review of biomedical research was established, both in terms of institutions and legal regulations. A number of international collaborations were initiated, and the number of publications in the field of bioethics began increasing gradually.

Three major factors shaped the development of bioethics during the transitional period from a totalitarian to a democratic society. First, reforms in health care, social policy, and other realms of social life caused growing academic interest in the Western heritage in the fields of philosophy, ethics, sociology, psychology, and other disciplines in humanities and social sciences. The need to incorporate medical humanities into the medical students' curriculum was a part of this process. In the early 1990s, individual scholars started to introduce into the curriculum topics of human rights, personal autonomy, and social justice as well as more practical problems, like those of informed consent, abortion, or allocation of scarce health care resources. Second, changing realities of the healthcare system triggered new practical challenges. Health professionals have expressed a growing interest in medical humanities because of the changing needs and expectations of patients and the shift from a paternalistic approach to one rooted in patient autonomy. The need to join international biomedical research is another example of those changing realities. The system of ethical review of biomedical research began with initiatives of individual researchers in the late 1980s, and resulted in a quite comprehensive system a decade later. The third factor was a legal development related to Lithuania's integration into the international scene and European structures, most notably joining the European Union in 2004. This process of harmonization resulted in a number of legal instruments being implemented in the field of bioethics in Lithuania, including Directive 2001/20/EC of the European Parliament and of the Council on the Conduct of Clinical Trials on Medicinal Products for Human Use in 2004.

The two major actors during the third stage of the development of bioethics in Lithuania were the academic centers of medical humanities and the Lithuanian Bioethics Committee, an official governmental institution responsible for policy making in the field of bioethics as well as ethical review of biomedical research. These two factors have played and are still playing a crucial role in the development of bioethics in Lithuania. Educational activities and the system of ethical review of biomedical research more specifically require a more detailed discussion.

Currently, there are no bachelor's or master's level study programs in bioethics or medical ethics offered in Lithuanian educational institutions. However, courses in medical humanities are an integral part of medical professionals' education.

Courses in bioethics are taught to students in some other study programs as well, such as philosophy. A notable example of international cooperation in the field of bioethics education is a combined online-onsite study program, the "Advanced Certificate Program: Research Ethics in Central and Eastern Europe," offered by the Vilnius University Department of Medical History and Ethics in collaboration with the Bioethics Program at Union Graduate College – Mount Sinai School of Medicine (USA). The fourth cohort of students from Central and Eastern Europe have finished their studies in 2012. These studies are focused on research ethics and international bioethics and the goal is to prepare students to function as independent research ethicists in their home countries.

The development of the system of ethical review of biomedical research started in the late 1980s with the establishment of the first hospital-based research ethics committees. In 1994, the Law on the Health System was adopted, which led to the establishment of the Lithuanian Medical Ethics Committee (now called the Lithuanian Bioethics Committee) a year later. The committee functions as a national bioethics council and it also has a subcommittee for ethical review of biomedical research. In 2001, the Law on Ethics of Biomedical Research introduced a two-tier system of ethical review with one central committee (the Lithuanian Bioethics Committee) and two regional committees. One of these regional committees was established at Kaunas Medical University (now known as the Lithuanian University of Health Sciences) in 2001 and another one at Vilnius University in 2008. Regional committees are assigned geographically defined jurisdictions. The Lithuanian Bioethics Committee supervises the regional committees and reviews their decisions upon appeal. It also issues decisions on clinical drug trials and on biomedical research studies that take place in more than one region. A more detailed account of the system can be found in Dranseika et al. (2011).

Healthcare ethics committees have been also operating in Lithuanian healthcare institutions since the early 1990s. However, their efficiency in addressing ethical concerns in the healthcare setting remains questionable (see Gefenas, 2001 for an overview).

The main institutional developments during the last two decades can be summarized as follows. Several academic departments related to bioethics were established in the early 2000s, a system of ethical supervision of biomedical research was established, and hospital ethics committees have been functioning in most healthcare institutions since the 1990s. In relation to these activities, a number of textbooks on bioethics, especially on medical ethics were translated into Lithuanian, mostly from English. Several monographs and textbooks on medical ethics and nursing ethics were written by Lithuanian authors as well (e.g., Blaževičienė & Jakušovaitė, 2008; Liubarskienė, 2005; Liubarskienė, Peičius, Blaževičienė, & Urbonas, 2008; Širinskienė & Narbekovas, 2007).

The academic and institutional development of bioethics in Lithuania was followed by some difficulties. First, new democratic values such as respect for persons, freedom, and civic participation challenged the heritage of previously widespread cultural traditions and moral values (i.e., obedience and paternalism). Second, competition between egalitarian and libertarian principles in the domestic

health policy and health care provision has continued to exist. Despite the fact that equitable access has been declared as a priority in the official Lithuanian health policy documents, a scarcity of healthcare resources constantly pushes the system towards a libertarian type of health care. Third, the emergence of secular bioethics has been followed by religious perspective on bioethics. However, a fruitful dialogue between these two perspectives is often lacking in Lithuania.

Current Bioethics Infrastructure

This section contains information on the main features of the current bioethics infrastructure in Lithuania: academic departments, educational activities, the system of ethical review of biomedical research, and the main legal instruments pertaining to issues of bioethics.

Currently there are four academic departments in different educational institutions of Lithuania dealing with (among other issues) research and teaching in the field of bioethics:

- Department of Medical History and Ethics, Vilnius University
- Department of Social Sciences and Humanities, Lithuanian University of Health Sciences (Kaunas)
- Department of Biolaw, Mykolas Romeris University (Vilnius)
- Research Center on Marriage and Family, Vytautas Magnus University (Kaunas)

Another institution, the Regional Bioethics Information Centre at Vilnius University, is an information and documentation center taking active part in a number of European research and networking initiatives with a special emphasis on activities in Central and Eastern Europe.

Courses in bioethics and medical ethics are currently part of the curriculum of medical schools at the Faculty of Medicine at Vilnius University and the Lithuanian University of Health Sciences. Courses in bioethics are sometimes taught for non-medical students as well, for example, students of philosophy at Vilnius University or students of biolaw at Mykolas Romeris University.

The system of ethical review of biomedical research in Lithuania consists of two tiers. The Lithuanian Bioethics Committee (Lithuanian Committee for Medical Ethics before 2000), established in 1995, is the chief institution responsible for bioethics policy in Lithuania and it is also responsible for the ethical review of multi-site biomedical research projects. In addition to the Lithuanian Bioethics Committee, there are two regional research ethics committees responsible for ethical review of biomedical research conducted in particular regions of Lithuania. The Kaunas Regional Biomedical Research Ethics Committee was established at Kaunas University of Medicine (now Lithuanian University of Health Sciences) in 2001. The second regional committee was established at Vilnius University in 2008.

The development of legislation in the field of bioethics in Lithuania is closely related to the integration of Lithuania into different international and European structures. Such international bodies as the Council of Europe,

the European Commission, and UNESCO played an important role in this process. The most important international instruments in force in Lithuania are the European Convention on Human Rights and Biomedicine (ratified in 2002), regulating the protection of human rights in the field of biomedicine (together with its Additional Protocols on the Prohibition of Cloning Human Beings (ratified in 2002) and concerning Biomedical Research (signed in 2005)), and Directive 2001/20/EC of the European Parliament and of the Council on the Conduct of Clinical Trials on Medicinal Products for Human Use (implemented in Lithuania in 2004), which sets the framework for clinical drug trials. The most important national legal documents are the following: the Law on the Health System (1994), which, among other things, led to the establishment of the Lithuanian Bioethics Committee; the Laws on the Rights of Patients and Compensation of the Damage to their Health (1996) and on Legal Protection of Personal Data (1996), which together set the framework of patient rights and protection of health and other personal data; and the Law on Ethics of Biomedical Research (2000), which completed the establishment of the two-tier system of ethical oversight of human biomedical research. (For a list of all the relevant documents including ministerial decrees see the website of the Lithuanian Bioethics Committee (http://bioetika.sam.lt)).

Major Bioethics Issues and Discussions

The development of bioethics in Lithuania, as indicated previously, was strongly influenced by the political and cultural shifts during the last two decades. A number of debates related to specific bioethical problems have been initiated in political, academic, and public circles while trying to apply European democratic values in practice, especially in the healthcare sector. Lithuanian bioethicists analyzed general concepts like human dignity, health, illness, and personal autonomy when discussing and often justifying pluralistic and patient-centered medicine, which was replacing the tradition of paternalism in Lithuanian medicine (Jakusovaite & Peicius, 2003). Integration of the practice and culture of respect for personal autonomy into decision making in health care met significant difficulties, mainly because the values and principles of a free and democratic society had been suppressed during the decades of totalitarian regime, where personal autonomy was regarded as secondary to the "best interests of the society." Recent efforts aimed at replacing traditional paternalism should be seen not only as attempts at developing a safeguard against abuse of patients' rights but also as part of a wider social and political effort to develop broader understanding of respect for persons (Gefenas, 2009a). Much of the current activities of Lithuanian scholars, researchers, and the public that is focused on such issues as ethics in clinical care, research ethics, and social ethics regarding the organization of healthcare system can be seen as a reaction to this fundamental challenge.

The analysis of the shift from paternalism to autonomy in the health professional–patient relationship currently is one of the most actively addressed issues in the country. The discrepancies between officially declared principles of

patient autonomy, informed consent, and rights to healthcare access, inherent in the legal system, and their implementation in medical practice have been repeatedly reported. Accordingly, the need for more active patient participation in medical decision making is one of the most important challenges in the reorganization of health care in Lithuania. Attempts at the application of a partnership relationship in, for instance, the general practitioner–patient relationship in primary care reveal a number of questions: How well are patients informed about their rights? How much and what kind of medical information should be disclosed to the patient and on what conditions? How is such information perceived by different patient groups? How should it be managed? And to what extent should health professionals take patient opinions into consideration if these opinions contradict the benefit of patients themselves? (Grabauskas, Peičius, & Kaminskas, 2004).

Paradoxically, the legislation of patient rights and its adoption in practice as a reaction to the widespread paternalistic culture in health care has led to some misconceptions. First, the formal adoption of bioethical principles such as informed consent did not affect medical practice in the way it was intended to: the gap between declarations and daily practice was noted by the public and the media as well as by the scholars. Second, the practice of informed consent became too formalized and too demanding, both in terms of time and other resources. Straightforward application of the principle of informed consent basically boiled down to the requirement to obtain a written form of patient's consent in every step of the treatment. This caused many complaints and increased mistrust between health professionals and patients rather than striking the right balance between physician duties and patient rights. Active debates on the procedure of informed consent in clinical practice have led to the amendment of the Law on the Rights of Patients and Compensation of the Damage to Their Health in 2010. New provisions have been included in order to respond to the growing complaints of health professionals regarding the requirements to obtain formal informed consent from the patient at every step of healthcare service provision. For instance, in the context of voluntary admission to healthcare service, informal consent of the patient could be deemed sufficient for many medical procedures if adequate information is provided to the patient according to his or her demands. Consequently, written informed consent must be obtained only in the case of performing interventional, invasive, or surgical procedures or when the patient opts for another treatment than the one recommended by the physician. These amendments have initiated wide debates on the patient role and adequate sharing of responsibilities, for example, in primary care or preventive medicine and public health. Moreover, different interpretations have appeared regarding the application of informed consent in special conditions such as psychiatric or emergency care and concerning who can be the proxy decision makers when a patient has lost the capacity to consent or if the patient's will contradicts the will of the patient's relatives.

Another field of debate involved practical problems of biomedical research involving humans. Issues addressed by Lithuanian scholars included questions of implementing ethical requirements of biomedical research, identification of vulnerable persons, and protection of their interests in research as well as in the

practice of informed consent, protection of privacy and confidentiality, civil liability of the sponsor and principal investigator, insurance of research subjects, conflict of interests, and others (see Gefenas & Cekanauskaite, 2003 for an overview). The implementation of informed consent of the research participants and conditions of valid consent in research were among the most actively discussed issues. Despite the fact that the requirement of informed consent was introduced into the legislation more than 10 years ago, it was found that a rather significant proportion of research participants do not really understand the key elements of the information provided. The issues of readability of informed consent forms in biomedical research and the failure to understand the nature of medical procedures can be traced to insufficient knowledge and the widespread passive social role of research participants in the country (Čekanauskaitė & Gefenas, 2010; Lukauskaite, 2003). Additionally, the legal provision to the effect that research without informed consent is prohibited by law in the country has been continuously challenged by emergency medicine representatives. Exceptions to informed consent and critical analysis of a minimal risk standard of research on incompetent (e.g., seriously injured) persons in the context of emergency medicine, as well as global tendencies toward its liberalization, remain contested issues in Lithuania. By enforcing the statement that research is allowed only on the persons capable of consent and having one of the strictest laws on biomedical research in Europe, Lithuania faces a number of questions in the field of research ethics. For example, is it ethical to use and apply the results of scientific research that was prohibited by law in Lithuania, but allowed and conducted in other countries, having different legal and ethical standards on research involving vulnerable groups of research participants?

Regulations on informed consent in relation to the use of bodies of the deceased for scientific research and especially for educational purposes were discussed repeatedly by the public and by scientists. The consent is allowed by law only in the cases of the donation of bodies for educational purposes. However, controversies over how the will of the dead should be expressed, interpreted, and formalized as well as who (close relatives only or someone else) may adequately represent the will of the person are still under debate. The issue of the consent requirements applicable to the research on biological materials removed from the deceased, however, was also addressed by expert and public debates. So far, there is no consensus on how to legitimate informed consent regarding the use of such biological materials for research purposes. These questions are important in the context of Lithuania, since the discussion has just emerged and the attitudes and preferences of various interested parties are little studied.

Next, issues of social justice and solidarity have been and remain of high importance in Lithuania. The common problems of the distribution of limited resources and equal access to health care become especially pressing in the context of healthcare reforms. Liberalization of service provision in health care as well as insufficient economical capacity of the country to cover growing public needs of health services induced tension and confusion between different approaches to social justice on the level of health policy decision making. In attempting to increase the cost effectiveness of health services in Lithuania, contradictory

strategies have been employed to date. For example, decentralization and privatization have been implemented as part of health policy to achieve greater efficiency (at least in theory). However, in practice, the reform of decentralization of healthcare organizations resulted in the emergence of private health care, which, according to some accounts, reduced access to health services for the most vulnerable social groups (Bankauskaitė & Jakušovaitė, 2006).

Additionally, financial deficits in the hospital sector have resulted in the unofficial but widespread practice whereby patients are asked to pay for medicines and disposable goods. Some empirical surveys indicated that about 30 % of pharmaceuticals used in hospitals were in fact paid for by the patients, though officially they are to be provided free of charge. The practice of under-the-table payments, inherited from the Soviet period, has been reduced in the outpatient sector, but it may have increased in the inpatient sector. As many as 40 % of hospital inpatients reported having paid money for services that are officially free of charge (Cerniauskas & Murauskiene, 2000). Previous studies revealed that, in Lithuania, households in the top 10 % income bracket spend 20 times more on health care than the bottom 10 % of households. As indicated by Eugenijus Gefenas, "egalitarian principles are still not followed in the domestic health policy," and "the economic and political reality is that access to health care is very much a function of the ability to pay and therefore amounts to a libertarian type of health care, despite the fact that equitable access is still declared as a priority in the official health policy documents" (Gefenas, 2009b, p. 599).

Among the ethical problems related to the outcomes of healthcare reform in Lithuania, a number of others can be mentioned, in particular, in reproductive medicine and palliative care. During the last decade, different projects of the Law on Artificial Insemination have been widely debated in parliament and publicly, however, with little results as the bill has still not passed. Controversial opinions regarding the artificial insemination model in Lithuania have engaged different social actors in a general discussion on the concepts of person, family, disease, and social welfare. Furthermore, competition between more liberal and more conservative (led by the Roman Catholic church) approaches to in vitro fertilization (IVF) or change of sex has resulted in serious debates on the questions of the moral implications of infertility and the status of such conditions from the medical point of view. Regarding IVF, the moral and ontological status of the embryo as well as defining its normative position in a legal system and the procedures regarding the excess of already produced embryos seem to be the major problems standing in a way of achieving considerable consensus. Opinions regarding use, storage, and donation of frozen embryos and the treatment of infertility are still very much polarized in Lithuania. In contrast to Western European countries, issues of surrogacy, bio-banks, and commercialization of germ cells are lacking on the legislative agenda and are little discussed by the public in the country.

Recently, there has been growing interest in medical decisions at the end of life, and the topic is beginning to be more frequently addressed in academic, public, and political discourses. Previously, discussions on ethical issues concerning death and dying were very sensitive because of the influential Catholic Church's pro-life stance.

However, discussions on the issues around the right to die or withdrawal of life supporting treatment have emerged naturally as the result of social and political changes in the country. In particular, issues related to potential legislation of euthanasia occurred in the context of economic difficulties to cope with the imbalance between the needs of the growing number of geriatric and terminally ill (such as oncologic) patients and the lack of resources to cover these needs, for instance, in palliative care. Taking into account global trends in bioethics, ethical dilemmas of the end of human life will obviously be among the central issues in Lithuania in the near future.

Future Challenges

Both academic developments in the field of bioethics and institutional changes in research subject protection in Lithuania were unsurprisingly followed by some concerns and challenges. In general, official and formal adoption of previously mentioned international documents and legislation of widely accepted bioethical approaches affect medical practice to a lesser degree than expected. Despite the fact that patient rights were widely highlighted by newly established regulations, the gap between declarations on paper and implementation in practice seems to remain. Overcoming professional and public skepticism concerning moral requirements as well as widespread stereotypes in moral reasoning and daily activities is one of important future tasks for bioethics in Lithuania. In this respect, public education, for example, introducing the principles of modern moral reasoning and argumentation, as well as active public involvement in the discourses around important bioethical problems are imperative. It should also be noted that the various discourses on the negative image of health professionals as well as malpractice, negligence, or even discrimination in clinical units are continuously emphasized by the mass media, and these problems require further attention. Other important problems of inter-professional relationships in health care are still less debated: for example, high professional insecurity and a poor capacity for teamwork sometimes result in inappropriate management of healthcare services and decreasing public trust.

Additionally, bioethics as an academic discipline is not regarded as sufficiently serious both in terms of philosophical contributions and empirical scientific research. The common criticism of bioethics is imposed by biomedical professionals who would think of bioethics as an obstacle to the progress of biomedical science. On the other hand, philosophers sometimes assume bioethics as being a populist and simplistic application of normative ethics. Lawyers may be dissatisfied by the dilemmatic character of bioethical discourse not resulting in any clear policy or legal framework. This opinion is sometimes seconded by biomedical professionals as well. So there is a deep conflict between the goals and constraints of the public policy process and the aims of academic scholarly activity in the discourse around bioethics in Lithuania (Gefenas, 2002).

Another challenge to be met by bioethics in the educational process is the integration of new interdisciplinary subjects. Integration of such disciplines as medical anthropology, medical sociology, human ecology, bioethics, and literature into the teaching of

bioethics are still works in progress in Lithuania. Currently, the multidisciplinary nature of bioethics in the medical education curriculum is usually reduced to medical ethics, basically because of insufficient attention to humanitarian disciplines in national education policy, which leads to a situation where medical humanities are not sufficiently represented in the academic curricula of medical professions.

Moreover, collaboration between scholars of different disciplines, even in the context of medical humanities, is an exception rather than a rule, not to mention the lack of efficient cooperation between competing research centers. Thus, studies of the bioethical issues are not systematic. Research on the ethical problems is usually framed as a supplement or part of social politics or medical sociology. Also, simplistic methodologies might be employed, for example, when, in order to determine the perception of medical information among terminally ill patients, quantitative research methodology is used instead of qualitative.

Finally, as a consequence, the emergence of secular bioethics has been followed by a surge of the religious perspective on bioethics. This process has been particularly active in Roman Catholic–dominated Lithuania, where some universities and medical schools filled the vacuum in medical humanities with courses of Catholic bioethics and medical ethics. In addition, the remains of post-Soviet thinking, ethical skepticism, and the lack of professional training result in a situation where bioethics is still at the crossroads in finding its place in Lithuania (Gefenas, 2009b). Establishing meaningful dialogue between different professional groups, for example, academics and policy makers or between groups holding different worldviews, is one of the foremost challenges in relation to the future of bioethics in Lithuania.

Conclusion

The development of bioethics in Lithuania during recent decades occurred mainly within the framework of medical education and ethical review of biomedical research. Scholarly interest in bioethical issues has significantly increased since the collapse of the totalitarian Soviet model of society, which brought enormous changes in political and social conditions in Central and Eastern Europe, including Lithuania. Additional input was provided by the processes of integration of Lithuania into European and international structures. A key event in the institutionalization of bioethics in Lithuania was the establishment of the Lithuanian Bioethics Committee in 1995. It played an important role in increasing the activities related to the development of research ethics and other bioethics issues in Lithuania.

Medical humanities were gradually encompassed into the education of healthcare professionals by including courses on medical ethics in the curricula of medical schools and establishing bioethics-oriented departments in a number of Lithuanian universities. The issues of patient rights shifting from paternalism to personal autonomy and implications of informed consent in therapeutic and research activities were the most frequently addressed in the studies and reviews, both academically and practically. Issues of social justice and resource allocation in health care as well as issues regarding the beginning and end of life are perhaps the

most actively debated issues in bioethics among public and experts in Lithuania. One of the foremost challenges is thinking ahead about future development of bioethics in Lithuania, as well as the more collaborative dialogue between different professional groups, between academics and policy makers, or even between parties with different world views.

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Malawi

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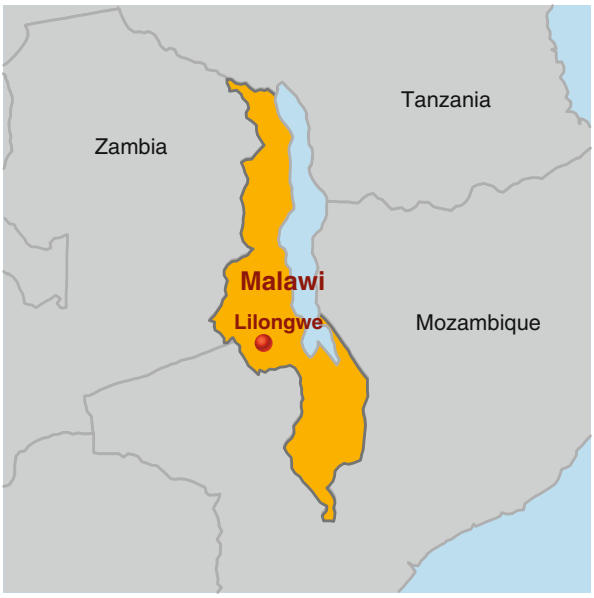
J. M. Mfutso-Bengo, Lucinda Manda-Taylor, Vincent Chipiliro Jumbe, Isabel Kazanga, and Francis Masiye



Bioethics Development

The history of bioethics in Malawi is closely linked with the University of Malawi, College of Medicine. It is at the College of Medicine where bioethics started. Today, the University of Malawi, College of Medicine, is one of the very few

J.M. Mfutso-Bengo (✉)
Division of Community Health, Centre for Bioethics in Eastern and Southern Africa (CEBESA), University of Malawi College of Medicine, Chichiri, Blantyre, Malawi
e-mail: mfutsobengo@medcol.mw

L. Manda-Taylor • V.C. Jumbe • I. Kazanga • F. Masiye
Centre for Bioethics in Eastern and Southern Africa (CEBESA), University of Malawi College of Medicine, Chichiri, Blantyre, Malawi
e-mail: lucindamanda@gmail.com; vjumbe@medcol.mw; ikazanga@medcol.mw; fmasiye@medcol.mw

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medical colleges in Africa that considers the subject of bioethics and research ethics as necessary and indispensable. It is one of the few medical schools in Africa that introduced a compulsory biomedical ethics curriculum, which covers all 5 years of medical training. All the initiatives in the areas of bioethics and research ethics at the college and in Malawi are spearheaded by CEBESA.

CEBESA was established in 2001 and falls under the Department of Community Health at the College of Medicine. The Center is committed to helping healthcare professionals, researchers, students, and policymakers in addressing ethical issues in Malawi. CEBESA seeks to promote the ethical practice of medicine and the ethical conduct of biomedical research in Malawi. The Center also seeks to reach out to various institutions, projects, researchers, and communities, using various means. It also provides training to ethics committee members and researchers on research ethics, clinical trial monitoring, and good clinical practice. In addition, it provides advice to various stakeholders including government, health practitioners, research ethics committees, hospitals, members of the public, and others on issues related to bioethics, research ethics, and good clinical practice (GCP). The major concerns so far are in the areas of funding for research and trainings.

What Resources Have Been Developed (e.g., Books, Programs, Media, Networks, Societies)?

CEBESA has established a related human rights initiative called the Medical Rights Watch (MRW). The MRW was born in a bioethics class and it is taking bioethics to the grassroots and making people aware of their rights and responsibilities. The primary objective of the organization is to bring basic ethical values to the attention of all key health decision makers at all levels, with the goal of transforming the health system into one that effectively applies justice, beneficence, and autonomy. MRW is achieving this through making basic bioethics knowledge available to all these decision makers and giving them guidance on how to resolve ethical dilemmas, so as to achieve ethical decision making. The goal of MRW is to promote and protect the rights and responsibilities of patients, research participants, and health practitioners in Malawi. As the first and so far the only health rights organization in Malawi, MRW is fighting for safe, accountable health care that does not compromise the rights of patients. This work is extending to all parts of the Malawian healthcare system, including research and training institutions throughout the country.

CEBESA is also championing the African moral theory of ubuntu/uMunthu, (which will be explained later in this Chapter) and urging medical students to apply it in their medical practice. The Center also has a newsletter which covers issues of bioethics and research ethics in Malawi. Members of CEBESA have published in the field of research ethics, bioethics, and human rights in local and international journals and book publications.

CEBEASs publications focus on applying ethical theories to ethical challenges and moral dilemmas that emerge in the context of research in Malawi, and by

extension, Africa. The aim of our publications is to provoke new ways of thinking. Key issues addressed in our publications apply ethical principles like informed consent, confidentiality, justice, beneficence and nonmaleficence to research. Of late, the central thrust underpinning our work is the promotion of African ethics and values in bioethics in the context of globalization. It is within this context that we hope to contribute to the African and global discourse of ethics by championing the ethic of uMunthu and Ubunthu.

What Have Been the Steps/Measures Taken (Policies, Legislation, Infrastructures, Teaching Programs, Committees, etc)?

In order to achieve its goals, CEBESA has two main components, which include research and training. Below are some of the major activities carried out by CEBESA: teaching of bioethics to undergraduate students in all programs in the College from the 1st year up to the 5th year.

- Teaching of bioethics and research ethics to postgraduate students in the Master of Public Health Degree (MPH) and Master of Medicine (MMED)
- Training Fogarty Fellows from Eastern and Southern Africa in international research ethics, as part of the University of Malawi College of Medicine and Michigan State University Fogarty Training Program
- Providing training to ethics committee members and researchers on research ethics, good clinical practice, and research methodology
- Conducting research on various topics in the area of bioethics and research ethics
- Advising various stakeholders including government, research ethics committees (RECs), hospitals, researchers, healthcare practitioners, students, members of the public, and others on issues related to bioethics, research ethics, and good clinical practice

Currently, CEBESA is running three projects funded by the Wellcome Trust Bioethics Research Project, the Fogarty International Research Ethics Training Program for Eastern and Southern Africa, and the European Union and Developing Countries Clinical Trials Partnership (EDCTP) projects on building and strengthening national capacities in ethical review and clinical trial monitoring in Malawi. Bioethics is thus being championed by at the University of Malawi, College of Medicine, with financial investments from the United States, the United Kingdom, and the European Union.

Current Bioethics Infrastructure

Teaching of Bioethics at University and Other Levels

As stated above, bioethics is being taught to undergraduate students from 1st to 5th year of medical training. Medical students are introduced to both bioethics and research ethics and understand theories and principles of bioethics and research

ethics. Bioethics is also taught to postgraduate students in the Master of Public Health and the Master of Medicine programs. Bioethics training is also offered to researchers and health workers. Other institutions involved in the training of health workers such as Kamuzu College of Nursing and School of health sciences also have medical ethics integrated into their curriculum.

Bioethics Committees

There are only two government approved research ethics committees in Malawi. They are the National Health Sciences Research Committee (NHSRC) and the University of Malawi, College of Medicine Research and Ethics Committee (COMREC). The NHSRC was established in 1988 as a Research Unit in the Ministry of Health, and in 1993 became incorporated as a committee in the National Research Council of Malawi (NRCM). A detailed description of the role of the NRCM is provided below. COMREC was established in 1996. The NHSRC is the technical committee of the National Commission for Science and Technology (NCST). The Ministry of Health (MoH), through its Research Unit, is the designated secretariat of the NHSRC. COMREC is the Independent Review Board (IRB) for the University of Malawi, College of Medicine. The Research Support Center at the College of Medicine provides administrative support to the secretariat of COMREC. Members of CEBESA are involved in running the Secretariat of the College of Medicine Research and Ethics Committee (COMREC), and they are also members of both the COMREC and the National Health Sciences Research Committee (NHSRC). The Director of CEBESA has also been appointed as the Chairman of the National Committee for Bioethics (NACOB) in Malawi. The IRB Administrator is also a member of the NACOB. Briefly put, NACOB is a committee which is located within the NCST that was set up to focus on advising government and policy makers on ethical issues that affect the country.

COMREC's mandate is territorial and jurisdictional in the sense that the IRB reviews research proposals from members of the University of Malawi's College of Medicine (COM) and Kamuzu College of Nursing (KCN) and their research affiliates, Blantyre Malaria Project (BMP), Centre for Reproductive Health (CRH), Malaria Alert Centre (MAC), Malawi-Liverpool Wellcome Trust (MLW), and Johns Hopkins University-Project (JHU-P). The committee's review is also limited to studies deemed to be of national interest, which are referred to the NHSRC. National interest studies include: vaccine trials, stem cell research, cloning research, genetic studies, national health surveys, and drug and medical device trials where patent issues are involved and where safety issues remain fully unknown. Thus, by way of deduction, the NHSRC reviews all research proposals from outside of COMREC's mandate and all studies deemed to be of national interest.

The achievements of both research ethics committees include the development of guidelines for the conduct of health-related research in Malawi, and Standard Operating Procedures (SOPs). These guidelines are within the parameters of national policy and sensitive international ethical guidelines on research. These

include the Declaration of Helsinki (WMA), the International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS/WHO), and Guidelines for Good Clinical Practice (ICH-GCP).

Relevant Legislation

Relevant legislation that supports bioethics and research ethics activities, especially in the field of health research in Malawi, is available. The National Research Council of Malawi (NRCM) was established on 30 March 1974 with a *co-ordinatory and advisory* function (Malawi Government Gazette, 11 June 1976, General Notice No. 398). Since 1974, NRCM was mandated to:

- Coordinate all research activities conducted in this country.
- Ensure that any research project proposed for execution was geared toward achieving national development needs and goals.
- Approve the establishment of sectoral research co-coordinating committees (REC/IRB) where it is necessary and justified.
- Approve procedures and guidelines of RECs/IRBs (NRCM procedures, 2002, p. 5).
- Accredit, register, and audit RECs/IRB.
- Establish and review national minimum standards or code of conduct to guide the operations of RECs/IRBs and any other stakeholders.
- Establishment of Research Review Committees.

The NRCM established the National Health Sciences Research Committee (NHSRC) and the College of Medicine Research Ethics Committee (COMREC) in exercising functional authority from central government, using executive powers of government.

In addition, The Pharmacy, Medicines and Poisons Board (PMPB) was established in 1988 with the main mandate to regulate the pharmacy industry in Malawi and to complement the role of ethics committees [Section 42(1) of PMPB Act, 2003 Supplement]. PMPB also issues product licenses for clinical trial–related products.

Since 2008, joint review of vaccine and drug development clinical trials is done by NHSRC and PMPB. However, PMPB Act only recognizes "*medical practitioner and dentist*" as only a cadre of investigators who can administer or under whose supervision administration of a trial medicinal product can be done and only to "*his patients*" (PMPB Act, 2003 Supplement).

The National Commission for Science and Technology (NCST) was established by a Science and Technology Act No. 16 of 2003 effectively which became effective from July, 2009. The Commission is now a body *responsible for all functions* which were being performed by NRCM. The NCST's Mandate is to advise government and other stakeholders on *ALL* matters of research, science, and technology in Malawi. Functions of the NCST include:

- Chart out national direction and establish national priorities in research, science, and technology development in relation to socioeconomic development needs.

- Promote the formulation and revision of policies, strategies, laws, and regulations for research, science, and technology.
- Coordinate all research, science, and technology-related issues in the country.

Thus, the NCST is an overall body that regulates all forms of research, science, and technology initiatives in Malawi. Health Research issues are co-coordinated by the Division of Health, Social Sciences and Humanities. The Division is supported by committees at national and institutional level with *legislative anchorage (Section 11) as outlined below:*

- National Committee on Bioethics (Advisory and policy making).
- National Health Sciences Research Committee.
- *College of Medicine Research and Ethics Committee*.
- The Drug Regulatory Authority (PMPB) continues to certify and offer joint authorization of vaccine and drug trials.
- Research Support Centre at College of Medicine spearheading research support and oversight services at college level.

Malawi just like any other African country is vulnerable to unscrupulous researchers. Therefore, collective responsibility in protecting human research participants is always critical. This calls for fair and objective policies and regulations that aim at promoting research and development while at the same time not compromising the protection of research participants.

Public Ethics Debate Activities

Members of the CEBESA are often invited to participate in public debates and discussions hosted by various organizations and institutions. For example, members of Centre have participated in 2 science cafes hosted by the Malawi-Liverpool Wellcome Trust on the following themes: "Should people participate in clinical trials" and "Why we participate in medical research as a community." The science cafes aim to engage the lay community on the ethical imperatives of research. Our participation in these debates is twofold: firstly, to provide ethical insights into some of the ethical requirements for research and to assure the community on how ethics committees ensure that human subjects are protected in research.

In Malawi, there are currently interesting public debates in the media and among the general population regarding different ethical issues. These debates include topics such as medical strike, equitable access to education and healthcare, homosexuality, abortion, mandatory HIV testing of pregnant women, research misconduct, and misconduct of medical professionals.

The country has recently experienced an increasing number of medical strikes. These strikes are due to a variety of reasons among which include issues related to dissatisfaction of medical workers with their work conditions, remunerations, and allowances (Ponje, 2012). Consequently, these strikes have contributed to the neglect and deaths of some patients. This has caused great concern, anger, and debate on the media and among the general public on whether or not medical professionals are justified to go on strikes.

The Government of Malawi is committed to achieving universal education and healthcare coverage. However, despite the intense government efforts and the positive developments in the education and health sectors in Malawi, equitable access to education and healthcare still remains a challenge and subjects of continued debate in the media and among the general population in Malawi. The education and healthcare systems in Malawi favor the rich and those in the urban areas (National Statistical Office, 2011). In rural areas, schools and hospitals continue to face various challenges such as shortage of qualified personnel, inadequate infrastructure, and poor transportation among others, which continue to undermine full realization of quality of education and health care service delivery. What this means is that poor students who are largely residing in rural areas do not have a good chance at furthering their education at the University of Malawi, because the selection process tends to favour those who attend schools in the cities.

Furthermore, the recent propositions to legalize homosexuality and abortion by the international bodies and local activists in Malawi have attracted uptight debates in the social media and among the general population. This is partly due to the fact that the majority of Malawians are religious people who regard homosexuality and abortion as sinful acts, and therefore do not support the proposals to legalize these practices.

The Malawi is proposing a contentious bill for mandatory HIV testing of pregnant women (PlusNews, 2012). This bill is aimed at promoting HIV testing and prevention of mother to child transmission. The current policy in Malawi obliges every pregnant woman to undergo routine HIV testing during antenatal visit. This practice and the proposed bill has raised debate on media and among the general public on whether it is ethical to subject pregnant women to obligatory HIV testing. In addition, issues regarding research misconduct and misconduct of medical professionals have also been areas of continued public debate in Malawi.

Major Bioethics Issues and Discussions

End of Life

Decisions concerning end-of-life issues and end-of-life care in Malawi are rather difficult for medical practitioners to tackle head on. This is because of "our Malawian culture of secrecy on issues of death and dying" (Chunda and Lavy, 2005, p. 552). In spite of this, the principles guiding healthcare practitioners in Malawi include the principle of respect for persons/autonomy, beneficence/maleficence, and justice. In Malawi, active or passive euthanasia or mercy killing is illegal and, therefore, withholding or withdrawing treatment would be tantamount to committing a crime. The most preferred option in circumstances where treatment offers no hope of improving the patient qualitatively or quantitatively, a gradual shift from restorative to palliative care is raised either by the family or healthcare practitioner.

There is no discussion, debate, or guidance on how to proceed with medical cases that can be declared futile to treat. Medical futility is defined and understood as "the inappropriate application of medical intervention that is unlikely to produce

any significant benefit for the patient" (Bagheri, 2008, pp. 45–53). In Malawi's context, HIV, AIDS, and cancer are common fatal diseases that present medical doctors with challenges, given the costs of treatment, lack of human resource and facilities, for example, bed space in often overcrowded hospital wards. These challenges also introduce moral and ethical dilemmas on whether or not to withdraw or withhold treatment. Often these dilemmas are resolved by quickly discharging patients that are terminally ill. As Chunda and Lavy explain, "In many developing countries, Malawi included, the existing health infrastructures are inadequate to provide in-hospital care for AIDS patients, and thus there is great pressure on hospital personnel to discharge AIDS patients quickly, with little or no treatment" (Chunda and Lavy, 2005, pp. 51–52). This is because in Malawi, active or passive euthanasia or mercy killing is illegal and, therefore, withholding or withdrawing treatment would be tantamount to committing a crime. The most preferred option in circumstances where treatment offers no hope of improving the patient qualitatively or quantitatively, a gradual shift from restorative to palliative care is raised either by the family or healthcare practitioner.

This is because, in the Malawian context, bioethics is seen as a relationship of a human being with himself/herself, with nature, and with other human beings. This relationship is based on cooperation and fairness, and it is rooted in the African moral thinking of umunthu/ubuntu, as it is commonly known in many Southern African countries (Mfutso-Bengo and Masiye, 2011, p. 155). Simply put, *ubuntu/umunthu* means being humane. Mfutso-Bengo and Masiye explain the theory of *ubuntu/umunthu* like this:

> It is a moral reflection or study of African humanism and moral systems. Malawian (African) bioethicists consider *ubuntuology/uMunthology* as the main theory of African Bantu bioethics. The *ubuntuology/uMunthology* theory starts with defining what African humanism is, and how one can become human. The theory presupposes that not every human being is human. One becomes human through positive relationships and encounters that are based on beneficence, respect, trust, hope, and justice (Mfutso-Bengo and Masiye, 2011, p. 155).

John Mbiti's popular quote reveals this. Only in terms of other people does the individual become conscious of his [sic] own being, his own duties, his privileges and responsibilities toward himself and toward other people. When he suffers, he does not suffer alone but with his corporate group: When he rejoices, he rejoices not alone but with his kinsmen, his neighbors, and his relatives, whether dead or living. Whatever happens to the individual happens to the whole group, and whatever happens to the whole group happens to the individual. The individual can only say, "I am, because we are; and since we are, therefore, I am" (Mbiti, 1970, p. 141). A person is thus defined in relational terms – "as a being whose nature is determined by its relationship to the community" (Sebidi, 1998, p. 66). The Zulu have a saying, "*Umuntu ngumuntu ngabantu*" (a person is a person through others), captures this. *Ubuntu/uMunthu* is an ethic that reinforces the idea of corporate existence. *Ubuntu/uMunthu* is human centered and concerned with the interests and welfare of humankind. The ethic of *ubuntu/uMunthu* is also expressed as an ethic of solidarity. Solidarity, as defined by Ezra Chitando, implies "standing for, and standing with

'the other" (Chitando, 2008, p. 156). According to African bioethics, "to be human is to be in relation, and to become human is to be constantly in right relation" (Mfutso-Bengo and Masiye, 2011). "Being in relation is an essential part of being human" (Kasanene, 2000). In short, the ethic of *ubuntu*/*uMunthu* and the ethic of solidarity provide a framework for putting into action values such as compassion, kindness, care, justice, and respect.

To clearly appreciate the application of *ubuntu*/*uMunthu* in the practice of medicine in end-of-life decisions in Malawi, one only needs to understand the role of culture in African societies which also shapes medical policy and law in Malawi. When one understands the role of culture, one also appreciates why palliative care is the most preferred option when dealing with medical cases in which no amount of medical treatment will improve the physical condition of the patient.

Health Care System; Access to Health Care

Access to health care is considered a human right in Malawi. The United Nations Universal Declaration of Human Rights affirms that "everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care" (Universal Declaration of Human Rights). The constitution of Malawi recognizes the right to health under section 13(c) and affirms that the state shall "provide adequate health care, commensurate with the health needs of Malawian society and international standards of health care" (The Constitution of the Republic of Malawi, 1994). Healthcare services in Malawi are provided by three main agencies, namely, government, private sector, and Christian Association of Malawi (CHAM). CHAM health facilities are nonprofit religious organizations, but they charge a small amount of user fees.

Although the government provides free healthcare services to all Malawian citizens, the health indicators for Malawi have generally remained poor. The average life expectancy at birth is estimated at 49 years (World Health Organization, 2008). The HIV/AIDS pandemic has significantly contributed to the country's low life expectancy. Malawi has one of the highest HIV prevalence in both African region and globally. About 11 % of Malawians aged 15–49 years are living with HIV/AIDS (National Statistical Office, 2011). The maternal mortality ratio in Malawi still remains high at 675 deaths per 100,000 live births. This rate is five times higher than the MDG target of 155 deaths per 100,000 live births, and it is highly unlikely that Malawi will meet this goal (Malawi Millennium Development Goals, 2010). The under-five mortality rate in Malawi is also high at 112 deaths per 1,000 births, while infant mortality rate is 66 deaths per 1,000 live births (National Statistical Office, 2011). Besides having poor health indicators, Malawi continues to experience higher levels of poverty. About 39 % of the population is living below poverty line, i.e., less than $1 per day (NSO, 2012), and the vast majority (86 %) of the population resides in the rural areas (WHO, 2008).

In order to address these challenges, the Ministry of Health in Malawi and its collaborating partners developed the Essential Health Package (EHP) and other

interventions aimed at improving the healthcare delivery system. The EHP refers to a prioritized but limited set of basic healthcare services that focus on the major causes of morbidity and mortality, particularly those affecting the vulnerable population (Ministry of Health, 2011). The Malawian EHP has 13 components including maternal and child health services. Its objectives include promoting equitable access to healthcare services and ensuring universal healthcare coverage. However, evidence shows that the delivery of EHP is constrained due to different challenges currently confronting the public health sector in Malawi. Prominent among these challenges are the shortage of health workers, inadequate infrastructures/services, insufficient health funding, and lack of essential drugs and other medical supplies (Mueller et al. 2011). The existence of high disease burden in Malawi also places demand on the available scarce resources for the effective delivery of EHP services.

Access to health services in Malawi remains a challenge, more especially for the vulnerable populations such as women, children, and the poor people. Different studies conducted in Malawi have documented inequalities in health status and access to health services among different population groups. For instance, the Malawi Demographic and Health Survey (MDHS) reports higher levels of morbidity and mortality among the poor, rural residents, women, and children (National Statistical Office, 2011) In addition, a study conducted by Mangham in 2006, revealed that women, children, and the rich people consume more public health care services than men and the poor (Mangham, 2006). The study findings further revealed that more urban population (38 %) than rural population (29 %) utilize public health facilities.

Documentation further shows that even though EHP services are provided free of charge, household out-of-pocket payments have increased during the implementation of EHP services (Mueller et al. 2011). In many cases, when patients visit public health facilities, they are often referred to private hospitals to access health services or to private pharmacies to buy medicine, using their own money. This becomes a huge problem and a burden especially on the poor people who cannot afford to pay the high cost often charged by private hospitals or pharmacies. As a result, out-of pocket payments act as a barrier to healthcare access for the poor people.

The Government of Malawi recognizes the importance of achieving fair and equitable distribution of wealth and health as crucial to the achievement of development, as outlined in the Vision 2020 plan (Malawi Vision 2020). The concept of health equity is an ethical value that is inherently normative, grounded in the ethical principle of distributive social justice or fairness and core human rights principles (Braveman and Gruskin, 2002). Pursuing health equity strategies entails promoting access to health services to vulnerable populations, thereby improving population health. In Malawi, there is a need for health systems strengthening to promote achievement of a greater coverage for and access to effective health interventions, without compromising efforts to ensure quality of healthcare and safety of patients. Promoting the right to access health care services in Malawi will help to ensure that people are not discriminated against for being sick or based on their social attributes. It will also promote economic productivity and ensure that Malawians live healthier and longer.

Levels of Healthcare in Malawi

The healthcare system in Malawi is designed in a three-tiered network of interlocking medical facilities. The bottom tier consists of a large network of rural hospitals and health centers throughout the country. Often, they serve as the first port of call for many people who reside in the rural areas of Malawi. "Their services are free and they are often the only medical facility that many village people will see in their lifetimes" (The Malawi Project). The rural hospitals and health centers serve around 30,000 Malawians covering 50 villages. Though the centers are deprived of doctors, nurses and clinicians substitute them. These rural health centers offer treatments for fractures, malaria, abrasions, and postnatal and prenatal care (Malawi Health). The middle tier consists of district hospitals and according to the government's healthcare plan when a medical case is deemed too difficult and critical for the rural hospital or health center to handle, the system calls for the person to be transferred to the district hospital. These facilities are centrally located in each of the 27 districts in Malawi. The district hospitals are better equipped in offering medical treatment to the people. Apart from having good doctors, these hospitals are equipped with x-ray machines, laboratories, and various other modern equipments. Surgical treatment is also available to the patients. The top tier hospitals are located in the major urban centers (Queen Elizabeth Central Hospital in Blantyre, Zomba Central Hospital in Zomba, Kamuzu Central Hospital in Lilongwe and Mzuzu Central Hospital in Mzuzu). They are bigger and designed to have more advanced technology, resources, medicines, and medical personnel in order to handle the more complicated cases that cannot be handled at district level. Patients are referred to such facilities when medical "problems cannot be resolved at either of the two levels" (The Malawi Project). To top it off, there are some expensive clinics and hospitals situated in the cities of Malawi that are quite inaccessible to the ordinary Malawians. Usually, these are fee-paying facilities that are linked to medical aid service providers.

Medical Research

Medical research in Malawi and in Africa has witnessed a tremendous growth in the past decade and yet to date. The great demand for clinical research in Africa is creating many challenges with respect to research ethics. For the past 50 years, ethical issues in biomedical research have received increasing attention. However, of late, focus has been on the ethical implications of carrying out biomedical research in low socioeconomic settings such as Malawi. This is especially so because of the increasing number of multinational biomedical research institutions working in developing countries. A key principle that informs and grounds all major ethical guidelines in research is the principle of informed consent. There is a general consensus among researchers and ethicists that acquiring an effective informed consent from research participants is a prerequisite to the conduct of an ethically sound study. Although it has been noted that getting genuine informed

consent in practice tends to be difficult, it is believed that problems of getting quality informed consent are even greater in settings with low social-economic settings. This is partly due to undue inducements to research participants in low socioeconomic settings.

CEBESA conducted a study which aimed at improving understanding of individuals and communities cultural attitudes, beliefs, and perceptions on research, community consent, and the informed consent process in urban and rural settings. The study sought to assess the validity of Western concepts of autonomy and informed consent in an African cultural and social context so as to provide a base for informing, reforming, and improving informed consent policy and practice. The study was conducted in Bangwe, an urban community, and Mpemba and Madziabango which are rural communities surrounding Blantyre.

The study yielded some very interesting results. The findings of the study revealed that the majority of participants chose to participate in biomedical research as a way of accessing better quality medical care and getting incentives. In a situation of poor service delivery as is the case in Malawi, medical care in a research setting is described in favorable terms and it is not surprising. In Malawi, medical care in Government facilities is free and yet, the quality of care is very low and characterized by overcrowding and scarcity of basic medicines. In this study, participants joined biomedical research in order to obtain health benefits. While the participants in the study differentiated biomedical research from normal health care, when they accepted to participate, they knew very well that they were participating in biomedical research. It thus became apparent in this study that people participating in biomedical research was not as a result of therapeutic misconception, but simply because of the desire to access better and faster medical attention. This finding thus prompts the question: Does biomedical research in limited resource settings constitute an undue inducement? Is it reasonable, ethically justifiable, and acceptable to take part in biomedical research with better quality medical care as a reason for participation within the Malawian context? If people are induced by better quality medical care, is it logical to conclude that they are unduly induced to participate in biomedical research? Similarly, participants in the various studies were given better and excellent treatment than the other patients in the same hospital. Findings suggest that people made their decisions autonomously but that they were motivated by better and excellent medical care. Their willingness to join the study on these grounds, therefore, is not unethical and does not constitute an undue inducement. This is echoed by Ezekiel Emmanuel when he notes, “it is not an ethical worry” (Emmanuel, 2004). In a context like the Malawian setting where access to good medical care is difficult, it can be argued that it is reasonable for one to make a decision to save his/her own life as failure to take the offer to participate in such a biomedical research is tantamount to one harming his/her child. This is further supported by African notions of morality, which do not allow and yet African morality does not allow a person to harm himself/herself. In other words, it is ethical for people to choose to participate in clinical research in pursuit of better medical care.

Unethical Aspects of Tobacco Control

This section discusses the unethical aspects of antitobacco lobby using three ethical principles of beneficence, respect, and justice. In principle, it is affirmed that smoking is a health hazard, and ought to be discouraged. However, in practice, Malawi is faced with an ethical dilemma. That is to encourage tobacco production for export – for external consumption on the one hand, and discourage internal consumption on the other. This is because tobacco is the biggest foreign exchange earner for Malawi. Malawi gets 75 % of its foreign exchange revenue from tobacco, and about 40 % of government tax revenue comes from tobacco. More than half of Malawian work force has to do with tobacco or related activities.

According to the principle of beneficence, there is a need to maximize what is good and minimize the cost and harm. There is no doubt that smoking is a big health risk. However, if a benefit and risk/cost assessment is calculated regarding the cultivation of tobacco in Malawi, it is apparent that the benefit of cultivating tobacco for Malawi far outweighs the health risk and economic cost of not cultivating it. Without tobacco, the Malawian health sector will collapse.

Smoking is not a big problem in Malawi, because many Malawians are nonsmokers, and tobacco industry is geared at export and not at the local market. However, this is not guarantee that this situation will remain the same. Unlike UK where tobacco revenue is only 3 % of GDP and their economic cost of smoking far outweighs tobacco revenue, in Malawi, about 40 % of government tax revenue comes from tobacco. Tobacco is the biggest foreign exchange earner for Malawi. And this is why, it is not to the best interest of Malawi to join tobacco control lobby. The antismoking lobby and tobacco control measures in the West have been triggered more by the rising economic cost of smoking and not primarily by the desire to improve global healthy. According to healthy indicators of Malawi, smoking is not national healthy problem number one and yet the hard currency obtained from selling tobacco is crucial in funding social services such as hospitals, schools, and in buying drugs.

The global campaign to control tobacco spearheaded by mainly USA and supported by WHO appears well intended but in fact might have unethical motivation because at its roots it is less motivated by the need to promote global healthy than to control the soaring economical cost of smoking, mainly in the Western countries. This campaign seems to neglect the interests of very poor countries like Malawi who are dependent on single export product such as tobacco for their survival. If the powerful nations have national interests and protect them, why should the poor and vulnerable nations not protect their national interest and autonomy or sacrifice the same for international concerns? Tobacco growing is of great national interest. One does not clearly know the criteria of firstly focusing on tobacco, and not, for instance, at arms trade and unfair trade. In Malawi, there is a growing increase of pollution from cars. The healthy hazards caused by polluted air in Malawi are bigger than the ones caused by smoking at present. In USA and Republic of South Africa, tobacco contributes a very small part of their huge economies and car industries are among the backbone of the western economy such as German, France,

USA, and Japan. Arms trade is a big business in Europe and USA, and yet little is being done to control the proliferation of small and big guns. It seems that the prioritization and selection of agendas at international forums is being dictated and dominated by the interests of Western powers with little consideration of interests of the least developed countries like Malawi. To the contrary, ethically, the least developed countries economies are the most vulnerable; hence, they need more protection and much needed attention.

The antitobacco lobby touches at the very existence of Malawi's economy. To impose it on Malawi without finding and funding the equivalent and alternative economic activities is unjust. Some may suggest that Malawi diversify to other more acceptable traded goods and products. Who defines what is acceptable traded product or goods? Diversification is a very attractive policy; however, on the ground, it is difficult to implement it. As of now, the manufacturing sector in Malawi is shrinking instead of increasing. Diversification will need very large capital input. It is in the best interest of Malawi, first to implement diversification, and then tobacco control, and not vice versa. However, diversification requires massive investments and capital input. Without fair trade, the least developed countries like Malawi have less chance to have successful diversification process. There is a need to handle the unfair trade issues with urgency. To tell Malawi to diversify its economy from tobacco to something else without guaranteeing this poor country a fair access to the most protected Western agricultural market is selfishness. The slashing of huge EU agricultural subsidy by half can fight food shortages in Africa by half, in doing so making African agricultural products more competitive, and in the process encouraging more investments in food production. There are many more global issues, which need more sense of urgency than this, such as unfair trade, environmental issues, and arms trade.

It is argued that tobacco control is unethical because it fails to understand and consider the negative social, economical, and healthy impact it has on the least developed countries like Malawi. Tobacco control predicates its argument on the principle of beneficence: to do good and avoid harm. One cannot avoid harm by avoiding justice. One cannot talk of health benefits of tobacco control without knowing exactly who is benefiting and how the benefits are distributed? In case of poor Malawi, it will benefit far much less from tobacco control than for instance UK. Tobacco control in the West is motivated more by economic interest than global healthy interests. In the West, the economic cost of smoking far outweighs the economic gains of tobacco production; that is why they are keen to control tobacco and not arms production, which is killing more people away from their countries.

The moral dilemma that is discouraging smoking in Malawi, and yet encouraging the farmers to produce more tobacco for export will continue as long as funding for diversification is not forthcoming. This contradiction can still be maintained without being unethical, as long as the world trade structures do not allow a fair trade and fair play in agricultural industry, which encourages cash crop production at expense of food production. It is noted that tobacco control is not only a health issue, but involves and impacts in other areas such as economics, politics, behavior,

and culture. All these aspects ought not to be forgotten if one wants to register success in tobacco control at global level. Those involved in global tobacco control ought to be aware that its endeavor to control tobacco should above all consider those vulnerable and poor countries, whose economies and healthy infrastructures are dependent on and sustained by tobacco production. Secondly, the question and the cost of diversification should be addressed honestly, if one wishes to control tobacco production worldwide. And thirdly, the question of unfair trade should be confronted honestly and fair solution ought to be sought as soon as possible.

As a conclusion, the basis of the argument on this dilemma in Malawi is between promoting tobacco growing and discouraging tobacco smoking, as guided by public health ethics principles of necessity and proportionality. The principle of necessity can be clarified from the perspective that Malawi's economy is largely dependent on tobacco; hence, banning its production without immediate alternative will endanger public health programs which are largely funded from funds generated from selling tobacco. On the other hand, the principle of proportionality can be viewed from a perspective that the burden of diseases caused by tobacco smoking is negligible, about less that 1 %, in Malawi. Therefore, there are more benefits in tobacco selling in Malawi than harm.

Conclusion

This chapter has provided an overview of the strides made in the area of bioethics in Malawi. In particular, it has provided information on how bioethics has developed; current bioethics infrastructure and major bioethical issues and discussions within the country. Malawi is one of the few countries in Africa that has made significant strides in promoting bioethical teaching, discourse, and practice. However, despite making significance progress, there are some challenges affecting bioethics and research ethics which include lack of funding for research and trainings. This chapter has also provided a discussion on the role of ubuntuology/uMunthology in the practice of medicine and ethical decision making in Malawi, as well as the one only needs to the role of culture in shaping medical policy and law in Malawi. Lastly, the chapter has also provided an interesting discussion and debate on unethical aspects of tobacco control in Malawi.

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Malta

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Pierre Mallia

Introduction

Officially, bioethics in Malta can be said to have started immediately after the 1987 general elections when, following 16 years of socialist administration, a more conservative Nationalist Party administration was elected. Setting up a "National Dialogue on Bioethics" was described by the then Minister of Social Policy, Dr. L. Galea, as one of his Ministry's "keynote acts." This was followed by a public conference to which Professor Laurence J. O'Connell from St. Louis University was invited. These two facts already quite simply dictate the path that bioethics was to take: the taking on of bioethical issues by a conservative government concerned

P. Mallia
Bioethics Research Programme, Faculty of Medicine and Surgery, University of Malta, Msida, Malta
e-mail: Pierre.mallia@um.edu.mt

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with traditional moral values, which the country embraced as they were felt to have been abandoned over the past years (Galea, 1989), and the invitation of a professor from a Catholic university in the United States.

The proceedings from that meeting (Cortis, 1989) remain a historical document, having laid the scene for the next years. In this book, the important role that the Church was to play was confirmed in various papers and reflected upon in one of the talks (Grima, 1989). An issue which was discussed by the Prime Minister was "Bioethics and Future Generations" (Fenech Adami, 1989). Following the recent contribution Malta had made at the United Nations in the context of proposals of a new Law of the Sea, and general rules governing "common heritage," the Prime Minister spoke about the relevance of genetics and its impact on future generations. At the time, the University of Malta also had a "Future Generations Programme" which dealt not only with bioethical issues but which also took a broader view upon future generations. Several years later, an international meeting on genetics was hosted by this program, the proceedings of which were published by Kluwer (Agius & Busuttil, 1998). Genetics however never really took on major debate in Malta, probably because there was never a successful attempt at genetic technology.

Many of the papers of the above public meeting however focused on reproductive technology, in particular, in vitro fertilization. This was already being practiced, and indeed people were starting to question not only the morality of the technology but also the lack of a legal framework within it was working (Grech, 1989). Grech pointed out that the Catholic Church sympathizes with couples who cannot conceive but that its position was that getting children is not a right. It can be said that this debate continues to this very day within the context of assisted procreation. The main question posed is that if we say that childless couples have a right to have children, it would be conveying a message of children being a property or a commodity. The Catholic Church has held this position in *Donum Vitae* (Ratzinger, 1987). Obviously in this context other issues, such as the respect for the embryo, embryo freezing and when human life begins, were brought up as well (Grech, 1989; Tabone, 1989).

The major concerns over time have been various but central to all these remained the issue of in vitro fertilization, with the government at times feeling paralyzed to move forward. A key contention was how to go about not freezing embryos while not putting the mother through undue and unnecessary procedures. With the recent developments of cryopreservation of ova, this seems to have been solved, but many remain skeptical as to whether this can be used for the masses (Mallia, 2010). Perhaps what kept legislation back was the lack of initiative of the relevant committees to start with agreeing on principles within the conflicts that existed. Clearly, there were conflicts of value about whether IVF should be used at all. An agreement to move forward on agreed principles between the government and the Church would probably have saved a considerable amount of time. At one point when all seemed to be ready for legislation, Archbishop Mercieca made a statement that IVF remained illicit and that it involved the killing of human life. Following this, then President of the Republic, Dr. Fenech Adami, stated that he will not give his signature of approval on any legislation put forward by parliament unless the Church is in agreement (Mallia, 2010b).

It is pertinent here to point out that Malta is a southern European and Mediterranean country and as such influenced by the deontological approach to bioethics in these areas (Gracia, 1993). Malta has always been under European influence, with the exception of a several hundred years in the first millennium, after the fall of the Roman Empire. During that time, it was under Arab rule, which in turn influenced the language. This Maltese has a Semitic background, although it is Latin in writing and influence.

Other than that, Malta has always been European and thus besides Mediterranean, southern European. It was part of the Kingdom of the Two Sicilies, during which period it was transferred from one nobility to another during the fiefdom period, until it was finally given to the Knights of St. John, from whence they obtained the name of the Sovereign Military Order of Malta. During this time, the Catholic Church was always very influential, and more recently the book by Montserrat, *The Kapillan of Malta*, clearly shows the social role priests play on the island. In bioethical debate, most Maltese people look to the Church for advice. This is not necessarily a disadvantage as the population has strategically placed individuals who are also easily accessible to guide them on what largely remain Catholic normative values.

Resources

Legislation in bioethics continues to be evasive. Malta is close to legislating on reproductive technology, but some issues with cryopreservation remain. Other legislation which challenged normative values, such as that of the introduction of divorce, and the periodic sermons by bishops which attack assisted procreation creating wide media response may have played a role in setting back legislation. The issue of IVF therefore was sidetracked a number of times (Op. Cit. Mallia, 2010b) due to the other consequential questions it raises: to whom to offer it (legally married couples, cohabiting couples, single parents, same sex couples, etc.), issues with freezing of embryos, and, when the issue became hot on a European level, what to do with frozen embryos and stem cell research. Conversely, there is general agreement about abortion (even the Green party, Alternattiva Demokratika, has taken a stand against it), that embryos have a right to life and not to remain frozen, and that IVF should be offered only to heterosexual couples who can offer a traditional family environment.

While legislation remains elusive, however, there are at the country's disposal a number of structures which have been set up. The main platform is the Bioethics Consultative Committee. Also, teaching programs within various degree courses at the University of Malta have been set up. The media plays a major role as many bioethical issues create a lot of sensation. This was seen especially with regard to IVF, stem cell research, and cases of removal of nutrition and hydration of people in a persistent vegetative state (namely, the Terri Schiavo and the Eluana Englaro cases). Moreover, some scholars commit themselves to public education on bioethical issues on newspaper columns and radio programs. These scholars and commentators are frequently invited on the more popular television debate programs. There is

therefore a considerable amount of public debate, which unfortunately, on a small island, can even taint the reputation of some who take more liberal stands, and abuse verging on subtle defamation has not been absent.

Infrastructure

Teaching of Bioethics

The main teaching of bioethics occurs under the aegis of the University of Malta. Both Faculties of Theology and of Medicine and Surgery have their own programs. Recently, the Faculty of Theology has started a Master's program in Bioethics. This will be followed shortly by a Master's program in *Clinical Ethics and Law* in the Faculty of Medicine and Surgery, within its Bioethics Research Program. This second degree is necessary because it is felt that while the MA degree offered by the Faculty of Theology offers a substantial humanities approach to bioethical issues, it does not prepare students for professional carriers such as clinical ethicists.

The Faculty of Medicine and Surgery's Bioethics Research Program falls directly under the Dean of the Medical School. This program is intended to be a platform for research in ethics by encouraging students to choose bioethical topics for their theses and by participating in local and international research projects, especially those related to the European Community Framework Program. In addition, it promotes the understanding of bioethical issues by the general public through media such as daily newspapers and television and radio program. The author, who is the coordinator of the program, has a regular column on *The Malta Independent* on Wednesdays and is a weekly guest on the morning program *Bongu* (meaning "good morning"), for example. These media are used to speak mostly about current affairs in bioethics when they arise and also to promote understanding of mainstream areas of bioethics including patients' rights issues.

The author occupies the only academic post in bioethics (with a special focus on patients' rights) in Faculty of Medicine and Surgery but has an agreement with the university administration to teach in the Faculties of Laws, Sciences, Health Sciences (including nursing school, laboratory technicians, and nursing Master's programs such as Mental Health), Education (in conjunction with Sciences), and Dentistry. He also participates in the Master's degree offered by the Faculty of Theology.

Bioethics Consultative Committee

This committee is non-statutory; members are not paid and are self-selected by the Minister of Health. It is a consultatory committee, as the name suggests, to the minister of health. In the past, it has also been under the Ministry for Social Policy. Thus, it has oscillated between these two ministries. It has taken on

a quasi-official role as being the "national" bioethics committee, and therefore it is members from this committee who participate in the CDBI meetings of the Council of Europe. For several years, it has been organizing a yearly seminar on a topic which is relevant to the country at the time. In the past, proceedings of these conferences were published along with any document the committee may have released. Such was the case when the committee worked on the Reproductive Technology Document and the Organ Transplantation Document (Cauchi, 2000).

As stated above, the members of this committee are selected by the minister. This has not always been ideal as it very much depends on the importance that the minister gives to the committee. Thus, although members from various sectors which are deemed to have a stake in bioethics are chosen, such as clergy, media, and lay representation, many members are also political appointments. In 1999, the committee contained no less than 50 % of its members who had contested the general elections for the same party. However, these situations were rare. But it has to be mentioned that the chair of this committee has been for several years a member of parliament who remains a politician. Nevertheless, he has a strong interest in bioethics, but one can argue that the opinion of the chair may be biased.

Health Ethics Committee

"Following EU Accession, Malta has to adopt EU Directives as part of its own legislation. Three such directives concern the conduct of clinical trials in European countries – 2001/20/EC, 2003/94/EC and 2005/28/EC. These directives, and the respective guidelines explaining their implementation, have considerably changed the way clinical trials are conducted."

Maltese researchers and hospital consultants have long participated in international trials, especially at phase three levels. It is envisaged that with the forthcoming construction of a science park near the University of Malta, which in turn has the Medical School at Mater Dei Hospital on adjacent grounds, phase 1 and phase 2 trials may also be feasible, where before they were not because there was no appropriate setup. At first, the introduction of the HEC was frowned upon as something interfering and impeding progress in research, but time has convinced researchers that it is indeed in their interest and protection that such a committee exists. According to protocol, the HEC must give an answer to an application within a stipulated time frame of 2 months. If that time is exceeded, it can legitimately be taken that the research has been accepted. On average, the HEC handles about five to ten international research applications annually (usually from local consultant who have been asked by drug companies to participate in a phase three trial). There is a separate scientific committee at the Medicines Authority. The HEC has to give its ethics approval. This usually concerns issues such as informed consent processes and data protection. There is still some concern on the informed consent process as the application forms do not address this appropriately.

The HEC follows guidelines which were transposed into Maltese legislation (Clinical Trials Regulations, 2004 (LN490 of 2004); Cauchi, Aquilina, & Ellul, 2006) from the relevant EU directives (above). The Medicines Authority and the HEC have not stipulated any further requirements than what is laid by the directives. The HEC has, however, to take into consideration all kinds of research, even research carried out by private family doctors in small private clinics. These would usually be questionnaires and may not pose large problems as clinical trials. However, there have been instances where family doctors were recruited by drug companies to participate in phase three or four trials.

Other Research Ethics Committees

There are several research ethics committees, all at the University of Malta. Both the Faculties of Medicine and Surgery and that of Health Sciences have their own REC for research done by students, graduates, and health professionals working in the NHS hospitals. The latter, being teaching hospitals, have at their disposal the service of these committees, which are chaired by professionals working within the same structure.

The RECs look into scientific validity and methodology of the study and ethical issues relating to informed consent, safety, and data protection. They are composed of professionals, ethicists, and lay representation.

The University of Malta also has a central REC – the University Research Ethics Committee (UREC) – which overlooks also research done in the humanities, especially psychology, which involves human interviews or studies, and animal research done in the Faculty of Science. It also overlooks the other two RECs mentioned above. Relating to research on animals, there have been ongoing tensions, as Malta has yet to implement EU directives with regard to research on animals, which is mostly done on mice in the department of neuropharmacology. The UREC therefore has to deal with this research, and it is being considered to establish a subcommittee to deal with animal welfare.

Research and Public Debate

Research in bioethics takes the form of theses and of participation in local and EU-funded projects. As stated above, the *Bioethics Research Program* has been developed specifically to aid such initiatives. The program has as yet no funds but has already conducted research in areas of palliative care (Abela & Mallia, 2010) and participated in several FP-EU-funded projects. The coordinator of the program (author) is also the ethics advisor to the Medical Council of Malta, the chair of the above-mentioned Health Ethics Committee, the Dean's delegate for ethical, social and public relations to the faculty of Medicine and Surgery, and also holds the academic post of the above-mentioned patients' rights and bioethics.

Public debate has been mentioned already, but only in the context of public seminars. It is important to note however that the media plays an important role in bioethical debate, with popular prime-time evening programs which choose different topics each week giving a major contribution. Cases which create sensation are usually debated and offer an opportunity not only for academicians and stakeholders to either explain the background and theory or to have their position stated but give a significant opportunity for the general public to participate. Issues which were significantly discussed were the reproductive rights, including the right to IVF, abortion, status of the embryo, and right to life, as well as the Elauna Englaro and Terri Schiavo cases, in which issues of hydration and nutrition and the meaning of a "natural death" were widely debated. Another significant case was the Maltese Siamese Twins debate, which followed the case of the separation of "Mary and Jody" in the children's hospital of Manchester which was resolved in the UK Courts of Justice (Kaveny, 2002).

Legislation

Although as discussed there is no specific legislation in bioethics, there are other laws which are worth mentioning that govern bioethical issues. Reference here is made to Cauchi et al. (2006).

Human dignity, rights, and freedoms are protected under the *Press Act*, the *Code of Organization and Civil Procedure*, and the *Criminal Code* which address the dignity of the victim. The *Commissioner for Children Act* set up a commissioner to oversee the dignity, respect, and fairness in the treatment of children. Also, the *Constitution of Malta* guarantees against discrimination and protects rights and freedoms.

Furthermore, especially in relation to bioethics, the *Data Protection Act* protects privacy and has generated considerable consideration in the area especially with regard to research. The *Criminal Code* distinguishes between intimate and non-intimate samples taken from a person (Cauchi et al. (2006)). Article 350 defines intimate samples as blood samples, semen or any other tissue fluid, pubic hair, and any swab taken from any orifice of the body other than the mouth. Non-intimate are defined as a sample of hair (other than pubic hair), samples of nail or from under the nail, swabs taken from mouth or other areas of body excluding other body orifices, urine, saliva, footprint, or other impression other than a part of hand. Magistrates are given the authority to authorize the taking of samples from intimate areas or to take intimate photographs.

The *Civil Code* describes the procedure for informed consent and where this is not valid (e.g., where it has been given by error or extorted by violence or fraud. Conversely, the *Prevention of Disease* ordinance requests doctors to notify the health authorities of communicable diseases, which are listed in the ordinance. The *Health Care Professions Act* regulates the medical professions and includes section on *ethical Codes of Conduct*. The Medical Council of Malta has requested from its ethics advisor a suggestion for an update on this part of the law. Suggestions have been made with regard to (1) obtaining consent, (2) research on human subjects,

(3) confidentiality, (4) dual responsibilities of doctors, and (5) advertisements. To date, these recommendations have not yet been entrenched into the law. They adapt the UK General Medical Council guidelines for the local scenario.

Malta also respects directives issued by the European Union. To date it has not signed or ratified the *Council of Europe's Convention on Human Rights and Biomedicine* due to some controversial areas of bioethics, such as abortion, which are still being studied, but it is expected to do so.

Finally, there is a *Mental Health Act*, which has recently been updated and which describes the rights of the mentally ill and the procedures necessary to admit patients into psychiatric wards without their consent. The law does *not* refer to research on mentally ill patients. Although this can easily fall under the general rules of research, the fact that mental patients as a vulnerable group had not been discussed with bioethicists during the drafting of the law shows the insufficient awareness of the field of clinical and bioethics when it comes to legislation.

Major Bioethics Issues and Discussions

Malta is largely a conservative society which is highly influenced by tradition, culture, and religion. This is slowly changing and more liberal ideas than those proposed by Catholic tradition are influencing secular society. The latter may defend issues like abortion and euthanasia, but by and large this does not mean that Maltese society has made substantial shifts to decrease ecclesiastical influence on legislation. For the purposes of this chapter, three selected areas, which have given rise to public debate, are discussed.

In Vitro Fertilization

Malta has been trying to regulate the use of in vitro fertilization since the beginning of bioethics debate on the island. In vitro fertilization poses problems in several areas. First of all, according to the Catholic Church, it does not follow natural law, as interpreted through divine law. The Catholic document *Donum Vitae* (literal translation: the gift of life) categorically states that IVF is "illicit" because it bypasses the conjugal act. Many often think that the Catholic Church has reservations on IVF merely because it results in the freezing of embryos. While this is also true, the whole nature of the matter, and therefore the debate, has been on whether IVF is licit or not. Although many priests in pastoral care have encouraged married couples to use the technology, once the issue came into public debate it was quite clear that the Church had the final say which halted the whole process (Mallia, 2010a). Part of the problem was that the true conflict – the nature of IVF itself – apart from other consequential issues like protection of the embryo and the family unit had not been discussed at high levels of government and curia. Had agreement on this been reached, then it would have been difficult for the curia to issue statements at the eleventh hour.

The debate continues to move forward, and the Prime Minister recently made a statement that all problems seemed to have been resolved with the possibility of cryopreservation of ova. A proposal was made by a parliamentary committee that the government should consider the possibility of a limited amount of embryo freezing, however, with the possibility of donating these embryos should the parents, for some reason or other, not use them within a stipulated time. But many remained uncomfortable with freezing and also with donating embryos. Certainly legislation would have to be put in place for the government to be able to take custody of these embryos, something which would need considerable legislative thought.

The issue of IVF brought on a persistent debate about the freezing of embryos. One possibility was to freeze an egg which has been fertilized before the two pronuclei have met – as is done in Germany. Again there was some debate on whether life should be considered to begin when fertilization is complete or when fertilization begins. Part of the problem was that debates went directly into the public realm, and there was no serious academic effort to provide proper information to the government and educate the public at the same time. Therefore, issues such as differentiating between a zygote and an embryo were very difficult to discuss on the media which continuously insisted with academics invited to participate on programs to speak in language which everybody can understand. Although the media contributed considerably to the debate, one cannot resolve the issues here. Although many priests did take part in the discussion, the Curia avoided debate completely and even when invited to comment on a report issued by the Bioethics Consultative Committee as early as 2000, it simply said that the priests that were on the committee were sufficient. And yet, when the bioethics committee held its annual seminar on the topic and the media reported on the issue, an angry archbishop called the minister who in turn called the then secretary of the committee for an explanation (Mallia, 2002).

The issue, according to many, has changed with the introduction of divorce, many feeling that the Church has lost its power. In this author's opinion this is not correct, losing on an issue (and divorce has been considered as a civil right in the mind of many) does not mean that the Church still does not enjoy ecclesiastical authority in matters of morality.

The government is committed, however, to move forward on legislation. This has been stated by the Minister of Health and the Prime Minister on several occasions. While it is recognized that the Church sees IVF as illicit, it is also recognized that the responsibility of the state is to legislate within good standards and that state law cannot be according to canon law. There is general agreement that there should be protection of embryos and of family values. However, an ongoing debate had been whether to offer IVF only to married couples or also to cohabiting couples. If the former, it meant that since most legally married couples marry within the Church, paradoxically, IVF will be offered only to these couples (Mallia, 2002). There were, however, strong arguments also to offer the service to cohabiting couples. Certainly since until this year divorce was not possible, people from broken marriages (legal separations) would have settled with another partner, and

some of these would invariably be infertile. Since they could not legally marry again, the argument was whether it would be an insult to the institution of the family if they were offered IVF. One compromise was to offer it to those people who had separated at an early stage and were awaiting annulment. In fact, it was often said that the problem with divorce took on a lot of force because of the considerable number of separated couples who either waited too long (sometimes up to 8 years or more) for a church annulment, or those who lost hope in ever obtaining such an annulment. State annulments took much less, on average 2 years, and this raises the issue whether it is licit. However, many young people still feel that the church annulment is the proper annulment to take. This raised the question that if the Church was more efficient, the question of divorce may not have gained momentum.

Divorce now will make IVF possible to many more couples and resolved the issue of offering the service to legally married couples. Naturally, for the Church, it is presumed that only the first marriage counts, but this does not seem to be an issue which impedes IVF; the stronger issue is the problem of freezing of embryos. Here, the government seems reluctant even to follow the advice of the parliamentary committee for social affairs which made a recommendation for a limited amount of freezing – as it is quite impossible to impose the technical fertilization of one ovum at a time. It is not clear whether the advent of cryopreservation of ova resolves this issue. In practice, one still has to see as this method was not introduced in any way to treat whole populations. Although it was a method for those who had problems with freezing of embryos, one has to ask whether it will be feasible for whole populations. Certainly one would need to employ an embryologist as freezing of ova is not without its problems. In the first instance, you lose much more ova than you lose embryos when you thaw them. Moreover, due to changes that occur in the outer lining of the ovum, one would have to use intracytoplasmic injection of sperm (ICSI) to fertilize eggs on each occasion. This method is more expensive and requires more time than current practices.

While with the freezing of ova one presumably needs less hormonal stimulation of women to obtain such embryos, one still has to use hormonal stimulation to emulate a pregnancy when introducing fertilized eggs. Again, a pertinent question remained: How many fertilized eggs are you going to introduce in one attempt? If you introduce more than one then you will still have to go through the process of ICSI several times. Practically, it is difficult to imagine embryologists working on populations fertilizing only one egg at a time, without risking waiting list and mistakes, such as (albeit on rare occasions) mixing accidentally ova and sperm of different people. The government has not yet tackled the numbers: up till now, only those who could afford went for IVF; once everyone would be entitled on the National Health Service (and therefore free of charge), it remains to be seen whether one would be able to cope with the demand. Certainly this mistake was done in the construction of the new main hospital. Besides, for some unknown reason, having fewer beds available, the planning team did not envisage that many would now want to go to the state-of-the-art hospital, whose hotel services were even better than those offered by private hospitals. The result was a considerable rise in waiting lists. Can infertile couples afford to wait

weeks or months before the embryologist/s have time to fertilize another ovum and have it introduced in the uterus due to the larger demand?

Another problem is that many seem to think that there is no moral weight with ova. Indeed, throwing away an ovum is not as problematic as discarding an embryo. But gametes do have moral weight attached to them for the simple reason that they are gametes. Unlike males, females have a limited amount of ova. Many may be uncomfortable with having them thrown away once they have conceived. Property rights have not yet been considered in this regard. What if someone refuses to have her ova discarded? Can she legitimately ask the court that they be preserved? In such an event, can she legally be made to pay for their preservation? What if she cannot afford this?

In the meantime, the issue of legislating IVF continues to elude at the time of writing of this chapter.

Hydration and Nutrition

The problem with hydration and nutrition was put in evidence following the Terri Schiavo case (in the USA) and later the Elauna Englaro case (in Italy) which were portrayed as euthanasia by conservative Catholics.

It was quite clear from the onset of the debate of Terry Schiavo that the moral theologians and ethicists in Malta were of the opinion that extraordinary treatment need not be given. When the case of Eluana Englaro surfaced a few years later, however, the public outcry in Italy (Italy being very close to Malta) and the fact that a bishop spoke to Prime Minister Silvio Berlusconi to prevent the removal of artificial feeding and nutrition created a situation where many erroneously believed, or started to believe, that removal of water and nutrition is always passive euthanasia. This was reinforced by the allocution of Pope John Paul II (2004) who had said that they should always be considered basic care.

Yet several statements were made on the media by ethicists at the time. The allocution of Pope Pius XII (1957a) that doctors cannot treat (even force-feed) without the consent of the patient was referred to. For all intents and purposes, this still holds. Secondly, patients need not accept extraordinary treatment but are morally obliged to accept ordinary treatment. What many people, including health-care professionals, often do not understand is that *it is the patient* who decides what is ordinary and extraordinary for himself. The allocution clearly states that extraordinary has nothing do to with the state-of-the-art of the treatment or care being provided. Rather it has to do with disproportionate care, with discomfort, and with respecting that people do die and that this is in itself not a bad thing.

Pius XII (1957b) also had explained the concept of double effect in the provision of pain relief – that death brought about unintended while giving pain relief, even if foreseen, is allowable. Standards of care have to be followed, but since a considerable amount of health-care provision in Malta is given at home, for many GPs who have to use limited resources, following specific protocols is not always feasible. Indeed, it would be extraordinary care to bring all resources

available in hospital to the bedside at home as this would require a disproportionate expense on the part of the patient. Doctors therefore can use their clinical training as a means of titrating proper doses of pain relief. A study done recently (Abela & Mallia, 2010) shows that GPs appreciate vocational training in this regard, for example, on the use of syringe drivers and other therapeutic issues in giving palliative care at home.

The point which was shown to the public was that not all that seems like euthanasia is indeed euthanasia and the frustration was that many Catholics seemed to believe so. The problem is made more complex by some theologians who seem to have a definition of artificial nutrition and hydration as being *always* ordinary treatment and who also seem to omit what the Catholic Church says also in regard to burden on the family (and not only therefore on the patient). Admittedly, the allocution of John Paul II on hydration make things more difficult to explain to the public especially in cases of persistent vegetative state which has lasted several years.

People in Malta often go to bishops to inquire about end-of-life issues when a relative is on life support. Bishops always explain that allowing nature to take its course is an option, which means that if there is no reasonable hope, then people, even if not brain-dead, can be removed from advanced life support as it is extraordinary. One had to extrapolate this argument to show that if this is allowable in people on advanced life support who are *not* brain-dead, then it should be allowable also to people in PVS. PVS is a state which is brought about by modern medicine, and when speaking on disproportionate efforts to keep people alive, Pope Paul VI made the point that it was immoral to push people into PVS. PVS was described in the early 1970s as something brought about by advanced care and in a letter to the International Federation of Catholic Doctors, Cardinal Villot, on behalf of Pope Paul VI, stated that it would be a useless torture to impose a "vegetative reanimation" (Petrini, 2011). So once this vegetative state occurs, the question is why cannot one alleviate any perceived suffering and terminate artificial means of keeping the person alive?

Moreover, it often has to be explained that hydration and nutrition in PVS is not ordinary feeding. In the first instance, it requires expertise to maintain the tubes and to provide the physiological solutions. Secondly, when infections do arise they are often treated and that therefore it is doubtful how only nutrition and hydration is being provided. Thirdly, people are not getting any sensation of feeding – a former relative explained on the media how his mother would crave for some tea when in hospital even though the nurse would have just poured the tea through her naso-gastric tube. There was no sensation of "drinking" tea. Fourth and most important, but one which people tend to comprehend least, is the fact that in a true PVS, only the brain stem is alive. This is a transition zone between the upper brain (basal ganglia and cortex), which gives experience and consciousness, and the spinal cord. Even dead people continue to have reflexes of the spinal cord for some time. Therefore, it is understandable that the brain stem may continue to function. This does not mean that the person is experiencing anything. Therefore, it does not make sense to "starve" a PVS patient, as starvation is a sensation. Nevertheless, the facial reflexes and the continued beating heart and respiration can often deceive people

that there is conscious life. But is this situation not the same one we declare people on life support brain-dead but whose relatives, seeing a body which is still warm and monitors showing a beating heart, refuse to accept that the person has died? Are not these advanced life support taking the place of the brain stem?

PVS creates an illusion of the possibility of conscious life. While there certainly is life, one has to return to the basics of whether basic ANH is ordinary or extraordinary. What is more, health-care professionals should accept that it is not their choice but that of the patient, and when the patient cannot make that choice, the family's wish should be taken into consideration. One has to accept that many will say that they opt to remain in that state if they ever find themselves in that position; others will not. Also many families can accept their loved ones in that state; others may want them to die peacefully. This is certainly an area where greater Catholic dialogue would illuminate Catholic countries like Malta.

Abortion

One would think that in a country where most people are against abortion and all political parties have declared themselves to be pro-life as well, that abortion would not be an issue of debate. Yet debate occurred on several instances. Three will be mentioned here: in the instance of emergency contraception, in the instance of the Dutch ship which visits countries providing abortion (Women on Waves), and in the instance of the Constitution of Malta.

Emergency contraception and some other contraceptive measures such as the coil have been known to provide a risk of aborting a fertilized egg. Traditionally, therefore, they have never been allowed into Maltese health care. It was only for a short while during a socialist administration and until awareness was raised that insertion of the coil was allowed in government health services. Coil insertion is still, however, done privately. Moreover, abortion is a criminal act, and so is assisting an abortion in any way. Legally, a pregnancy is defined as "woman carrying child." Yet it is clearly evident that in a Catholic country, to "carry" does not mean implantation – as decided by the UK courts of law in the case of the Society for the Protection of the Unborn Child (SPUC) challenging the provision of the morning-after pill (Levonelle) through pharmacies across the UK, claiming that these were abortifacient and therefore a criminal offense. Mr. Justice Munby held that since a woman is not yet carrying a baby, she cannot be said to miscarry. Maltese morality follows the Catholic teaching that life has to be protected from conception.

This is not to say that there are no advocates of abortion. Yearly data are published of Maltese women who have gone to the UK for an abortion. Although abortion is illegal in the UK, it is provided for health reasons (health being defined in the broader term of including not only biological reasons, as in Ireland where they provide abortion for *medical* reasons but also psychological and social).

Emergency contraception falls therefore in an area of difficulty. The Catholic tradition speaks of emergency contraception in instances of rape – it cannot allow

EC in marriage and for extramarital sexual activity. It is clear, following the British Episcopal Conference statement that a girl who is raped has a right to defend herself from pregnancy. She can only do so, however, if she is not ovulating. Therefore, ovulation tests may be used. There is an element of coercion here as the woman will not be provided with EC unless she accepts this test. There is ongoing debate in this area in which the author is involved, and hopefully it will be resolved in the future. There has been an argument (Mallia, 2005) to show that it can fall under double effect. Moreover, recently Sulmacy (2006) argues that testing for pregnancy should be morally equivalent to testing for ovulation, which of course is more acceptable – the test is more directly implying a pregnancy or not.

Women on Waves (WOW) had created some public debate with advocates of abortion coming forward in the media. In general, they are still small in numbers. It is interesting to note however that democracy can tie or untie moral values. Although morality is never a statistic, as one experienced with the divorce debate, numbers do count. It may be the case that some politicians will privately speak in favor of abortion, but they and their parties will know that this will be a cause for condemnation by the religious community and can thus cause a loss of votes. WOW also sends abortifacient medication to women by post. There are no statistics to show whether this service is being used and how many women use it. There do not seem to be any restrictions by the post either as when one sends for medicine, one only has to state that they are not for commercial use.

However, the visit by WOW and the ensuing debate created a movement of people to protect the unborn child and which even advocated, at one stage, that there should be a law which not only prohibits women to travel abroad for an abortion and that the partner may actually impede a pregnant woman from traveling as well if he suspects her intent. Moreover, they argued that the state should protect the unborn child also from women who abuse alcohol, drugs, etc. Of course these proposals did not find any support as they were largely based on emotion and ignorance. Although good in intent, they ignored the freedom of the woman and basic human rights that a pregnant woman should enjoy other than prohibiting direct abortion. This triggered discussion on whether we should have a "protection of the embryo act."

This "embryology act" was proposed in 2005 by the Vice Prime Minister following pressure from pro-life groups to prevent abortion, freezing of embryos, and the use of embryos for research. It made considerable debate at the time but never actually reached implementation as existent law already prohibits abortion and that any new reproductive technology law will legislate against freezing irresponsibly anyway.

This was followed by a push to insert an antiabortion law into the Maltese constitution. This move was motivated primarily to make a statement, especially in view of Malta's entry into the European Union. Amendment to the constitution requires a two-third majority in parliament and not a simple majority vote which can be passed by a presiding party. The idea was to protect that law and enshrine it into the constitution. The Church even invited speakers to encourage this move. Although there would not have been anything wrong with this, it was not really

necessary as abortion is not seen as a problem in Malta: it is already illegal, and all political parties have stated they will never legalize abortion. The idea was therefore shelved as it is understandable that with so much work facing parliament, one cannot use up valuable time to pass unnecessary laws.

Conclusion

This overview has shown that Malta remains largely a country with Catholic normative values, but social change is occurring over time and people are challenged to object to some of the Church's teaching when it comes to medical treatment. Although there are no great debates on abortion and euthanasia, when it comes to reproductive technology and end-of-life issues, legislation is showing a change in trend of these normative values. However, people often find solace in seeking advice from Catholic authorities.

This is not to say that there are disadvantages to this. Many priests in pastoral care would not hesitate to help people to make an ethical choice to have IVF. Moreover, the application of natural law also means application of allowing a natural death, which in turn translates into helping people and families with loved ones at the end of life, not to feel pressured to allow extraordinary measures to be taken. Conversely controversy at the beginning of life is more difficult to tackle as it challenges the very concept of when life begins and the protection of that life from the beginning. This does not mean that dialogue in areas such as emergency contraception and IVF is still not possible. Recent developments of Trinitarian ontology within the Catholic Church and how this may be applied to social problems such as bioethics provide a hopeful window for a better understanding while maintaining one's fundamental position in favor of life.

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Netherlands

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Gerrit K. Kimsma and Evert van Leeuwen

Introduction

Bioethics has become "of age" in the Netherlands slowly after the 1960s, with a slow recognition of its value and significance for clinical academic medicine. Technological developments, educational renewal, and societal demands for more transparency in medicine and medical decisions have strengthened the importance

G.K. Kimsma (✉)
Department of Ethics, Philosophy and History of Medicine, Radboud University Nijmegen Medical Center, Nijmegen, HB, Netherlands
e-mail: g.kimsma@iq.umcn.nl

E. van Leeuwen
UMC St Radboud, Radboud University Nijmegen Medical Centre, Nijmegen, HB, Netherlands
e-mail: e.vanleeuwen@iq.umcn.nl

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of ethical expertise, in addition to political and judicial pressures in the areas of the beginning and end of life. Since the eighties the input of ethics has been stimulated both at the level of complex patient care and the level of future developments of affordable care at the national level. Institutional and national committees have inspired the development of a vast group of academically trained group of professional bioethicists, without whom the field of health care is unthinkable.

Bioethics Development

The field of ethical reflection on medicine and health care in the Netherlands became robust in a relatively short period in the late sixties and seventies of the previous century. Not only because of the increasing need for ethical reflection because of the growth of medical technology but no less also because of important changes in Dutch society that together had profound effects on the nature and scope of the ethical debates and the infrastructure of bioethics.

These changes can be observed in the succeeding descriptions of the field. As in other countries, the term "medical ethics" is gradually being replaced by "ethics of health care" and then "bioethics." This change is indicative of a massive shift in focus and social weight of the field. "Medical ethics" traditionally focused on the professional activities and behavior of physicians, as "ethics *in* medicine." "Ethics *of* health care" refers to a broader field, of the implications of the health-care system on both individuals and society, while "bioethics" again covers a much larger field with a focus on the effects of the biological sciences and biotechnology for the future of mankind, guided by a sense of urgency, based on the realization of the need to focus on the survival of the human race and life on planet Earth.

The subjects of "old medical ethics," viewed from the present perspective in the twenty-first century, were confined to the practice of medicine, with a guiding concept on combatting disease from the point of view of physicians. Ethics was based on self-evident convictions that medicine was the prerogative of physicians, assigned to and best managed by the profession. The outcome of this conception can be observed in the topics in one of the few books on medical ethics in the early sixties, by *Gerrit Arie Lindeboom (1905–1986)*, professor in internal medicine, the history, and encyclopedia of medicine: the doctor-patient relationship, professional secrecy, the beginning of life, abortion, and the end of life, with a focus on dealing with incurable and terminal patients (Lindeboom, 1960).

This narrow conception of medical ethics received new broader orientations, as the maintenance of health rather than curing disease, due to developments both in medical science and society.

Of essential importance for Dutch medical ethics, in hindsight, is the publication in 1969 of a small, prophetic booklet by psychiatrist *J.H. van den Berg* (1946–2012), a prolific author on psychiatric, medical historical, and cultural subjects, with his *Medische Macht en Medische Ethiek*, (Medical Power and Medical Ethics) (Van den Berg, 1969). In it he argues, with examples of extremely problematic "heroic"

life-saving cases, the need for a *new ethics*. This ethics should not be based on the premise to save biological life at all costs through medical technology, *but to save, protect, and prolong life only in so far as life will be meaningful*. At the time this new conception of medical morality seemed a quaint voice, but its prophetic significance has become "normal medical practice" in daily nontreatment decisions and patient choices in modern medicine.

These changes are reflected in the topics of the "first" textbook on *Ethics and Health Care* by *Paul Sporken, a Roman Catholic theologian* and the first appointed professor of medical ethics in 1974 at the Medical University of Maastricht.

Besides traditional subjects, a different broad line of issues is the focus of "health-care ethics" (Sporken, 1974). Ethics is introduced as a philosophical science; social aspects of the health-care system are included, such as the relationships between individuals, society and the system of health care, and the structure of health care as a societal system based on financial regulations. Chapters on scientific progress are discussed, such as eugenics/genetics, artificial procreation, organ transplants, and resuscitation. And the "new position" of patient rights is dealt with in chapters on abortion, euthanasia, gender transformation, and sterilization.

This further expansion of the field of health-care ethics in the Netherlands is best illustrated by the publication in 1988 of the *Handboek Gezondheidsethiek (Manual of Health Care Ethics)* edited by *theologians* Heleen Dupuis and Inez de Beaufort, collecting 40 authors with more than 600 pages in 53 chapters on "old" but also on many more "new subjects," such as the relationship between health-care ethics and health law, quality of life, health-care costs, patients' rights, neonatology, anencephalics as organ donors, genetic screening for hereditary diseases, ethical aspects of AIDS, and many others (De Beaufort & Dupuis, 1988).

The newly professed concept of maintenance of health as opposed to curing disease not only presented a whole new set of ethical issues but also resulted in an expansion of recognized participants in the system of health care other than physicians: these workers demanded a voice in the search for the correct medical procedures and decisions. This development was exacerbated by scientific progress, creating new dilemmas that forced other than physicians alone to deal responsibly with the issues at the level of direct care and the procedures of health-care decisions. But progress in medicine also created an awareness of the dangers of scientific applications and questions that arose on quality issues, forcing reflections on the ever-expanding medicalization of society.

Social Developments

In a fairly limited number of years in the early seventies, Dutch society and its social institutions underwent fundamental changes with profound effects on the system and perception of health care, designated by terms as paternalism versus self-determination, individualism, hierarchical views versus loss of traditional systems of morality in society, and consensus on shared values. Dutch society became secularized in a relatively short period of time.

Social values changed from churchgoing community values to neoliberal and social democratic values. One of the legacies of World War II time was a certain benign neglect of church authorities in medical ethical issues. But in the fifties and sixties, progressive Dutch theologians participated in ethical debates and often supported their philosophical views with ideas from French existentialism (Sartre, De Beauvoir, Camus) with its focus on authentic realization of individual existence and the demand for uncompromised freedom to act for individuals. Other factors in the national debates were the effect of the coming to age of the postwar "baby-boom generation," intending to fulfill the hopes of the wartime generation. When this "baby-boom generation" from 1945 and on entered the workplace or went to college and university, students and workers successfully demanded the right to participate in managing workplaces and teaching programs at universities.

They also demanded the right to exercise their newly found freedom with the use of soft drugs and to experience sexual liberties that became available through the rapid introduction of female contraceptives by the Dutch pharmaceutical company Organon. These developments caused the end of traditional hierarchies, shifting from a religion-organized society with separate religious-oriented health-care institutions to "neutral" social institutions. The emergence of movements of emancipation to end paternalistic relations, both within the religious and other societal systems, leads amongst others to the emancipation of the profession of nursing but also in society in general in developing patients' rights.

Changes in the Health-Care System

Not only technological changes but also changes within the distribution of social power enhanced the rise of bioethics. Steep increases in health-care costs forced a confrontation of the issue of "medical scarcity" and the potential injustice of inequality in rights and access to health-care provisions. In 1974 the *Secretary of Health Hendriks* introduced the *Structuurnota Gezondheidszorg*, the *Structure Policy Health Care Paper*, as a first attempt to regulate and limit health-care expenses by focusing on the cost impact of primary health-care facilities and regional health-care insurers. This move however caused unintended mergers of insurers in the field without accountable effects on the actual cost developments.

The conclusion that rising costs would exceed the possibility to pay health care within 30 years was however not disputed. Changes and choices had to be made. In the early nineties, a governmental commission, called after its chair *Dunning*, presented a model to make those choices transparent. Efficacy, need, efficiency, and accountability were to be the four criteria of the health-care delivery process that should produce sustainable and affordable care within a collective system of health insurance for every citizen, with free access for all. Politicians struggled for several years with this concept, trying to evade the financial consequences and

the realization that different innovations should be imposed to curb an ever-expanding medical need. A new system was developed more than a decade later, *forcing basic health insurance as an obligation on every citizen* in order to be able to continue the maintenance of the ideals of solidarity and justice. It was decided also to open up the health-care institutions and services for economic competition through the "laws of the market." Following neoliberal beliefs it was expected that "the invisible hand" would eventually be effective to curb costs through competition. The new system started in 2006. Since then costs however have increased even steeper, driven by a combination of growing demand and "medical" willingness to supply. Hence, the system is again under review with the same ethical questions as in 1974: Should distributive justice govern the health-care system? What treatments should be included in the basic insurance and should accessibility be limited? The area of health care as a basic social institution becomes a field of conflicting moral values between medicine and economics.

Moments of Crisis

Looking back at the start of what is called bioethics today leads to the inevitable conclusion that its development resulted from many different factors, mostly the same as in other developed Western countries: the growth of technology in the post-World War II period and changes in societal perceptions of promise and risk of this technology in an ever-expanding system of health care.

There are also a few "moments of crisis" that put the spotlight on distinct dangers of unforeseen effects of medical technology itself. The first one has become known as "the Softenon affair." The term refers to the sudden appearance, between 1957 and 1961, of babies born without arms and/or legs from mothers who during pregnancy had taken the drug thalidomide. This resulted in the existence in many European countries of more than 10,000 babies with *phocomelia*, as the medical diagnosis became known. Since the drug was not marketed in the USA, the "disease" did not appear on the North American continent. The scandal brought on by an apparently "innocent" drug shocked not only the medical and pharmaceutical world but society as a whole and resulted in a decrease of trust in technology and an increase in societal demands for involvement and more careful research practices ever since.

Another "scandal" became known as "the DES daughters," daughters of women who had been treated in case of earlier miscarriages with diethylstilbestrol. The period ranges from 1946 to 1977 when the drug was taken off the market because of the unforeseen effects on daughters and sons. In the Netherlands the estimate is anywhere between 189.000 and 378.000 cases. The female offspring showed rare forms of the so-called clear cell vaginal cancer, including a risk of infertility and anatomical disfigurations in the male offspring's genital organs. The affected women also had a risk of twice the normal figure for breast cancer.

Also, mostly unknown outside of the Netherlands, the Dutch public was confronted with the so-called Planta affair in 1960. Thousands of citizens suddenly came up with skin "rashes" that were caused by a new chemical in a popular margarine. It was immediately withdrawn from the market but nevertheless started a public and political awareness of the dangers of technology and meant the beginning of the field of modern toxicology.

End-of-Life Issues

In hindsight there seems to be one area of attention that has dominated the ethical debates throughout the past 50 years. That is, the subject of dealing with death and dying patients. Even though there has not been a distinct "death awareness movement" in the Netherlands, the subject of dying and "medical death" has dominated and inspired ethical debates ever since the sixties of the past century.

The line of thinking on the "end of life" expressed itself in several areas or subjects with a more or less specific Dutch trait. Successively we will deal with the areas of truth at the bedside, euthanasia, palliative care, hospice movement, and termination of life of severely incurable neonates.

Truth Telling

Contrary to medical custom to hide a diagnosis of malignant diseases for patients, more and more it became an obligation to tell the truth about possible effects of therapies and prognoses for the future, even in cases with an extremely short life expectancy. Books and articles from nonphysicians, mostly pastors and theologians, set the tone. The name of the "American" psychiatrist *Kübler-Ross* must be mentioned, because her ideas have, and still do, motivated many in and outside the field of health care in the Netherlands. Her ideas on the stages she developed of the psychological process to accept death have shaped that field until today. Even earlier in the sixties, a shift occurs from doctor-centered towards patient-centered conceptions and policies. "Terminal sickbeds" seem to be a central place for truth telling, of which the Protestant minister Buskes in his *Waarheid en Leugen aan het Ziekbed*, (Truth and Lies at the Sickbed), from 1964, with many reprints, is a good example (Buskes, 1964). His book is also an example of the influence of continental existential philosophy in theology, especially French philosophy from Camus (The Plague) and De Beauvoir (A Very Easy Death), with an appeal to sincerity in matters of life and death, without evading the tragic moments of life.

Justifications of "respect for patients as persons" were augmented with more general ideas on the "rights of patients" for a death with dignity. These ideas were

generated in a period of deep social changes in Dutch society in the early seventies, with a focus on authenticity, self-determination, autonomy, and individualism. And "a right to die with dignity" is seen as the utmost and most genuine expression of that position. The intention is to confront death and dying in adult ways rather than focus on health care as an institution with a nonrealistic ideal to be able to prolong life indeterminately.

Euthanasia

The subject of euthanasia is dealt with in extenso because of the leading position of the Netherlands from a "historical" perspective. Several developments should be kept in mind before the history of euthanasia is described in more detail. In the first place, euthanasia as a practice emerges from public pressure, medical cases, and jurisprudence rather than from legislation. Secondly, the Dutch medical profession, organized into the *KNMG*, discussed the issue since 1968 in generally affirmative terms. Thirdly, the supporting legal decisions in subsequent court cases from 1974 onward with their focus on medical science and medical ethics instead of criminal law resulted in, especially after 1984, a lasting cooperation between the medical profession and the Departments of Justice and Health Care in developing guidelines, regulations, and evaluation procedures. For a comprehensive evaluation of Dutch "euthanasia," see Youngner and Kimsma (2012).

Legal Development Through Jurisprudence

Ideas and convictions on the right to death with dignity and one's own choice became hotly debated public issues with the "first" euthanasia case in the Netherlands that went to court in 1971 and ended with a "light" conviction in 1974. The case concerned family physician Mrs. Postma-van Boven, in the province of Friesland in the northern part of the country, who ended the life of her paralyzed and incontinent mother, whose senses were compromised severely, at her repeated request, with an intravenous injection of 200 mg morphine. When her action became known in the nursing home where she stayed, she was arrested. The surprising angle of the Regional (Lower) Court in Leeuwarden was not on ending the life of the patient from a criminal point of view, but the Court rather focused on how physicians deal with seriously ill patients and what is to be considered normal medical care, even if life of a requesting, suffering patient is shortened by intravenous increasing doses of morphine, with the intention to alleviate suffering and accept a shortening of life. Mrs. Postma was found guilty because she did not follow the medical standard of increasing doses of morphine(!), but injected 200 mg at once. She, however, received a light suspended sentence of 1 week in jail. Also the Leeuwarden Court stipulated that helping someone to die should not be limited to terminal patients, but could apply to persons with for them serious physical

or mental suffering, but with the possibility of a longer life expectancy. This ruling was generally experienced as a landmark case that opened to the door for "acceptable euthanasia." For several years the case fuelled the debate on euthanasia and physician-assisted suicide in the Netherlands. A conference on euthanasia was attended by an unusual large number of more than 2,000 participants, with a large share of nurses. Mrs. Postma became one of the founders of the *Netherlands Voluntary Euthanasia Society* that quickly counted a membership of thousands and today is the largest euthanasia society in the world.

This focus on "medical science and medical ethics" has been consistently maintained by the *Dutch Supreme Court (the "Hoge Raad," literally: the High Council)* cases. The important issues have always been two items: a voluntary request of a legally competent person and what constitutes "unbearable and hopeless suffering" in justifiable ending of life. There were a large number of "euthanasia cases" during these years; the cases from the Dutch Supreme Court are described here.

From a legal point of view, in the important *Schoonheim case* (1984), named after the defendant physician, the Supreme Court for the first time defines the judicial acceptance of ending life after a request by ruling that in case of a conflict of duties, namely, the duty to protect life versus the duty to alleviate suffering, ending a life could be excused. Unbearable suffering in this case was described as the presence of ailments and defects that were unbearable for the 94-year-old patient and would only increase in severity and further loss, denying her a death with dignity, without options to alleviate that suffering.

In the *Chabot case* (1994), also named after the accused physician, the Supreme Court rules that not the cause of suffering was fundamental, but the nature of suffering, in case of ending a life of a person whose suffering had no somatic origin, but the person suffered mentally and psychically, without a psychiatric disorder with additional incompetence. This ruling seemed to "open the door" for allowing to pass almost any type of personal suffering or anguish as a justification for euthanasia. However, the *Brongersma Supreme Court case*, from 2002, named after the patient, the Supreme Court finds physician-assisted death in this case not justified because the unbearable suffering of a person must be based on or rooted in a "medical classifiable disease or affliction."

In one other case before the Supreme Court, the *Van Oijen case* from 2004, the physician was found guilty of ending the life of a patient because of the absence of a request, while a claim of compassion was deemed to be insufficient justification.

Politics and Euthanasia

Compared to the practice of a permissive policy based on actual cases after 1974, jurisprudence and regulations worked out between the Department of Justice and the KNMG, the final acceptance of a "Euthanasia Law" has been long in formation. Lines of division between the political parties ran between the opposing Christian

Table 74.1 Percentage of medical decisions at the end of life

% of all deaths	1990	1995	2001	2005	2010
Euthanasia	1,7	2,4	2,6	1,7	2,8
PAS	0,2	0,2	0,2	0,1	0,1
LAWER	0,8	0,7	0,7	0,4	0,2
APS	19	19	21	25	36
NTD	18	20	20	16	18
Palliat. sedation			5,6	7,1	11,1
Reporting	18	41	54	80	77

PAS Physician-assisted suicide, *LAWER* Life-ending without explicit request, *APS* Alleviating pain and suffering, *NTD* Nontreatment decisions

parties and the supporting liberals, with a hesitant position of the socialist parties. Even within the group of proponents, opinions differed with respect to the urgency to realize legalization or whether a responsible euthanasia practice could be realized within the context of existing laws. The period 1984–1986 proved to be crucial. A liberal party (Democrats '66) introduced a law proposal, known by the name of the member of the Parliament that took the initiative, *Wessel-Tuinstra*, the *medical profession* came out in favor of euthanasia; the *Supreme Court* published a lenient decision, and a *State Committee on Euthanasia* published its report in 1985 with a positive advice on accepting the option of medical ending of life, even though a minority report against euthanasia reflected sharp dissension on the subject. Because the Netherlands has a democratic multiparty system, with shifting coalitions depending on election results, opposing positions along the religious-secular divide are pacified through complex rules of the "political game," intending to reach consensus in the end. This is to be observed in both the areas of abortion and euthanasia. The liberal D'66 Wessel-Tuinstra initiative forced the then coalition government to reach a decision. In the Netherlands the "solution" of politically dividing issues often is delayed by the political parties' elites, by putting off decisions through delegation to a committee for further study in depth. The effect of this procedure leads to a certain de-politization of the issue by focusing on the facts. In the case of the problem of euthanasia, the Government inaugurated the *Research Committee Medical Practice on Euthanasia* that became known under the name of its chairman, the *Remmelink Committee*, of 1991. This committee carried out a national survey on end-of-life decisions in the Netherlands and produced representative data for all medical decisions at the end of life, death after nontreatment decisions (NTDs), in the course of alleviation of pain and suffering (APS), voluntary active euthanasia, and physician-assisted suicide (PAS), and collected also data about life-ending actions without explicit request (LAWER). This national investigation, producing data that were representative of all medical decisions on patients who died in the entire country of the Netherlands, was repeated in 1995, 2001, 2005, and again in 2010. The massive amount of data shows that the percentage of voluntary active euthanasia cases varies between 1,7 % (1990) and 2,8 % (2010) (Table 74.1).

Reporting, now mandatory under the present law, increased from 18 % (1990) to 41 % (1995) and 54 % (2001) to 80 % (2005). 2010, the last year investigated, shows a rate of reporting of 77 %.

Legally Regulated Ending of Life

Around the turn of the century, a government formed by liberals and socialists, supporting the realization of a "Euthanasia Law," was in power. In 2002 that *Law on Termination of Life on Request and Physician-Assisted Suicide* was activated. The Law maintains the criminal nature of euthanasia in general but defines the *conditions under which physicians shall not be prosecuted*. These "due care criteria" are – the attending physician must:

(a) Be satisfied that the patient has made a voluntary and carefully considered request
(b) Be satisfied that the patient's suffering was unbearable and that there was no prospect for improvement
(c) Have informed the patient about his situation and his prospects
(d) Have come to the conclusion, together with the patient, that there is no reasonable alternative in the light of the patient's situation
(e) Have consulted at least one other, independent physician, who must have seen the patient and given a written opinion on the due care criteria referred to in a. to d. above
(f) Have terminated the patient's life or provided assistance with suicide with due medical care and attention

Significant is the provision in section 2, article 2, stating that an attending physician may comply with a written declaration of a patient age 16 or older, no longer capable of expressing his will, while the above stated due care criteria apply mutatis mutandis (italics in the legal text).

The Medical Profession: KNMG

Of undeniable importance during all these years, from 1970 on, has been the position and policy of the medical professional organization, the *Koninklijke Maatschappij ter bevordering van Geneeskunst (KNMG)*, the *Royal Dutch Medical Association or RDMA*. The KNMG discussed "euthanasia" in publications from 1968 to 1977, tending to come out in favor of it, but as a profession remained divided. In 1984 the *KNMG Board* came out with prudential policy in favor of active ending of life, justifying and attempting to regulate an already existing practice of euthanasia, wishing to end the legal uncertainty for physicians and inequality for patients, with guidelines following the lenient jurisprudence. The policy's focus is on accepting conscientious objection of opponents, stressing a choice for physician-assisted suicide rather than euthanasia, defining the conditions, underwriting the position that *assisting in ending life should only be possible for physicians within*

the doctor-patient relationship, and pointing out the need for prior consultations, from both nearby colleagues and of a colleague independent of a case.

The Board's recommendations became a guiding force, in spite of minority objections of members of the dissenting Dutch Doctor's Association, and formed the basis for future discussions with the Departments of Justice and Health Care and political parties preparing legislation. In fact, one observer concluded that "the rules and procedures that govern euthanasia were largely worked out within the medical profession before being adopted in the case law and in (proposed) legislation" (Griffiths, 2000).

In 1985 the KNMG appointed the *CAL*, the *Commissie Aanvaardbaarheid Levensbeëindigend handelen*, (Commission on the Acceptability of Medical Behavior that Shortens Life (MBSL) that subsequently published four reports on medical interventions in general, with neonates, with comatose, and with psychiatric patients. These reports, though without a clear legal position, nevertheless contained the outlines for future legal procedures in cases of incompetent patients.

The affirmative position of the KNMG has been consistently maintained with follow-up policy papers in 1995, in 2003, after the Law of 2002 regulating euthanasia became in force, in 2006, and in 2011.

In essence the RDMA cooperated with the state in defining justifiable ending of life or the state allowed the profession to self-regulate end-of-life decision making. One example of this cooperation is the *KNMG Richtlijn Euthanasie bij een verlaagd bewustzijn* (*2010*), (*KNMG Guideline Euthanasia in case of lowered consciousness*) formulated at the request of the Department of Justice. Other relevant policy papers are the *KNMG Richtlijn Palliatieve Sedatie, (KNMG Guideline 'Palliative Sedation)* (*2009*) and the last policy paper so far, *De rol van de arts bij het zelfgekozen levenseinde, (On the role of a physician involved in a self chosen end of life)* (*2012*), in which not only the options and limits of a physician's role in case of euthanasia and physician-assisted suicide are treated but also additionally in cases of intentionally choosing suicide by stopping with food and liquids and when patients choose to die through the ingestion of overdoses of medication.

Checks for a Careful Procedure: Consultants Before and Euthanasia Review Committees (ERC's) After the Act of Euthanasia

One of the early recommendations of the KNMG proposals from 1984 was the inauguration of the function of consultants before euthanasia could take place. This idea was realized in 1997 when the KNMG, in cooperation with the *Amsterdam General Physicians Society*, developed a training program for independent euthanasia consultants for the Amsterdam area, later to be expanded over the country and to be known under the acronym *SCEN: Steun en Consultatie Euthanasie Nederland, (SCEN: Support and Consultation Euthanasia Netherlands)*. This was the beginning of a national, efficiently functioning network of consultants for medical assessment of the conditions for a prudent practice, set up with continued financial support of the government, that today counts more than 500 physicians. Consultants

are available 7 days a week for information, support, and consultation, can be reached through a central phone number to assure independence, and can conclude a visit at the patient's site and write up a report, if necessary at the same day of a request. The system has been successful and appreciated by the medical profession, the government, and the *Euthanasia Review Committees*; the second function to assure the goals of the euthanasia procedures of *transparence, carefulness, and reluctance* to have "the law" dominates discussions between patients and physicians on how and when to die.

Before the inauguration of the five Euthanasia Review Committees, mandatory reporting by physicians, with an estimated low yield of 18 % of calculated euthanasia cases in 1991, leads to criminal proceedings of local prosecutors, with a final decision whether or not to prosecute taken at the Department of Justice by its Secretary.

In 1998 this system was replaced by a review of the *ERC's*, consisting of a legal expert, a physician, and an ethicist. This semilegal committee, putting "the law at some distance," evaluates whether each reported case has been within the limits of a prudent euthanasia practice, as set forth in the jurisprudence, with the expectation of an increase of reporting by including nonlegal experts. Reporting has increased from 18 % in 1999 to 80 % in the 2005 national survey and 77 % in 2010. The ERC's have been incorporated into the "Euthanasia Law" of 2002, while their area of authority has been expanded. They now have the final authority of assessment on all reported cases, including incompetents, such as comatose, psychiatric, and Alzheimer's patients.

When an ERC concludes that a case of physician-assisted dying has not been within the limits of the law, it refers the case to the legal authorities. However, of the 38 "not careful" cases out of a total number of 20,623 reported cases between 1998 and 2008, none have led to criminal proceedings. A 2005 evaluation of the ERC's and SCEN consultations shows adherence to the norms and intentions of the Law of 2002, while the SCEN reports excel in substantial information to complete the evaluation of the ERC's.

Neonatal Care

The debates on and legal developments in euthanasia, with regulations for persons over 16 years of age, were not without consequences for end-of-life decisions in pediatrics and neonatal care. Decisions to continue intensive care in cases of newborns with limited chances of survival and/or a prospect of severe impairment of the quality of life already were discussed in 1992 by the *Dutch Society of Pediatrics* in a report *Doen of Laten* (Acting or Letting Go). In the aftermath of criminal charges in one neonatal case, neonatologist and lawyer *Verhagen of the Groningen Medical Center* developed a protocol to regulate decisions to terminate the life of severely suffering neonates without prospect for survival. This protocol was accepted by the Society of Pediatrics in 2004 (Verhagen & Sauer, 2005). It caused intense national and international debates on the morality of ending life

of neonates but nevertheless received a legal status in 2007. Consequently every case of ending the life of a neonate as well as cases of abortion after 24 weeks of gestation, since 2007, needs to be formally reported to a state review committee (*the Central Expertcommittee on late terminations of pregnancy and life-ending of neonates*) that judges the carefulness of each case on the same conditions as the "Euthanasia Law" for adults. In case of interventions "without due care," physicians can be prosecuted for murder. This committee reviews only a few cases each year and far less than expected. One of the explanations is the use of ultrasound imaging after the 18th week of gestation that has increased abortions before 22 weeks, the time line for "legal abortions." However, in cases of newborns with none or a very limited prospect in life, the protocol seems to function well as a public review of medical decisions of ending or not supporting the life of some newborns.

Palliative Medicine

The development of palliative medicine in the Netherlands is thoroughly colored by the polarized national and international debates on euthanasia. That is an undeniable factor in both the debates and the actual growth of the field. Opponents of euthanasia in the eighties and nineties, both in- and outside of the Netherlands, claimed a lack of palliative options in the Netherlands that, if they had been in place, might have resulted in less requests for euthanasia. Proponents of euthanasia claimed a disrespect of opponents for the requests of autonomous patients, to fulfill their vision on the end of their life. Both claims have no scientific empirical foundation but nevertheless dominated the debate about the adequacy of palliative care in the Netherlands.

There is no denying that palliative medicine in this country was developed late in comparison to other European nations, especially to the "founding nation" Great Britain. But then again, the Netherlands was not the only country trailing in this development. However, given the international ambivalence towards the euthanasia policies in the Netherlands, palliative medicine and care have developed in relative isolation.

Early Initiatives

Early publicly funded initiatives to promote and improve palliative care, usually described as terminal care, are from 1975, with the establishment of a separate unit at the "Antonius IJsselmonde" nursing home near Rotterdam, aimed at a broad program of medical, nursing, psychological, and spiritual support. The seventies in general were a period of more public and private initiatives to improve care for terminal patients, with intensive contacts with St. Christopher's and St.Lukes hospices in London. The Dutch initiatives for similar hospices were inspired by religious convictions and privately financed. In 1988 the Protestant "Johannes Hospice" opened its doors in Vleuten, followed by "Hospice Rozenheuvel" in

1994 in the city of Arnhem and funded by Roman Catholic supporters and the Salvation Army. Many other initiatives followed, with a multidisciplinary care focus, supported and also staffed by volunteers. In 1996 practitioners of palliative care organized themselves into the *Dutch Association of Palliative Care*. The proliferation of both institutions and practitioners, with in addition the interest of members of parliament, forced the government to develop policies to guide and regulate the area of palliative care. The formation of policies, also with hopes of public funding, took place in an atmosphere of opposition to euthanasia. Views differed widely on the quality of expertise in existing institutions, such as nursing homes and hospitals, in comparison with the newly founded private hospices. Especially physicians in nursing homes were biased towards independent hospices, which they experienced as an intrusion into their field of expertise, with for them questionable justifications.

So the development of palliative care in the Netherlands has been distinguished by opposing views on the most desirable location of palliative care: inside nursing homes with special units or outside existing institutions in small-scale hospices. Even the terminology of "bijna thuis huizen," meaning "nearly/almost? home house" for hospices, reflects a bias against formal institutions, underscored by a claim of care in surroundings where patients can take along their personal furniture and be supported by family and friends. The ideal remains to provide for patients in need of palliative care in their own homes, cared for by a general practitioner and supported by a multidisciplinary team, on a daily basis. Institutionalization only is an option if the home-care delivery becomes problematic or insufficient.

Fact remains that the Dutch government and especially its liberal Secretary of Health Care Els Borst (Democrats '66), after promoting legal options for euthanasia, in 1996 took national initiatives to promote palliative care with funding for beds, institutional support, and research, both at the level of care and the ethics of palliative medicine. Much funding went to six academic centers where "*Centres for the Development of Palliative Care*" *(COPZs)* are established for both research and integration of palliative expertise into the curricula. Programs are coordinated with regional cancer centers; care teams put into practice the results from research and "disseminate their expertise through consultations in the context of primary, secondary, and tertiary care settings" (Ten Have & Janssens, 2001).

In addition, invaluable input has been received from the European Commission through the international *Pallium Project*, enabling research into the organizational aspects of palliative care, concepts, ethical debates, and development of the field. Two journals appear: *Pallium, Tijdschift over Palliatieve Zorg* (Pallium, Journal on Palliative Care) and the *Nederlands-Vlaams Tijdschrift voor Palliatieve Zorg* (the Dutch-Flemish Journal for Palliative Care).

Where in most countries palliative medicine is seen as an alternative to euthanasia, in the Netherlands (and Belgium) the dominant view has become that euthanasia is an option at the end of life after all palliative interventions have been exhausted or found insufficiently effective by terminal patients. This claim implies an adequate level of palliative care services, and this position is underpinned in the report *Ranking of Palliative Care Development in the*

European Union. Proposal by the European Association of Palliative Care from 2007. Based on the indicators: hospital units, support teams, home care teams, specialized beds, and full-time physicians, the report situates the Netherlands in a fourth position of the 27 European Community countries, after the UK, Ireland, and Sweden. With respect to the issue of legalized euthanasia as a substitute, or even an obstruction for palliative care, it appears that such a statement has no empirical foundation. On the contrary, this statement is substantiated by a *Report for the Commission on Assisted Dying Briefing Papers from October 2011 of the European Association for Palliative Care*, called *Palliative Care Development in Countries with a Euthanasia Law*. Its conclusion is that "palliative care is well developed in countries with legalized euthanasia/assisted suicide or at least no less well developed as in other European countries. Though international comparison is difficult given the differences in organization and structure of palliative care provision, these countries (Belgium, the Netherlands, Luxemburg, and Switzerland) rank high in Europe for most structural or national indicators."

Abortion

The area of abortion shows shifts in moral and legal appreciation in the Netherlands over the past 200 years. In 1811 it became criminalized in the Netherlands and to be regulated by the state. In the early 1900s abortion became an offense as part of the *Zedelijkheidswetgeving*, the *Morality Acts* from 1911, together with the display and advertising of contraceptives, pornography, brothels, pimping, and homosexual acts (Outshoorn, 2000). Abortion is only allowed in case a woman's life is in danger, even though until World War II, a more liberal practice could be observed with a focus on the woman's life, not only physically but also in case of mental stress. A change from illegal to legal abortion takes place in the Netherlands in the early sixties of the past century, initiated also by the abovementioned thalidomide disaster of severely deformed babies. A group of physicians identified with women with unwanted pregnancies. Physicians and a progressive part of the public realized that the old restrictions could no longer be maintained. This is the period when oral contraceptives become widely available, provided through "Organon," an established Dutch company. However, the medical profession as a whole remained divided on the issue of liberalization of abortion. After a permissive report of the *KNMG and the RDMA*, a conservative faction left to form its own *Nederlands Artsen Verbond*, the *Dutch Association of Doctors*. This polarization occurred also within politics and society as a whole. The professional organization of the Royal Dutch Medical Association comes out in support of careful procedures within a clinical environment, and feminist movements support the position of *Baas in Eigen Buik*, meaning the "self-control of women over their own bellies." Specialized "abortion clinics" in the sixties, run by doctors, defy attempts by the government to close them down, forcing parliament to regulate the issue, with supporting positions of the socialist and liberal parties and opposition from the Christian parties. Parliamentary debates on abortion discuss the principles of protection of

unborn life and the autonomy of the pregnant women. They end up focusing on defining the authentic interest of the state in this area of regulating public and individual morality. And the debates lead to a conclusion that in the end the state should adopt a neutral position as opposed to religion-based "paternalism."

The present *Law Terminating Pregnancies* (*Wet Afbreking Zwangerschap*) from 1981 aims to guarantee the protection of unborn life to the 22nd week of gestation, the right of women to gain aid to end unwanted pregnancies, and to assure careful procedures to end these. The Law however did not change the permissive practice and abortion is still easily available, also for non-Dutch inhabitants from countries where it is still prohibited.

The combined options between abortion and contraception have resulted in one of the lowest abortion rates in the world. In recent years there has been a slight increase due to the sexual mores and lesser use of effective means of contraception of women originally from non-Western, mostly Islamic cultures, where premarital sex is not officially accepted. The combined abortion rate then adds up to 8,6 in 1,000 women between the ages of 15 and 45, according to accumulated figures from 2001 through 2005 (Wijsen, Van Lee, & Koolstra, 2007). The use of contraceptives by women in these age brackets, oral contraceptives, IUDs, and sterilization, in about 60 % undoubtedly explains the low figures.

Early Activities and Early Centers

Ethics in the Netherlands as a separate scientific discipline becomes a serious academic activity in the seventies of the previous century. In these years medical ethics also becomes a distinct academic discipline, at first more often practiced by theologians and philosophers than physicians, even though the latest appointments are again of physicians with or without a philosophical education.

Medical ethics as a separate academic discipline takes off with the appointment of the progressive priest *Paul Sporken* in 1974 in the medical school at the newly founded public University of Maastricht, followed by philosopher *Jan Broekman* in 1980 in a part-time appointment at the Dutch-Reformed Protestant Vrije Universiteit, both at the medical and philosophical faculties, and was succeeded by *Evert van Leeuwen* in 1994. In 1986 the Leiden University Medical Faculty followed by elevating *Heleen Dupuis*, a graduate in law and theology and associate for many years, to the Chair of Medical Ethics. In 1991 the Roman Catholic Radboud University at Nijmegen appointed *Henk ten Have*, physician and philosopher, at the newly founded Department for Ethics, Philosophy, and History of Medicine. In 1992 the public Erasmus University followed by appointing theologian *Inez de Beaufort* to teach medical ethics, while in 1996 philosopher *Guy Widdershoven* became the Chair at the Maastricht University. The other universities followed suit in this century, starting with philosopher *Marian Verkerk* at the public University of Groningen in 2001, *Hans van Delden* in 2003 at the public University of Utrecht, and *Dick Willems* in that same year at the public University of Amsterdam, at its Academic Medical Center.

In 1984 the *Institute for the Ethics of Health Care* was founded as a publicly funded multidisciplinary research institute to act as a scientific "service center" to promote quality in health care through research in the ethical aspects of the ever-expanding fields of research, genetics, chronic and psychiatric care, issues of equality and fairness, and the end of life. Its first director was the Belgian philosopher *Maurice de Wachter*. The institute published a newsletter called *IGE Nieuws*, literally in Dutch "News from the Institute of Health Care," and a book series focusing on the relevant issues of the time: quality of life, medical confidentiality, medical scarcity, genetics, AIDS, and end-of-life issues. It also published funded research and policy papers, such as "drugs in sports."

In 2001 this institute was absorbed into the Medical School of the Maastricht University, while *Ruud ter Meulen* was its chair.

In 1987 the *Lindeboom Institute* in Ede in the Netherlands was founded, named after the well-known general internist and historian of medicine Gerrit Arie Lindeboom (1905–1986). The foundation of this privately financed Christian institute was motivated by a rejection of ethical developments of the day against the absolute protection of life, understood as the guiding Hippocratic inspiration for medicine, both at the beginning and end of life, as seen in abortion and euthanasia. *Henk Jochemsen*, its director, became an extraordinary professor of medical ethics at the Faculty of Medicine of the Protestant Dutch-Reformed Vrije Universiteit in 1988.

In 1988 the *Center for Bioethics and Health Law* was founded at the Utrecht University Faculty of Theology by theological ethicist *Egbert Schroten*, intended as an interfacultary institute. In 2003 this center changes its name to *Ethics Institute* and becomes located at the Faculty of Philosophy of the University of Utrecht.

In 1989 the *Interfacultary* I*nstitute for* E*thics* is founded at the Vrije Universiteit (IEVU) by theological ethicists.

In the early years from 1970 on, several professional organizations were established. The ethicists, mainly from a theological background, founded the *Vereniging van Ethici in Nederland*, the "Society of Ethicists in the Netherlands."

In 1981 the *Vereniging voor Filosofie en Geneeskunde*, the "Society for Philosophy and Medicine," was established by academic philosophers at medical faculties and medical practitioners as a forum for both internal and public debate. It published the journal *Scripta Medico-Philosophica* for several years and still organizes yearly meetings intended for interested professionals from all areas related to health care. This society appealed to a relatively small group of mainly philosophically interested members. In 1993 it associated itself with the already existent *Tijdschrift voor Geneeskunde en Ethiek*, "Journal of Medicine and Ethics," that became its official professional outlet. This journal has a history that is symbolic of social developments in Dutch society. As in many other areas of Dutch society before the seventies, reflective journals on the ethics and philosophy of medicine were divided along lines of religious affiliation: a Catholic, Protestant, and liberal a-religious orientation. Starting out as *Katholiek Artsenblad*, the "Catholic Physicians' Paper," it changed its name to the more neutral *Metamedica*, "Metamedicine," and then to the *Tijdschrift voor Geneeskunde en Ethiek*.

In 1993 a Nederlandse *Vereniging voor Bio-Ethiek*, "Dutch Society for Bio-Ethics," was founded on the initiative of Egbert Schroten of the Utrecht "Institute for Ethics," as a society with an open admission and with a broad focus on bioethical issues in the original biological sense, ranging from issues in health care to agriculture, ecology, and animals. This society, with a large membership, publishes a newsletter four times a year and a substantial "pre-advice" on relevant issues for its yearly meeting.

International Orientation

After the seventies of the previous century, a significant change in focus occurs with a shifting orientation from an internal national towards an external international orientation. Not only did Dutch ethicist broaden their perspective early on by active participation in the European *Societas Ethica*, established in 1964, but in later years they were also more or less forced to publish in international journals by their professional peer groups that had decisive roles in dividing government furnished research grants, holding international publications as a condition for continued financing. This international focus became relevant also for philosophers and ethicists in medicine and health care. Was the early postwar interest in the Netherlands directed towards the German intellectual sphere; since the seventies this position more and more is taken over by the English-speaking countries and especially the leading role of developments in the USA. Personal contacts, especially with philosopher David Thomasma from Loyola University in Chicago and the publication of his book on "The Philosophical Basis of Medical Practice," together with Ed Pellegrino, made a significant contribution towards establishing ethics of health care as a recognized independent scientific field.

Following the example of the then called *American Society for Health and Human Values*, Henk ten Have and Gerrit Kimsma in 1987 took the initiative to establish the *European Society for Philosophy of Medicine and Health Care (ESPMH)*, with a founding meeting in Maastricht, the Netherlands, on *The Growth of Medical Knowledge*. This society with a major European membership and also with many international members from other continents meets yearly for a conference, with invited presentations on a specific topic of interest. In 1994 the ESPMH organized the *First World Conference on Medicine and Philosophy* in Paris, in association with the French *Association Descartes* and *UNESCO* at the Sorbonne, followed by the *Second World Conference* on this subject in 2000 in Cracow, Poland, together with the *Central and Eastern European Association for Bioethics* and the *Jagiellonian University* of Cracow.

In 1998 the *European Society* started with the publication of the three-monthly *Medicine, Health Care and Philosophy. A European Journal*, edited by Henk ten Have and presently also coedited with Bert Gordijn. A guiding idea of this journal is to be a platform for European philosophers, physicians, and bioethicists with the intention to focus on European philosophical sources and traditions in confrontation with modern-day medical and health-care problems.

Dutch ethicists also have been active in helping realize the *International Association of Bioethics (IAB)* of which the founding meeting in 1992 took place in Amsterdam and then again a meeting was organized in 2012 in Rotterdam.

Government Interventions

The nature of government interventions with ethical issues in the Netherlands has not been in reaction to crises or undesirable events. Technological progress forced the state to react. This reaction has the nature of a response but at the same time also caused a process of reflection on its own tasks and the division of responsibilities in the area of ethics between the state, the relevant organizations, such as the universities, and the workers in the field. In a general sense, the state considers its interventions from three different perspectives. The first one is *to create order* between public pressures, initiatives, and the actual legal system. The second one is *to protect citizens* in their encounters with the system of health care, and the third motive is the *promotion of equal access* to a system of health care of adequate capacity and quality (Struijs & de Beaufort, 2010).

The actions of the state expressed itself in two broad areas: research and policies. Initial activities of the government in the area of ethics from 1989 on focused on the promotion of quality research by inaugurating "schools for research" and "work groups" in theology and philosophy, intending to subsidize peer group-evaluated projects. In this period the field of theological and philosophical ethics shifted from theoretical towards more practical and applied ethics, and the ethicists organized themselves in 1994 into the *Onderzoekschool Ethiek*, the "Research School of Ethics." The *Nederlandse Organisatie voor Wetenschappelijk Onderzoek* (NOW), literally the Dutch Organization for Scientific Research, became the dispensary of state funding in cooperation with established leaders in the various scientific fields, organized into the Koninklijke Nederlandse Academie voor Wetenschappen (KNAW), the "Royal Dutch Academy for the Sciences." From 1996 on the government stimulated programs as part of its *Ethiek met Beleid*, "Ethics with Management" program. Especially the condition of interdisciplinary research between ethicists and researchers in other fields of health care, biology, and technology resulted in quality research and significant progress that led to a continuation of further funding from 2003 onwards.

The second area of ethical initiatives of the Dutch government also came in reaction to technological developments, such as the possibility of cloning. The state realized that it should respond to these developments together with the workers in the fields. From that time on, ethics was placed on the agenda of the various advisory organs of the state such as the *Raad voor de Volksgezondheid en Zorg (RVZ)*, the "Council for Public Health and Care," a more regulatory institution for public health and health insurance, and the *Gezondheidsraad*, the "Health Council," an advisory organ for the government itself. The state established the *Centrum voor Ethiek en Gezondheid*, the "Center for Ethics and Health," a cooperation between the aforementioned councils, with the assignment not only to advise the government but also to be an information

center for the general public and function as an intermediate for all possible and potential parties with interests in ethical issues in health care. Essentially, the Center is an institution for anticipatory detection of potentially "ethically loaded" issues.

In its existence since 2003, it has published opinions on many issues. The growth of the state's participation in ethical debates is undeniable, but the nature of its involvement is also subject to substantial change. As said before, this development also meant a reflection on its own role in shaping morality in issues of health care and other areas of public life. Several shifts may be concluded (Struijs & de Beaufort, 2010). In the first place, a shift in policy is seen in the area of moral paternalism towards a more neutral liberal conception of its role. Instead of setting a norm, the focus shifts towards stressing procedures. The government's angle shifts from reacting on events and developments towards proactive or more anticipatory developing of policy. The state's focus also changes from orientation at the level of individuals to the meso and macro level of ethical issues, as becomes apparent in areas of medical treatments, issues of science and technology, and scarcity issues in the system of health care. Councils and centers function as both signaling new developments and providing policy choices in their advisory capacity.

Bioethics as a Discipline

The intense involvement after the seventies of ethicists in areas of health care, technology, agriculture, and the environment automatically led to reflections on the nature and the value of ethics, its methodology, its claims, and its conceptions of ethics as a science. Both in the international arena and in the Netherlands, the need for conceptualizing the "new ethics" as opposed to the old "Hippocratic" variety led to lively debates. In the Netherlands the ethicists from theology and philosophy carried on a debate characterized as a conflict between paradigms, between the "universalists" and the "contextualists." The question concerned the possibility of a universal morality in order to analyze particular moral traditions, the nature and value of ethical theories, and the nature of moral argumentation (Musschenga, 2010). The universalists tended to agree on the option of a "narrow morality" versus a "broad morality," and their ideas on consensus fitted the concept of consensus on a basic social morality, as the basis for a democratic society. In a pluralistic society, the dominant political morality is the liberal approach that prescribes the limits of interactions between the states and individuals. The conception of a "narrow morality" also influenced debates about the relationship between political morality and broader life- and worldviews on the "good life," in this case a broader vision than in medical practice itself. The difference between "narrow" and "broad" conceptions becomes visible also in visions on the relationship between "theory and practice," with pragmatic positions on a minimally necessary shared political views threat to function as opposed to a view that foresees the loss of philosophical foundation and content for ethical analysis. The latter approach aims to regain ethics as a science to "uncover" and articulate the meaning of moral experience behind or in actual moral behavior, the so-called hermeneutical approach. This debate continued when

ethicists were confronted with questions of empirical research in institutions and actual policies of health care. This debate of the ethicists took place in a context where physicians more and more felt threatened in the control of traditional and inherent morality in medical practice, as if medicine in itself did not express adequate morality and was in need of extern expertise. *Widdershoven* can be seen a leader in the "hermeneutical" movement to analyze the internal morality of medical practice in a dialogue with practitioners, patients, and ethicists, describing various justified approaches, depending on the issues: principled, phenomenological, narrative, hermeneutical, discursive, and care ethics, depending also on the level of health-care problem (Widdershoven, 2000).

This change in perspectives for physicians was in detail described by Ten Have, already in 1989, in an analysis and confrontation with the international, primarily the American, developments, of applied ethics, clinical ethics, and the ethics of interpretation. His conclusion is that the position of ethics needs to prevent the approach of "moral engineering" of applying outside ethical principles on individual cases in the practice of medicine. Instead a "prudent" approach is most effective in recognizing the inherent moral components in medical practice, to make the implicit explicit. This approach should function both at the level of medical ethics committees for patient care within a cultural setting and in comparing medical practices between cultures. Only then the critical function of the ethicist will come to full force and possibly have a material addition also in medical training (Ten Have, 1990).

Other Issues and Discussions

Research Ethics and Institutional Research Boards

The need for regulation of medical experiments on animals and human beings has increasingly been felt in the post-World War II period. Not only the Nazi experiments during the war, leading to the *Neuremberg Code* in 1947, but also the reality of unacceptable experiments in the USA after the war underscored the need for regulation of the research activities in Europe, also the Netherlands. At least one unauthorized experiment on radiological experiments, with institutionalized mentally handicapped, became known in the seventies, and in general the conclusion was that several researchers did not live up to the necessary standards. Even though the urgency of the matter was clear, the legal regulation of animal experiments crystallized in 1977 before the inauguration of a law on experiments with human beings in 1999. Before 1999 medical research involving human subjects was *regulated by the medical profession itself* through adopting international codes, such as the mentioned *Neuremberg Code* from 1947 and since 1964 the *Declaration of Helsinki* of the *World Medical Association* followed by its successive later revisions, and the World Health Organization (WHO) together with the *Council for International Organizations of Medical Sciences (CIOMS)* from 1982. The first *Hospital Research Ethics Committees* were established already in 1965, at the

University of Leiden by pharmacologist Noach and at the Vrije Universiteit in Amsterdam by general internist Van der Meer, followed by most hospitals. These hospitals, with a decisive role for academic medical centers, founded the *Nederlandse Vereniging voor Medisch-Ethische Toetsings Commissies (NVMETC)*, the *Dutch Society for Medical-Ethics Review Committees*.

Government advisory organs and hospital associations in 1984 developed a system of norms and licenses in the spirit of these codes, delegating responsibilities for good clinical practice in research to hospital management. Much energy is devoted to issues of defining the various experimental designs and the inherent ethical differences. Distinctions between therapeutic and nontherapeutic experiments, patients and non-patient volunteers, and the competent and the incompetent, such as minors and mentally handicapped, psychiatric patients, prisoners, and military personnel, are discussed in detail and prudent procedures for each category are established. The intense discussions and regulations over the years resulted in the parliamentary acceptance of the *Wet Medisch-Wetenschappelijk Onderzoek met mensen (WMO)*, the *Medical Research Involving Human Subjects Act* in 1998. The law covers the protection of research subjects, of minors and incompetent subjects, protocol requirements, patient information, the consent form, outside consultation of an independent physician not connected with the research in question, and the insurance for research subjects. Hospital review committees, as a result of this law, became legally required, independent local advisory organs for hospital management.

A national committee, the *Centrale Commissie Medisch-Wetenschappelijk Onderzoek (CCMO)* with its bureau becomes responsible for establishing a system of licensing local review boards, but also for review in specific complex areas such as gene therapy, xenotransplantation, embryo research, nontherapeutic interventional studies in minors, and observational research of psychological behavioral interventions. The CCMO as an agency has overall responsibility for the administration of all ongoing research protocols; it functions as arbiter in conflicts between Review Boards and researchers and its bureau serves as an information center for the medical field and the public.

Institutional Ethics Committees

The development of Institutional Ethics Committees in the Netherlands has been profoundly inspired by the history of the American Committees. The original so-called God Committees in case of a morally acceptable practice to share kidneys when transplants became possible cleared a conception of medical decision making involving "the public" in final choices. This development enhanced a publicly shared conviction that others than the medical profession needed to be involved in final choices about acceptable moral choices in health care, especially where it concerned a scarcity of organs and also of a balanced choice between possible medical progress and risks of new research projects. A publication of the Dutch Society of Bioethics on *Ethiek in Commissies*, "Ethics in Committees," in 1999 is

representative of this development and the institutionalization of these Committees. An important theme is the broadening of the basis of committees with outside expertise other than the professionals, both in case of animal experimentation and experiments with human beings. In the late eighties most institutions, either academic hospitals, general hospitals, psychiatric institutions, and nursing home facilities, possess an "ethics committee," in accordance with a concept text of a law on medical experiments from 1987 that became finalized in 1999 but nevertheless had influence on shaping the practice of committees. After that period the potential of ethics committees for both research and individual case analysis leads to a diffusion of this instrument throughout the health-care system, realizing goals of consultation in individual cases, developing protocols for care and treatments, realizing educational objectives, and more generally in activities of reflecting on debates in society and health care (Verweij, Brom, & Huibers, 1999).

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New Zealand

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Grant Gillett

Introduction: Bioethics Development in New Zealand

The growth of bioethics in New Zealand really began in 1988 with the Cartwright Report in which the treatment provided for women in National Women's Hospital was found to have been distorted by the theoretical commitments of a senior medical figure, Professor Green. Over more than a decade, he had pursued a study of cervical cancer based on the presupposition that early changes in the cervix were not precancerous, were being far too aggressively treated, and could be observed rather than excised when first detected. This put him at odds with orthodox medical approaches, but he pursued his convictions in the treatment

G. Gillett
Bioethics Centre, Dunedin, New Zealand
e-mail: grant.gillett@otago.ac.nz

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regimens he offered as standard treatment for women presenting for state-funded treatment. The Cartwright Inquiry was convened to examine the discrepancies between practice at National Women's Hospital and international opinion.

The treatment was, in the inquiry, seen to be closely linked to ongoing research and close scrutiny of the events revealed that ethical standards had been deficient both in terms of patient autonomy and their protection in clinical practice and medical research. It also led to an upsurge in public and professional interest in bioethics.

The Cartwright Report

The events at National Women's Hospital became known as "The unfortunate experiment" and their exposure caused an upheaval in New Zealand medicine (Coney, 1988). The idea that senior medical figures might have acted unethically toward their patients was, at the time, almost unthinkable, but the Cartwright Inquiry (1988) and its conclusions overturned that belief. They instituted a social change in ethical review of research and clinical practice and a major change in bioethics education. The Cartwright Report is, however, critiqued in a controversial recent history (Bryder, 2009) claiming that doctors were unfairly victimized by the inquiry and that the post-Cartwright reforms have not only been to the detriment of a healthy professional-public relationship but also caused a breakdown in the ethos of medicine.

This debate is very important to the ethics of health care throughout Australasia, in which the New Zealand model has been influential (McNeill, 1993). However, that critique of the Cartwright Report and its effects has itself been called into question (Manning, 2009). The author is, for instance, accused of distorting medical history in that she "relies on selective evidence, misreads sources, and makes no attempt to weigh the quality of the sources" (Brookes, 2009, p. 101) suggesting that the author "ran with one side." And the principal epidemiologist advising the Cartwright Report speaks of a "misrepresentation of the medical context" that "should be of serious concern to the profession in New Zealand" (Paul, 2009, p. 138). The observations of a medical student during the contested events will be used to reexamine "the internal morality of medicine" (Paul, 2000; Veatch, 2001) that prevailed before the Cartwright reforms.

"Internal morality" is an ethos, focused on the good of patients, that should guide professionals and protect patients against harm, but the alternative focus on patients' rights led to a radical interrogation and reform of NZ health care that introduced an "external morality" into health governance. Independent ethics committees and patient advocates, nonaligned with medical professional interests, were intended to counterbalance the paternalism thought to dominate existing clinical contexts and professional surveillance mechanisms. The relative disempowerment of patients was depicted as a moral crisis needing to be addressed so that abuses of power in health care could be overcome. The relative disempowerment of patients and the ways in which it led to clinical abuses are evident in the lived and transformative experiences of a medical student of that time (Gillett, 2011).

The relevant experiences cast a revealing "light from within" on a proud and highly principled profession as it existed in New Zealand in the 1970s. Take the example of a patient with metastatic breast cancer encountered during a surgical attachment. The students were told to examine her axilla for "shotty lymph nodes," and then, as the group left the bedside to discuss findings with the surgeon, the patient spoke up; "Excuse me but could you tell me what is wrong with me?" The surgeon's dismissive and breezy reply conveyed no reassurance at all, no indication that he would return to discuss her condition with her, and irritation at her interruption. As the group continued out the door, she screamed "Please, won't you tell me what is wrong with me!" One feels compelled to ask: Why didn't the students say something?

Another example was student puzzlement during apparently contradictory and clearly charged lectures about gynecological cancer and its management and of clinical tutors who acknowledged the problem and tried to help. Increasingly, desperate measures were taken to indicate the sinister implications of cytological findings and the necessity of follow-up in line with international practice. This acrimonious dispute exposed a political schism at the heart of medicine and its science. It would have taken a great deal of personal courage and confidence for any student to form an opinion and speak out in that climate. One woman student did so and was dismissed from an ob-gyn theatre during a session on per vaginal examination with a patient under anesthetic; her sin was speaking up to say that the patient, under anesthetic and about to be examined by half dozen or so medical students, had said that she would be willing to be examined by the student she had met but not by a group of anonymous others. The professor ordered the student from the theatre and refused to allow her to participate any further teaching from him. What should her classmates have done?

The medical profession was, and is, a club that medical students want to join; they are being socialized into the junior role, learning their place. They do not fully understand the ethos of bullying and intimidation (even in some enlightened medical settings). To be sure, there are mentors who take a personal interest, make themselves available to speak frankly, and discuss students' worries, but the "internal morality" sometimes has little to do with collegiality, core purposes, and "morality of the practice of medicine" (Veatch, 2001, p. 622). Internal morality exists at two levels: one deeply humane, caring, and engaged and the other political and riddled with power. There are some traditional doctors perhaps a little anachronistic but with a twinkle in their eyes who do not quite fit the establishment line. These are often memorable characters who embodied an unspoken criticism of some features of the health-care establishment. Other good, solid, and caring doctors, a little apart from the internecine tensions around them, also embody traditional values. Thus the internal morality of medicine (which Pellegrino [2001] derives from the art of medicine and its aims and purpose) was not a uniform concretion of virtue but, in fact, a complex and disrupted reality. It is often effaced by institutions and discourses that embody privilege, power, and positioning and that "qualify, measure, appraise and hierarchize" (Foucault, 1984, p. 266). In fact, students enter medicine asking

a question that also worries many patients entering health care: "What is it OK to do around here?" The answer is conveyed implicitly rather than explicitly and the values conveyed within that milieu inscribe themselves to form clinical "souls." "This real, non-corporeal soul is not a substance; it is the element in which are articulated the effects of a certain type of power and the reference of a certain type of knowledge" (Foucault, 1984, p. 177).

Senior medical figures sometimes use clinical discourse to achieve their ends, often driven by their own convictions about the best way to do good for patients; their lives are a crusade, fuelled by dedication to their work. Such was Herbert Green, a man appalled by the disfiguring and distressing surgery done in the attempt to eradicate gynecological cancer. He was convinced that there had to be a way to spare women the evils caused by the collateral damage of the battle against cancer. Unfortunately, there was a disconnect such that his enthusiasm led to outcomes antithetic to the ethos that should sustain caring clinical medicine (Cartwright, 1988):

> Peer review is almost non-existent ... The lack of systematic seeking of consent to inclusion in research or treatment (except for operative procedures) and the inadequate procedures for approval and surveillance of research and treatment pose a serious risk to patient's rights. (212)
>
> Patients have not always been properly informed of the treatment and options available to them. (215)
>
> Relationships have been poor in the past and from time to time have contributed to the failure to put patient's health and welfare first. (216)

But the proper ethos of caring professionalism and "those values, norms and rules that are intrinsic to the practice of medicine ... brought the problem to light and limited the harm to patients" (Paul, 2000, p. 499). Policymakers reacting to events that had attracted intense public interest imposed an "external morality" – a set of societal and quasi-legal regulations that constrain the powerful players. This "external morality" and the effect of the moral crisis on the profession led to a more concerned, extensive, and inclusive response that has subsequently proved transformative to clinical and research practice, to professional regulation, and to medical education.

Partnership, as promulgated by the medical profession in the last decade (BMJ, 1999), is a change that fosters the well-being not only of patients but of the health-care professionals who care for them: "Partnership means that patients and doctors must change, sharing responsibilities as well as information and decision making. It takes two to tango"(BMJ, 1999, p. 719).

The Cartwright Report has helped create a reflective understanding essential in a profession that has been and is, increasingly worthy of the aspirations of some of our finest young people and of the trust of the public. It already had stability and an established, older, assured, set of mores and mentors able to guide those who joined it toward a liveable character and professional integrity but to that was added the wisdom of being able to listen and respond with understanding. The chance to reflect on the lessons emerging from moral crises and the experiences of those caught up in them is often denied. Such anomalies (the Alder Hey scandal,

inadequacies of consent and sensitivity associated with postmortem practice, scientific corruption – often inadvertent – in medical publishing and regulation, and the destruction or undermining of social roles and responsibilities intrinsic to professional practice) repeatedly threaten the internal morality of medicine. The Hippocratics saw the problem that can alienate doctors from patients and our need to respond to it:

> Physicians come to a case in full health of body and mind. They compare the present symptoms of the patient with similar cases they have seen in the past, so that they can say how cures were effected then. But consider the view of the patients. They do not know what they are suffering from, nor why they are suffering from it, nor what will succeed their present symptoms. Nor have they experience of the course of similar cases. (Lloyd, 1978, p. 142)

They also devised their code to try and entrench an internal morality, but when looking back at the Cartwright Report, it is clear that some doctors saw the code as recommending unstinting and sacrificial dedication rather than a genuine openness to the needs of patients and an understanding of the contributions they had to make to their own regimens of care. The women of New Zealand were seen as attacking the profession, but one could, with profit, reflect on *The Medea* by Euripides where a woman finds that certain promises are undermined by one she trusted. Her fury knew no bounds, and, in a similar way, strident advocates for women in New Zealand turned on the medical profession as an enclave of privilege. They spoke for the powerless demanding remediation, a restoration of balance, and a new mode of interaction that was sounder and less naïve. Many lament the "golden weather" of late twentieth century medicine and its harvest of wonderful technologies and remedies for the ills of the body but can forget that these were devised within an atmosphere somewhat like that of *noblesse oblige*. That time is past. The events of the moral crisis that was the Cartwright Report exposed internal morality and made New Zealanders rethink it.

The Sequelae of Cartwright: Bioethics Infrastructure in New Zealand

The post-Cartwright changes have also affected other areas of the New Zealand health-care environment.'

Patients in Research

The various government level initiatives which have waxed and waned over the last few years include the Health Research Council Ethics Committee and its partners including the Genetics committee, the Independent Biotechnology Advisory Committee, the Bioethics Council, National Advisory Committee on Health and Disability Services Ethics, National Ethics Advisory Committee, and the Ethics Advisory Panel of The Environmental Risk management Authority. The trend

recently has been to reduce public attention to ethical issues, knowledge among ethics committees, and the protection of patients. Changes were made in the ethical review of clinical research applications after the Gisborne hearings report in 2004 (McMillan, 2011), and recently, more changes [based on poor or no audit-based evidence (Cranleigh, 2011; HSC, 2011)] have also threatened to compromise the interests of research participants in New Zealand.

The Cranleigh Health Report and the Health Select Committee Report on the system of ethical review of clinical research in New Zealand, together with the government's response, convey an impression that ethical review of research in New Zealand is in a bad state. But there have been no formal audits of the work of the Multi-region Ethics Committee from 2006 to 2011, so it is unclear that any evidence shows that ethics committees have contributed to the loss of income in clinical trials in New Zealand over the last 10 years.

The Cranleigh Report claims that the clinical trial industry in New Zealand currently earns much less than half the NZ$100 M. p.a. it earned 10 years ago, a time span that is helpful in the analysis of the role of ethics committees in the decline. A thorough audit of the multicenter ethical review system (in 2002, its third year of operation) was undertaken by the Health Research Council Ethics Committee when similar accusations were being made (Evans, 2002). It showed that the views fuelling the current ferment concerning the committees are unfounded.

First, it is not true that clinical research is half what it was 10 years ago. In fact, there has been an increase of more than 320 % in the annual applications for ethics review during that time, and health research is alive and well in New Zealand. What has declined is the amount of money earned from abroad in conducting it. The reports suggest that this is related to a lack of timeliness in ethical review but, tucked away in the Cranleigh Report, is the interesting fact that NZ is among most expensive group of 15 % of 50 countries undertaking clinical research. Other developed countries are very much aware of the threat of developing countries in capturing research funding. India, where the cost of conducting a clinical trial per patient is only 10 % of that in many developed countries, has allegedly had a large increase in research income of this sort. In many of these destinations, there is not the same robust system of ethical review that was in place in NZ research but, surely, to reduce the protections to research participants, hard won following the Cartwright Report is detrimental to the maintenance of a fine system of ethical review in the country.

The issue of outsourcing medical research from New Zealand is also raised in the report, and much of the media discussion following its publication concerned New Zealand companies sending their research elsewhere. Fisher & Paykel Healthcare were mentioned as, by a long way, the most successful biotechnology company in the country for whom "clinical trials are a pivotal activity in the process of generating value in New Zealand's biotechnology sector" (Cranleigh, 2011, p. 29). The report claimed that the company is moving research overseas as a response to problems with ethical review but omitted to mention that the company not only expressed satisfaction with the service provided by New Zealand ethics

committees but gratitude for those committees making special efforts to review applications at short notice and at difficult times in the calendar of ethical review (Graydon, 2011, Letter to D Evans, personal communication). The overseas research being commissioned by F&P Healthcare, in fact, has been contracted abroad to develop products specific for countries like France and Germany which represent important markets. This positive feedback sits uncomfortably with the opinions quoted in the report, but complaints by biomedical industry are a worldwide phenomenon putting pressure on the ethical and scientific governance of research (Elliot, 2010).

It is possible that poorer countries, looking to become favored research sites, will be pressured into making ethical compromises to attract health research money, a problem that arose some years ago when the Health Research Council of New Zealand refused approval to a clinical trial being outsourced to the Cook Islands. Any research sponsored from a country should satisfy ethical standards both of that country and the setting in which it is to be performed (as in the Universal Declaration on Bioethics and Human Rights Article 8, UNESCO, 2005) and that such ethical requirements should not be able to be evaded by sponsoring companies in order to "get over" the "red tape" of a country's ethical review system.

The report based dissatisfaction on evidence that was hard to find in that it does not seem that there was widespread dissatisfaction with ethical review; in fact, only two second opinions on ethical decisions were sought during this period and only one resulted in a change, an excellent record by any standard. The evidence never appears in the discussions.

The Cranleigh Report measures ethical efficiency by using "turnaround time" – the time between the receipt and approval of applications. A 2002 audit, however, found that a major cause of extended times resulted from poorly prepared applications in terms of incorrect or incomplete applications, lack of Maori consultation (either by design or by oversight), or lack of adequate distribution to relevant ethics committees. In fact sometimes it took three months from initial receipt to the preparation of an adequate proposal, delays that were all included in "turnaround times" (though they were not the fault of ethics committees). When the times were analyzed, a different picture emerged: 18–21 % of the "turnaround time" was caused by the committee and 79–82 % by researchers (often reminders were sent from the committees). In some cases, it emerged that researchers were unwilling to amend protocols to comply with ethical standards. Thus the "turnaround time" used was a clumsy measure and should have been replaced by an index calculating the time between the receipt of the complete application (including all documentation) and the date of approval *minus* the time taken by researchers to respond to requests to clarify or amend protocols. This is a clear example of the way that interested parties or lobby groups within a government, who are focused on collaboration with the medical research industry, even in a health-care setting with high ethical standards, can manipulate political decision-making. Given that the Cranleigh Health did not have access to any proper audit of ethics committee function, it could not base its conclusions on sound evidence and implies that the ready

acceptance of its findings as authoritative almost certainly reflected a preconceived agenda rather than a genuine desire for improvement of the research review system. The example therefore highlights the potential for unfortunate developments at the interface between ethics and politics.

All parties in this episode emphasized the importance of maintaining robust ethical review, but the subsequent recommendations and policy proposals do not reflect that intent. Similar difficulties were encountered by analysts of proposed reforms to ethical review procedures in the United Kingdom (which mirrors almost exactly some of the proposals in New Zealand).

In the literature detailing complaints from the research community, issues of delay and bureaucracy feature strongly, and the insistence by ethics committees on real safeguards for participant well-being is disproportionately balanced with the value of medical science. "Ethics committees were perceived as getting in the way of valuable research. It created a danger that the UK would not be seen as a viable site for for lucrative international research. What resulted was pressure, particularly from industry to refine the remit and freedom of research ethics committees in the interests of facilitating research" (Cave & Holm, 2002).

Article 5 of the Declaration of Helsinki clearly declares that "In medical research on human subjects, considerations related to the wellbeing of the human subject should take precedence over the interests of science and society." Thus changes, for illusory economic gain, that compromise the independence and thoroughness of ethical review, should be resisted. The curtailments of ethics committee activity and excellence in New Zealand are exactly the kind of development the declaration warns us about.

The ethics system in New Zealand was reorganized in 2004, largely stimulated by researcher pressure: the number of ethics committees were reduced; the review of all multicenter studies were allocated to a new committee; "observational studies" were excluded from full ethics committee review (on the basis that no serious harms were possible in such research). This kind of measure has theoretical appeal but, in the event, proved no more cost effective than the old multicenter review system at great ethical cost in terms of thoroughness and skill creation in research ethics. The lesson therefore has global significance.

For many New Zealand studies, ethical review is carried out a long way (250–500 km) from the site of research resulting in some important losses (that are further intensified by recent changes).

First, the relationship between clinical researchers and ethics committees is weakened as researchers cannot attend meetings at which their applications are being discussed. Thus the gains arising from face to face discussion are lost, together with any sense of collaboration between researchers and ethics committees in a worthwhile activity.

Second, the voice of many research participant communities becomes muted. The population of New Zealand is heterogeneous, and specific community features may give rise to specific issues of which a local committee is more aware (such as

cultural restrictions on certain interventions in women). In this way, New Zealand can be very different from other countries of a similar size (e.g., Denmark with its relatively homogeneous population). The Minister of Health recognized that local assessment is important in ethical review and that this task went beyond the concerns of health-care providers, but, in that some research communities might be situated more than a 1,000 km from the committee assessing their study, further reductions of the number of ethics committees make proper locally informed ethical assessment impossible. The number of ethics committees in New Zealand should not be based on a per capita calculation but on the needs of diverse research populations. Thus a small country with a geographically scattered population like New Zealand may need more committees per capita than a densely populated country like the United Kingdom.

Third, compliance with ethical aspects of protocols is better addressed when research participants are closer to their ethics committees. No country has a good means of policing the compliance of researchers once an ethics committee has signed off the research protocol. New Zealand, largely because of its size, has done this more successfully than most largely through informal means (the committee keeping its ear to the ground and gathering information about local research activities). One committee, for instance, halted a study until compliance was achieved and ethical approval was withdrawn from another study because of the failure of the researcher to adhere strictly to the approved protocol. Geographical distance and lack of local networks undermine the possibility of "scrutiny" of that type for most approved protocols and even more streamlined measures would only worsen that situation.

The quality of any ethical review depends on the range of skill sets of the committees doing it. Under the old multicenter system, every committee in areas where research was to be carried out looked at the proposal so that many more non-lay (i.e., health-care professional) members, from different disciplines, examined the proposals together with a wide range of lay members. If only one set of professionals see the protocol (assuming a full attendance at the relevant ethics committee meeting), review cannot possible be as well informed or "robust." What is more, removing some "observational studies" from full committee review means that professionals alert to subtle (e.g., psychological) dangers may never see the proposals concerned. The "low risk" to participants justifying this decision is, however, often relativized to biomedical assessments only, and cultural and other concerns may highlight risks that many researchers would ignore and that are only likely to be picked up by locally knowledgeable ethics committees making informed judgments. The gap between well-intentioned researchers and research participants was highlighted by the Cartwright Report in relation to the unfortunate experiment, but we seem to be losing sight of that in the rush toward the industry-driven standards that have led to recent scandals in developed countries. What constitutes an unacceptable risk may mean that questions in observational studies may be very distressing when asked by the wrong person and yet may be judged to be low risk. Neither researchers nor selected subcommittees who may not have the

spread of relevant expertise to form a good judgment should be left to decide whether this is so or not in any given case.

The Health and Disability Commissioner

The establishment of the post of the Health and Disability Commissioner (HDC) and the appointment of patient's advocates was a further innovation that resulted from the Cartwright Report to empower patients who had difficulties with or complaints about their health care. Professor Peter Skegg (a leading medicolegal academic) in "A fortunate experiment? New Zealand's experience with a legislated code of patients' rights" (Skegg, 2011) points out that the HDC legislation creates a "middle road" between regulation and tort. It effectively creates patients' rights to respect, fair treatment, dignity and independence, appropriate standards of care, adequate communication about illness, informed choice and consent, support (including culturally appropriate support), a clear understanding of their role in teaching and research, and an open and transparent mechanism for the investigation and resolution of complaints (Skegg, 2011, p. 236). The code applies to both public and private health-care providers and practitioners and to both orthodox and complimentary health-care services.

The HDC allows for discussion and resolution as an alternative to a hearing leading to a censure (or other adverse finding) against a practitioner. Complaints can reach the HDC from a variety of sources: consumers/patients, other professionals, "whistle-blowers," and health care or patient organizations. Skegg concludes "The provision of a legislated Code of Rights has transformed New Zealand's medico-legal environment … [and] warrants its characterisation as a fortunate experiment" (Skegg, 2011, p. 266). We can therefore say that the enactment of legislation giving effect to bioethical principles in New Zealand has been a very positive move for all parties involved in health care.

Major Bioethics Issues and Discussions in New Zealand

Informed Consent and Patient Autonomy

Informed consent has evolved, or perhaps, based on the Hippocratic advice quoted above, gone back to the future. Current medical decision-making allows the patient to participate in and therefore take part ownership of medical treatment. Patient autonomy is a flagship issue for the post-Cartwright reforms and the mutual growth of medical law and health-care ethics in company with one another. Many doctors have been shaken by moving from the *Bolam* (1957) standard (the health-care professional view or a reasonable practitioner test) to a derivative of the *Sidaway* (1985) standard (reasonable practice plus truthful response to patient inquiries). But, in Australasia following Cartwright, a *Rogers and Whitaker* standard (1992), which is sometimes seen as a subjective patient test, has become the ethical norm. This has caused dismay in some reactionary quarters of the profession provoked but has been a welcome shift for many patient groups. In fact, autonomy is sometimes

said to be in full cry in New Zealand medicine to the point of entrenching a new hegemony as dangerous as unbridled medical paternalism, and some would say that moderating balance needs to be restored.

Informed consent should enable the patient to make a reasoned decision in the light of an adequate understanding of the facts about an illness. The information given to the patient, as determined in a recent New Zealand Health and Disability Commissioner (HDC) decision, should also cover the options open to the patient including nonintervention (HDC, 2004). The patient can then evaluate a health-care professional's recommendation (not prescription) and take a proper part in the decision-making. Clinical research and innovative treatment are bound by the same principles so that it is mandatory to disclose the fact that certain interventions are part of a research trial, unproven, or innovative in some way and therefore that they depart from standard clinical practice. Generally, a fairly comprehensive written information sheet about the nature of the research or innovation is required with, where practical, the usual reassurances about withdrawal. Any health-care professional who follows these guidelines should not have any serious worries about the adequacy of her or his practice in the area of informed consent and patient empowerment. But there are difficulties.

First, when the natural history and the odds of intervention are not clearly framed and the patient makes a decision on less than transparent information. Second, where informed consent is misconstrued on the basis of an ethical and legal separation (or even opposition) between the patient and health-care provider and in particular where the criteria of "disclosure" and "voluntariness" are interpreted in ways that negate the *duty of care* of the health professional. Therefore, proper attitude to informed consent is based on recognizing that the patient is on a journey and has lost the way in the badlands of illness and disease. Health-care professionals are the patient's guides in this strange and threatening place and therefore must be trustworthy as the illness journey is traced out. A health-care professional draws on experience to anticipate the patient's fears and uncertainties and should reach across the divide of professional distance (that prevents over-involvement or boundary violations between health professional and patient). The patient needs companions and an idea of what happens in *The land of Clinicum* (Gillett, 2004) and health-care professionals must meet that need. The patient is then part of the team that can bring the illness journey to the best possible conclusion. Thus informed consent should not be medicolegal standard that restricts the health-care provider's role and can be used as a defense but should indicate a duty to provide the relevant information, to ensure that it is understood, and to help the patient to make a good decision. Clinical care is a problem-solving exercise and when this partnership functions properly, informed consent enables good therapy in that intervention is attuned to the real needs of the patient. In New Zealand, as everywhere else, the reality is complex.

A key question within this partnership is the information that should be disclosed to the patient by the professional so that the patient to make an adequately informed decision. The legal "goalposts" in Australasia, as we have noted, have moved as

a result of some key court decisions but the difference between *spontaneous* and *responsive* disclosure is sometimes not reflected in ethical or legal discussions of the practice of consent.

Spontaneous disclosure concerns the information given in spoken, written, or video form. It should tell patients about their problem, its natural history, the aims of treatment, and the risks. The legal test is still *material risk* or *material relevance*, i.e., a risk that would be taken into account by a reasonable person making the decision in question. In effect, it means that serious but low probability risks, e.g., quadriplegia or incontinence, or less serious but more probable risks, such as wound infection or bone-graft pain would all be mentioned. A reasonable rather than an individual patient (with, perhaps, idiosyncratic concerns) makes this an *objective* rather than *subjective* patient standard and allows informative material to be devised and standardized.

Responsive disclosure comprises the information given in response to questions, and here *Sidaway* (1985) is still pivotal; in that the information given should satisfy the patient's needs. In practice, the requirement presupposes the partnership model requiring the health-care professional to enter into and appreciate the patient's perspective, as that unfolds over a normal conversation about the treatment regimen. Spontaneous and responsive disclosure occur within an ongoing and open-ended relationship and when teaching about informed consent in New Zealand, it is common for educators to detail criteria such as "disclosure," "understanding," "competence," and "voluntariness" (Beauchamp & Childress, 2009, pp. 120–141). Although that is useful in teaching informed consent, it can create the impression that informed consent is a series of tasks to be "checked off" by the health-care professional.

Reflective physicians following the partnership model are quickly alert to this problem and may regard the legal and ethical requirements as "out of touch" with "real" clinical practice but that rests on a mistaken view of the law (as something definitively expressed in legal writings) and of ethical norms. Both law and ethics should be informed by an understanding of the health-care partnership, and in New Zealand, the post-Cartwright climate tries to foster that understanding. That can be disconcerting to those who have not learnt skilled communication and sensitivity to the relevant cues from a patient (rather than just medical facts) as part of their training. Some health-care professionals are good at it and others have difficulty, but, in general, the health-care professional must make the relationship work and deal with the problems arising from the fact that one partner necessarily wields more power. The need for an active contribution by the patient must be made clear to both partners even though the power dynamics in the physician-patient relationship may mean that, despite patients believing their consent to be valid, they may not have been sufficiently empowered to make good decisions that are right for them. When the relevant events are examined retrospectively and critically, that may be apparent to the unbiased eye and then in New Zealand, the health-care professional will be held not to have met the required standard of care.

Because physicians generally know much more about the medical facts, patients must trust them to share the information needed to engage with the real clinical issues;

thus, despite a health-care professional thinking that a clinical encounter was adequately informative, it may not have been. This problem can only be overcome when, as a trusted guide in the illness journey, the physician justifies the patient's confidence in helping with the problem-solving that the illness occasions. Patients need accessible information in which they can take an intelligent interest, and they also need to see the difficulties and uncertainties involved in medical diagnosis and treatment. They should feel free to inquire about their tests and the rationale for medical decisions by being "given permission" to cross the patient-professional divide in terms of the clinical discussion. When that happens, the patients find, often to their surprise, that they can understand what is going on, claim genuine (part) ownership of the decision being made, and, as a result, share the burden of decision-making and relieve some of the moral burden on the clinician in any regimen of care.

A clinical interview should also decrease rather than increase the stress on patients.

Drawing the patient into the appreciation of tests and the planning of interventions empowers her not just to consent (in a way that is informed and voluntary) but to be part of the problem-solving therapeutic alliance whereby decisions are made in a collaborative way, uncertainties shared, and clearly understood recommendations followed, even if the outcome or process may not be exactly as initially envisaged (Gillett, 2004).

We should not, however, assume that a good relationship will compensate for neglect of the objective basics of consent, as a recent HDC decision demonstrated (2009). In the case in question, a bariatric surgeon became aware that the risks of surgery were significantly higher than what had been communicated. He arrived in the operating room to find the patient anesthetized and, believing that he could decide because he and the patient had a good relationship, proceeded with the operation. He was held to have breached the standards for informed consent in not ensuring that the patient had understood the real risks of the procedure prior to making the decision for surgery. Despite the surgeon's belief that he acted in the best interests of his patient, the objective standard was deemed not to be able to be set aside on the basis of an assumption about a doctor-patient relationship.

The decision in the New Zealand bariatric case revealed ethical and legal limits to a relationship-based approach and means that the patient should become an educated and intelligent co-traveller on the medical journey. That is reflected in our teaching on this subject. Even if an experienced clinician believes that only harm and neither benefit nor cure will result from using the latest medical technology, many cases are not clear-cut, and there are contested margins of information disclosure in relation to these. In every case, our skills and the relevant uncertainties must be communicated so that the patient has a realistic view of the issues. The patient should not be treated like an outsider offered a tiny peep into a complex situation interpreted in terms of current medical assumptions but should rather be treated as part of the team trying to solve a health problem in the face of uncertainty.

"Consent" can be a fairly shallow gloss on a forced choice made against a background of facts largely unknown to the patient, on "unfamiliar turf" according to a timescale fixed by somebody else (Gillett, 2004). Autonomy ought

to be part of a free, responsive, and rational cooperation and enables a patient to contribute to a management plan leading to an outcome he or she can accept as worthwhile, rather than a kind of pseudo-autonomy.

The ethico-legal evolution of informed consent has empowered patients and forced health-care professionals to relinquish a degree of control, even if gracious and kind, of the clinical relationship. That makes clinical life a much more cooperative and ultimately satisfying, adventure albeit with fearful risks. As such, it is healthier, not only for those who are cared for but also for those who care.

Future Challenges: Education and the Climate of Health Care

Bioethics Education

Prior to the Cartwright Report, individual academics and concerned professionals were interested in the issues raised by medicine and its technological advances in such areas as the determination of death, embryo research, and the patient as a person, but the Cartwright Report suggested the creation of explicit teaching and research programs in bioethics. That suggestion was taken up especially by the Otago University Medical School which introduced ethics components throughout the undergraduate and clinical medical curricula. These elements focused on the ethical aspects of decisions about treatment including informed consent, considerations of benefit, and harm from the patient's perspective, justice and resource allocation decisions, and the dignity of the patient. The initiative has continued and been strengthened with the expansion of the Otago Bioethics Centre and the postgraduate courses it offers for professionals and others. The academic staff of the Bioethics Centre produces a wealth of teaching material for pharmacy, dentistry, and physiotherapy courses all of which cover basic ethical issues like consent, confidentiality, the assessment of harm and benefit, research and patient participation in research, as well as legal and professional aspects of clinical practice. A growing set of Medical Humanities lectures on topics such as "consciousness, value, and the brain," and the history and philosophy of medical science are also part of the curriculum. Sessions on alternative medicine, the placebo response, and the political context of contemporary medicine jostle for space with related areas like communication skills, holistic clinical care, the biomedical paradigm, and the bio-psycho-social model of medicine. Some students find these sessions quite challenging as they are not used to the types of thinking involved, and it is hard to evaluate this educational input as the changes in the curriculum are ongoing.

A steady stream of students pursuing dedicated bioethics research and higher degrees in biomedical ethics is further evidence of a positive influence and certain practices, such as the unthinking application of intensive end-of-life interventions in service of a misconceived sanctity of life imperative have been brought under increasing ethical and clinical scrutiny recently. The climate of ethical reflection in New Zealand medicine has definitely been enriched as is evident from the topics

covered in academic meetings, continuing professional education, and health-care conferences. The Otago Bioethics Centre has played a key role in these developments.

A Bioethics Research Centre

The Otago Bioethics Centre (established in 1990) has a comprehensive program in teaching, professional education, and research. It has nine academic and two administrative staff and a growing body of graduate students making it a desirable setting for international academics wanting to work in a wide range of bioethical inquiry. As a center, it developed the *New Zealand Bioethics Report* (and then *The New Zealand Bioethics Journal*) which has become an international publication (the *Journal of Bioethical Inquiry*) that includes and encourages bioethics scholarship that arises from both Anglo American Analytic and Continental Philosophy and a range of disciplines within the social sciences and humanities. The Bioethics Centre embraces a similar range of topics through PhD and Masters programs covering standard bioethical issues like abortion, euthanasia, informed consent, and genetics and more specialized areas such as the philosophy of psychiatry, Neuroethics, and post-modern approaches to bioethics.

Some of its alumni have become distinguished contributors to the field, Tom Douglas, John McMillan, and Josie Johnston, to name but three. It has particular research strengths not only in Neuroethics and the philosophy of Psychiatry but also in the philosophy of medical science, end-of-life ethics, ethics in sports medicine informed consent, and the doctor-patient relationship.

Economic Versus Health Benefits

The Cranleigh Report, produced by a group of analysts from a merchant bank, reflects economic- and business-oriented attitudes rather than developed ethical thinking and reflects the mind-set of those who commissioned it. It is allied to a refusal to fund District Health Boards (DHBs) to undertake clinical research because that may distract them from the improvement, promotion, and protection of the health of people and communities; the reduction of health disparities; and the promotion of care and support for people with disabilities. Health-care research does, however, play a role in achieving these goals particularly when it is alert to clinical epidemiological concerns rather than the self-promotion of interested parties (whether political, professional, or commercial) and is aware of the conflicts that arise from externally commissioned and funded research that is not necessarily guided by well-informed ethical opinion and where ethical scrutiny has been "streamlined."

Evidence from clinical trials is a fundamental driver of innovation, patient safety, and improved care. In general, it is at least as safe and beneficial for patients to receive care in a clinical trial as it is outside a clinical trial, because care in such trials is more systematically planned, delivered, monitored, and followed up. Clinical trials can

bring treatments to the clinic before they would otherwise be introduced. Additionally, health-care organizations that are active in clinical research generally practice excellent patient care and have high retention of key clinical staff (NEAC, 2005).

Despite the possible link between clinical trials and patient welfare such that patients in clinical trials may receive better care (even when in the non-treatment group) than those receiving standard clinical care, ethics committees have the responsibility to ensure that standards of equipoise, for instance, are properly met and patients in trials are, in fact, adequately protected. While it is correct that evidence from clinical trials is a fundamental driver of innovation, patient safety, and improved care, those trials must not compromise care to research participants in doing so, for instance, by using a washout phase of significant psychotropic drugs with the risk of a deterioration in a serious mental disorder (Healey & Aldred, 2005). Patients *may* receive better care in clinical trials than elsewhere, but clinical trials test research hypotheses, and there have been instances where the research aim has damaged patients through unforeseen risks (Graham et al., 2006). All health-care research involves potential additional risks above and beyond standard care, and this can only be kept to a minimum when the safety of the research patient is ensured by adequate ethical review. The additional care in clinical trials may be beneficial but only if protections from unknown contingencies, not present outside the context of the clinical trial, are carefully built in.

Current changes to the ethical review of research in New Zealand are based on a poorly researched assessment of Ethics Committee function. The real reasons for some of the problems with review are not known but may have included poor ethical education of researchers and insufficient training of ethical committee members, activity which has been systematically squeezed out of health-care budgets. Adequate resources exist in New Zealand to remedy the situation, but no initiatives are in place to preserve New Zealand's international reputation for effective and well-informed ethical governance of clinical research. The report of the Cartwright Inquiry recommended a comprehensive system of research review involving the Health Research Council Ethics Committee and Regional Health Ethics Committees sufficient in number for a small and scattered population. These committees were resourced (never generously); they networked effectively and created a milieu where they educated and trained themselves for their work. In addition, a National Bioethics Council was created to safeguard ethical, cultural, and spiritual values in health-care and related areas (Good practice, 2013). Sadly, this set of measures has been extensively reduced for economic reasons resulting in a trade-off between the protection of New Zealand patient research participants and the cost and convenience of the ethical review or research. That is lamentable in a nation that has always prided itself on valuing what is truly valuable for its citizens.

Conclusion

Bioethics in New Zealand has a major public scandal – the Cartwright Report – as its effective defining moment and has developed in the basis of that scandal and the

issues that came to light. The scandal concerned treatment, research, and teaching in a major academic hospital, and it led to a reform of the attitude of the profession to clinical and research ethics in particular and bioethics in general. The scandal left a precious legacy in terms of the importance of patients, their stories, their integrity, and their value in health care and health-care research. Some believe that legacy to be under threat under the drivers of current health-care initiatives but it is hoped that the tangible structures and initiatives produced since the Cartwright Report stand us in good stead to resist those tendencies and political agenda that promote them.

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Norway

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Jan Helge Solbakk

Introduction

The history of bioethics in Norway is a narrative about the formative role of physicians in establishing bioethics as an academic field. At the same time, it represents an account of how bioethics slowly grew into an interdisciplinary field attracting individuals from other branches of academia such as engineering, law, philosophy, theology, nursing science, and social sciences. A third characteristic of this history is the paramount role played by the institutionalization of research ethics in the country, something which makes it reasonable to raise the question

J.H. Solbakk
Centre for Medical Ethics, Institute of Health and Society, Faculty of Medicine, University of Oslo, Oslo, Norway
e-mail: j.h.solbakk@medisin.uio.no

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whether Norway has reached a level of *ethicization* that may not only generate better research conduct and transparency but also lead to adverse effects of a kind that may hamper a genuine promotion of ethical reflection and bioethical discourse. Fourth and last but not the least, it is a narrative about lost opportunities and about recent regulations and legislations pertaining to bioethics moving in a direction not in compliance with international human rights law and commitments.

Bioethics Development

When and How Has Bioethics Started?

The story of bioethics in Norway may be dated back to 1935, when Ragnar Vogt, a professor of psychiatry at the University in Oslo, published the book, *Etiske problemer* (Ethical problems). His focus was the ethics of the medical profession and the need for reassessing it in the light of scientific, technological, and social changes. He was concerned about the academic neglect of ethics among his philosophical colleagues, and he pointed to the need for implementing systematic ethics teaching at the university, as only students in theology received some sort of moral guidance and training. In 1952, another psychiatrist, Trygve Braatøy, published the book, *Pasienten og lægen* (The patient and the physician), emphasizing the need for protecting the art part of medicine against the dehumanizing implications of specialization. From the 1950s, ethics became a part of the curriculum in social medicine at the Faculty of Medicine in Oslo. In his textbook on social medicine from 1963, *Legeetikk. Lærebok i sosialmedisin* (Physician ethics. Textbook in social medicine), Professor Axel Strøm included a chapter on ethics. In 1976, he published a new book, entitled *Legen, pasienten og samfunnet: problemer i legeetikk* (The physician, the patient, and the society: problems in physician ethics), a book which also reflected his experience as the first chair of the Norwegian Medical Association's Council of Physician Ethics. Also, research ethics had an early academic blooming in Norway, as its story may be dated back to 1966, when a young Norwegian physician, Erik Enger, was awarded his Ph.D. in medicine on a dissertation dealing with medical, ethical, and legal aspects of randomized clinical trials (Enger, 1966). The empirical part of his dissertation consisted of two huge randomized clinical trials, one dealing with patients having suffered a brain stroke and a second study dealing with heart infarction patients. The studies had been performed in the late 1950s and early 1960s, that is, before the first *Declaration of Helsinki* had been adopted in 1964. In contrast to the *Nuremberg Code*, the *Declaration of Helsinki* did not only deal with medical experiments on healthy subjects but also contained ethical guidelines for clinical research involving *sick* people. The patients participating in the studies had been informed about the purpose and scope of the studies, but no information had been given to them about the randomization procedures or about the use of placebo nor had formal consent from each patient been procured. The Helsinki guidelines challenged the young physician to include in his dissertation an ethical analysis of

this type of research design. Dr. Enger's doctoral dissertation represents one of the very first academic treatises in modern medical ethics – in Europe as well as worldwide. His dissertation was published the year Henry K. Beecher's famous article "Ethics and Clinical Research" sent shock waves through the American medical research establishment (Beecher 1966). In the two decades following his Ph.D. dissertation, Enger played a key role in the further development of medical ethics and research ethics in Norway. Besides forming a part of the small Nordic committee preparing the important 1975 revision of the Declaration of Helsinki requiring the assessment of all medical research protocols by an independent research ethics committee, as chair of the Council of Physician Ethics of the Norwegian Medical Association he was also a central figure behind the process of establishing research ethics committees. Although it took almost 10 years from the original proposal in 1975 of establishing such committees, the process witnessed that slowly medical research ethics had become an area involving many more stakeholders than physicians. For this reason, when the committees finally were established in 1984, they were given a broad, interdisciplinary composition, including ethicists, lawyers, and lay people and, notably, with medical and healthcare researchers in a minority position.

Who Have Been the Major Actors/Forces?

The *medical* part of the story of bioethics in Norway illustrates two features which could be said to be "pathognomonic" of the emergence of academic medical ethics and bioethics in Norway. First, it illustrates the role of physicians as academic initiators of the field. Nurses, theologians, philosophers, and lawyers entered the academic field of bioethics later. Other physicians who played a seminal role in making medical ethics an academic discipline in Norway were Professor Jarle Ofstad, the first chair of the National Committee for Medical and Health Related Research and chair of the Research Council of Norway's (RCN) program of medical ethics (for more about this, see Bioethics Committees and Expert Bodies/ Centres), Professor Astrid Nøklebye Heiberg, Professor Christian Fredrik Borchgrevink, and Professor Petter Andreas Steen. To this adds, Reidar Krumradt Lie, a M.D. also trained as a philosopher and with a Ph.D. in philosophy of medicine, who in 1992 became the first professor of medical ethics in Norway and the first Head of Center for Medical Ethics (CME) (for more about CME, see Expert Bodies/ Centres). Second, it draws attention to medical research as the original object of bioethical concern, besides physician ethics and codes of good medical conduct. The medical branch of bioethics would, however, not have become a visible academic discipline in Norway in the late 1980s without the enormous amount of preparatory work and diplomatic negotiations with medical academia undertaken by Knut Erik Tranøy, a professor of moral philosophy and founding father of science ethics. Already in the late 1960s, Tranøy started to give classes in medical ethics and philosophy of medicine for dentistry students and medical students at the University of

Bergen. Before retiring as a professor of moral philosophy at the University Oslo, he also served for 3 years as senior researcher at the Faculty of Medicine with the mandate of developing and implementing a teaching program in medical ethics for the faculty's students in medicine. Another key figure in the academic institutionalization of medical ethics was a professor in systematic theology, Inge Lønning, who served as rector at the University of Oslo in the most formative years of medical ethics in Norway, that is, the period of 1989–1995.

What Have Been the Major Concerns Over Time?

The main concerns underlying and driving forces behind the institutionalization of medical ethics and bioethics in Norway have been the perceived need for establishing systematic teaching in medical ethics for medical students, something which already in the 1930s came to expression as a request for physician ethics and training in codes of good medical conduct, coupled with the 1975 revision of the Declaration of Helsinki and the concomitant establishment of independent research ethics committees.

What Resources Have Been Developed (e.g., Books, Programs, Media, Networks, Societies)?

The first systematic textbook in medical ethics that came into use at the time all four medical schools in Norway had implemented a formal teaching program in medical ethics (early 1990s) was Knut Erik Tranøy's, *Medisinsk etikk i vår tid* (Medical Ethics in our time, 1991). Thirteen years prior to this event, another important publication from his hand saw the day, *Fra filosofi til fysiologi: filosofi, naturvitenskap og biomedisinsk etikk* (*From philosophy to physiology*: philosophy, natural sciences, and biomedical ethics, 1978), a book containing seminal historical texts in medical ethics and philosophy of medicine with introductions written by Tranøy. This publication proved to have profound influence on the way bioethics was conceived and implemented at the University of Bergen, first at the Faculty of Medicine and later at the Centre for the Study of the Sciences and the Humanities (SVT), as the interrelation between *medical epistemology* (or more broadly speaking – *philosophy of medicine*) and medical ethics here became a focal point of reference. At the University of Oslo, on the other hand, the philosophy of medicine approach to medical ethics adopted in Bergen was not implemented. Instead, Tranøy's second seminal book from 1991 became the master plan according to which the teaching program at the Faculty of Medicine in Oslo was designed. The approach in this book was strongly influenced by Beauchamp and Childress principle-based approach to biomedical ethics. Accordingly, medical ethics became to be conceived of as a form of applied ethics within the domain of medicine and with an ethics curriculum organized around teaching sessions with participation of clinicians in addition to an ethicist. In 1996, the Faculty of Medicine introduced a problem-based teaching curriculum.

One implication of this reform was that the number of ordinary amphitheater lectures was reduced to a minimum, in favor of the system with PBL-groups. Among many teachers in medicine, this reform was denounced as representing a fundamental threat to possibilities of providing the students with sufficient theoretical medical knowledge. This is not a view shared by the ethics teaching staff at the Faculty of Medicine in Oslo, as the system with PBL-groups may be viewed as representing a return to – and imitation of – the intimate format and moral space originally depicted by Plato in his dialogues. Consequently, the ethics teacher's primarily role is not perceived as a provider of theoretical and practical knowledge but as a discussion partner and helpful knower as well as an example of lived morality to be observed, be it good or bad. An additional reason for this preference is that within the moral space provided by a PBL-group medical students are not only made aware of but hopefully also become used to a shared form of "solving" or "resolving" ethical problems. This seems to be particularly suitable in view of the interdisciplinary nature and relational structure of today's medical practice. In a textbook in medical ethics designed to comply with the PBL 1996 reform at the Faculty of Medicine in Oslo, this issue is explicitly addressed (Ruyter, Førde, & Solbakk, 2007). Seven different theoretical positions in medical ethics are presented and discussed – a doctor's ethics approach, principle-based ethics, utility-based ethics, duty ethics, casuistry, virtue ethics, and last, but not least, a common morality approach to medical ethics. The presentation is structured as follows: After a short description of the position in question comes the confrontation with an authentic case, aimed at testing each position's resolution capacity. As the same test case is used in relation to all positions presented, the students are given the possibility of assessing the relative as well as the "absolute" strengths and weaknesses of each position. In the presentation, the authors try to demonstrate how each position can be used to defend diametrically opposed solutions. The intention behind this is partly to show that in moral decision-making ethical theories can be used to reach theoretically consistent and coherent solutions. More important, however, is the intention to demonstrate that an ethical theory is only an instrument and that depending on who is using the instrument – and the way it is used – the result might also differ. During the last 20 years also, a whole range of other bioethics textbooks have been published (Fjelland and Gjengedal, 1990; Nortvedt and Vetlesen, 1996; Nortvedt and Grimen, 2004; Brinchmann, 2005; Slettebø and Nortvedt, 2006; Slettebø, 2009; and Nortvedt, 2012).

Current Bioethics Infrastructure

Teaching of Bioethics at University and Other Levels

Today, medical ethics is an integral part of the medical curricula (undergraduate and postgraduate level) at all four medical schools. In addition, other health professions and academic disciplines have established systematic training of undergraduate and Ph.D. students in the ethics of professions and in research ethics and science ethics.

Bioethics Committees

The first committee in Norway was set up by the Norwegian Medical Research Council (MRC) in 1978. Since the establishment of the system of *Regional Ethics Review Committees* in 1984, the MRC's Committee acted as a coordinating and advisory body in medical research ethics. A working committee consisting of one member from each of the RECs and headed by the chair of the MRC's Ethics Committee used to meet three to four times a year. In June 1989, the Norwegian Parliament (Stortinget) endorsed the recommendation of a 1988 White Paper from the Ministry of Education and Research for the establishment of national research ethics committees within the following three subject areas of research and development:

- Medicine in a broad sense ("health and life sciences")
- The social and behavioral sciences and the humanities, including law and theology
- Natural science/technology including those parts of biotechnology and genetic technology that do not fall under medicine

Great importance was placed on securing representation in the national committees from the fields of ethics and law, as well as on the adequate membership of lay persons. The members of the three national committees of research ethics are appointed by the Ministry of Education and Research on recommendations from the National Research Council (in 1993 the five existing discipline-specific research councils were merged into one council and named the Research Council of Norway, RCN). The secretariats of the national committees are administered by the Norwegian Research Council. It should be noted that the directors of the secretariats are required to have background training in ethics and in the first formative years of the committees they were also given the right to dedicate half of their time do their own research in ethics in addition to their administrative responsibilities. Lately, this right has been deleted from their job descriptions. For the subject area of medicine, the government in 1990 gave the Norwegian MRC's Committee for Medical Research Ethics the status of the *National Committee for Medical and Health Research Ethics*. The committee has 14 members with different professional backgrounds, including ethics and law. Besides, there are lay representatives in the committee. Traditionally, the committee has been chaired by a physician, but it has also been chaired by an individual with background training in theology. The members of the Committee are appointed for terms of 4 years, and no member may sit on the Committee for more than two terms. The Committee meets 5–6 times a year. According to the mandate laid down by the Ministry of Education and Research, the main assignments of the National Committee for Medical and Health Research Ethics are the following:

- To keep itself continually informed of current and potential questions of research ethics in the field of medicine
- To act as a coordinating and advisory body for the RECs
- To inform researchers, the administration, and the public of current and potential questions of research ethics in the field of medicine

- To submit reports on matters of principle relating to medical research ethics and comment on specific matters of special significance relating to research ethics
- To report on its activities at an open meeting at least once a year and in whatever ways it finds suitable promote informed discussion in society of ethical questions relating to medical science and knowledge
- To keep other national and international research ethics committees informed of its activities and in cooperation with them seek to establish a platform of principles of research ethics which extends beyond the boundaries of the respective research subjects

Similar charges are given in the mandates of the two national research ethics committees.

Since 2008, the National Committee for Medical and Health Research Ethics has also functioned as an appeal body for the seven regional committees for medical research ethics. These committees evaluate all individual medical research projects, while the National Committee for Medical and Health Research Ethics gives its opinion on issues that are more a matter of principle. Biannual meetings attended by the chairs and secretaries of all the councils deal with issues on which the committees need to collaborate. Furthermore, all members of the National Committee and the regional committees attend a two-day joint meeting in the autumn, for professional replenishment and discussion (http://www.etikkom.no/en/In-English/Committee-for-Medical-and-Health-Research/). During the parliamentary debate discussing the proposal of establishing the system of three national research ethics committees, a group of MPs from the opposition parties proposed in addition the establishment of a *The Norwegian Biotechnology Advisory Board*. This proposal was also endorsed by the Parliament. The Norwegian Biotechnology Advisory Board is an independent body consisting of 21 members appointed by the Norwegian government. Each member has a relevant background and/or education to competently discuss questions regarding modern biotechnology. Eight members of the Board represent different public organizations. The main task of the Norwegian Biotechnology Advisory Board is to evaluate the social and ethical consequences of modern biotechnology and to discuss usage which promotes sustainable development. The Board has approximately ten regular board meetings and organizes two to three public meetings annually. The Board publishes the free, quarterly journal "Genialt" in Norwegian. In addition, it makes information pamphlets on various topics regarding modern biotechnology (http://www.bion.no/index_eng.shtml).

During the last 13 years, there has been a further growth in the number of national bodies dealing with the ethics of scientific research and development, through the establishment of four additional institutions: the *Norwegian Board of Technology* (1999), the *Norwegian Advisory Board on Ethical Aspects of Patenting* (2004), the *National Commission for the Investigation of Scientific Misconduct* (2007), and the *National Committee for Research Ethics on Human Remains* (2008). The *Norwegian Board of Technology* works in the interface of science and technology. It aims to assess impacts and options of technology in all areas of society, to stimulate public debate on technology, and to support the political decision-making process and shaping of technological change. The Board

furthermore monitors international technological trends and methods for technology assessment. The results of its activities are communicated to the Parliament, governmental bodies, and the public at large. The Norwegian Board of Technology has 14 members appointed by the government. The members have a broad insight in different areas of technology, innovation, and societal issues. The secretariat is situated close to the parliament building and government offices in Oslo, colocated with the National Committees for Research Ethics. The work is organized in projects, and the Board sets its own agenda. The secretariat manages the projects and reports to the Board. The Norwegian Research Council acts as the supervising authority (http://www.teknologiradet.no/FullStory.aspx?m=5). The *Norwegian Advisory Board on Ethical Aspects of Patenting* was established by parliamentary decree and appointed in Royal Council ("Statsråd") in 2004, basically as a reaction to the need to adapt to the European Patent Directive. The Board is to be advisory for the Norwegian Industrial Property Office. Till date, the advice of the Board has only once been required. This was the case of a patent on a genetically modified salmon in which growth was enhanced. After in-depth discussions within the Board, it was concluded to advise negatively because of presumed sufferings of the animal and negative environmental effects. The Norwegian Industrial Property Office did not follow this advice, even though it first modified some of the patent claims on the basis of animal welfare issues. However, when the company claimed that no such negative effects where observed, the patent was eventually granted. In view of the paucity of cases sent to the Board, the Board wrote a report on the ethics of patenting (2008), where it suggested that the mandate of the Board be changed so that it could take a more proactive role and include a closer collaboration with the Norwegian Industrial Property Office, as well as a role in public debate. In light of this report, efforts are currently underway to improve the modus operandi of the Board (http://www.etikkom.no/en/In-English/Patent-Board/). *The National Commission for the Investigation of Research Misconduct* is responsible for assessing allegations of serious research misconduct and issuing a statement on whether any scientific misconduct has occurred or not. Ironically speaking, the establishment of this Commission was greatly facilitated by the publication of two spectacular research scandals in 2006 involving internationally acclaimed researchers. The first scandal involved two of the leading stem cell researchers worldwide, W.S. Hwang from *Seoul National University* in South Korea and G.P. Schatten from the University of Pittsburgh in the USA. The mastermind behind the second scandal was Jon Sudbø, a young Norwegian physician, dentist, and cancer researcher working at the most prestigious university hospital in Norway, the Rikshospitalet-Radiumhospitalet in Oslo. In both cases, the investigating committees found strong indications of deliberate fabrication and falsification of data on the part of the main researchers, Dr. Hwang and Dr. Sudbø. The report on J. Sudbø and coauthors was published on June 30, 2006 (report from the Investigation Commission appointed by Rikshospitalet-Radiumhospitalet MC and the University of Oslo). The committee's verdict was that 13 out of 48 papers published in the period of 1993–2005 had to be retracted, including three of six articles in his Ph.D. dissertation. Consequently, in December 2006, Sudbø was

stripped of his Ph.D. and his professional license in medicine. He was, however, allowed to continue to work as a dentist. Sudbø's coauthors, on the other hand, were acquitted of the charge of having participated in the fabrication and falsification of data, but they were criticized for not having paid sufficient attention to the rules of coauthorship. The National Commission for the Investigation of Scientific Misconduct covers all research fields and deals with research carried out by Norwegian research institutions private or public. It can also investigate cases abroad, if the research has been carried out by researchers employed by a Norwegian institution or if a substantial part of the funding stems from Norway. The commission is composed of seven members and four substitutes who all are nominated for a period of 4 years (renewable not more than once). The members cover different fields of research. The commission is independent but the members are appointed by the Ministry of Education and Research following the proposition of the Norwegian Research Council. The commission is expected to give advice to individuals and/or research institutes and to be a kind of knowledge base for questions and experience concerning research misconduct in Norway and other countries. The commission is cooperating with similar organizations abroad (http://www.etikkom.no/en/In-English/Scientific-Misconduct/). *The National Committee for Research Ethics on Human Remains* was established in 2008 by the Norwegian Ministry of Education and Research. The Committee consists of ten members: two lay representatives and members with different professional backgrounds. The committee evaluates the ethical aspects of research where the source material consists of human remains which are in public museums and collections, or which will be found in future archeological and other surveys (i.e., complete skeletons, parts of skeletons, and other human remains). These are often human bones found in archeological excavations, but may also include human remains which have never been in the ground, for example, parts of bodies used in artifacts, bodies contained in coffins, and sarcophagi (http://www.etikkom.no/en/In-English/Human-Remains/).

Expert Bodies/Centers

University of Oslo

Center for Medical Ethics (CME). CME is a national, interdisciplinary unit for research, teaching, and information in medical ethics at the Institute of Health and Society, Faculty of Medicine, University of Oslo. It was established in 1989 as the first of its kind in Norway and was during its first 5 years organized as a research program outside the university structure. During this period, the Center was governed by its own Board of Directors, which included representatives from the University of Oslo, the Norwegian Nursing Association, the Norwegian Medical Association, the (then named) Medical Research Council, and one representative from the Pharmaceutical Industry. The composition of the Center's first Board reflects its initial funding. Since 1995, CME has been located within the organizational structure of the Faculty of Medicine and with basic funding from the

University of Oslo. In 1990, CME was granted a five-year research program in medical ethics from the Medical Research Council of Norway (approximately 16 million NOK for the period of 1990–1995). Since the merging of the different research councils in the 1990s, MRC has been a part of the Research Council of Norway (RCN) and forms at present a part of its Division of Society and Health. In the first years of recruiting Ph.D. and postdoctoral research fellows, priority was given to applications within three areas:

1. Questions related to the normative basis of medicine
2. Research ethics, including normative as well as historical studies
3. Health policy, planning, and resource allocation

Since 1995, priority has also been given to *clinical medical ethics*, a field of research that has been undergoing rapid growth at CME during the last years. At present, the Center has five permanent full-time academic positions and two adjunct chairs. The interdisciplinary nature of CME is reflected in the professional background of permanent academic staff, covering fields such as history of ideas, medicine, nursing science, philosophy, theology, and engineering. At present, CME has two postdoctoral researchers and eight Ph.D. fellows. Till date, 17 doctoral fellows have defended their Ph.D.s. Since 2002, CME has been responsible for the coordination of the system of clinical ethics committees (CEC) in Norway. An important part of CME's responsibility as a coordinator is to evaluate the activity of CECs and conduct research on different ethical challenges pertaining to CECs. The activity of CEC is of great value for the prosperity of CME, in particular, the input it gives to the education of medical students, doctors, and other healthcare personnel in Norway. CME receives an annual amount of 2.25 million NOK from the Ministry of Health and Care Services to coordinate the committees, conduct research, and facilitate competency building for committee members. In 2008, CME was also given a national role in the strengthening of medical ethics at all levels in Norwegian community health care. CME has been granted an annual amount of two million NOK for this capacity-building activity and is now in the process of building up a research group in this field as well. Since the inception of the first research project in 1990, the academic staff at CME has given priority to international research collaboration, something which throughout the years have resulted in partnership in 7 EU-funded research projects, coordination of 3 RCN-funded projects with international collaboration, and partnership in two other international research projects funded by the RCN. In addition, CME is coordinating a research and capacity-building project with partners at University of Dar es Salaam, Tanzania. Through the work of the clinical ethics unit at the Center, CME has developed international cooperation through a European network for clinical ethics (ECEN) and also cooperation with researchers in the USA. In addition, CME has research collaboration with colleagues in Argentina, Brazil, and Colombia. At the national level, CME has a long-lasting research collaboration with colleagues at the *Centre for the Study of the Sciences and the Humanities* at the University of Bergen and with colleagues at the *Programme of Applied Ethics* at the Norwegian University of Science and Technology in Trondheim (http://www.med.uio.no/helsam/english/).

The ethics program. In 1991, the Norwegian Humanities Research Council (now an integral part of the Research Council of Norway) started a ten-year ethics program. The principal aim of this program, led by Dagfinn Føllesdal, Clarence Irving Lewis professor of philosophy at Stanford University and professor of philosophy at the University of Oslo, was to support foundational ethics research and area-specific ethics research within all academic disciplines. The University of Oslo was offered to host the program, something which gave this institution a unique opportunity to boost its development of ethics research. At its inception, there were relatively few individuals in Norway with scholarly competence in ethics, and with the exception of medical ethics (which since 1990 had had its own research program, see CME, above) and the traditional shareholders of ethics research, that is, the faculties of theology and the departments of philosophy, there were few sustainable ethics research ambiences in Norway. The recruitment of candidates was based on three pillars. First, a strong formative background within one's own academic field (preferably at Ph.D. level). Second, one year of pre-qualification courses in ethics, taught by the foremost experts in the field (Sam Scheffler, Robert Nozick, Martha Nussbaum, Alan Gibbard, and many others). These courses should provide potential Ph.D. candidates with sufficient knowledge about ethical theories and methods to carry out foundational and/or disciplinary ethics research within own academic disciplines. And third, interdisciplinary research collaboration. Only candidates with proven ability during the qualification period in addressing ethical issues in a competent way (through the writing of mandatory essays) were then offered the possibility of opting for a 3 years Ph.D. research scholarship. For these reasons, "double competency" also became a defining hallmark of the program. About 40 participants received their Ph.D. in ethics through the program. In 2002, when the program came to the end of its ten-year period, the activities were continued along the same lines by ethics centers at the various Norwegian universities. The University of Oslo started its Ethics Programme as one of the University of Oslo's three prioritized research areas in the program period (2002–2011). Its overriding aim was to promote and support ethics research and normative reflection at the University of Oslo. The Ethics Programme continued the interdisciplinary research school and provided stimulation funds for ethics research and teaching at the University. In addition, the Program coordinated a series of national research courses through the Norwegian Ethics Network, ran the site www.etikk.no, and hosted the fortnightly Ethics Seminar at the University of Oslo and the annual Oslo Lecture in Moral Philosophy. Throughout its last 10 years of existence, 36 Ph.D. research fellows and 17 postdoctoral research fellows have been part of the Ethics Programme. When the University of Oslo in 2002 decided to continue the successful Ethics Programme of the Research Council of Norway, and notably with substantial funding from the Council to coordinate a national network for ethics research training, an interdisciplinary research group at the university suggested the establishment of a permanent Center for Ethics Research. Since then, similar proposals from other relevant stakeholders have been forwarded to the university leadership, but to no avail. And in spite of the fact that the University of Oslo throughout the period of

1990–2011 had become the "owner" of an ethics research ambience at the international forefront, the University Board in 2011 decided to close down its program. "Audacity" is definitely not the wording best covering this situation; "loss of a great opportunity," on the other hand, is an expression easily coming to mind.

Centre for the Study of Mind in Nature (CSMN). Another research ambience at the UiO carrying out research with fruitful and interesting implications for bioethics is CSMN, a Norwegian Center of Excellence, funded by the Norwegian Research Council and the University of Oslo for the period 2007–2017. The goal of the Center, as stated on its website: "is to understand the *characteristic features of human minds and their place in nature*. On the one hand, human beings are natural, biological beings, subject to laws of nature. On the other hand, they are capable of acting rationally, morally and of using language to communicate and think. In its attempt to understand the mind and its place in nature, CSMN is focusing on central mental capacities as expressed in (1) rational, (2) linguistic and (3) moral actions. Rational, linguistic and moral agency are all forms of *rule-governed activities*. Rules and norms differ from natural laws in that they can be violated, but nevertheless give rise to obligations. Human beings naturally care deeply about these prescriptive or *normative* features of human agency. But as science reveals more and more about our physical nature it becomes pressing to show how they can be squared with a view of human beings inspired by the natural sciences. Understanding human normativity is therefore crucial to understanding the human mind as a *natural phenomenon*" (http://www.csmn.uio.no/).

University of Bergen

The Centre for the Study of the Sciences and the Humanities (SVT) was established in 1987 as a permanent interfaculty institution at the University of Bergen, Norway. The field of study, *Theory of Science*, was defined as research in the fields of philosophy, history, and social sciences focusing on the roles these different sciences play in society; in addition, it was defined as research into the theoretical and ethical aspects and uses of such scientific research. Bioethics, both in its narrow and broad sense, has throughout the years been important fields of teaching, public engagement, and research at the Center. The bioethics practiced at SVT has been influenced by its particular theory of science approach, in which the normative and the epistemological tasks are not severed from each other but seen as influencing each other. Thus, while bioethics sometimes (rightly) has been criticized for taking epistemological and political assumptions merely as givens, the theory of science approach has, to an important degree, been critical. In recent years, SVT has played an active and critical role in the national and international ethics debates on biobanking, biotechnology, clinical care, climate change and environmental ethics, global health, GMOs, nanotechnology, reproduction technologies, scientific integrity, xenotransplantation and systems biology, and synthetic biology. At present, the Center is coordinating several international research projects funded by the Research Council of Norway and the European Commission: *Reflexive Systems Biology*: explores ethical and social issues of systems and synthetic biology; *Value Isobars*: when new technologies enter into the public cross fire, important societal

values are at stake. Do we know what we are talking about?; *Technolife*: public imaginaries and ethical concerns with emerging technologies; *SEAT*: Sustaining Ethical Aquaculture Trade. Buying seafood from Asian aqua farms – what do we know about the sustainability and the ethics?; *PEGASUS*: genetically modified animals will soon be used in the food and pharmaceutical industries. Will we accept this (http://www.uib.no/svt/en)?

Global Health: Ethics, Economics, and Culture. This research group is organized under the Department of Public Health and Primary Health Care at the Faculty of Medicine, University of Bergen. It is closely linked to Centre for International Health (CIH), but the studies taking place under this department are distinctly focused on the thematic areas ethics, economics, and culture. The professional staff consists of four professors (two employed by the Department of Public Health and Primary Health Care, and two employed by CIH) and two associate professors. In 2011, 19 Ph.D. students were registered, coming from Norway, but also from Tanzania, Zambia, Ethiopia, and Sudan, with bachelor degrees in medicine, ethics, economics, anthropology, political science, history, nursing, and sociology. The research activities are concentrated into two main areas: (1) justice and priority setting in health and (2) health systems and patients' experience. Some projects are focused on specific problems and countries and are performed in Tanzania, Sudan, Ethiopia, and Uganda, while others embrace general research areas, such as *Gender in poverty reduction*, *The right to health through litigation*, and *Setting equitable priorities in health and health care: from theory to practice*. The group has been involved in developing more than 30 guidance documents for how to prioritize among patients seeking specialized care for cardiovascular diseases. The group collaborates with WHO in providing guidance on how to set health priorities directed at decision-makers from low and middle income countries. They are further involved in collaborations with the aim to develop guidance documents on equity concerns relevant for setting health priorities. The group has also done important research and developed a guidance tool to be used during counseling of HIV-positive women with infants. These guidelines were developed for Tanzania, but have received attention also from the WHO in developing guidelines for HIV-positive women in general (source: Evaluation of biology, medicine and health research in Norway, RNC, 2011).

Norwegian University of Science and Technology (NTNU)

Bioethics research and teaching at NTNU takes place within several organizational units (the *Institute of Community Medicine*, the Faculty of Medicine; the *Programme of Applied Ethics*, Department of Philosophy; and the *Institute of Social Work and Health Sciences*). The main areas of research are assisted reproduction, biobanking, genetically modified organisms (GMOs), issues pertaining to death and dying, prenatal medicine, and nanotechnology. At the Institute of Community Medicine, the professional ethics staff consists of one professor, one adjunct associate professor, two postdoctoral research fellows, and one Ph.D. student. This group is in charge of the ethics teaching for medical students at the faculty, following an "integrated" model, in the sense that the ethics teaching is integrated with the topical teaching the

students receive and with the aim of covering the majority of "classical" bioethics topics. The professional staff at the Programme of Applied Ethics consists of three professors, one associate professor, and one postdoctoral research fellow, while Institute of Social Work and Health Science has one associate professor and one postdoctoral researcher involved in bioethics-related research and training. The Nordic Journal of Applied Ethics, an open-access journal dating from 2007, originates from the bioethics and applied ethics ambiences at NTNU.

University of Tromsø

At the Faculty of Health Sciences, bioethics makes part of the *Health Services Research Group* at the Institute of Community Medicine (with one full-time permanent position). The group's research interests and activities include epidemiology, mental health, health technology assessment, health economics, medical ethics broadly defined, medical sociology, primary care, and complementary and alternative medicine (CAM). Bioethics is an integrated part of several curricula, for example, medicine, dentistry, and public health.

Relevant Legislation

Of particular relevance for the subject field of bioethics are the *Act relating to the application of biotechnology in medicine* (1994) 2003, the *Act on clinical biobanking* (2003, 2008), the *Act on medical and health research* (2008), and the *Act on patient rights* (1999). Norway was one of the first countries in the world establishing all-encompassing laws covering the fields of biotechnology and biobanking. The original Act on Biotechnology pertaining to medicine contained a total ban on research on fertilized eggs and human embryos. The Act also had a prohibition on egg donation and preimplantation diagnosis (PGD) except for in situations where the woman is a carrier of a serious sex-linked hereditary disease. Likewise, the Act banned sex selection except for in cases of incurable sex-linked hereditary disease. To this adds a total ban on reproductive cloning, inserted in the Act shortly after the publication of the first successful example of reproductive cloning in mammals, that is, of Dolly the sheep. In 2004, however, the restrictive stance on preimplantation diagnosis was lifted so as to allow for PGD not only for X-linked diseases but also for serious, hereditary diseases with high probability of being transferred to a future child. Additionally, the law opened for PGD in combination with HLA-typing and IVF so as to safeguard that the future child is an HLA match with an already sick sibling. This child could then potentially become a stem cell donor for its sick sibling, either by umbilical cord stem cell donation by birth or by bone marrow transplantation at a later stage. In 2007 also, the total ban on human embryonic research was lifted, so as to permit research on spare embryos from IVF younger than 14 days. In December 2011, the Norwegian Biotechnology Advisory Board presented its assessment to the Ministry of Health and Care Services of a report of evaluation of the Biotechnology Act prepared by the Norwegian Directorate for Health and Social Affairs. A small majority of the Advisory Board suggests a lifting of a total ban on egg donation so as to permit donation of

eggs to an infertile women and also of donation of spare embryos for others in need of IVF. In connection with the implementation of the Act on medical and health research in 2009, the original Biobanks Act from 2003, covering also research biobanks, changed its name to the *Act on clinical biobanking*, and the section on collection, storage, processing, and destruction of human biological material and data for research purposes was repealed from the Act. The alleged intention behind transferring the regulatory issues pertaining to research on human biological material and health and personal data derived from such material to the Act on medical and health research was pragmatic; that is, to gather the majority of legal requirements pertaining to medical- and health-related research under the jurisdiction of *one* law. Retrospectively, it has, however, become clear that this transfer did not only represent a contextual shift of certain legal paragraphs related to biobank research; it also implied a dilution of the original requirements pertaining to such research. First, in the original section on consent in the Biobanks Act, it was stated that in case of changed, expanded, or new use of material from a donor, deviation from the basic requirement of explicit, informed consent can only be justified in situation where it is "very difficult or impossible" to seek new consent. On the other hand, in the Act on medical and health research the paragraph pertaining to new or changed use of collected human biological material or personal health data (§ 15), this expression has been reworded to "difficult." To this weakening of the original wording has been added: "This may only be applied if the research in question is of significant interest to society and the participants' welfare and integrity are ensured." Second, also with regard to the paragraph pertaining to withdrawal of consent, the original requirements have been watered down so as to allow deviation from the rule not only in situations where the material or data have been anonymized, the material has been processed and has become part of another biological product, or the data have been included in scientific publications, but also: "If particularly strong social or research considerations so warrant, the regional committee for medical and health research ethics may allow continued research on the material and defer destruction, deletion or surrender until the research project is concluded" (Act on medical and health research, § 16). In paragraph 5, *On responsible* conduct, of the Act on medical and health research, it is stated: "Research must be based on respect for the research participants' human rights and dignity. The participants' welfare and integrity shall have priority over scientific and social interests." At first glance, this may seem to be a phrasing in compliance with Article 3 on *Human dignity and human rights* in the Universal Declaration on bioethics and human rights. This is, however, not the case, as the Declaration's wording is "the interests and welfare of the individual. . ." and not the participants' welfare and *integrity*. What is evident here, is that the considerations about the individual in the Act of medical and health research has been reduced to encompass only two interests, that is, welfare and integrity. To this adds that also in relation to Article 27 of the Declaration, *Limitations on the application of the principles*, the Act on medical and health research permits deviations from the requirement of explicit informed consent and the right to withdraw from research that are clearly at odds with the limitations specified in this article: "If the application of the principles of this

Declaration is to be limited, it should be by law, including laws in the interests of public safety, for the investigation, detection and prosecution of criminal offences, for the protection of public health or for the protection of the rights and freedoms of others." In Article 27, there is no mentioning of "research of significant interest to society" as a possible legitimate justification for a deviation from the rule of the primacy of the individual and his/her welfare and interests. Finally, in a report from 2008 on Article 6 of the Universal Declaration on bioethics and human rights, issued by the International Committee on Bioethics (IBC), blank and open consent procedures are deemed inacceptable while the Norwegian Act on medical and health research contains a paragraph (§ 14) explicitly allowing for the use of broad consent procedures in research pertaining to the use of human biological material and personal health data. In 1999, the *Law on patient rights* was enacted, based on the principles of autonomy, beneficence, nonmaleficence, and justice and guaranteeing patients certain inviolable rights to health care. Although this Act evidently represents an important part of the current bioethical framework in Norway, it still contains reminiscences of paternalism as the medical doctors have the ultimate responsibility for making decisions on behalf of noncompetent persons and as advanced directives and decisions based on proxies have no legally binding status.

Public Debate Activities

Since their creation, the three national research ethics committees and in particular the Norwegian Biotechnology Advisory Board and the Norwegian Board of Technology have organized open meetings, public hearings and consultations, educational campaigns, workshops, and consensus conferences on new emerging and potentially controversial issues. Examples of topics that have been addressed are aging and new technology, biobanks, biofuel, bioterrorism and biological weapons, climate change, DNA vaccines and gene therapy pertaining to animals, DNA registries for whole populations, egg donation, fertility tourism, genetic resources and rights, genetically modified plants and food, genmodified plants and sustainable development, globalization, health research and privacy, nanotechnology, the Norwegian gene pool, preimplantation diagnosis, sperm donation to single women and lesbians, religion and biotechnology, research on human embryos, sustainable fish farming, stem cell research, synthetic biology, the carbon footprint of food, the use of internet and mobile phones among young people, early ultrasound screening of pregnant women, vaccines, and whole-genome sequencing.

Major Bioethics Issues and Discussions

In this section, two major issues pertaining to beginning of life and to access to health care will be dealt with in more detail, *preimplantation diagnosis* and *access to health care*.

Preimplantation diagnosis. In Norway, PGD became the subject of a hot political and public debate in 2003 in connection with the case of Mehmet Yildiz, a Norwegian-Turkish boy who suffers from beta-thalassemia major. The only existing curative treatment for this disease is stem cell transplantation (bone marrow transplantation) from a genetically related, tissue-compatible living donor. The success rate with such treatment is well beyond 90 %. In Mehmet's family, no compatible donor was found. The only alternative source for the stem cells Mehmet was in need of was umbilical cord blood (eventually in combination with bone marrow) from a newborn, tissue-matching sibling. The alternative of undergoing a succession of pregnancies in combination with prenatal diagnosis and selective abortion until a matching fetus was traced was never an option for the Muslim couple. On the other hand, PGD and discard of affected and/or tissue-incompatible fertilized eggs prior to implantation, the couple considered morally acceptable. Although Mehmet's parents wanted to have a new child that was unaffected by thalassemia, they wanted as well to be sure that the child was tissue compatible with Mehmet. Therefore, they started to pursue the possibility of having access to PGD of thalassemia in combination with HLA-typing and IVF. The lack of this kind of *explorative* treatment in Norway, combined with the strict legal situation, compelled the parents to privately seek access to such treatment abroad. In December 2003, they were offered treatment in Turkey. At that time, the case was still unknown to the news media in Norway as well as to Norwegian politicians and the public. Unfortunately, the treatment was unsuccessful, as the mother had an early miscarriage due to extrauterine pregnancy. On January 1, 2004, the newly revised Act on Biotechnology came into force and notably with a ban on PGD except for in situations of serious, X-linked disease with no possibilities of treatment. On February 28 and 29, the story of Mehmet's sickness was broken by one of the main TV channels in Norway. The core message broadcasted was that Mehmet would soon risk dying if he was not offered stem cell transplantation. Besides interviews with Mehmet's physician and a specialist on IVF who had helped the family to trace treatment contacts abroad, the leader of the Parliament's Social Affairs Committee, a prominent representative from the progressive party, was interviewed. His message was clear: "The law must be changed immediately so that Mehmet's life can be saved. Mercy should prevail over the law." A few days later the progressive party proposed a Bill to change the paragraph on PGD in the Act on Biotechnology to enable Mehmet and/or children with other forms of *serious* diseases (genetic as well as nongenetic diseases) in need of stem cell transplantation to have access to this kind of explorative treatment. In the following days and weeks, a stream of newspaper articles, interviews, and debates about the case involving politicians, health professionals, patient representatives, and ethicists were published and/or broadcasted. The Minister of Health strongly defended the strict regulation of PGD, and he deemed it to be irresponsible if the Parliament decided to change the law just a few months after the revision of the Act on Biotechnology had taken place. With explicit reference to an expert report on thalassemia, PGD, HLA-typing, and IVF delivered by the Directorate of Health and Social Affairs just 2 weeks after the story of Mehmet had been broken, the

Minister of Health characterized the treatment Mehmet's family was requesting as *experimental research* and stated that the boy received the best *established* treatment currently available. The socialist leftist party that had sided with the parties forming the government coalition in the course of the parliamentary debate on the revised Bill on Biotechnology came under heavy pressure to change their newly adopted stance on PGD. Approximately 1 week after the Directorate of Health and Social Affairs had delivered their report, the party gave a press conference to inform that they had changed their mind on PGD as well as on PGD and HLA-typing in combination with IVF. The core element in the party's new stance was that the current ban on PGD except in situations of serious X-linked diseases without treatment possibilities should not be formally lifted. Instead, the paragraph in the Act on Biotechnology dealing with PGD should be supplemented with new subsections to make possible an *exemption* from the ban if and when "particular considerations" speak in favor of a case. By "particular considerations" were meant the presence – or the risk – of *serious, genetic disease without treatment possibilities*. An *independent* medical ethics committee enforced to grant exemption from the main rule on PGD should be set up and given the charge to evaluate individual applications. On May 11, 2004, the progressive party's Bill as well as the Bill proposed by the socialist leftist party were debated in the Parliament. After 3 hours of fierce and heated debate, the first Bill was thrown out while the second Bill won a majority vote against the three parties forming the government coalition in 2004. The mandate of the already existing Norwegian Governmental Appeal Board regarding medical treatment abroad was broadened to include also the responsibility for assessing applications of PGD to be carried out abroad. In 2008, the PGD part of the Appeal Board's responsibility was transferred to a separate Preimplantation Diagnosis Board. A study from 2010 evaluating the experiences with PGD in Norway so far revealed that the lack of a systematic report and evaluation system for PGD couples in Norway creates problems at several levels: It precludes the Preimplantation Diagnosis Board to know hardly anything about the outcome of the applications it is approving, a knowledge evidently of relevance for the Board in its assessment of future applications. Besides, it greatly hampers the possibility of evaluating the experiences with the current practice, something which is not in compliance with the Norwegian Parliament's stance on PGD. Furthermore, the lack of a systematic report and evaluation system implies that healthcare professionals in Norway in charge of advising couples in need of PGD lack vital information for undertaking such a service in a sustainable way. Finally, the lack of such a system makes it very difficult to undertake reliable cost-benefit analyses of this practice.

Healthcare system, access to health care. Norway was the first country worldwide that put priority in health care at the political agenda through the appointment in 1985 of an interdisciplinary working party with the mandate to look into the processes underlying [actual] prioritizations as well as assess and suggest different criteria and guidelines on which [future] prioritizations should be based. The working party was chaired by Professor Inge Lønning. The model of prioritization presented to the government in 1987 differentiates between five priority levels of healthcare services:

- *First* priority: emergency services of vital importance to individual patients, patient groups, or the society as a whole
- *Second priority*: *necessary* services, that is, services that if not offered will have disastrous or very serious long-term consequences for individual patients, patient groups, or the society as a whole
- *Third priority*: services with documented effect but with less negative consequences if not offered than services under first and second priority
- *Fourth priority*: requested services with perceived positive consequences for health and life quality but with less negative consequences if not offered than services belonging to higher priority levels
- *Zero priority*: requested services which are not necessary and without clearly documented utility

The two main criteria for prioritization underlying this model were *seriousness* and *cost*-effectiveness. In addition, *age* and *unhealthy lifestyle* was explicitly rejected as acceptable criteria for prioritization (but the latter with some minor qualifications). In addition, *unhealthy lifestyle* was explicitly rejected as an acceptable criterion for prioritization. Although the model suggested was unanimously adopted by the Norwegian Parliament, its impact on actual prioritizations was spare. For example, although highlighted in the report as areas in urgent need of more resources, that is, psychiatry, (re)habilitation, and care services, in the decade following the publication of the report, the distance between healthcare needs and factual capacity increased within these areas. The report came, however, to play an important *pedagogical* role, in the sense that it triggered a broad public debate pertaining to healthcare priorities. In 1995, a new working party was set up by the government, again chaired by Mr. Inge Lønning, with the mandate to propose a model for prioritization easier to implement in the Norwegian healthcare system. While the original model from 1987 was a *top-down* oriented model focusing on administrative and policy decisions at the macrolevel, the orientation in the new report was bottom-up, in the sense that it included a suggestion to establish representative groups of healthcare professionals with the mandate to classify and range services in terms of priorities within the context of the new model of prioritization proposed in the report and within their own areas of responsibility. Three criteria of prioritization were proposed – *seriousness*, *utility*, and *cost-effectiveness* – but with main emphasis on the two last criteria. Instead of differentiating between five different levels of prioritization, the new report suggested a distinction between four *priority groups* and with a substantiation of these four groups according to (medical) *conditions* and required *services*:

I. *Shall*-services, that is, basic healthcare services
II. *Ought*-services, that is, supplementary healthcare services
III. *Can*-services, that is, healthcare services with low priority
IV. Services outside the publicly funded healthcare system

In addition, the establishment of an *independent* and *interdisciplinary* National Council on Priority Setting was suggested. On the website of the Council, at present named the *Norwegian Council for Quality Improvement and Priority Setting in Health Care*, it is stated:

Assessments of patient benefit, cost-effectiveness and total costs will provide an important foundation for the Council's evaluations. The Council will handle complex and demanding issues, and their assessments will be based upon the best available evidence. In addition, dilemmas and elements of uncertainty also have to be highlighted for every each case. The Council's members will independently take initiatives they believe are necessary vis-à-vis follow-up, based on their positions of responsibility across the health services (http://www.kvalitetog-prioritering.no/R%C3%A5det/About+us).

While in its first years of existence the Council may be said to have been organized and functioning as an independent and interdisciplinary body with the mandate to advice health authorities and health policymakers with regard to priority setting, this can no longer be said to be the case, as today most members of the Council themselves hold top administrative positions within the Norwegian healthcare system. In addition, the Council is chaired and cochaired by the directors of, respectively, the Norwegian Directorate for Health and Social Affairs and of the Norwegian Institute of Public Health, that is, the two principal public institutions mandated to implement Norwegian health policy. The main argument for this "recompositioning" of the Council was to increase its impact on healthcare prioritizations. This may well have come at a loss of procedural independency and transparency.

Future Challenges

The abundant growth of national bodies dealing with the ethics of scientific research and development during the last 20 years makes it reasonable to ask whether Norway – in terms of research and technological development – has reached a level of *ethicization* that may not only generate better research conduct and transparency but also lead to adverse effects of a kind that may hamper a genuine promotion of ethical reflection and bioethical discourse. Several such effects can be identified: First, the existence of eight different bodies at the national level involved in assessing the ethical dimensions of scientific research and development may generate a perception among politicians and the public that scientific research is such a potentially dangerous and dubious enterprise that it needs to be constantly controlled and monitored. Second, the existence of eight such bodies at the national level may generate a normative landscape that is perceived as almost impenetrable by researchers and the public. Third, it may generate conflicts and power struggle between the different ethics bodies with regard to division of labor and division of responsibilities. This is already evident in the field of biobank research and genomic research. For these reasons, it may be due time for relevant ministerial authorities in Norway, in consultation with representatives from the ethics boards and committees themselves and the community of researchers, to discuss ways of making the Norwegian ethics bureaucracy a simpler and more transparent one, so that it does not lose its credibility but continues to promote ethical reflection and bioethical discourse within academia as well as in the society at large.

A second challenge relates to taking the necessary steps to secure that present and future regulations and legislations pertaining to bioethics are revised and shaped in compliance with international human rights law and commitments.

Summary Conclusion

Audacity and lost opportunities. The Norwegian history of bioethics is a narrative located in the interphase between these two opposing conceptions. In addition, it is a narrative about the formative role of physicians in establishing bioethics as an academic field as well as an account of how bioethics slowly grew into an interdisciplinary field attracting individuals from other branches of academia. The paramount role played by the institutionalization of research ethics in the country needs also to be acknowledged, both its role in turning bioethics into a sustainable academic field and a field of public discourse, but also its role in moving recent bio- and life sciences regulations and legislations in a direction not in compliance with international human rights law and commitments.

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Oceania

77

Darryl Macer

Introduction

The Pacific encompasses thousands of islands and communities across the Pacific Ocean. The most populated countries are Australia, New Zealand (called Aotearoa by the Maori indigenous population), and Papua New Guinea. Although there are also a number of large island nations in the West Pacific such as the Philippines and Japan, these are commonly considered part of Asia, though some of the indigenous communities of Asia share much in common with those of the Pacific. While some of the inhabitants of those communities also identify themselves as Pacific people, this chapter's scope will focus on Oceania. Because other chapters in the compendium review bioethics in Australia and New Zealand, this chapter will focus on the other countries of the Pacific.

D. Macer
Eubios Ethics Institute, Christchurch, New Zealand
e-mail: darryl@eubios.info

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The term "Pacific peoples" is an umbrella term, as is "Pacific ethics," that in no way should diminish the richness of variety of Pacific Island nations and communities who are linguistically, culturally, and geographically distinctive from each other, while at the same time sharing some common situations and approaches to bioethics. Further scholarship is required to fully describe the diversity of approaches to bioethics in each community, but this review includes some general trends and a few specific examples, from regions of Melanesia, Micronesia, and Polynesia.

There are 22 Pacific Island countries and territories with great diversity in terms of their geography, populations, cultures, economies, and politics. Based on their ethnic, linguistic, and cultural differences, these countries and territories can be categorized under three Pacific subregions:

Melanesia

Papua New Guinea (PNG), Fiji, Solomon Islands, Vanuatu, and New Caledonia (territory of France)

Polynesia

Samoa, Tonga, Cook Islands, Tuvalu, Niue, Tokelau, *American Samoa* (territory of the USA), *Wallis and Futuna* (territory of France), *French Polynesia* (territory of France), and *Pitcairn* (territory of the UK)

Micronesia

Federated States of Micronesia, Kiribati, Marshall Islands, Palau, Nauru, *Guam* (territory of the USA), and *Northern Marianas Islands* (*territory (Commonwealth) of the USA*)

The 15 independent countries cover an ocean area of nearly 5 million square kilometers, have over 1,500 separate languages, and vary in population from just over 1,000 persons to over 6 million. They are all undergoing an epidemiologic transition in health terms from mainly infectious diseases to mainly noncommunicable diseases (NCDs). All face demographic transitions with gradually aging populations despite the presence of many young persons because of high reproductive rates and significant emigration of young persons to Australia, New Zealand, the USA, and other countries. Because they are small populations, they are particularly vulnerable to outward migration, and transitions in values are rapid with introduction of global media and communications.

The grouping together of peoples who have richly diverse sets of languages, customs, cultures, and homelands involves many tensions. Some of the peoples are grouped as nations, but in some modern nations, there are hundreds of communities and language groups (e.g., Vanuatu) or thousands (e.g., Papua New Guinea). Political power has also promoted the use of the term Pacific, to quote Tongan writer Epeli Hau'ofa, "We are the ocean, we must wake up to this ancient truth and together use it to overturn all hegemonic views that aim ultimately to confine us physically and psychologically in tiny spaces which we have resisted and from which we recently liberated ourselves" (Hau'ofa cited by Thaman, 2002, p. 8).

Bioethics Development

When and How Has Bioethics Started?

Bioethics is both a word and a concept. Bioethics in the Pacific is identified closely with a broad concept of love binding all of life together, and the terms and values used to translate English words of bioethical principles in Pacific languages have deep historical roots. Although there were a wide variety of concepts prior to European colonization of the Pacific, the modern Pacific is predominantly Christian in faith, with a blend of indigenous culture and a theocentric approach to life ethics. Thus, although the actual word "bioethics" comes to us only from a German paper of 1927 (Jahr, 1927), amplified by Potter (1970) in English, the concept comes from human heritage thousands of years old (Macer, 1994), and there has been rejection of attempts to introduce the term "bioethics" when it is associated with universal ethical principles.

The concept of love as a binding force resonates well with the modern Christian approaches of Pacific culture. This includes more than humans, however, with strong love of animals which live in the land and water and a love of nature. In Maori the word *aroha* is used to denote something broader than love but including a oneness with nature and animals. Bioethics has origins in exploring human relationships with animals and with nature (ocean and land) and spirituality.

Love continues to be taught to children from a young age as a noble ethical character. In Tonga, *ofa*, which means all forms of love, and *fe'ofo'ofani*, caring love as a family, are some of the basic values taught to children from a young age which influence their behavior. These concepts are expressed in the way that Pacific Islanders care for the sick, often with practical expressions that family members will accompany the sick person to the hospital and a relative will always stay with the person day and night in the hospital (Mafi, 1998).

Stories explaining the deeds of past generations and the symbolic nature of the landscape can be found in songs, laws, history instruction, and social systems (Fairbairn-Dunlop, 2009). It is not possible to trace the origin of bioethics back to their beginning, as the relationships between human beings within their society, within the biological community, and with nature and God are formed at an earlier stage than history provides (Macer, 1998). Love is recognized as both the biological heritage given to humankind by genes and a social heritage, as the society tries to pursue harmony between individuals and communities.

Because Pacific values and beliefs are transmitted orally, many have incorrectly assumed that bioethics were effectively nonexistent before the expansion of modern bioethics in the 1990s (Macer, 1998). Ethics has a central place in the Pacific's indigenous knowledge systems and processes. "Each daily life event is seen through a lens of ethical values, mores, and codes of conduct developed over years. Indigenous ethical systems incorporate technical insights and wisdom-based observations of natural, social, and spiritual phenomena which, in turn, validate place and identity, as well as the survival of Pacific nations in our increasingly globalized societies" (Fairbairn-Dunlop, 2009).

Ethical values and principles have developed in the context of epistemological systems and are central to how knowledge is gained and organized, how knowledge is used, and who has access to it. In the development of ethical principles for medical research, the Pacific Health Research Council in New Zealand wrote:

> Every Pacific society has a framework of knowledge that is systematically gathered and formulated within a paradigm of general truths and principles. Knowledge gathering and systems of validating knowledge and legitimizing information are processes that are often determined and regulated (but not exclusively) by a select group within the traditional hierarchy of knowledge with the aim of protecting the quality and wellbeing of people (Health Research Council [HRC], 2004, p. 10).

Tui Atua Tupua Tamasese Ta'isi Efi (2009) described the importance of the Samoan concepts of *tapu* (the sacred) and *tofa sa'ili* (the search for wisdom) in identifying ethical practices for application in research. He argued that it is possible to find a middle ground between ideas and practices grounded in religion, the spiritual, the sacred, and science. Against the background of an exploration of different facets of the Samoan concept of *tapu*, which encompasses the sacredness of the origins of all things as well as the affinity between people, the cosmos, and animate and inanimate earthly phenomena, he envisages a Pacific bioethics that reaches out for wisdom. Such activity and the search for knowledge would be grounded in a sense of connectedness to all things, the awareness of people's responsibilities as protectors of the earth, attention to the sacred essence of all things, and a desire for increased understanding without ever presuming to know God.

Who Have Been the Major Actors/Forces?

Colonization has been a major force to articulate bioethical value systems that were previously implicit in the relationships of people and nature. Along with colonization came waves of Christian missionaries, and the Christian faith was readily adopted in a "Pacific" form. Anthropologists also described a number of traditions, although some "sacred" knowledge is preserved among chiefs and only informed to those they decide to entrust such wisdom to. As more persons left the shores of the islands to study, they started to document more of these traditions, and in turn, these values in a more articulated form were discussed among many of the communities.

There has been funded medical research throughout much of the twentieth century. From New Zealand, the first research was funded in 1946 (Rankin, 1997). Pacific people are shifting from historically being the subjects of research to becoming active agents of research, but still some are concerned that they are over-researched. "Although there have been positive outcomes, there have also been instances where research has resulted in Pacific peoples being presented inaccurately, or in a negative light. There is also a history where the benefits of research have not been shared with the research subject population" (HRC, 2004).

Researchers have also played important roles in recent decades as they attempted to articulate Pacific values into Western social science models. Theoretical frameworks include the "Metaphor of Kakala" (Helu-Thaman, Tonga),

the "Faafaletui Model" (Tamasese, Peteru, and Waldegrave, Samoa), and the "Tivaevae" (Maua-Hodges, Cook Islands). These are frameworks that are based on Pacific values and necessitate the use of research methods that are most appropriate for Pacific peoples. The recognition of the need to govern research in the Pacific in a way consistent with historical Pacific values was behind the development of the "Guidelines for Pacific Health Research in New Zealand" (HRC, 2004). Those guidelines describe 11 principles that can be found to some degree in a number of international texts but are well accepted because of the consultation process associated with the document. They are centered on relationships as the overarching principle that binds each of the following ethical research principles: Respect, Cultural Competency, Meaningful Engagement, Reciprocity, Utility, Rights, Balance, and Protection. These have been identified as the guiding principles for conducting ethical relationships for research. These values are a summary of many of the values found around the Pacific, and further examples of values will be discussed when reviewing specific cases.

To develop, cultivate, and maintain principled relationships between persons and communities is integral to all ethical practice in the Pacific, more than individual rights. Each person is a member of the whole, and the whole includes the parts. Therefore, the bioethic is centered on building and maintaining ethical relationships. For example, the term *Va Fealoaloa'i* refers to the various spaces and places within which Samoan people interact in a meaningful and non-coincidental way and makes people sacred.

The research should enhance relationships, and an action may be deemed unethical if it harms relationships not only between people but also with nature. The relationship between the researcher and the research participant is based on respect for the inherent value of each human being and on each being, whether they be a dog or a tree. Rather than promoting a universalistic worldview, to practice in a culturally competent manner, the researcher must have an awareness of their own cultural beliefs, values, and practices and an understanding of how these impact upon their interaction with others. The beliefs, knowledge, and experience of the research participant are true to themselves, and the researcher must respect this even if it is different from their own beliefs, knowledge, and experience. Researchers are encouraged to build their cultural knowledge of the Pacific communities they work with. Researchers are encouraged to create safe and enabling research environments that support culturally competent practice, to seek ethnic-specific and context-specific advice on culturally competent practice, and to understand the importance of communicating appropriately translated information to Pacific people.

What Have Been the Major Concerns Over Time?

One of the principle concerns that people have had is the lack of engagement and miscommunication. As the HRC (2004) document states, "4.1 To conduct ethical research with Pacific peoples there must be meaningful engagement."

Effective "face-to-face" consultation is critical to establishing meaningful relationships with people in most societies, and this may take longer time in many Pacific communities.

Because relationships between patient and health-care professional are very important, reciprocity should be a guiding principle for research relationships. This has often been neglected in the Pacific Islands where there are significant social hierarchies.

Each individual, group, or community has the right and freedom to make an informed choice as to whether to participate or not, in any research. However, there have been abuses of people who have not been informed about the medical procedures. In the case of research, any risks inherent in a particular type of research must be made clear to the research participant, and they must feel completely free as to their decision to participate or not (HRC, 2004). There are a number of structural societal inequalities in most countries, so care must always be taken to protect those less powerful.

Reciprocity in research also requires that knowledge gained through research will be used to benefit research participants and (where relevant) other people. If knowledge acquired from research generates significant financial returns, then the people from where the original knowledge should share in the financial rewards generated by the research. However, there have been disputes about patenting of traditional medical compounds, and products of other wisdom, that was not compensated to the communities they came from. Any research partnerships formed with Pacific peoples should be equitable and fair for both parties, engendering symmetry in the balance of power.

One of the significant events was the controversies associated with intellectual property rights (IPR) and the attempts to patent DNA in the 1990s and research to explore human genetics associated with particular diseases. These concerns led to particular statements such as the Mataatua Declaration (1993) as well as responses from UNESCO (Chee et al., 1995). The Mataatua Declaration on Cultural and Intellectual Property Rights of Indigenous Peoples of June 1993 includes several recommendations to member states of the United Nations. Recommendation 2.7 states that "commercialisation of any traditional plants and medicines of Indigenous Peoples must be managed by the indigenous peoples who have inherited such knowledge," while Recommendation 2.8 demands that "a moratorium on any further commercialisation of indigenous medicinal plants and human genetic materials must be declared until indigenous communities have developed appropriate protection mechanisms."

The declaration also indicates the concern for increasing capacity for research in the Pacific, with the promotion of a "co-operative rather than competitive framework," and an "increase in the involvement of indigenous communities" in "research and training as well as education" that would make them participants in the process of development of industrial goods from human genome research and beneficiaries of possible commercial profits rather than being simply suppliers of samples that may eventually lead to significant therapeutic discoveries.

There are differences in the views towards use of genetically modified organisms (GMOs) between the South Pacific which tends to be negative and the Northern

Pacific which has a more positive attitude in line with the US agricultural policy that finds some genetically modified papaya and other crops being grown. Another significant activity in environmental ethics was the eventual abolition of nuclear weapons testing in the Pacific Islands, though there are still a number of islands off limits because of residual radioactive contamination.

Overall considering the directions of cross-cultural bioethics across the globe and the unanimous agreement with the Universal Declaration on Bioethics and Human Rights (UDBHR, UNESCO, 2005) by nation states, there is support for the approach linking the Pacific values of love of life with international ethical principles. However, Pacific communities insist that there are many forms of wisdom, each found in different countries and communities. The Western construction of knowledge has been questioned in a postcolonial Pacific, as many communities of persons start to think more widely and rediscover their indigenous roots and traditions. This led to some questioning of the Universal Declaration on Bioethics and Human Rights.

The UNESCO Ethics of Knowledge Production Conference in Dunedin in February 2006 considered a number of issues in ethics in the Pacific including that document, and the outcomes formed the basis of a further conference, Pacific Regional Ethics of Knowledge Production Workshop, held at the Tofamamao Centre, Apia, Samoa, on 13–15 November 2007. Understanding ourselves and others and understanding place and position all contribute towards fuller understandings of Pacific ethics, knowledge, and values. UNESCO also held national workshops in Apia, Samoa, and Suva, Fiji, in September 2006 to explore the concerns on so-called universal ethics. References to Christian values were made by Pacific speakers and workshop participants, noting that the UDBHR seems to have no spiritual grounding, as they would have liked a more Christian basis. This may appear ironic, since the spread of Christianity in the Pacific was associated with colonization; however, it reflects the strong theocentric mentality of understanding life ethics in modern Pacific culture.

Ethics systems and processes are central to every aspect of the life of Pacific indigenous communities. Although not well documented, and long disregarded in the privileging of Western ideas about ethical practice, Pacific ethics processes integrate epistemological, pedagogical, and methodological considerations. For Pacific people, each daily life event is seen through a lens of ethical values, mores, and codes of conduct that have developed over many years, while remaining responsive to changing times (Du Plessis & Fairbairn-Dunlop, 2009).

What Resources Have Been Developed (e.g., Books, Programs, Media, Networks, Societies)?

There are a few papers on Pacific ethics, emerging from the conferences described above, and networks in Asia-Pacific region include the UNESCO Asia-Pacific School of Ethics and the Asian Bioethics Association. Some are referenced in the chapter here, but there are still relatively few compared to the diversity of values that exist (Du Plessis & Fairbairn-Dunlop, 2009). The Asia-Pacific Science,

Technology and Society Network has held several conferences on indigenous bioethics issues, and the papers have been published (Hutchings, 2012; Yamaguchi, Cronin, & Macer, 2012).

What Have Been the Steps/Measures Taken (Policies, Legislation, Infrastructures, Teaching Programs, Committees, etc.)?

The conclusion of the 2007 UNESCO **Pacific Regional Ethics of Knowledge Production Workshop** was summarized in the **Tofamamao Statement**, which reads,

That we Pacific peoples, local and global, genealogically, spiritually and culturally connected to the lands, the skies and seas of the Pacific region:

i. Undertake to lead, support and promote the development of Pacific indigenous ethical guidelines and protocols governing contemporary Pacific research implementation; with the respective aim of protecting, upholding and vitalising Pacific indigenous knowledge;
ii. That such ethical guidelines and protocols take into consideration our unique ancestral legacies governing traditional inquiry processes; and reflect a common epistemic heritage which upholds the mana of all things, sentient and insentient, and is cognisant of tapu and sacred relations between and among all things;
iii. That we undertake these responsibilities through our institutional, cultural, religious, global, regional, national, provincial, local, governmental and non-governmental organizations, groups, agencies/agents, families and communities; for Pacific generations, past, present and future.
iv. That the Tofamamao working Party and other interested persons and parties, including UNESCO, should work collaboratively to advance focused activities in this area.

Current Bioethics Infrastructure

Teaching of Bioethics at University and Other Levels

There are few courses related to bioethics in universities in the Pacific, except for the well-developed programs in Australia and New Zealand universities. Among these, the Otago Bioethics Centre, University of Otago Medical School, has had significant numbers of students looking at Pacific ethics, though the focus has been more on Maori values.

Bioethics Committees

There is a national bioethics committee in Fiji linked to Fiji School of Medicine. Pryor, Morse, Prasad, Koloi, and Kennedy (2007) found that

PNG, Fiji, Solomon Islands, Vanuatu, Samoa, Tonga, and Palau all have a functional structure and processes in place for the technical and ethical review of health research proposals. The other countries undertake an ad hoc process as needed, although they did not find a process or structure for this in Niue and Nauru. There is variability in the degree to which the existing ethical review structures utilize standard operating procedures and forms to help guide the review process. Some of these processes for ethical review were through National Research Committees, such as the Cook Islands. The research committees consider ethical issues in addition to scientific aspects, and with small populations, the case could be made for inclusion of ethical review duties in the total review of the application, rather than by a separate committee.

The Vanuatu National Cultural Council is responsible for research (see Chap. 186, 6(2) of the Laws of the Republic of Vanuatu). The Vanuatu Cultural Centre is the executing arm of the National Cultural Council and responsible for implementing the policy. The guidelines identify priority research topics, charge fees for applications for research, consider traditional copyright, and request Vanuatu participation in research and training.

Expert Bodies/Centers

There are no bioethics centers in Oceania, except for those in Australia and New Zealand. In Oceania, the University of the South Pacific (head office, Nandi, Fiji) is the main research university in the Pacific, and some researchers have explored bioethical topics. Because the academics are spread out over many small campuses in different islands, they often take the role of generalists and may also play important roles in community decision making. Informal decision making by elders and those considered "wise" plays a role that at times substitutes for formal ethics committees.

Relevant Legislation

While Pacific research continues to emphasize the endurance of customary ways, there is also a growing recognition of the role of universal rights and principles. For example, the recent public monarchy confrontations in Tonga (2005) began on a platform of poverty-related grievances, but they moved quite quickly to impassioned appeals for rights and democratic principles. Sovereignty issues are also gaining prominence in Pacific Small Island Developing States (SIDS) – including the emergence of more critical appraisal of the relevance of global conventions to the Pacific and the "right" of external agencies to set those agendas.

Case law in most countries upholds the principle of informed consent.

Fiji in its 1997 modification to its Constitution applied a number of ethical principles of the 2005 UDBHR for medical research, for example, some excerpts:

> Chapter 4, Section 22, Life: "Every person has the right to life. A person must not be arbitrarily deprived of life."
>
> Section 23, Personal liberty: (1) A person must not be deprived of personal liberty except: . . . (g) for the purpose of preventing the spread of an infectious or contagious disease; (h) for the purpose of the person's care or treatment or for the protection of the community if he or she is, or is reasonably suspected to be, of unsound mind, addicted to drugs or alcohol or a vagrant; or . . .
>
> Section 25, Freedom from cruel or degrading treatment: (1) Every person has the right to freedom from torture of any kind, whether physical, mental or emotional, and from cruel, inhumane, degrading or disproportionately severe treatment or punishment. (2) Every person has the right to freedom from scientific or medical treatment or procedures without his or her informed consent or, if he or she is incapable of giving informed consent, without the informed consent of a lawful guardian.
>
> Section 37, Privacy: (1) Every person has the right to personal privacy, including the right to privacy of personal communications.
>
> Section 42, Human Rights Commission: (1) This section establishes a Human Rights Commission.
>
> Section 38, Equality: (1) Every person has the right to equality before the law. (2) A person must not be unfairly discriminated against, directly or indirectly, on the ground of his or her: (a) actual or supposed personal characteristics or circumstances, including race, ethnic origin, colour, place of origin, gender, sexual orientation, birth, primary language, economic status, age or disability; or (b) opinions or beliefs, except to the extent that those opinions or beliefs involve harm to others or the diminution of the rights or freedoms of others; or on any other ground prohibited by this Constitution. (3) Accordingly, neither a law nor an administrative action taken under a law may directly or indirectly impose a disability or restriction on any person on a prohibited ground. (4) Every person has the right of access, without discrimination on a prohibited ground, to shops, hotels, lodging-houses, public restaurants, places of public entertainment, public transport services, taxis and public places. . . .

Public Debate Activities

There have been public debates over the use of genes from living organisms found in the Pacific for development, especially when attempts to patent these genes have been made (Mead & Ratuva, 2007; Ratuva, 2009). One of the famous cases is the Hagahai patent from a PNG tribe. In March 1995, the United States government issued a patent on a human cell line from an indigenous Hagahai man from the rain forests of Papua New Guinea. The US National Institutes of Health (NIH) were issued patent No. 5,397,696 by the Patent and Trademark Office (PTO), the first time that an indigenous person's cells have been patented, and there was much debate until its eventual reversal (Robie, 1997).

Other

A substantial proportion of Pacific persons live in Australia and New Zealand (Dunsford et al., 2011). Some of the traditional ethics influence the actual bioethics that governs the interactions of citizens and health professionals in those countries, and readers should refer to the chapters on those countries.

Major Bioethics Issues and Discussions

Beginning of Life

Most Pacific countries have Christian faith. However, abortion is available with various criteria considering the health of the mother and fetus. Let us explore in detail a Samoan analysis of Tui Atua Tupua Tamasese Efi (2009). The Samoan term *faatosaga* literally means "planting and growing the seed," which advocates a particular model for encouraging successful fertilization where the techniques of *fofo* (massage) and a strict regimen of physical health and diet are prescribed. According to the traditional midwives, *faatosaga*, the main objective of the massage is to place the fallopian tubes in the best possible position to the ovaries. This is to help ensure the ease of passage for male sperm. The main objective of healthy eating and exercise is to ensure that the body and mind of the potential mother are in synchrony. Harmony of the mind and body allows for easier (and more enjoyable) sexual activity, which is considered a necessary precursor to successful conception.

From the moment the egg is fertilized and the mother experiences the symptoms of conception, a human life is said to exist. Here, the fetus is recognized as a person. As a person, the fetus gains a sacred essence. It becomes tapu. When the fetus is deliberately terminated by abortion, a breach of tapu has occurred. Pardon must be sought for this breach. Throughout the process from conception to birth, the main job of the faatosaga is to steer the mother using massage and good advice towards a successful birth. The regimen of massage and counseling is holistic. The relationship between the mother and the unborn child is sacred. In ancient Samoa, once conception was established, there was a ritual celebration. This was known as afuafua (literally, meaning beginning). The prayers, chants, and rituals of the afuafua are today replaced by Christian prayers and special food, in the few families which still practice it.

End of Life

Traditional medicinal remedies are still widely used, and some of these offer pain-killing properties. Although active euthanasia is rejected, there is a recognition of the limits of Western medicine as well as limited intensive care facilities in most islands. Rather than sending elderly relatives to distant hospitals on other islands for intensive therapy, palliative care among family may be preferred.

Health and Disease

Diabetes is a major health issue with Western diets, leading to significant obesity, with its associated morbidity and mortality. Tropical diseases are a significant issue in some islands, such as Papua New Guinea. Some parts of the disease require storage of samples in a refrigerator.

Health-Care System: Access to Health Care

Pryor et al. (2007) studied the health-care systems in 15 Pacific countries and described wide diversity in the governance and management of the health-care systems. Palau was an exception, having the highest per capita GDP and highest Human Development Index, with substantive overseas health research partnerships, associated with its close association to the USA. The Melanesian and larger Polynesian countries generally have a more developed national health research and health-care structure and management processes than the smaller Polynesian and Micronesian countries.

The fundamental belief is that family communal systems ensure the spiritual, economic, and social security of family members, and they set the standards for all behavior. This knowledge has been passed on by word of mouth, from generation to generation (Fairbairn-Dunlop, 2009).

Traditional Medicine

Traditional practices and holistic approaches to health are common. For example, see the Samoan example of birth, described above. Traditional medical knowledge is extensive, and medical wisdom is one of the sacred knowledges associated with traditional healers.

Genetics

Access to genetic testing services follows the general trends for the health-care systems, which can be difficult on dispersed small islands. There will be significant improvements in access as genetic testing kits become cheaper and require less technical support.

There was some debate over a possible tendency for increased violent tendencies in those children exposed to childhood abuse who were born with higher monoamine oxidase A (MAOA) levels, in what was commonly termed a "warrior gene." Gillett and Tamatea (2012) urged persons to focus on the main causative elements of family cycles of abuse, rather than complex genetic possibilities.

Reproductive Medicine

Life is to be promoted, and having birth using assisted reproductive technologies can be supported, with the right attitudes. Extended family systems have also allowed adoptions of children into nuclear families that do not have a child.

The use of a dead fetus for research is a breach of *tapu*. To tamper with the body of a dead fetus is to show disrespect for the sacred. The dead body returns to its Creator after death without having been tampered with. It is to return by the very route of its birth back to the earth. This principle of respecting the origins of human genealogical links with the earth is implicit in ancient Samoan practices of ritually burying the placenta and umbilical cords in the earth. Regarding the tapu on burying the placenta and umbilical cord, the cultural claim to any land or earthly inheritance is premised on a genealogical connection with the earth. The sacred aspects of rituals are commemorated in a belief held among most faatosaga that omitting to bury the placenta and cord in the earth can materially affect people. The faatosaga suggests that a dead body, born or unborn, belongs at death to none other than God, the Creator Progenitor, and so should be returned to Him without being tampered with. This, too, has significant implications on research using cadavers.

Medical Research

Pryor et al. (2007) found in a survey that few countries had a clearly articulated policy on health research. Among 15 countries, only 4 have invested in dedicated personnel and/or a dedicated unit responsible for development in the area of health research and evidence-based policy and practice (PNG, Fiji, the Solomon Islands, and Tonga). Only PNG had specific legislation on health research pursuant to establishing the PNG Institute of Medical Research (PNG-IMR).

Papua New Guinea (PNG) with its great diversity of population groups has a history of exploitative anthropological research, and some controversies regarding HIV testing and vaccine trials, because of the high HIV rate. One of the challenges for new drug development is that the population sizes are low which means that there are few persons available for any one clinical trial. This has also led to a phenomenon of persons being "over-researched," with some resentment of researchers if there is no expected benefit.

The rights framework used in modern medical research guidelines is considered to be based on individualized understandings of ethical practice and Western notions of autonomy, individual responsibilities, and freedoms. This contrasts with Pacific notions of interrelationship, responsibility to others, and decisions made with due consideration of the consequences for all (whom one is connected to). The issue of a collective – as opposed to an individualized – understanding of rights goes beyond the issue of consent. Pacific people are advocating for the validation of alternative

ways of viewing and approaching rights (New Zealand, 2007). For example, collectivist understandings of rights can be described in the following ways:

There are situations where the "I" (or individuals) do not have the right or authority to give consent for something that is communally owned.

- Rights are inseparably bound to responsibility.
- Rights only occur within the context of relationships.
- A collective rights framework is based on an understanding of humanity that is relational, collective, and concerned with others, as well as the individual.
- The concept of the individual is not negated, but instead they are viewed as contributors to collective and communal development.

Individuals are primarily seen as agents who contribute to collective and communal development with specialist skills, knowledge, and talents. Some of these features are seen in the New Zealand Health Research Council (HRC, 2004) Guidelines for Pacific communities discussed above.

If research targets the Pacific population, Pacific peoples should participate at all levels of that research project. Participation of Pacific peoples in a research project is encouraged on a number of levels, e.g., investigators, advisors, students, and interviewers, and can provide support for Pacific members of the research team. This concern has also been raised regarding the level of participation in discussions of bioethics.

Public Health

The Secretariat of the Pacific Community (SPC) has a public health program that supports Pacific Island communities. There is substantial funding also from Australia, New Zealand, WHO, and the USA to supporting these programs. The stated goals on the website are "The SPC Public Health Division (PHD) is dedicated to improving the health, and therefore the future, of all Pacific Islanders. PHD strives to promote and protect the health of Pacific Island peoples. It advocates a holistic approach to health, supports sustainable capacity development, and facilitates and promotes collaboration with partners."

At the 2011 Pacific Islands Forum leaders meeting in Auckland, the political leaders recognized the seriousness of the threat that noncommunicable diseases (NCDs) pose and declared the "Pacific is in an NCD Crisis." The leaders expressed their deep concern that NCDs have reached epidemic proportions and have become a "human, social, and economic crisis" requiring an urgent and comprehensive response. There is an SPC campaign for a healthy Pacific lifestyle, with focuses to promote physical activity and healthy nutrition and to combat alcoholism and smoking.

Infectious Diseases

The Samoan pandemic influenza case in 1918 clouded relations with New Zealand when a ship with many patients was allowed to dock leading to many deaths among the

resident population. There are laws regulating infectious disease control, and/or public health, in many countries. In the Constitution of Kiribati 1979, for example, it reads:

> Chapter II, Section 5, Protection of right to personal liberty: (1) No person shall be deprived of his personal liberty save as may be authorised by law in any of the following cases, that is to say - . . . (h) for the purpose of preventing the spread of an infectious or contagious disease; (i) in the case of a person who is, or is reasonably suspected to be, of unsound mind, addicted to drugs or alcohol, or a vagrant for the purpose of his care or treatment or the protection of the community.

The Secretariat of the Pacific Community (SPC) has been engaged in issues relating to HIV and other sexually transmitted infections (STIs) for the past 15 years. Its position has evolved according to the needs of the Pacific Island countries and territories (PICTs) and in response to emerging trends in HIV and related issues. The Pacific Regional Strategy on HIV and other STIs 2009–2013 as well as the Pacific Regional Strategy Implementation Plan II (PRSIP) are available online (SPC, 2013) (http://www.spc.int/hiv/index.php?option=com_contentandtask=blogsectionandid=12andItemid=123). In addition to HIV and STIs, there are efforts to combat tuberculosis among other diseases.

Transplantation Medicine and Organ Donation

Full range or organ transplantation services are offered in Australia and New Zealand, though patients have to wait for organs, which can be limited. However, patients in many islands have limited services because of shortage of clinical services as well as donors and may have to be shipped and flown to facilities in Australia, New Zealand, or Hawaii that offer transplants. In some cultures, there is a taboo against cutting up the dead body; however, the predominantly Christian religion has been used to promote the concept of the gift of life that organ donation can provide.

Emerging Technologies (Nanotechnology, Information Technology, etc.)

To some extent, there are two conflicting views of knowledge, that is, "sacred versus open." One perspective is that all knowledge should be openly and freely accessible to all. This is linked with the sense that people have a "right" to know things – i.e., what is known and what is not known about a subject. Thus, notions of privacy are complex and require specific knowledge of the community, and family, to know what should be provided.

Another perspective is that some knowledge is considered sacred, and it is not advantageous for this knowledge to be in the public domain. To be fair, all societies deem that some knowledge is best kept confidential or "sensitive" and is therefore not available in the public domain. In these cases, only the "trusted" and "initiated" have access to this knowledge, and stewards of such knowledge actively protect it.

For emerging technologies that relate to the environment, environmental ethics is dominated by concepts of stewardship and the interrelatedness of all parts of the

environment to God. The use of nanotechnology products in textile industry is being supported, although it does not reach to many islands who will continue to use traditional practices. There is little data processing ability to monitor what is actually happening.

Intensive Care

Critical care facilities exist in some islands, but ICUs are limited. There are ethical issues of rationing and providing access to the limited number of spaces for intensive care in small Island states. Most patients will be unable to be transported to ICUs in time, except for larger Island states.

Palliative Care

A time to go back to nature, and be with God, is recognized; thus, palliative care is accepted. The care will often be given in the family setting, rather than a clinic, event when there is an option of an ICU. The Christian faith helps a number of persons who cannot be treated to accept death. Traditional medical therapies are used to ease the pain of some diseases and are more accessible and affordable in most cases.

Care for the Elderly

There is care for the elderly in traditional community models which can have extensive and close family networks. There has been a challenge that many young persons have left the islands in search of employment, leaving older persons in the care of extended family.

In some communities, there is low life expectancy, but still when persons live longer, they will be taken care of by relatives. Emigration is challenging this when the elderly are left in the country, but relatives are often counted on to care for the elderly. Churches also provide broad support to the community.

Chronic Diseases

Chronic diseases like diabetes and cardiovascular disease are major sources of morbidity and mortality and targets under the public health campaigns.

Psychiatric Care

A holistic approach to health used in traditional practice includes counseling and emphasizes relationships among people rather than individual patients with

mental disease. There are also laws regulating the protection of patients with mental diseases in many countries. One of the ethical debates in these cases is whether the disease is due to the presence of evil spirits, or ancestors, in a sense similar to some types of belief in karma seen in Southeast Asia. In that sense, psychiatry is less recognized as a medical art but relates to the concerns that traditional healers use exorcism and other forms of spiritual "healing" to attempt to treat.

Pediatric Care

In some countries, there are good networks of pediatric care, and in critical cases the children may be sent to Australia or New Zealand to be with families there, in cities with modern health-care facilities (Dunsford et al., 2011). One concern has been the sensitive issue of child abuse by parents, which is a concern expressed by some, but also has been linked to calls of racial profiling in communities of Pacific Island peoples in Australia and New Zealand. However, there is no doubt that all peoples wish their children to be treated, but lack of knowledge of mental health issues may see reduced empathy in some circumstances. The statistics present a poorer record of child care in some communities, but the causative factors are not simple.

Emergency Care

Emergency care ranges between advanced in a few cities and local community measures in the islands that are very remote. For some islands, the only possibility of air emergency services would be helicopters if they are available, and at times cruise ships may provide emergency services for local communities. For example, Tokelau in 2012 decided not to build an airstrip on the precious land, rather renewing a ferry ship that requires a 2-day passage to Samoa.

General Practice

General practice is guided by the ethics of relationships and love. There is still a tendency towards maternalistic or paternalistic decision making in medical choices, although younger generations who return from more Western countries may expect greater communication, more shared decision making, and more informed consent. Officially the practice of informed consent is promoted in all countries; however, in practice the benevolent physician, midwife, or nurse may be more influential for decision making.

At the same time, there are laws specifically for health practitioners in Cook Islands, Fiji, Kiribati, Nauru, Solomon Islands, Tonga, Tuvalu, and Vanuatu. These laws focus more on professional conduct and generally do not enshrine detailed descriptions of informed consent, for example.

Health Promotion and Education

There are national campaigns for healthy lifestyles through schools, tribal chiefs, and community centers. Obesity and lack of activity are recognized as major health problems, and community bodies such as churches can also assist in promoting health. Obesity can be even more of a problem among Pacific persons living in Westernized environments in Australia, New Zealand, and the USA, with access to carbonated drinks and fast food, despite the health education in those countries.

Scientific and Professional Integrity, Conflict of Interest, and Corruption

There have been attempts to regulate scientific research and control corruption in all countries. The principle of trust is important among the relationships that people make. In particular areas, model legislation to govern the practice of researchers has been proposed, such as the draft *Model law for the protection of traditional knowledge and expressions of culture*, 2002 (the Model Law) which is an attempt by Pacific Island states to protect their traditional knowledge and expressions of culture. The draft Model Law was a result of a joint effort of Secretariat of the Pacific Community (SPC), Pacific Island Forum Secretariat, UNESCO, and the Council of Pacific Arts comprising the 27 countries and territories which participated in the Festival of Pacific Arts. It was endorsed by the First Conference of Ministers of Culture of the Pacific Region at SPC in 2002 [online] available from http://www.mabs.jp/countries/others/pdf/331e.pdf.

Relations with Industry and Donors/Sponsors

The traditional views on knowledge in Pacific societies is that it is collective and aimed at maintaining the relationships between people – past, present, and future generations – and the environment. While ownership of knowledge is familial and collective, differentiation can be made between knowledge that is protected and knowledge that is shared. In addition, because the focus is on maintaining relationships, knowledge sharing is an interactive and dynamic process.

It is not surprising therefore that there have been some controversial cases when pharmaceutical companies become involved in genetic prospecting. One case involved an agreement between the King of Tonga and a biotechnology company for human genetic sampling in the Tongan population, which, after controversial publicity and dissent, was terminated before sampling of the population was made. The King initially gave consent for the whole country to provide genetic samples to the company who could explore potential commercial uses of the genetic markers associated with diseases in some individuals in the community. It was ethically questioned whether any head of state could give consent on behalf of any ethnic group or country, and the decision was reversed after public outcry.

The question of who owns the primary knowledge that is derived from the experience and expertise of participants suggests that this knowledge indeed belongs to the research participants. The question as to who owns the combined outputs of the accumulated primary knowledge suggests that this belongs to the community of Pacific families and the community of researchers. Researchers should, where appropriate, protect indigenous Pacific knowledge and knowledge holders.

Future Challenges

In the Field of Bioethics Infrastructures (Need for Legislation, Ethics Committees, Ethics Education, etc.)

Capacity and capability building is a tangible example of reciprocity in action that is expected of any researchers who operate in the Pacific. It will demonstrate a commitment to the empowerment of the Pacific community. Participation is an important principle of Pacific research. Pacific research requires the active involvement of Pacific peoples (as researchers, advisors, and stakeholders), and Pacific people will no longer just accept to be the subjects of research. Where a research project targets Pacific populations, Pacific people should participate in the research team at all levels (e.g., interviewers, research assistants, investigators, and advisors). This ensures that the project is responsive and accountable to the research needs of the participant research population.

There is a core belief in many Pacific communities that knowledge should be used responsibly, and with wisdom, so as to not harm others. Pacific knowledge is tied to the collective good. To transmit knowledge to those who are not able to care for that knowledge, process it appropriately, or keep the meanings safe can however be seen as an irresponsible approach to knowledge. In the traditional Pacific context, a person earns the right to know through proving that they are worthy and ready for the information. This prevailing attitude may mean that some researchers face barriers that they might not experience if working with a different population.

In the Field of New and Emerging Issues

Although there have been several subregional bioethics meetings and UNESCO also organized workshops in Samoa and Fiji, there are still many communities in the Pacific who have not been involved in discussions of bioethics. Without considerably more expense, it will be difficult to describe the ethical worldviews and practices of all the diverse communities across the Pacific. Inclusiveness is important to Pacific values, and thus until describing more of the variety of ethical views scholars and policy makers have, we cannot adequately describe what is the representative regional ethics, as we will not have adequate participation to describe what is "Pacific bioethics." There is a continued need for more indigenous

research, including the mobilization of researchers and communities, healing, decolonization, and transformation (Smith, 1999).

An extension of love to other species and the concept of stewardship is one important lesson that could be applied to environmental ethics and ethics of climate change globally. Stewardship can apply to both the way people use other humans and the rest of nature. The concept has often been neglected but has a long history in many religions, being central to a Judeo-Christian doctrine of creation (Macer, 1998). Usually people prefer to ignore it and to think of dominion of humans over the earth, treating the earth with little value; however, this has caused many environmental problems. There are numerous pollution problems that affect humans and other species.

Any Other Problems and Opportunities for the Further Development of Bioethics in the Country?

Few would question the need for the Pacific to develop legislation and policies in bioethics that will guide national decision making and also protect Pacific communities from incidents such as external researchers carrying out research in the Pacific that would be prohibited in their home country and acts of biopiracy.

There is also a great opportunity for research and scholarship to document indigenous ideas and see how these are applied to contemporary challenges. There is a delve of research and, with proper partnerships, tremendous potential to rediscover many lost values and ideas.

Summary Conclusion

There is diversity of circumstances among the different Pacific countries and territories and diversity of language and worldview. However, some common principles of community involvement and participation emerge across all communities in the Pacific (Macer, 1994, 1998). The Pacific concept of *va* means the space between people – "the space that connects rather than separates" (Mila-Schaaf, 2009). By nurturing *va*, relationships among people and between them and everything else can be sustained. Pacific ethics is thus based on relationships between persons, organisms, and God, rather than rights.

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Philippines

78

Leonardo de Castro and Sarah Jane Toledano

Major Forces on the Development of Philippine Bioethics

Influence of Catholicism and Christianity

The development of bioethics in the Philippines cannot be divorced from the influence of Catholicism and Christianity on local culture. The strong influence of religion continues to prevail over many aspects of life and human relationships in

L. de Castro (✉)
Centre for Biomedical Ethics, National University of Singapore, Singapore
e-mail: Decastro.bioethics@gmail.com

S.J. Toledano
Department of Philosophy, University of the Philippines, Diliman, Quezon City, Philippines
e-mail: sctoledano@up.edu.ph

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the country. Filipino values have long evolved against this backdrop. One should try to understand developments and prevailing attitudes relating to issues of bioethics with this backdrop in mind. There is a huge Catholic majority – exceeding 80 % – among the population, and the Catholic influence does not lie merely in numbers. The social dynamics reflect the way in which religion has been imbedded in ordinary life, and any serious account of Philippine bioethics cannot avoid being an effort to understand those social dynamics at the same time. Moreover, there are parallel political dynamics that need to be considered, these being closely intertwined with the former as well as with other factors bearing on bioethical developments and policy-related decision-making.

The Catholic Church in the Philippines has seen itself as a guardian of public values. This is how it positioned itself when the colonization of the Philippines by Spain started in the sixteenth century, and this is how the Catholic Church continues to position itself long after the colonial era. It is as if the Spanish colonizers installed a proxy to try to maintain their hold on the Filipino psyche and continue their subjugation of the locals. In this role, the hierarchy of the Catholic Church has chosen its battlefields, which are mainly to be found in the area of health care. Abortion and the broad family of reproductive health issues have provided one major battleground. Over the years, people identified with this religious sector have engaged in public debate with various protagonists regarding family planning and the promotion of contraceptive use. Lying at the foundation of this religious perspective is the idea that it is necessary to protect "the life of the unborn from the moment of conception" (the Constitution of the Republic of the Philippines). Given this fundamental position, it is no surprise that contraception is regarded as "intrinsically evil" with only "natural" family planning methods and abstinence being accepted as exceptions. In this area, we see how bioethics discourse almost inevitably takes on a religious dimension.

Notwithstanding its constant access to the ears of its followers, the voice of the Catholic Church has not gone unchallenged. It has been a magnet for strong organized resistance coming from groups advocating women's rights as well as from health-related nongovernmental organizations (NGOs). The participation of some of these groups in national debate may be seen to represent a kind of bioethical activism in that it goes beyond debate and public declarations. Wary of the dangers of leaving religious doctrine to define health-related policy, such groups have vigilantly contested the ultraconservative stance of the hierarchy of the Catholic Church on bioethics issues. They have also added an important dimension that helps to define Philippine bioethics discourse.

The proposed Reproductive Health Bill (RH Bill) has provided the most recent battlefield for heated exchanges between the Catholic Church and some of its opponents. Disagreements regarding the RH Bill have provided a venue for each side to unleash its brand of activism. The Catholic Church has expressed opposition to, among other things, what it takes to be the "non-consideration of moral principles"; "the antilife, anti-natal, and contraceptive mentality"; "the overall trajectory of the RH Bill toward population control"; "the use of public funds for contraceptives and sterilization"; and "the provision for compulsory sex education." Through a widely disseminated Pastoral Letter in 2011, the Catholic Bishops

Conference of the Philippines articulated its determination to "defend human life from the moment of conception or fertilization up to its natural end" and reiterated its belief in the responsible and natural regulation of births through Natural Family Planning. It also asserted that "conscience must not only be informed but most of all rightly guided through the teachings of one's faith." Thus, the Catholic hierarchy has referred the faithful back to fundamental Church dogma. Moreover, through the emphasis on being "rightly guided through the teachings of one's faith," the Pastoral Letter has the effect of negating an individual's freedom of choice as there is no escaping religious dictates in the end. Although there is an endorsement of "the freedom of religion and the right of conscientious objection," it is quite clear that these cannot be exercised to express sentiments regarding reproduction and conception that are contrary to what the Church sees as part of one's faith.

Supporters as well as opponents of the Bill have engaged in "activism," by encouraging or organizing mass action or by pursuing activities calculated to influence the outcome of the legislative procedures. The Catholic religious establishment itself has been engaged in its own kind of bioethical activism as described below. The weapons have included public demonstrations and vigorous lobbying, in addition to the sustained orchestrated preaching that has been its standard fare.

The activism that is referred to has the effect of intimidating people rather than merely presenting them with options backed up by convincing reasoning. With legislators as a target, the power to intimidate comes from a presumption of the intimidator's capability to influence the outcome of popular elections. In relation to the general public, intimidation hinges on the credibility of the threatened religious outcomes.

The dogmatic approach of the Church has been a target of criticism for those who support the passage of the Reproductive Health Bill. Supporters of the RH Bill have gained strength from among the ranks of nongovernmental organizations (NGOs). These NGOs have emerged as another notable locus of power in the country's bioethics scene. Many of them have carried their advocacies very forcefully. Those that see themselves as protectors of women's rights have battled with the Catholic Church and its allies in matters pertaining to reproductive health. Other NGOs have also been visible on the bioethics landscape in connection with their own specific advocacies. For instance, there are NGOs that have focused their energy in a campaign against the use of genetically modified organisms in agriculture and food development. There are others that have battled to keep pesticides out of agricultural farms. And there are those that have fought very hard for the enactment of laws and implementation of policies that are meant to provide broader access to effective health care and inexpensive medicines and treatment. They have sought to carve their respective niches in the bioethics spectrum.

On the other hand, the religious opposition continues to resist the RH Bill's role in family planning as a national mandated priority health program. It appears that religious influence is threatening to encroach on political decisions even at the level of local governments. This encroachment can be scary because of the way it threatens to erode the boundaries that separate Church from state. More and more, sympathy for religious authority is being translated into official actions upon the initiative of elective local authorities.

Decentralization and the Politicization of Health Services

The Congress of the Philippines enacted the Local Government Code of the Philippines in 1991, setting in motion the devolution of health-care services from the national government to local political authorities. The transfer of authority and responsibility aimed to increase the responsiveness and integration of government programs to local needs, thereby strengthening community ownership and accountability. The presumption was that local governments would have been in a better position to address health concerns within the context of their own developmental priorities. Local government units included the cities and municipalities within the 77 provinces of the Philippines.

While devolution was meant to improve the effectiveness and efficiency of health-care delivery and services, the Department of Health (DOH) was justifiably concerned about some troublesome issues. For one, the decentralization and devolution meant that the DOH assumed a diminished role in controlling and managing health-care funds that had to be given directly to local government units (LGUs). Because of the greater power thus given to local government units, the health policy agenda of the national government has been relegated to the background. Allocation decisions tend to be dependent on an elected leader, whose term of office is as short as 3 years, thus leading to variability (and possible long-term instability) in the position taken on some important health-care issues. Oftentimes, decisions made by elected leaders in the local government units have to reflect pragmatic and politically motivated considerations that could be highly incompatible with the crucial health-care requirements of the community. Unfortunately, the visibility of community projects has more immediate political value than long-term effectiveness and sustainability.

In consonance with the prescribed national system for allocating financial resources, funding for local governments has been dependent on the population and geographical size, and there are small local government units that suffer from a lack of resources to fully address local health-care needs. Taken together, the political exigencies and economic realities in vulnerable communities have resulted in a distorted sense of priorities that do not always depend on fair and equitable principles of allocating health-care resources. A truthful depiction of the bioethics situation in the country has to take this reality into account.

Maternal and reproductive health services have been greatly affected by devolution as these services are among those that were first discovered to be underfunded. This point is relevant to the understanding of bioethical developments since the current and highly controversial Reproductive Health Bill (like its precursors in previous congresses) has sought to address this finding. However, the progress of the Bill has been blocked because of very emotionally charged disagreements regarding ethical and religious implications.

To illustrate, finding sources of modern contraceptives became a problem when donations from a major foreign agency ran out some years ago. Local governments had to allocate money out of their limited funds or generate them from new donors in order to provide the needs of poor constituents. Executive officials of some local

government units were so heavily influenced by the official Catholic stance on modern contraceptives that they chose to promote only what they regarded as "natural" family planning methods. They decided to have nothing to do with more effective means that were opposed by the Catholic hierarchy.

One must understand the implications of such a policy in a context where health insurance coverage has been very limited and certainly does not extend to the reproductive health needs of women. Comprehensive health-care agreements existed that were intended to set priority health targets agreed upon by the DOH and the LGUs, but these were effectively set aside. These were not recognized as binding by the municipal governments that were dealing face to face with the public in the delivery of health services. If one imagines this experience repeated several times over in various parts of the country, one could see why the allocation of health services took place with suspect planning resulting in inefficiency and an overall system that often has been unresponsive to the needs of the population, especially the poor. There has been a lot of unfairness and inequity.

To be sure, experiences have not all been gloomy. Studies on maternal health and child welfare relating to reproductive health implementation have reflected stories both of success and suffering. But local leaders still have to show consistency of political commitment to actualize effective services to the citizenry and to forego political fears of losing the Catholic community's electoral support. They cannot surrender to political expediency when ethical responsibilities clearly point in the opposite direction. But such are the realities, and one could see in this area of health services an illustration of one of the major currents running through bioethical debate and dynamics in the country. As self-declared guardian of public morals, the Catholic hierarchy sees certain key issues as falling within its domain, and it has not been shy to assert its influence either on its members directly or on the political leaders who seem to get easily convinced that they need support from church leaders to further their electoral ambitions.

Major Concerns Over Time

Poverty

Bioethical issues in the Philippines must also be understood against a background of extreme poverty and vast disparities in wealth and power. The impact of poverty on people's lives has helped to characterize discourse and deliberation on matters of bioethical concern. The inability of government to deal successfully with poverty has also affected the manner in which authorities have responded to some of these issues. As in many other countries, economic barriers severely limit the options available to people when they have to make health and bioethical decisions. These barriers tie the hands of policy makers and hamper efforts to allocate resources in a fair and equitable way. In many cases, poverty-stricken individuals and families find themselves only with options they would ordinarily not be willing to take. This is not to say that poverty could make some decisions right that are otherwise wrong.

In this context though, issues of justice and access become more pronounced. When extreme poverty characterizes the context within which bioethical issues arise, realistic options tend to be diminished. Moreover, tensions among possibly conflicting ethical principles come to the fore and become very difficult to resolve.

Located in Southeast Asia, the Philippines is a developing country – an archipelago of 7,107 islands with an estimated population of 92 million people. It is a lower middle-income country with a wide chasm between the rich and the poor. In spite of the poor economic conditions, the country has a high literacy rate of 95 % for both men and women. Although many economic indicators have improved in the last two decades, the failure of wealth distribution has left millions of Filipinos mired in poverty. There was an increase of about 185,000 in the number of poor families – from 3.67 million in 2006 to 3.86 million in 2009. This meant an increase by almost 970,000 individual Filipinos from 22.2 million in 2006 to 23.1 in 2009.

If poverty were to be understood to include the impact of food sustenance and income on quality of life and human development, then the country has a long way to go before it can attain the United Nations' Millennium Development Goal of eradicating poverty. Poverty has become one of the important lenses for examining issues of bioethical significance. Its impact on the donation or selling of human body parts for transplantation has been documented. For many, it has been a big factor in deciding on end-of-life options, and we are familiar with economically informed dilemmas pertaining to the retention or withdrawal of life support systems among terminally ill patients. We also hear plenty of stories about difficulties in accessing health care because of the absence of comprehensive health insurance.

Migration of Health Professionals

The imbalance between the capacities of rich and poor countries to maintain a decent level of health-care services will continue to highlight the injustices that bioethics discourse has largely ignored. In the Philippines, the related issues have been openly debated. However, they are often looked upon with an economic rather than an ethical eye. Migration brings economic opportunities not only for the Filipino workers who move abroad but also for the rest of the country in terms of increased purchasing ability and its impact on local production and on related industries. A lot of people are thus satisfied with the economic outcomes of health manpower *outmigration* while they remain oblivious to its impact on local health-care delivery.

The situation with nurses has grabbed the attention of national health officials as well as the general public. The fact that the country spends a huge amount of its scarce educational resources to train nurses only to find those nurses serving foreigners abroad rather than Filipinos in their own country constitutes a glaring injustice in the eyes of many locals. Out of all nurses trained in the Philippines, only about 15 % remain in the country to serve local patients. The country has been the biggest source of nurses worldwide with up to 85 % of its nursing graduates going abroad to find jobs in the United States, the United Kingdom, Saudi Arabia, Libya,

United Arab Emirates, Ireland, Singapore, Kuwait, Qatar, and Brunei. During a critical period, the hemorrhage of nursing talent left many local hospitals severely understaffed, with 200 hospitals being forced to close between 2003 and 2005. A shortage of doctors and nurses also resulted in hundreds of hospitals having to stop operating some of their wards during the same period. The magnitude of the problem was also evident in the deterioration of the nurse to patient ratio to a level of one nurse to between 40 and 60 patients during the given period. This development has been thought to have resulted in other health-care anomalies: (up to 70 % of deaths between 2002 and 2003) taking place without the benefit of medical attention and the immunization rate among children going down to about 60 % in 2003.

In addition to nurses, physicians, physical therapists, occupational therapists, laboratory technicians, and other health-care professional have been joining the human resource migration bandwagon. At the turn of the millennium, Filipino nurses were in such demand in some developed countries that local medical doctors were enticed to switch careers in order to improve their chances of overseas employment. The effects of the health-care labor market have been truly unsettling for economic plans and, in many cases, for individual dreams. Health worker migration clearly points in the direction of unsettled bioethical issues that ought to be debated with sobriety even as the situation has given rise to impassioned calls for effective and immediate steps to stop the hemorrhage of health-care human resources.

The outward migration of health workers arises as a bioethical concern because justice demands that health-care services of sufficient quality and quantity be made available to Filipinos across different economic strata. The outflow of manpower has led to a lack of capacity to provide local health institutions with health-care manpower resources having the necessary skills and experience. When very new health-care workers are recruited to take over the work left by senior counterparts, overall quality is sacrificed and the cost of services even rises because there is limited supply relative to the demand. The Philippines (as well as other supplier countries) is left to provide stop-gap solutions, while the recipient countries receive a huge boost to their own capacity to provide skilled health care within their already thriving health infrastructures.

This draining of competent health-care workers has been blamed for an insufficient supply that has had a negative impact on the quality of health services, the morale of local nurses, the capacity of hospitals to cope with patient care demand, and the well-being of patients within the health-care system. However, the situation is complicated further by the active encouragement of migration coming from the national government as it takes into account the contribution of remittances from overseas workers to the economy. Clearly, economic considerations take top priority. The injustice is overlooked when the price is right.

One analysis of the situation tends to pin the blame on health workers themselves. The idea is that, having been subsidized greatly by the national educational system, health professionals ought to repay the cost of their training by rendering their services to the country. Another view finds blame in the national government

for neglecting to provide enough incentives to keep health-care workers at home and for promoting an outlook that sees health-care workers as assets who can bring economic resources to the country through their remittances. Then there is the view that focuses attention on the effects of international recruitment programs tempting developing country health-care workers with salary offers that are too good to refuse. These perspectives are tied to ascriptions of blame and responsibility that reflect dissatisfaction with migration trends. They also represent an ethical outlook that conflicts with a purely economic valuation of impact and outcomes. Each perspective correctly calls attention to an important facet of a nagging global phenomenon. However, one must also take into consideration the economic realities that various stakeholders have to contend with. There is an urgent need to discuss these outlooks openly but without presuming that the situation with regard to the movement of health-care professionals across national boundaries is a purely economic matter that can be resolved by determining how best to increase material wealth. It makes good ethical sense to undertake a broad assessment of where responsibilities lie. The possible causal factors for the problems that are being experienced are many, varied, and complicated. Some of these factors transcend national boundaries. It appears that assessment of responsibility should consider not so much who ought to be blamed but who could be in a good position to do something about the situation. Some kind of collective governance appears to be in order. The problems are global, and the root causes have global origins. Source countries and destination countries have their share in giving rise to these problems, and they must have their fair share in seeking to provide solutions not only for their respective concerns but also for other matters arising at either end of the migration process. This would entail fair and equitable bilateral and multilateral arrangements for recruitment and international deployment that acknowledge direct economic, social, and ethical responsibility on the part of destination countries for the effects of their recruitment on the source countries. A limited insular approach that only takes into account the interests of the parties separately will be not only ineffective but also unethical for failing to consider the full impact of prevailing policies on populations that inevitably have to suffer unpalatable consequences.

Bioethical Activism

Medical controversies often serve as catalysts for public debate on bioethics issues. The controversies catch public attention and engage people's imagination while also inviting media coverage. Bioethics discourse tends also to take the cue from exploding controversies However, the discourse often is associated with academic reasoning and medically related law as the venue is provided by academic institutions and publications. Still, it is important not to lose track of developments outside an academic context as these developments reflect a perspective that could be very different from realities portrayed by academics and expressed in academic verbiage. Bioethics discourse outside the academic community could be very lively and exciting. Using a language that perhaps lacks the clarity, consistency, and

sophistication of academic scholarship, it should not be discounted nevertheless, and its importance should not be diminished. Academics ought to try to understand popular bioethics discourse without having to reduce such discourse into academically precise formulation. While academic discourse is meant to appeal to academically established reasoning, lay discourse understandably appeals also to the feelings, emotions, and folk values that people have to deal with in their daily lives. Public discourse also tends to have a greater political impact that results in policy formulation.

It is important to make this clarification about varying bioethical perspectives (or various levels of bioethical discourse) if only to explain the phenomenon that is referred to here as bioethical activism. This phenomenon is explained in part by this distinction between levels of discourse but also by the intensity of people's commitment to competing bioethical values, beliefs, or principles. One aspect of this activism relates to the prominent role that nongovernmental organizations have assumed in society on matters having to do with health concerns that easily give rise to bioethical issues.

Bioethical activism has also been manifested in the efforts of local government officials to use their political power to propagate religious values. The Philippines is a constitutional democracy that recognizes the separation of church and state. Religious authorities are barred from holding positions in government or to run for elective posts. In the few instances when men of religion have pursued political positions during elections, they have had to give up their religious positions as a prior condition. However, this separation has tended to be challenged in relation to bioethical issues of reproductive health. The reference goes beyond conscientious refusals on the part of some government officials to engage personally in activities seeking to promote the use of contraceptive or similar devices that are regarded by the Catholic Church as contravening religious precepts. Behavior of this type is quite common and is to be expected. Government physicians have invoked conscientious objections in refusing to carry out tubal ligation or even some cases of abortion when mothers' lives were under severe threat.

Among other things, "bioethical activism" refers to efforts of government officials to impose their religious convictions on others by administrative or legislative fiat. The efforts go beyond merely trying to convince or influence and is more akin to coercion.

As mayor of the city of Manila in 2000, Joselito Atienza threatened to arrest government officials who introduced RU-486 (Mifepristone) to the city. He rationalized his order by citing a duty to enforce the provision of the constitution protecting the unborn from the moment of conception. Atienza issued an Executive Order entitled "Declaring Total Commitment and Support to the Responsible Parenthood Movement in the City of Manila and Enunciating Policy Declarations in Pursuit Thereof." City Health Department officials used the Order as basis for refusing the use of condoms, birth control pills, intrauterine devices, and surgical sterilization in the city's reproductive health initiatives.

The official stance was carried over to the next city administration. As a result, some residents decided to sue the city because of the practical impact of the policy.

The complainants decried the lack of birth control pills and other contraceptives at health centers. One mother said she already had six children because she could not afford to buy the pills on her own. According to the complainants, the policy prejudiced their right to health and well-being and resulted in deteriorating reproductive health outcomes – the policy deprived them of access to health care and health development and resulted in numerous pregnancies.

In other jurisdictions (and at about the same time that Mayor Atienza was in power), the governor of the province of Laguna and the mayor of the city of Puerto Princesa also initiated similar policies limiting support for family planning (FP) clinics providing only "natural" FP methods to their clients. Thus, some local government officials have engaged in their own brand of political activism. This kind of establishment-based activism should not be looked at in the same vein as activism on the part of nongovernmental organizations that are expected to support their advocacies in a way that does not depend on the use of government resources. When officials who have government resources at their command use those resources in a way that promotes advocacies based on their religious or ideological leanings, they betray the trust of the electorate by imposing, rather than democratically espousing, ideological perspectives. Thereby, they bring a disservice to the cause of democracy and fail to advance free and enlightened bioethical discussions. The practice does not necessarily help to cultivate an ideal context for bioethical maturation and advancement.

Through bioethical activism, individuals or groups try very hard to improve the situation and make things happen in accordance with their sense of what is right. This is potentially a very powerful tool for political involvement within a democratic society. However, society also has to ensure that activism takes place within a framework of objective, enlightened, and free deliberation and debate.

Measures and Resources Developed Over Time

Teaching of Bioethics at University and Other Levels

Formal teaching of bioethics and the corresponding offering of academic degrees have been going on in the country at the University of Santo Tomas (UST) and the University of the Philippines. The University of Santo Tomas (UST), the oldest Catholic university in Asia and a pontifical university that has roots deep within the Catholic tradition, was the first to offer academic degrees. The Department of Bioethics at UST has been part of the Faculty of Medicine and Surgery where it seeks "to stimulate future physicians to develop mature moral reasoning and to act in accordance with principled moral judgment thereby developing the attitude of a competent and compassionate Catholic physician." In addition to offering degrees, the Department of Bioethics seeks to educate medical students on bioethical issues in order to enable them to identify, define, and apply bioethical concepts and principles. Medical students go through a longitudinal bioethics program,

where they are taught basic bioethical principles, attitudes, and virtues in the first of a 4-year curriculum. Second-year medical students undergo a course on "Healing and Caring for Patients" that covers a broad range of topics including the beginning of life, death and dying, organ transplants and justice in the allocation of scarce resources, the human genome project, genetic manipulation, genetic engineering, prenatal testing, genetic counseling, and embryonic stem cell research. Third-year medical students are taught about the dynamics of the physician's relationship with the various stakeholders in a medical and hospital setting. Lessons also deal with the rights of patients, human rights, bioethics committees, and the role of physician in advocacy. Fourth-year students, referred to as medical clerks, present clinical cases and analyze them from a medical and ethical perspective with the assistance of the teaching staff and invited resource persons.

A Master of Science Program in Bioethics has been on offer at the University of the Philippines since 2006. The Program, jointly developed by two autonomous campuses of the national university, was set up with generous financial support coming from the United States National Institutes of Health – Fogarty International Center. It is a unique program in that graduates earn a dual degree that is granted both by the College of Medicine, which is based at the health sciences campus in Manila and the College of Social Sciences and Philosophy, which is based in a different autonomous campus in Quezon City. In addition to the Master of Science (Bioethics) degree program, the partnership of the two campuses has led to training programs in Bioethics and Research Ethics conducted throughout the country since 2001. These programs have been useful in educating members of ethics review committees, bioethics teachers, researchers, research administrators, and health-care professionals. Support from the Fogarty International Center has also enabled the training program to benefit professionals from other Southeast Asian countries.

Before the establishment of the Master of Science Program, a Diploma Program in Bioethics was offered as a 24-unit, postbaccalaureate degree in 2004. Many of the students had professional backgrounds and occupied key positions in the academe, health-care institutions, and government. Some of the graduates have gone on to serve on the Philippine Research Ethics Board, representing their professions and fields of expertise. Others have returned to their respective institutions to teach bioethics courses.

Other than the degree programs, short courses of various types have been offered by governmental and nongovernmental organizations, including the University of the Philippines Bioethics Training Program, the National Institute of Health, the Philippine Health Research Ethics Board, the Philippine Council for Health Research and Development, and the Bioethics Society of the Philippines. Collaborative initiatives among these institutions have also been quite common as they try to fill the bioethics training and educational needs that arise across the country. Courses on offer have been designed for the variable requirements of ethics review committees, researchers, research ethics monitors, and others involved in the ethics review chain throughout the country.

Collaboration between local and international institutions has also been a factor in enhancing bioethics capability in the Philippines. International conferences have

been organized with the support and participation of the United National Educational, Scientific and Cultural Organization (UNESCO), the World Health Organization (WHO), the European Union and the European Community, the Forum for Ethics Review Committees in Asia and the Pacific (FERCAP), the International Association of Bioethics (IAB), and the Asian Bioethics Association (ABA). Individuals and official representatives from the country have also participated in international activities organized abroad by the above-mentioned organizations. Some have taken on prominent leadership roles in the UNESCO International Bioethics Committee, the IAB, the ABA, and FERCAP.

Since nursing education is a very huge part of the health-care training burden in the country, it is worth noting that the Commission on Higher Education issued a memorandum in 2009 requiring bioethics to be part of the Bachelor of Science curriculum. To improve capability in this regard, the University of the Philippines has offered training programs for bioethics teachers in nursing schools.

Ethical, Legal, Social Issues (ELSI) Program, Philippine Genome Center

An Ethical, Legal, and Social Issues (ELSI) Program was established in 2011 in conjunction with the Philippine Genome Center. The ELSI Program was organized for the purpose of mapping a series of workshops for scientists, researchers, and legal scholars to identify and propose solutions to current ethical, legal, and social challenges for genomic research in the. The Program also has a mandate to take up governance, security, utilization, and sharing issues pertaining to genomic sample and data repositories, including those obtained from the newborn screening program. In addition, the Program could deal with issues of informed consent, privacy, confidentiality, public health concerns, and intellectual property. It is also expected to deal with the regulation of genetic tests and products directly marketed to the public, agricultural applications of genomics, the nonmedical use of genomic information (e.g., forensic, litigation, paternity, migration patterns), the practice of genetic counseling, and the conduct of public education.

Bioethics Committees

National Ethics Committees

Foremost among the bioethics bodies currently existing in the country is the Philippine Health Research Ethics Board (PHREB). This national body has been charged with the task of promoting the ethical conduct of biomedical and behavioral research. Having quasi-regulatory and monitoring functions, the body heads an ethics review infrastructure that also consists of regional ethics boards and institutional ethics review committees. With the Philippine Council for Health Research and Development providing its secretariat, PHREB lies at the core

of the Philippine National Health Research System as it undertakes its functions among researchers and research institutions working with the Department of Health, the Department of Science and Technology, the Department of Education, and the Commission on Higher Education. PHREB's guidelines are also observed in the conduct of health research by private individuals and institutions.

PHREB's functions were originally exercised by the National Ethics Committee, a body that was originally created in 1985 under the Philippine Council for Health Research and Development. After the research functions of the Department of Health and the Department of Science and Technology were integrated under the Philippine National Health Research system in 2003, it became necessary to set up a more broadly based body to take over the NEC's functions, with a supporting regional infrastructure. Shortly after taking over the ethics regulatory and monitoring functions, the PHREB conducted consultations leading to the revision of the National Guidelines for Biomedical and Behavioral Research in 2006. A training program for members of institutional ethics review committees was implemented nationally. In 2012, PHREB released the fourth edition of the national guidelines. This latest revision attests to the continuing effort of PHREB to keep up with rapidly changing health-care science and technology. In addition to general guidelines that offer heath research in general, the new guidelines have specific provisions regarding the most recent developments in biomedical research.

Not having a single national body to preside over matters of bioethics, the government's response to controversial developments in medicine and the biological sciences has been compartmentalized. There has been a National Transplant Ethics Committee (NTEC) for about a decade, with specific functions pertaining to the ethics regulation and monitoring of organ transplantation. It has been organized and reorganized several times in the past 10 years as authorities have struggled with effective remedies for dealing with problems such as organ selling, human trafficking, and various practices involving the coercion and deception of donors. Several reincarnations of the NTEC have failed to provide it with the autonomy fitting of a national body of such importance. The NTEC has a mandate to oversee the work of institutional transplant ethics committees on the basis of self-proposed national guidelines. However, its proposals are subject to the higher approval of the Philippine Board of Organ Donation and Transplantation (PBODT), thus preventing it from implementing its mandate independently, or without the interference of a higher body made up of members with conflicts of interest. It seems that in an effort to satisfy the desire of various stakeholders to be represented in the bodies that are being established to monitor and regulate the practice of organ transplantation, the government has inadvertently allowed conflicted interests to be entrenched and to put the integrity of transplant ethics under a cloud of doubt.

Relevant Legislation

The Philippines has been thin on legislation having significant impact on matters of bioethics. Perhaps because of the attention that the two houses of congress have had

to give to economic measures, they could not give much time to matters of bioethics. The most prominent that can be mentioned – and the one with the greatest impact – is the constitutional provision for protection of the unborn from the moment of conception. This provision was written into the basic law when it was rewritten in 1987, thus bolstering the basis for an old law that renders abortion as a criminal act.

Known as the "Generics Act of 1988," Republic Act No. 6675 was passed to promote, require, and ensure the production of an adequate supply, distribution, use, and acceptance of drugs and medicines identified by their generic names. As an item of social justice legislation, the Act meant to ensure the production of drugs with generic names at the lowest possible cost and endeavor to make them available free for indigent patients. It took 20 years before Republic Act 9052 or the Universally Accessible, Cheaper and Quality Medicines Act of 2008 was signed into law by the president. The latter Act sought to provide access to essential medicines through a combination of measures that were strongly opposed by the pharmaceutical industry for what its members characterized as restrictions on free enterprise.

Republic Act 9288 provides all Filipino newborns access to screening for congenital metabolic disorders. Known as the "Newborn Screening Act of 2004," the legislation mandated the National Institutes of Health to create the Newborn Screening Reference Center (NSRC), with the responsibility to be the repository of technical information relating to newborn screening.

The Philippine AIDS Prevention and Control Act was passed in 1998. It sought to protect infected individuals from discrimination and injustice in various ways. The Act prohibits compulsory HIV testing as a precondition for a broad range of rights and services including employment, admission to educational institutions, exercise of the freedom of abode, entry to or continued stay in the country, travel, or the provision of medical or any other kinds of service.

Republic Act No. 7170 Authorizing the Legacy or Donation of All or Part of a Human Body after Death for Specified Purposes provides the basic legal framework for the retrieval of organs for transplantation. It allows the declaration of death to be made on the basis of cardiac and respiratory functions or on the basis of brain functions.

Equal significance may be attached to unsuccessful attempts at legislation. Efforts to legislate a basis for advance directives illustrate the caution that has attended deliberations by lawmakers on Bills relating to bioethics. After the current constitution came into force in 1987, Bills seeking to provide a legal framework for advance directives have been filed every legislative cycle. None of these Bills have been passed. All efforts to enact a law defining and penalizing medical malpractice have also failed. When a malpractice Bill gained strong public support in the 1990s, it still ended up as a failure because of strong opposition by medical practitioners. The experience proved the dominant influence of the medical community and the power it wields on policy makers. It also showed that the medical community will do its best to prevent external review of decisions commonly made by medical practitioners.

In the 14th Congress, Senate Bill (SB) No. 812, "An Act Declaring the Rights and Obligations of Patients and Establishing a Grievance Mechanism for Violations Thereof and for Other Purposes," was also unsuccessful. Known as the "Magna Carta of Patient's Rights and Obligations," it sought to recognize the following as basic rights of patients: right to appropriate medical care and humane treatment, right to informed consent, right to privacy and confidentiality, right to information, right to choose health-care provider and facility, right to self-determination, right to religious belief, right to medical records, right to leave, right to refuse participation in medical research, right to correspondence and to receive visitors, right to express grievances, and right to be informed of his rights and obligations as a patient. Aside from the individual rights, the Bill also identified societal rights of patients: right to health, right to access to quality public health care, right to healthy and safe workplace, right to prevention and education programs, and right to participate in policy decisions.

Access to Cheaper Medicines

To make medicines affordable and accessible to the poor, the Philippine legislature passed the Generic Drugs Law in 1988 and the Universally Accessible Cheaper and Quality Medicines Act of 2008. The Generic Drugs Law requires the use of generic terminology in the importation, manufacture, distribution, marketing, advertising and promotion, prescription, and dispensing of drugs. Pharmaceutical companies operating in the Philippines have been required to produce, distribute, and sell generic counterparts for medicines they produce while all medical, dental, and veterinary practitioners have been required to use the drugs' generic names in writing prescriptions. Pharmaceutical companies have also been mandated to indicate generic names prominently in their products. Nevertheless, the generics initiative has had, on its own, very little success in making essential drugs widely available to the population. Before the passage of the Cheaper Medicines Act of 2008, as many as 7 out of every 10 Filipinos were thought to have no regular access to lifesaving drugs. Moreover, the country ranked second only to Japan in the cost of critical medicines. Relative to economically comparable India and Pakistan, some drugs are priced 5–45 times higher in the Philippines. Thus, we see why there is no regular access to drugs. The situation has made it quite easy to provide ethical justification for taking unusual legislative and regulatory steps to make lifesaving drugs available to those in need.

The Universally Accessible Cheaper and Quality Medicines Act of 2008 has put together several remedies to deal with the access and cost issues. The Act (a) provides for the parallel importation of patented medicines from foreign markets where these are available at a lower cost; (b) prohibits the grant of new patents where these based only on newly discovered uses of an already known drug substance; (c) enables the testing, production, and registration of generic versions of patented drugs by local generics firms; and (d) allows government use of patented drugs when public interest is at stake. In addition, the Act gives the president the power to set price ceilings on essential drugs.

Multinational pharmaceutical companies lobbied very strongly against the passage of the Bill when it was still being debated. They invoked, among other things, the country's commitment to a free enterprise economy. On the other hand, government instrumentalities argued that this commitment was easily outweighed by the very persuasive medical reasons as well as by considerations of social justice.

Newborn Screening

Considering that the government has not been able to provide sufficient medical coverage to its citizens, it is quite surprising that the Philippines has put in place a national newborn genetic screening program that has been mandated by legislation. It is equally surprising that the legislative process leading to the enactment of the Newborn Screening Act occurred without inviting adverse publicity. The Law provides all Filipino newborns access to screening for congenital metabolic disorders. It has also provided for the creation of a Newborn Screening Reference Center (NSRC), with the responsibility to be the repository of technical information relating to newborn screening. Medical assistance is meant to be given to newborns detected with life-threatening congenital metabolic disorders before the onset of the clinical symptoms.

Under the Law, parents are required to present their children for newborn screening except when they have religious objections. And if they refuse, Article 3, Section 5 of the Act requires them to acknowledge in writing that their decision "places their newborn at risk for undiagnosed heritable conditions. . . ." This hardly leaves parents with a choice, although an alarming number of families are known not to be able to afford the cost of screening. Moreover, it is not clear that parents are properly educated about the procedure and its implications or that there are qualified counselors to give proper advice. Meanwhile, samples collected for screening have accumulated, thus presenting temptations for their use even before ethical guidelines could be clearly formulated.

Major Bioethics Issues and Discussions

Abortion

Notwithstanding the legal prohibition and the firm opposition coming from the Catholic Church, an increasing number of induced abortions are being close to half a million taking place each year, and about 800 women die annually from unsafe abortions. One out of every three women who unintentionally get pregnant seeks an abortion, most of them poor and reporting themselves to be Catholics. Many of them rely on nonmedical personnel for help in ending their pregnancy. Only about 30 % obtain an abortion from a medical doctor. Obviously, socioeconomic factors play the key role in the decision to abort.

The alarming experience with unintended pregnancies and induced abortions may partly be due to a failure to legislate and implement a good reproductive health program that makes options available to women and gives them reliable information regarding those options. The Reproductive Health Bill currently being debated in Congress seeks to enhance women's options, but it remains to be seen whether the Bill will generate sufficient support to stand up to the opposition presented by the Catholic Church. If it does, we can say that the country is truly on the way to the maturation of its collective bioethics sense.

Reproductive Health

The Philippines has had to deal with the economic impact of its huge population and robust population growth rate over several decades. It has gone through a series of population control programs but has never succeeded in lowering the rate at which its population has grown. Starting out as a poverty-alleviation strategy in the 1970s, the family planning program became part of a combined social welfare and health initiative in the late 1980s. Recently, it has emerged as a reproductive health program seeking to balance the population, the available resources, and the environment. Faced with a population growth rate of 2.5 % and an estimated current population of close to 100 million, the government has taken initiatives to address population management as a poverty-alleviation, health, and development strategy. Many people feel that the population figures reflect a sad state of reproductive health that is also characterized by a surprising number of unintended pregnancies, induced abortions, and maternal death.

The Local Government Code of 1991 empowered local governments to undertake initiatives in their specific jurisdictions to deal with critical health issues. As a result, ordinances relating to reproductive health have been passed in some municipalities in the Philippines, the most prominent of which have come as a response to church lobby. Obviously, the Catholic Church has been busy promoting adherence to its core principles relating to reproduction: (1) The use of "artificial obstacles" to prevent the formation and birth contradicts the idea that "human life is the most sacred physical gift" from God, and (2) Parents have the "primary inalienable right and responsibility" to care for, nurture, and educate their kids.

In Quezon City, the response went against the expectations of the Catholic Church. While the ordinance reiterated the prohibition on abortion, it sought to make access to reproductive health information and services available to all, which included even the "nonnatural" means that the Church opposed. The ordinance also allocated funding for basic services that included adolescent health education beyond the confines of the family. The other ordinances in the city of Manila and the provinces of Palawan and Laguna supported only "natural" methods of birth control. The most controversial among the lot was an ordinance passed by the barangay council of a place called Ayala Alabang. The barangay is known to be a residential area for some of the country's rich and famous.

On January 3, 2011, Barangay Ayala Alabang passed an ordinance seeking to protect the unborn and the institutions of marriage and the family by penalizing any natural or juridical person who would advertise, endorse, prescribe, or distribute abortifacients where abortifacients were defined as "any device, medicine, substance, or practice which may damage, injure, interfere with the natural development, endanger or cause the expulsion or death of an unborn child." Abortifacients included intrauterine devices (IUDs) and hormonal contraceptives. The ordinance also required that contraceptives (including condoms) be sold only to consumers with a written prescription. This last provision easily caught public attention and resulted in a backlash that would have made the members of the barangay council regret their moment of legislative adventurism. The controversy that the ordinance generated showed that bioethical activism is alive and vibrant.

End-of-Life Issues

Advanced Directives

In November 3, 2010, Senate Bill 2573, the "Advanced Directives Education Act," was introduced by Senator Miriam Defensor Santiago that required the Secretary of Health to "develop and implement a national public education campaign on the importance of advance care planning and of an individual's right to direct and participate in his or her health care decisions" no later than January 2012. The Bill recognized the importance of having an advance directive that reflects the patient's values and wishes for care. It stated the right of the patient to direct and participate in his health-care decisions. It also spoke of the need for an ongoing dialogue among the family members, relatives, health-care proxies, and health-care providers to determine and be guided on how to come up with health-care decisions especially when the patients are already unable to express his/her wishes. The Bill calls on the Department of Health to employ the use of media materials and culturally and linguistically appropriate information to raise greater public awareness of advance care planning.

The passing of the Bill would have signified progress on the way to overcoming the paternalistic tendencies in Philippine hospital settings where many patients accept leave all decisions to doctors almost without regard for their own wishes and values. Thus, even if patients and families are instructed and encouraged in hospitals to assert their rights, further efforts need to be undertaken to truly enable them in this regard.

The filing of the above Bill acquires particular significance in view of the experience with proposed legislation seeking to provide a clear legal framework for implementing life or death decisions. In the meantime, medical doctors privately speak of cases where they allowed or advised relatives of patients to take matters into their own hands by pulling the plug themselves when they were convinced that further treatment was futile. Problems also arise when patients no longer could afford the cost of hospitalization and are forced to check out of the

facility even at the risk of death. Few hospitals have clearly laid out rules regarding the release of patients against medical advice although the practice goes on without much controversy. Even in situations when further treatment could still reverse the likelihood of a fatal outcome, economic factors dictate unpalatable decisions that hospital administrators have learned to recognize as part of everyday reality. In this kind of settings, futility could be seen in relation to economic rather than merely (or mainly) medical indications.

HIV/AIDS

The threat of HIV/AIDS gave rise to a legislative response in the 1990s that showed a highly mature bioethical sense. At the same time, the Department of Health thought it useful to draw attention to the problems the country was facing by engaging the help of a patient who was to go around the country and provide a "face" to the disease as authorities explained the imperative for cautious sexual behavior and for treating victims with care and compassion. For this purpose, the government selected a young female patient who had previously engaged in sexually promiscuous behavior. The young woman was to take on the task in the Philippines that a highly popular and successful basketball player had performed in the United States. While this gimmick succeeded in calling attention to the disease and the problems that came with it, the effect on the young woman herself was a tragedy. The public attention seemed too much for her to bear as continued to engage in unprotected sex with multiple partners. She finally settled down with an equally young partner with whom she bore a child, and their collective life story provided a touching and very educational illustration of the problems that HIV/AIDS victims faced.

Passed in 1998, the Philippine AIDS Prevention and Control Act sought to protect infected individuals from discrimination and injustice. The Act prohibits compulsory HIV testing as a precondition for employment, admission to educational institutions, exercise of the freedom of abode, entry to or continued stay in the country, travel, or the provision of medical or any other kind of service. It also protects the right of HIV/AIDS patients to seek an elective or appointive public office, to access credit and insurance, to receive health-care services without additional cost, and to decent burial services. There is also a clear commitment to privacy and confidentiality, as the Act requires HIV testing to ensure anonymity. Even though it provides for the mandatory reporting of HIV/AIDS cases to authorities, the Act provides for the "confidentiality of any medical record, personal data, file, including all data that may be accessed from various data banks or information systems." The use of information in data banks and information systems is limited to statistical and monitoring purposes.

Seeing the utmost regard to protect the rights of patients in the Act, it is quite ironic that this concern has not been reciprocated by countries with whom Filipinos have had to relate in their capacity as overseas workers. Filipinos who are seeking to find work in other countries have had to put up with the requirement for

HIV/AIDS testing as part of their application. It is also ironic that many reported HIV infections in the country have been imported from overseas by Filipino workers. As the country complies with international standards for the ethical management of HIV/AIDS, it finds its own citizens shortchanged when those standards are not maintained in countries served by Filipino workers.

Assisted Human Reproduction

Assisted human reproduction is a practice that has gone on mainly beyond public bioethical scrutiny. Local practitioners are mostly those who have established their practice in the country after having undergone training in fertility clinics abroad. They have brought with them not only the technology but also the ethical framework that provided the context for their practice abroad. As they operate on the basis of the same protocols that guided their training abroad, many of them may not be fully aware of the ethical implications of transporting a practice to a sociocultural environment that is not necessarily informed by the same values and traditions.

There has not been much awareness of the practice in the country, and this probably explains why there has not been much public discussion of ethical issues surrounding the practice in the local setting even as the first delivery of a child conceived through the use of either assisted insemination or in vitro fertilization (IVF) took place in 1996. The National Ethics Committee anticipated this development when it included in the 1995 edition of the National Guidelines for Biomedical/Behavioral Research provisions pertaining to the use of and research on embryos. In particular, the 1995 guidelines sought to prohibit the intentional creation of human zygotes, embryos, or fetuses for study, research and experimentation, or for commercial and industrial purposes; to limit research on an embryo to procedures intended to improve its life and health; to prohibit the sale of human gametes or zygotes; to limit the application of assisted reproductive procedures to married couples; to direct medical practitioners to ensure the emotional stability and maturity of beneficiary couples; to uphold the dignity and anonymity of the couples involved; and to prohibit the selective reduction of embryos.

The guidelines issued by the Philippine Society of Reproductive Endocrinology and Infertility (PSREI) in 2006 allow the use of techniques that utilize preconception sex preselection but with a qualification that does not allow "embryonic gender identification for social reasons alone." Operationally, this means allowing preimplantation genetic diagnosis for embryonic gender identification only in cases where there is a strong family history of sex-linked genetically transmissible disease (hemophilia, muscular dystrophy, etc.).

An effort to satisfy the Catholic position is also evident as the guidelines mention that "the zygote, pre-embryo, or embryo, are already considered unique human beings and are therefore entitled to full moral support as that of an adult." Couples undergoing the procedure are expected to give prior agreement to cryopreservation of excess embryos, but it is not clear how this could be sustained over prolonged

periods. There is also an expectation of minimal stimulation of ovarian follicles so that all embryos formed are transferred during the fresh cycle in order to avoid fetal reduction.

While official Catholic thinking is reflected in the recognition that the zygote, pre-embryo, or embryo is a unique human being entitled to full moral support, the guidelines appear to get into some contradiction by accepting "pre- implantation Genetic Diagnosis, whether carried out on gametes or embryos. . .when carried out to identify specific genetically transmissible abnormalities to help couples avoid the possibility of having abnormal children." One also wonders what could be meant operationally by the provision in the same section that "the disposition of the genetically abnormal embryos shall be the responsibility of the couple and shall be ascertained before the evaluation is done." These provisions of Section 24 appear to open the door for exceptions to a traditional interpretation of Catholic doctrine. It seems that specific guidance pertaining to the implementation of the guidelines under certain conditions is necessary.

Organ Transplantation

Organ transplantation is one of the areas of health care that have drawn the attention of lawmakers in the country. The story of bioethics pertaining to this field has unfolded in various stages corresponding to headline-worthy controversies. During the early period of its introduction into the country, organ transplantation elicited adverse publicity as it became known that prisoners were being recruited to serve as organ donors. Pioneer practitioners spoke of going to prisons to find donors unaware of the ethical considerations and the controversy that this could generate. Anecdotes of prisoners being given monetary compensation and material rewards for transplantable organs circulated. Nevertheless, authorities could not react readily in the absence of a clear and explicit ethical or legal framework that could be applied. Some reports were documented by foreign researchers.

The passage of Republic Act No. 7170 Authorizing the Legacy or Donation of All or Part of a Human Body after Death for Specified Purposes provided the initial legal framework for the retrieval of organs for transplantation by allowing the declaration of death to be made on the basis of cardiac and respiratory functions or on the basis of brain functions. A person could be declared dead in the absence of unaided cardiac and respiratory functions or in the event of the irreversible cessation of all functions of the entire brain, including the brain stem. The Law also gives heads of hospitals permission to authorize the retrieval of organs from brain-dead patients whose relatives could not be located after reasonable search.

The first case that brought the provisions of this Law into public attention arose after transplant physicians were sued for removing the kidneys, liver, and pancreas of a brain-dead accident victim. The relatives of the victim went to court as they failed to appreciate the legal implications of brain death. This happened after they discovered that the subject of a newspaper story about a successful multiple-organ transplant was actually the relative they were looking for. Surprised that the

transplant could take place without their consent or that of the donor, they accused the doctors of committing murder. For them, their relative was not "truly dead" when his organs were taken – he was only "brain-dead." It was one thing for a person to be dead in the eyes of the law and another thing to be dead in the eyes of loved ones, especially when taken in the context of organ retrieval for unconsented transplantation. The doctors were eventually acquitted but only after months of adverse publicity that effectively scared potential organ donors away as organ transplantation ground almost to a halt. More controversial developments were to follow.

The next controversy erupted when living donors grew quickly in number and filled the transplantation demand in a way that cadaveric organs could not. A massive trade in organs in various communities in Metropolitan Manila. The program host interviewed freshly scarred impoverished men from slum areas in Manila who had sold their kidneys. The donors jumped at the opportunity to make money in such amounts they had never seen previously in their entire lives. Some of the organ vendors were happy with the result, but most were not. Many soon realized that rather than monetary gain, they were left with debts still unpaid and an economic predicament no better than they were in prior to the organ sale. Many of them were also stigmatized, discriminated against in the search for jobs, and left to deal by themselves with the emotional and social scars resulting from their experience. People quickly realized that the poor were being exploited, the benefits went only the rich, and the rich were mostly foreigners who came with their valuable foreign currency.

Seeing the inevitability of the unfortunate outcome for paid organ donors, one easily understands why arguments supporting their right to receive payment could not be accepted. The poverty and ignorance of potential recruits clearly are being exploited, and available evidence strongly supports the need to protect them from unscrupulous agents.

Controversy also erupted when the demand for transplantable organs led to a proposal to offer sentence commutation to prisoners who were willing to donate. Because the actual use of prisoners as organ sources earlier had not been documented, the practice did not generate much public attention. The floated proposal did, mainly because proponents genuinely thought implementation could be workable, given the clamor among patients with end-stage renal disease. Much discussed was the example of a death convict who could be given a chance to have the punishment reduced to a life sentence in exchange for an organ to save another person's life. The proposal came from an interested party that stood to gain directly from its approval and implementation – the Kidney Patients Association of the Philippines. A highly placed leader of the Catholic Church expressed support, but no legislator was courageous enough to sponsor a Bill in Congress. The proposal made no further progress, and it appears unlikely now that it would be revived.

The use of support foundations to provide material and medical assistance to kidney donors has been a growing practice. These foundations have been known to ensure the delivery of pre- and post-transplant care to donors who are recruited under their auspices. These nongovernmental organizations are supposed to look

after the donors without situating the provision of assistance within a context of organ trade. However, it has not always been easy to ensure that the foundations have not merely been a cover (deliberate or inadvertent) for commercial transactions. The support given by these foundations includes monetary or other material assistance that could easily serve to incentivize the transactions for the vulnerable poor in a way that exploits their economic vulnerability.

Some of the experiences with these foundations are indicative of how they have been perceived. For example, there are many who have seen these establishments as commercial brokers. On many occasions, donors come to their offices indicating their willingness to make an organ available for a fee and inquiring about terms. Although these foundations insist that they have turned away individuals who have clearly wanted to sell organs, there is no denying the fact that their assistance packages have included money or material equivalents. It is not easy to explain why there is a substantive ethical difference between an outright sale and a donation made with a view to receiving an assistance package with such a material component.

After having donated organs in the past, some donors have been known to come back to ask if there is another organ that they could be asked to donate. Moreover, although donors are advised that they have to come back for follow-up medical examinations after the donation, not all of them actually do, partly because middlemen warn them that they have to make themselves scarce after the procedures to avoid having to answer questions pertaining to the donation that could be incriminating. And some of them are so poor that they would not be able to come back for medical checkups because of the cost involved. It could also be their ignorance of the health risks involved in organ removal that prevents them from coming back.

The latest official development regarding organ transplantation in the country is the release of Administrative Order No. 2008-0004-A by the Secretary of Health declaring the official policy that "foreigners are not eligible to receive organs from Filipino living non-related donors." The Order appears to have put a stop to the travel of foreigners to the country to be transplanted with local organs. However, the initial reaction to this announcement was a flurry of requests for exemption, confirming the extent to which medical tourism for the purpose of organ transplantation was being practiced.

Consistent with WHO guidelines on organ transplantation as well as with the Declaration of Istanbul on Organ Trafficking, current policy in the Philippines has been implemented successfully. In this respect, the country has been able to protect the vulnerable poor from transplant-related exploitation by foreigners. Nevertheless, the use of monetary incentives to recruit organ donors for transplant to local patients still prevails. This practice deserves to be given continuing attention by authorities.

Health Literacy

Article 2, Section 15 of the 1987 Constitution states that "the State shall protect and promote the right to the health of the people and to instill health consciousness among them." The Department of Health has the mandate of creating, regulating,

and promoting the health and health consciousness among the Filipinos through its health representatives in the municipalities.

The strategy of the Department of Health was to aggressively launch its campaigns during those periods when they are most timely. For example, in the rainy season, it will not be surprising to have commercials on *dengue prevention* (hemorrhagic fever) when mosquitoes are most prevalent and when many Filipinos suffer from floods and stagnant waters near their living areas. During the holidays of Christmas and New Year, gory images of amputated body parts caused by firecracker accidents are shown to raise caution on the hazards of their use. One of the most retentive campaigns was the one on the dangers of smoking where they used the catchy phrase "Yosi Kadiri" (roughly translated as "smoking is disgusting") together with its representative mascot. Nowadays, hospitals use the visual illustrations of a smoker's body to instigate a more fearful attitude for their body should they be firsthand or secondhand smokers.

Health literacy programs and awareness campaigns are helped spread by nongovernment organizations. The Likhaan Foundation, an NGO representing women's interests, made a documentary on the implications of the lack of support on modern contraceptives and failure of the government of Manila for a more responsive reproductive health agenda. They presented women who underwent illegal and unsafe abortions because of their unintended pregnancies. Notable also is the network on the Muntinlupa Youth Health Development program that primarily is targeted to improve health-care services and information to the urban poor youth of the municipality of Muntinlupa. The program involves cooperation with various stakeholders within the community including the teachers and the youths themselves.

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Portugal

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Doutora Ana Sofia Carvalho

Bioethics Development

In the last decade, bioethics has gained status and relevance in Portugal. Due to postgraduate teaching, a core of doctors, lawyers, nurses, and others have attained an excellent knowledge and a solid basis for teaching and research activities. Thus, the field is dominated by amateurs, albeit of good will, but rather by people who have acquired experience and skills. This is a novelty, as well as the emergence of academicians with Ph.D. degree in bioethics.

D.A.S. Carvalho
Instituto de Bioética, Universidade Católica Portuguesa, Porto, Portugal
e-mail: acarvalho@porto.ucp.pt

H.A.M.J. ten Have, B. Gordijn (eds.), *Handbook of Global Bioethics*,
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When and How Has Bioethics Started

If the early phases of the development of bioethics are considered as a fast growing new area of science and morals, which independently of its American origins showed a marked tendency to expand in different continents, its beginnings were relatively late in Portugal. In fact, the first organized and structured group devoted to bioethical questions was established in Coimbra in 1988 as a nonprofit-making and independent organization (Centro de Estudos de Bioética) after the founding group had met informally for 2 years. Since then, however, there has been a remarkable evolution, a rapid expansion having occurred, with a relatively large number of graduates enrolling on Ph.D. and master courses. This has led to a considerable number of people of diverse backgrounds (doctors, nurses, philosophers, theologians, teachers, etc.), to acquire solid academic skills in the bioethical area.

Who Have Been the Major Actors/Forces

The main fora of bioethical debate are based in academic institutions and in societies which attract interested people. Curiously enough, universities generally were slow in recognizing the need for bioethical institutions to be created inside their own structures. The first institution responsible for acceptance and diffusion of bioethics in Portugal was undoubtedly the Centre of Bioethical Studies (Centro de Estudos de Bioética), which, since its foundation in Coimbra in 1988 in consequence of an informal think tank which had been working for 2 years, i.e., since 1986, has contributed enormously to the positive evolution of the area in this country. The CEB is an independent, non-confessional, nonprofit organization with a long roster of activities (see below).

The National Council for Ethics in Life Sciences (CNECV) is an advisory board dealing with all kinds of bioethical questions and giving opinions to the Government, National Parliament (Assembleia da República), and President. Founded in 1990, the CNECV has up to the present published 63 opinions on a variety of themes, ranging from medically assisted reproduction or the use of embryos for scientific experiments to obligatory testing for HIV-AIDS, from genetic data management to end-of-life questions, from drug abuse policy to death and transplantation, etc. It is a highly regarded organ and has exerted appreciable influence on the laws passed by the parliament. The chairperson was formerly nominated by the Prime Minister, while the other 20 members were nominated by 10 different entities (parliament and ministries, but also doctors', bar, and biologists' associations, the Academy of Science, and other academic bodies and/or citizens' organizations). Portugal was one of the first European countries to feel the need for a bioethics committee at the national level, established by Law No. 14/90, of 9 June 1990 (amended by Law n° 24/2009, of 29 May). On 29 May 2009, Law No. 24/2009 was enacted. In addition to other changes, the chairperson is currently elected by the members and modifications have also taken place with regard to the entities responsible for choosing the members.

The Centre for Biomedical Law (Centro de Direito Biomédico, CDB), an institute of Coimbra University Law School, has a relatively long history and since 1988 has reflected on problems arising from clashes of interest and the interpretation of deontological codes of the medical (and pharmaceutical) professions and their strict legal aspects and consequences.

The schools of medicine located at the universities of Lisbon, Coimbra, and Porto resorted to various means of teaching medical ethics, but it was only in 1996 that Porto University School of Medicine created a Department of Bioethics and Medical Ethics (Serviço de Bioética e Ética Médica, SBEM); thus for the first time the word bioethics appeared in the curriculum and organization of a medical school. In Lisbon, the School of Medicine was to follow suit, creating a Centre of Bioethics (Centro de Bioética) in 1998.

Nevertheless, the only university department dealing with bioethics in a wider sense, i.e., without conceptual and institutional links with medical teaching, is the Institute of Bioethics of the Portuguese Catholic University, which evolved in 2002 from a preexisting bioethical research group founded in 1995. This does not exclude other university departments from having contributed significantly to bioethical thought. In particular two philosophy departments should be mentioned, namely, that of the University of Azores (in Ponta Delgada) and the one in Braga (Faculdade de Filosofia da Universidade Católica Portuguesa). Both have a curriculum of postgraduate teaching of bioethics and have published books on relevant matters.

The Portuguese Association of Bioethics (Associação Portuguesa de Bioética) was formed at a relatively late stage (2003), the above-mentioned Department of Bioethics and Medical Ethics (University of Porto) maintaining very close personal and institutional links with this association.

Needless to say, all these institutions exert functions which are of relevance to the national evolution of bioethics. This will be summarized in the following sections.

What Have Been the Major Concerns Over Time

What Resources Have Been Developed

It is no surprise that the increase in bioethical activities and the considerable amount of research have resulted in a growing number of publications.

The "Revista Portuguesa de Bioética" (former Cadernos de Bioética), edited by the CEB, is the sole regular journal dedicated to bioethics. It has published quite an impressive array of articles in its 42 issues. Of course, a number of contributions dealing with bioethical questions are regularly published in medical journals, publications of doctors' and lawyers' associations, confessional journals, and cultural magazines. Popular and TV channels give (sometimes sensational) coverage to cases considered to be paradigmatic, such as the Schiavo case or the alleged cloning of human beings. Although people with bioethical knowledge are usually interviewed in this context, the majority of these reports are of poor quality.

Almost 80 books, strictly pertaining to bioethics, have been published in the last decade. These publications range from textbooks to more specialized books, dealing with various themes, like bioethics for nurses or for members of institutional review boards (the existence of which is obligatory in every hospital). Some of the themes addressed include ethics of genetics or of the initial stages of human life, cloning, common good and individual interest, clinical trials, eco-ethics, and assisted reproduction.

Two volumes with comments addressed the text of the European Convention of Human Rights and Biomedicine, as a result of the workshops organized by the Institute of Bioethics; they represent the interest of discussing legal documents (the convention was adopted by Portugal) with wide implications for care and cure. Lastly, collections of monographs, either of papers presented to congresses or representing the work of a sole author, complete the roster of these publications. In this area, the National Council of Ethics for the Life Sciences has launched an impressive series of 10 books with the contributions presented in the seminars which it organizes (besides 12 books containing the opinions presented by this body).

Current Bioethics Infrastructure

Public Debate Activities

Impossible as it is to refer to these in detail, within the remit of this short overview, the numerous activities undertaken by the above institutions will be summarized below.

Large meetings were organized by the Centre of Bioethical Studies (CEB) and the Institute of Bioethics to discuss questions of national relevance and themes with important implications for public policy in such a way that both members of the professional bodies and the general public were able and welcome to attend. Furthermore, in 1997 the CEB organized the European Congress of Medical Ethics Centres. At its Coimbra headquarters and branches in Lisbon, Porto, Azores, Évora, Madeira, and Braga, a number of regular meetings took place to deal with many important questions of bioethical interest. The annual seminaries organized by the National Council on Ethics for the Life Sciences (now in its 11th edition) represent important events and are usually attended by large audiences. The National Congress of Bioethics (now in its 12th edition) meets also annually; the last seven conferences have been organized by the Portuguese Association of Bioethics. There are still a large number of smaller meetings and workshops, often dealing with specialized areas (e.g., vulnerability at the beginning and end of life, teaching of bioethics in secondary schools, problems in the care of premature babies, terminal patients and palliative care, conservation of water resources) and attracting selected scholars. Moreover, scientific societies, lawyers' associations, and lay and confessional organizations often include in their conferences or meetings extra sessions dealing with bioethical questions of special interest to their members. Thus, there are actually several opportunities for either extending one's bioethical knowledge or interesting oneself in or acquainting oneself with the pertinent questions.

Teaching of Bioethics at University and Other Levels

As stated before, the university has been rather slow in recognizing its mission to teach and diffuse the knowledge of bioethics. In fact, only in 1986/1987 was the first postgraduate course on bioethics (dealing with the theme of medically assisted reproduction) launched (by the Faculty of Philosophy of the Catholic University, on its Braga campus). Since then, postgraduate and master courses of much larger scope, encompassing the whole gamut of bioethical issues, have been or are being organized by the above-mentioned universities where bioethics is a recognized constituent of the academic structure. Thus, the Institute of Bioethics of the Catholic University and the Department of Bioethics and Medical Ethics of the Medical School of Porto University each organized seven master courses, the Faculty of Philosophy of the Catholic University and the Centre of Ethics of the Medical School of Lisbon University being responsible for five courses each. As a result, approximately 100 students, after the successful completion of their master's dissertation, have so far been awarded a Master in Bioethics. More recently, the Institute of Bioethics initiated a Ph.D. program, approved by the Portuguese Accreditation Entity from the Ministry of Education, which is now in its second edition; about 10 students already obtained the Ph.D. degree.

At the graduate level, not only the medical schools but also a majority of law schools and nursing schools reserve a place in their curriculum for teaching bioethics. Surprisingly, faculties of biology and related sciences appear to include the teaching of bioethics only on some courses in their respective curricula.

A number of published studies have dealt with the need to teach an introduction to bioethical questions in secondary schools, and some concrete proposals are being tested in a research study organized by the Research Centre of the Institute of Bioethics. It is hoped that it will be recognized by the authorities that the implementation of a strategy offering young people first contact with the main questions of general bioethics would be worthwhile, for example, by choosing questions which can be discussed under the guidance of teachers of biology and philosophy. This innovative pedagogic approach has still a long way to go before being adopted.

Moreover, postgraduate students, albeit in small numbers, can make exchange visits to other foreign countries. São Paulo, Brasília, and Bahia in Brazil and Barcelona, Rome, Padova, and Paris in Europe have been cities at the hub of this international exchange.

Links to the United States, the UK, and other European countries also exist, kept alive by people who obtained their degrees in these countries or as a result of cooperation with foreign scientists on several research projects funded by the European Union. Portuguese scholars have been regularly appointed to the specialized bodies of the European Council, the European Union, and UNESCO, which deal with bioethical questions (respectively, Comité Directeur pour la Bioéthique, the European Group on Ethics of Science and New Technologies, the International Bioethics Committee).

Needless to say, a significant proportion of bioethicists from other countries have been invited to give conferences and seminars in Portugal and have contributed to the tutoring of postgraduate students preparing their dissertation.

Bioethics Committees

In Portugal, besides the National Council on Ethics for the Life Sciences (CNECV) and following the transposition of the European Directive 2001/90/CE, a National Committee for Clinical Research (CEIC) has been created in 2005; since then, all clinical trials must be approved by this committee.

Before the implementation of this new law, all the clinical trials were approved by the hospital ethics committees which by law are mandatory for all hospitals. After the implementation of the clinical trials directive, these committees are responsible for all research, apart from clinical trials, as well as for matters rising from the relationship of patients with health professionals and the institution itself.

Expert Bodies/Centers

The development of the master's dissertation involves a certain degree of research, and this has certainly been the case with the ones already approved. A much higher degree of quality research is undertaken by the school that offers a Ph.D. program. Apart from the individual research involved in the preparation of a master's dissertation or a doctoral thesis, research projects (both of a national and international cooperative nature) have and are being conducted by two institutions, namely, the Institute of Bioethics (Catholic University) and the Department of Bioethics and Medical Ethics (Porto University School of Medicine). For the time being, the only institute which may grant a Ph.D. degree in bioethics fully approved by the Portuguese accreditation agency is the Catholic University Institute of Bioethics, offering a program with classes in the 1st year followed by a structured program of research. Research, via the institute's research unit – the Bioethics Research Centre – has been another fundamental area for the building and credibility of the Institute of Bioethics. An international evaluation panel, mandated by the Foundation for Science and Technology from the Ministry of Science and Education, classified it as "very good," ensuring that the center's activities have been supported. The center also received funding from other institutions and recently a "trust" on bioethics has been established. The Bioethics Research Centre is currently focusing its activities on five research areas: medical ethics (with three research lines: (1) pediatric palliative care; (2) who cares for the carer, "burnout" in carers; and (3) ethics in public health) and ethics, science, and society (with two research lines: (1) teaching of bioethics in secondary schools and (2) using bioethics as strategy for teaching science to lay people).

Some examples of research lines from the Department of Bioethics and Medical Ethics (Porto University School of Medicine) include deaf-mute recuperation and ethical problems, xenotransplantation, and the ethics of allocation of means to health-care providers as well as living wills.

Thus, the outlook for the progressive involvement of Portuguese bioethicists, and especially of those of the younger generation, in research in fundamental and applied ethics appears to justify some optimism.

Relevant Legislation

It is understandable that all laws which in one way or another affect health and environment are of relevance to bioethics. Here, however, only those laws which appear to be of the utmost importance in the field and/or those which have been submitted to the CNECV for opinion (which is mandatory in the present legal framework) will be mentioned. Since the CNECV is an organ of a consultative nature, it follows that the law is not forced to follow the opinion and recommendations of the CNECV, but its statements clearly exert an influence on the legal text.

In Portugal abortion is a crime punishable by imprisonment (from 2 to 8 years), except under conditions such as danger of physical or mental harm to the pregnant woman, presence of severe and incurable disease in the fetus, and pregnancy after rape. In 2007 a referendum was conducted with the following question: do you agree with decriminalization of abortion, if done by women's option, in the first 10 weeks, in a legal authorized health service? Although there was a high proportion of abstentions, the result was favorable to the pro-choice current (59.25 % vs. 40.75 %). After the referendum a new point of exclusion has been included in the law, and since then, women may request an abortion till 10 weeks of pregnancy.

Following the law Lei n° 12/93, of April 22 (now amended by Law n° 22/2007 of June 29), transplantation is possible, the donors being dead (after diagnosis of brain death) or alive, subject to certain requirements; there is a registry of non-donors (people who declare that they do not allow their organs to be removed after death for transplantation purposes; all other people are presumed to agree with donation of their organs). Corpses may be used for teaching and research purposes under very limited conditions, prior informed consent of the person still living being mandatory.

Clinical trials are strictly regulated by the European Directive that has been adopted by the country (Law 46/2004 is a transcription of European Directive 2001/90/CE). Following that directive a National Commission (CEIC) has been established and is in charge of all clinical trials.

Medically assisted reproduction (MAR) has been regulated by a law in 2006, after decades of practice outside the legal framework. The present law restricts MAR to heterosexual couples (married or otherwise), but in exceptional cases allows heterologous fertilization and even surrogate motherhood. Surplus embryos may be used for research, and donation to other couples is also possible, with parental authorization and after a couple of years in a frozen state.

Finally, the incorporation into Portuguese Law of the European Convention of Human Rights and Biomedicine represents an important milestone along the path of bioethics in Portugal. With its insistence on informed consent, dignity of the human being, priority of individual interest over common interest, and prohibition of the production of human embryos for research purposes, it conveys an important array of bioethical notions which will strongly influence future legislation of bioethical significance.

Future Challenges

In the Field of Bioethics Infrastructures

Due to its characteristics, bioethics tends to be more international in its scope than many other areas of academic research. The goal, which many will call utopian, of reaching a universal bioethics consensus, which may guide attitudes and actions in vast areas of life sciences and preservation of the biosphere, is not attainable if people from different countries and continents do not exchange their views, discuss their cultural backgrounds, compare their basic tenets, and try to find some common ground. It is hardly surprising, in this context, that since the beginning of the "bioethical era" (which in Portugal really took place in the mid-1980s), Portuguese scholars have tried to establish and maintain links with colleagues and institutions in other countries. Due to language and cultural affinities, regular contacts were established with Brazil and other Latin countries (Spain and Italy). Portuguese and Brazilian scholars have held conferences and courses in each other's countries, and from this cooperation a Congress (Encontro Luso-Brasileiro de Bioética) has emerged (with its 7th edition in Lisbon in July 2012, following earlier conferences in Lisbon, Brasília, Ponta Delgada, São Paulo, Porto, Salvador da Bahia). This represents an important meeting opportunity, in which points of view are exchanged and approaches are discussed, with the bonus of common cultural and linguistic backgrounds being shared.

The UNESCO Portuguese Chair of Bioethics has been established at the Institute of Bioethics of the Portuguese Catholic University in 2007 and is held by Professor Walter Osswald. The project "UNESCO Portuguese Chair of Bioethics" focuses specially on development of bioethical training in Portuguese-speaking countries (apart from Portugal, Republic of Angola, Republic of Cabo Verde, Republic of Guinée-Bissau, Republic of Moçambique, Democratic Republic of S. Tomé e Príncipe). The main objective is the realization of a formation program of constitutive members of ethics committees. The unethical experiences, reported in several scientific publications, concerning research tests which are offensive to dignity and to the integrity of human persons in African countries that have no ethics committees (or in those which do not work), lead to the important collaboration with the local authorities, in order to form responsible and knowing elements able to integrate competent and active ethics committees.

A large community of Portuguese-speaking bioethicists can only gain from a cooperative effort to identify particular points of interest, approaches, and challenges in their respective countries and to foster collaboration between them in the capacity-building effort directed to students coming from Portuguese-speaking countries. This project can be subdivided in two main objectives: bioethics training program and strengthening and launching of ethics committees within African Portuguese-speaking countries.

Any Other Problems and Opportunities for the Further Development of Bioethics in the Country

A very important contribution to the international recognition of Portuguese work in this area depends on the publication in international journals of papers originating from this country. This is happening on a rather modest scale, and this type of activity needs to be encouraged and fostered. Portugal needs also to set up a local or national research ethics committee, ideally working in close cooperation with the main research funding agency, the Foundation of Science and Technology. A recent development consists in the creation of an ethics review structure in the frame of this institution, the ethical evaluation of all projects involving human beings and animals being thus warranted.

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Contacts

In order to obtain further information on the institutions referred to above and for their activities, please contact:

Centro de Bioética – Faculdade de Medicina da Universidade de Lisboa (Director: Prof. Doutor A. Barbosa) Av. Professor Egas Moniz, 1649-028 Lisboa. Telefone: (+351) 21798 5100, Fax: (+351) 217985110. E-mail: fml@fm.ul.pt

Centro de Direito Biomédico – Faculdade de Direito da Universidade de Coimbra (Director: Prof. Doutor G. de Oliveira) Pátio da Universidade, 3004 – 545 Coimbra, Portugal. Telefone: (+351) 239859801/02. Fax: (+351) 239 823 353. E-Mail: fduc@fd.uc.pt

Centro de Estudos de Bioética (Director: Prof. Doutor Filipe Almeida) Rua de Diogo Botelho 1327, 4169-005 Porto, Portugal. E-mail: filipenunoalmeida@gmail.com.

Conselho Nacional de Ética para as Ciências da Vida (President: Prof. Doutor Miguel Oliveira e Silva, Executive Secretary: Dra Cíntia Águas) Avenida D. Carlos I, n.° 146 - 2° Esq.1200-651 LISBOA PORTUGAL Tel. +351 213 910 884 Fax +351 213 917 509. www.cnecv.pt E-mail: caguas@cnecv.pt

Instituto de Bioética da Universidade Católica Portuguesa (Director: Prof. Doutora Ana Sofia Carvalho) Rua de Diogo Botelho 1327, 4169-005 Porto, Portugal. Telefone: (+351) 226196216. Fax: (+351) 226196291. E-mail. ib@porto.ucp.pt.

Serviço de Bioética e Ética Médica da Faculdade de Medicina da Universidade do Porto (Director: Prof. Doutor Rui Nunes) Alameda Prof. Hernâni Monteiro, 4200-319 Porto, Portugal. Telef: (+351) 225513625. Fax: (+351) 225513697. E-mail: ruinunes@med.up.pt

Universidade dos Açores, Departamento de Filosofia (Director: Prof. Doutora Maria do Céu Patrão Neves) Campus de Ponta Delgada, Apartado 1422, 9501-801 Ponta Delgada, S. Miguel, Açores, Portugal. Telefone: (+351) 296650000. Fax: (+351) 296650005. E-mail: patrao@notes.uac.pt

Singapore

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Calvin W. L. Ho, Jacqueline J. L. Chin, and Alastair V. Campbell

Introduction

Bioethics in Singapore is principally encapsulated in three main systems of values, practices, and concerns. The first to be formalized in regulatory and institutional structures relates to the practice of medicine and its allied disciplines. Naturally, this value system incorporates clinical ethics. The second is generally referred to as research ethics and applies to a broad range of biomedical research and clinical trials. The third is concerned with bioethics as an academic discipline and is

C.W.L. Ho (✉) • J.J.L. Chin • A.V. Campbell
Centre for Biomedical Ethics, Yong Loo Lin School of Medicine, National University of Singapore, Singapore
e-mail: calvin_ho@nuhs.edu.sg; medhwlc@nus.edu.sg; Jacquelinecbd_chin@nuhs.edu.sg; Alastair_v_campbell@nuhs.edu.sg; medavc@nus.edu.sg

H.A.M.J. ten Have, B. Gordijn (eds.), *Handbook of Global Bioethics*,
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referred to as biomedical ethics. All three have been profoundly shaped by the healthcare infrastructure as well as the Singapore Government's Biomedical Sciences Initiative that was rolled out in June 2000 to establish the city state's biomedical and pharmaceutical capabilities as one of its key economic drivers.

This chapter provides an analytical overview of each of these systems, beginning with a brief description of the healthcare infrastructure. In the past decade or so, the Ministry of Health (MOH), the Bioethics Advisory Committee (BAC), and the Centre for Biomedical Ethics (CBmE, at the National University of Singapore) have been three important actors that shaped the ethical governance of medical practice and education, as well as biomedical research, in Singapore. MOH was responsible for establishing a system comprising hospital or clinical ethics committees to consider and address ethical issues in clinical practice. It has also implemented a variety of policies directed at meeting existing and emergent healthcare and public health needs and concerns. Some of the policies to be discussed in this chapter include those relating to reproductive medicine, infectious diseases, organ transplantation, palliative care, care for the elderly, and mental health. Working collaboratively with MOH, BAC has been instrumental in setting up a research ethics governance framework, primarily administered through institutional review boards (IRBs). It has also promulgated ethical guidelines for research relating to human pluripotent cells, genetics, human tissue, and personal information. Since its establishment, CBmE has supported both MOH and BAC by its research and expertise and has developed training programs for ethics committees and IRBs. Its scholarship has been important in establishing Singapore as a center for the ethical conduct of (bio-) medical practice and research. This chapter presents bioethics in Singapore as the outcome of the collaborative work of the MOH, BAC, and CBmE and concludes with a brief indication of some challenges in the foreseeable future.

Overview of the Healthcare Infrastructure

The healthcare infrastructure comprises different healthcare components, including primary, hospital, as well as intermediate and long-term care. In 2011, private practitioners provide 80 % of primary healthcare services, while 20 % is provided by government polyclinics. These proportions are reversed for tertiary care, where public hospitals account for 80 % of hospital care, whereas the remaining 20 % is met by private hospital care. There are seven public hospitals, comprising five general hospitals, a women's and children's hospital, and a psychiatric hospital. Inpatient and specialist outpatient services and a 24-h emergency assistance are provided in all general hospitals. In addition, there are six national specialty centers for cancer, heart, eye, skin, neuroscience, and dental care. As for long-term care, a range of resident and community-based healthcare services is available. They include community hospitals, chronic sick hospitals, nursing homes, sheltered homes for patients who have recovered from mental illnesses, inpatient hospice institutions, various home-based services, day rehabilitation centers, dementia day care centers, and psychiatric day care centers and rehabilitation homes.

There are a number of relatively distinctive characteristics of the system. First, it may be broadly described as "bifurcated" in that it comprises a large private general practice and specialist healthcare sector on the one hand and a network of government-subsidized polyclinics and "restructured" hospitals on the other. The two are not necessarily linked, as financially well-endowed patients can choose to seek treatment from specialists without requiring a referral from a polyclinic. Second, clinics in private general practice are responsible for both the examination and diagnosis of patients, as well as dispensing or prescribing drugs. Third, the healthcare infrastructure operates on mixed financing in three tiers: (a) government subsidy of up to 80 % of the total cost of treatment in acute public hospital wards; (b) a "co-pay" arrangement whereby a Singaporean can draw on funds from his or her Medisave, which is a compulsory individual medical savings account scheme that requires all working Singaporeans and their employers to contribute a part of the monthly wages into their accounts that are portable across jobs and into retirement; and (c) coverage under a low-cost catastrophic medical insurance scheme (or MediShield), which can be further enhanced (with integrated private insurance policies) for treatment in the private sector or supplemented (by obtaining additional coverage against severe disability, for instance). As an ultimate safety net, the government has established a medical endowment fund (known as Medifund) to meet the medical costs of Singaporeans who fall through the three levels of support. The supervening philosophy of this complex financing arrangement is to incentivize individual responsibility toward healthy living in a way that is calculated to keep the overall costs of healthcare down.

These structural features have contributed to a number of ethical challenges in all three domains of bioethics in Singapore. The ability of patients to decide on when and where they prefer to seek treatment could account for a general absence of long-term relationships of trust between doctors and their patients. The question of whether private clinics should be allowed to sell medicines has been an ongoing debate for some time now. More recently, the disciplinary proceeding against a surgeon for charging her patient (a member of the Brunei royal family) S$24.8 million for treatment over 7 months raised widespread debate as to whether a doctor in private practice should be free to operate on purely "market" principles (*Lim Mey Lee Susan* case, 2011). On the research front, a growing emphasis on industrial collaboration and commercialization has fueled concerns that research integrity and welfare of research subjects could be compromised. In the sections that follow, these and other issues, developments and discussions, are considered as concerns in clinical, research, and instructional ethics.

Clinical Ethics

Clinical ethics has been a concern of the MOH, which has overall supervisory jurisdiction over healthcare institutions and standards-setting professional bodies, including the Singapore Medical Council, the Singapore Nursing Board, and Singapore Pharmacy Council. In 2009, hospitals have been directed by the MOH

to set up Hospital Ethics Committees (HECs) to "encourage and promote the ethical care and treatment of patients within the hospital and to assist in resolving ethical problems involving their care and treatment" (Ministry of Health [MOH], 2009b: Section 3). To better enable the ethical provision of healthcare services, the functions of HECs include making recommendations to the hospitals concerned on the formulation of policies, fostering education and training, as well as reviewing and providing advice and recommendations on specific cases. The MOH is itself supported in its formulation of ethical policies and guidelines by its National Medical Ethics Committee (NMEC). Established in 1994, the NMEC assists the medical profession in addressing ethical issues in medical practice and to ensure a high standard of ethical practice. Since 1997, it has issued guidelines on a variety of ethical issues relating to medical practice, such as organ donation, end-of-life issues, apportionment of healthcare expenditure, and advance care planning.

From 1 January 2003, the SMC has been administering the continuing medical education (CME) program, which requires all medical practitioners to attain a level of medical training each year in order to maintain their registration status in order to practice medicine. The CME program includes ethical training to ensure that doctors keep abreast of ethical concerns and expectations. The profession has itself taken different initiatives to develop and promote clinical ethics. Annual scientific meetings of the two main hospital groups (referred to as "clusters") in Singapore include sessions on clinical ethics. Apart from these, the Singapore Medical Association (SMA) has been also been concerned with the development of clinical ethics. Formed in 1959 as a professional medical organization that represents the majority of medical practitioners in Singapore, the SMA has as an explicit goal the support of a higher standard of medical ethics and conduct. In addition, it emphasizes the need to recognize and remove barriers to good ethical medical practice, as well as to strengthen the culture of medical professionalism, through various means including promoting CME and personal professional development throughout a doctor's career. The Centre for Medical Ethics and Professionalism was established by the SMA to help doctors apply clinical ethics in daily clinical practice. The center's goal includes serving as a resource center on medical ethics and health law, developing and providing educational programs for doctors and allied health professionals, developing standards of ethical medical practice, and promoting public awareness of current medical and ethical issues in healthcare.

Research Ethics

Until 2000, engagement with biomedical research ethics has mainly occurred either within highly institutionalized and defined fields of practice, such as clinical trials, or on a "when necessary" basis, by an *ad hoc* IRB or similar body within academic and healthcare institutions. On the former, the term "clinical trials" has been defined by legislation to encompass all biomedical research that relates to the testing of a "medical product" or drug on a human subject. Detailed

provisions are set out under the *Medicines (Clinical Trials) Regulations*, which also incorporate and thereby confer regulatory effect on the *Singapore Good Clinical Practice Guidelines* (SGGCP) of 1998. The SGGCP in turn adapt the international standards prescribed by the guidelines of the International Conference on Harmonisation. Under this regulatory framework, a clinical trial may only be conducted after a clinical trial certificate has been obtained from the Health Sciences Authority (HSA). Initially, ethical approval from a HEC was a precondition to the application for a trial certificate. With the systematization of the ethics review process, this ethics review function has been assumed by an IRB and assessed independently of regulatory approval by the HSA. However, both regulatory and ethics approval will have to be obtained before a clinical trial may be commenced.

It is also a regulatory requirement for a locally registered doctor to obtain ethical and regulatory approval for a proposed clinical trial. In view of the fact that doctors are involved in clinical trials and other types of biomedical research, the NMEC has provided ethical guidance on research involving human subjects. It indicates that the Belmont principles of beneficence, justice, and autonomy upon which the guidelines are premised should be implemented by a research ethics committee (or IRB), to be established by each institution hosting or sponsoring the research (National Medical Ethics Committee, 1997: paragraphs 2.3, 3.1 and 3.2). A number of operational requirements, including the composition of a research ethics committee, have been detailed in the guidelines, along with considerations to be taken up in assessing the ethical acceptability of research proposals. Also important is an explicit indication for members of a research ethics committee to be indemnified (and explicitly indicated in their letters of appointment) by the institution concerned against "the cost of any legal representation and any compensation ultimately awarded to research subjects" (Biggs, 2010: 55–73; National Medical Ethics Committee, 1997: paragraph 3.3.4). The ethical guidelines of the NMEC apply only to hospitals and doctors licensed with the MOH and do not extend to researchers who are not so registered under this professional licensing scheme. However, a bill is currently being drafted, which, if enacted, would extend regulation across the whole field of biomedical research.

Effectively from 2002, an institutional framework on biomedical research ethics was put in place as a matter of national policy mainly through the efforts of the BAC and the MOH. The BAC was established in December 2000 by the Cabinet to provide the government with advice on ethical, legal, and social issues. Since 2002, the BAC has provided recommendations to the Steering Committee on Life Sciences, which was constituted by the Cabinet in June 2000 as the Life Sciences Ministerial Committee. The Steering Committee is responsible for advancing Singapore's biomedical research capability and establishing Singapore as a premier center for research and development activities. Between the years 2002 and 2010, seven sets of recommendations have been published by the BAC, and they relate broadly to the subjects of human embryonic stem cell research and cloning, human tissue, human subjects protection, and genetics. All the recommendations have been accepted by the government.

Although there is an overlap, the BAC's recommendations are directed at the biomedical research community in general, whereas the MOH is primarily concerned with research that either occurs within healthcare premises or conducted by healthcare professionals. This dual approach is due in part to historical factors, particularly since the medical profession and healthcare establishments have traditionally been closely regulated (Singapore Statutes, 2004a, 1999b), whereas researchers and research institutions have not (except for biosafety). In spite of these differences, a governance framework has emerged incrementally and through ever closer connections between the biomedical research and medical communities.

Ethics Review Infrastructure

In 2004, the BAC built on the guidelines of the NMEC and enlarged their application to all human biomedical research conducted in Singapore. Its report on research involving human subjects essentially formalized the requirement for all human biomedical research in Singapore, including research involving human tissue or medical information, to be subject to ethics review by IRBs (Bioethics Advisory Committee, 2004). The guidelines promulgated in the report built on the existing system of regulations for pharmaceutical trials and human biomedical research conducted by hospitals, private clinics, and other healthcare establishments under supervision of the MOH. They also set out the constitution, accreditation, and operation of IRBs, as well as their roles and responsibilities, in addition to those applicable to research institutions and individual researchers. In the main, the BAC regards high standards of ethical governance for the protection of life, health, privacy, and dignity of human subjects in biomedical research as vital to the progress of biomedical sciences in Singapore.

Concerned that there might not have been sufficient resources assigned to enable proper ethical review to be conducted, a number of measures were proposed, including reference to the institutional purveyor of ethical opinion on research projects as IRB rather than "research ethics committee." A major contribution to the entrenchment of this system of ethics review is the BAC's recommendations for institutions to ensure that "core members of the IRB … [have] sufficient and protected time commensurate with the workload of the IRB" and for the IRB to be supported by a permanent secretariat (Bioethics Advisory Committee, 2004: 51–52, paragraphs 7.6–7.8). It expresses a desire "to see institutional review boards established as full-time permanent supervisory bodies organised at and integral to the function of the highest administrative level in all institutions in which research is carried out" (Bioethics Advisory Committee, 2004: 28, paragraph 5.2). The fundamental responsibility of an IRB is set out as conducting ethics review with the "primary objectives of the protection and assurance of the safety, health, dignity, welfare and well-being of human research subjects" (Bioethics Advisory Committee, 2004: 41, paragraph 5.20). By this formulation, the ethical perimeter appears to be broader than the Belmont principles, although there is continued emphasis on free and informed consent, respect for privacy and confidentiality, and

respect for vulnerable persons. References to "dignity" and "welfare" further suggest a more deontological orientation, whereas the NMEC's guidelines could be viewed as consequentialist in its rather substantial discussion on risk and benefit analysis (National Medical Ethics Committee, 1997: paragraph 2.4). To be sure, the guidelines of both the NMEC and the BAC are ethically pluralistic and hence do not reflect a single philosophical ideology, even if one ethical position might be more pronounced than another on a particular subject matter. In the light of increasing research collaborations across institutional and geographical boundaries, more elaborate guidance has been provided by the BAC on ethics review of cross-institutional and cross-border research (Bioethics Advisory Committee, 2004: 36–38, paragraphs 5.42–5.57). Like the NMEC, the BAC similarly highlights the need for IRB members acting in good faith to be indemnified against any liability arising from their actions (Bioethics Advisory Committee, 2004: 54, paragraphs 7.20–7.21). Although the guidelines of the BAC do not have any direct regulatory authority, they have been accepted by the MOH (Ministry of Health, 2006a) and by the Agency for Science, Technology and Research (A*STAR), the principal public funder of biomedical research in Singapore. Consequently, the medical profession and biomedical researchers who are funded by A*STAR are required to observe these guidelines.

In 2007, the MOH issued supplementary guidelines on the day-to-day workings of an IRB, for which the BAC has set out the operating principles. These include guidelines on the composition of an IRB, a more elaborate discussion on the informed consent process, meeting requirements, and requirements relating to documentation (Ministry of Health, 2007b: 8–9, paragraphs 7.10.5, 7.12, Section 10). Interestingly, it did not adopt the BAC's broader formulation of ethical principles but reiterated the three "fundamental" ethical principles (earlier adopted by the NMEC) as respect for persons (encompassing autonomy), beneficence, and justice (Ministry of Health, 2007b: paragraph 3.1). A reason for this could be its primary focus on research involving patients (rather than healthy individuals) as research subjects. Indeed, the governance framework for research ethics in Singapore should not be confused with medical ethics (Ministry of Health, 2009a). The BAC does not address issues of medical ethics (whereas the NMEC does) although a number of its recommendations (particularly those relating to genetic testing and genetic information) could relate to both research and medical practice. As noted above, HECs, rather than IRBs, formulate policies, educate, review, and provide advice on ethical implications arising from the provision of healthcare services (Ministry of Health, 2006b: Section 2).

Research Integrity

The BAC-MOH framework does not explicitly address the requirement of research integrity, however. The NMEC recognizes that the research proposal must be scientifically valid and determined to be so by those with sufficient scientific expertise (National Medical Ethics Committee, 1997: paragraphs 2.4.1 and

3.2.4.1). The BAC goes further in its indication that "scientific review of research proposals does not lie with the IRB. It is for the researchers to satisfy the IRB that an objective review of scientific merit has been carried out and to make these findings (whether positive or negative) available to the IRB" (Bioethics Advisory Committee, 2004: 5, paragraph 24). However, the BAC discusses at some length the issue of conflicts of interest, which is recognized as research misconduct in the USA and the UK (Bioethics Advisory Committee, 2004: 35, paragraphs 5.36–5.41 (institutional conflicts of interest); 44 at paragraph 6.14 (on the part of the researcher); and 47–48, paragraph 6.36 (where the researcher is also the attending physician)). The MOH reiterated the BAC's position on conflicts of interest in its 2007 operational guidelines for institutional review boards (Ministry of Health, 2007b: 11 at paragraph 7.13). Even then, the discussion addresses conflicts of interest as an ethical concern, particularly where the well-being and interests of the research subject are compromised, rather than as a matter of proper research practice. At an institutional level, key research institutions such as A*STAR and the National University of Singapore (NUS) have policies on research integrity. They incorporate to varying degrees the key principles set out in the Singapore Statement on Research Integrity as honesty, accountability, professional courtesy and fairness, and good stewardship of research on behalf of others, while also defining irresponsible research conduct as essentially falsification, fabrication, and plagiarism (Kleinert, 2010).

Academic Biomedical Ethics

The work of the BAC comes within the genre of public bioethics, as it addresses ethical conundra arising from biomedical research by recommending policies that are intended to apply to all members of society (Evans, 2006; Hedgecoe, 2010). It is neither a body that debates foundational issues nor is it concerned with clinical ethics, although a number of its recommendations do affect clinical practice. Foundational bioethics and clinical ethics are addressed by other ethical bodies in Singapore. The former lies within the broad remit of the CBmE, which was established in 2006 at the Yong Loo Lin School of Medicine of NUS. The center operates under the direction of Alastair V. Campbell, who is the Chen Su Lan Centennial Professor of Medical Ethics, a position established in honor of one of the nation's best known philanthropists, the late Dr. Chen Su Lan. In December 2008, CBmE published the inaugural issue (and then subsequent issues) of the quarterly online journal *Asian Bioethics Review* in collaboration with the Hastings Center, which is one of the field's premier research bodies in the USA. CBmE undertakes a wide range of bioethics research, much of it in collaboration with overseas institutions. Current topics include ethics education, stem cell research and therapy, organ transplantation, human enhancement, medical jurisprudence and professionalism, clinical trials, equitable access to medications, and end-of-life issues (see http://cbme.nus.edu.sg/).

Medical Education and Instructional Ethics

The history of Yong Loo Lin School of Medicine (YLLSOM) of the NUS could be traced back to July 1905, when it commenced medical education. Since that time, YLLSOM has provided undergraduate medical training that has ensured a steady supply of doctors in Singapore (Law, 2012). The 5-year curriculum that leads to an undergraduate medical degree is broadly based on the British model of medical education. In 2005, a second medical school was jointly established by Duke University and NUS, as part of the Biomedical Sciences Initiative. Unlike YLLSOM, Duke-NUS Medical School is focused on training clinician-researchers at the postgraduate level, and its curriculum is patterned after that of the Duke University School of Medicine. In 2013, a third medical school jointly managed by Imperial College (London) and Nanyang Technological University (or NTU of Singapore) is expected to admit its first batch of students.

Ethics education is a component of the curricula of both YLLSOM and Duke-NUS Medical School, and it is likely to be included in the curriculum of Imperial College-NTU Medical School. This chapter focuses on ethics education implemented by the CBmE at YLLSOM. Designated as the Health Ethics, Law and Professionalism (HeLP) track in the medical curriculum, which arose out of a recognition by the medical profession here and abroad, knowledge of an ethical and legal basis of medicine is as relevant to clinical practice as knowledge of basic medical sciences (Stirrat, Johnston, Gillon, & Boyd, 2010: 55). This track is a longitudinal one in that it is fully integrated in such a way that pertinent issues in ethics, law, and professionalism are presented as an integral part of the five-year medical curriculum and clinical postings. It aims to develop in medical students ethical sensitivity, theoretical understanding, reflective and critical skills, and professional attitudes. The knowledge, skills, and attitudes acquired are continuously revisited and reinforced throughout medical education.

The five phases of the medical curriculum that the HeLP track follows through are introduction to health and disease and organ systems I (phase I), organ systems II (phase II), the core clinical practice phase (phase III), advanced clinical practice phase (phase IV), and the student internship program (phase V). In phases I and II, the HeLP track provides students with a basic grounding in medical ethics and law as well as an appreciation of medical professionalism. More specifically, it aims to provide an understanding of (1) ethical considerations and behavior that underlie and support good medical practice; (2) the legal and professional frameworks in Singapore, including the *Ethical Code and Ethical Guidelines* of the Singapore Medical Council; (3) the importance, scope, and implications of a doctor's duty of care; and (4) professional values and attitudes. A good grounding in professional values and attitudes will enable students to appreciate the practices, conflicts, and boundaries that they will encounter in the clinical environment. In particular, it highlights (a) the implications of practicing medicine in a multicultural, racial, and religious society; (b) the importance of trust, integrity, honesty, and good communication in all professional relationships; (c) the need to accept personal responsibility and be aware of limitations of your practical skills or knowledge and to know

how and where to seek appropriate help; and (d) the need to maintain professional boundaries with patients and to recognize and avoid all forms of unfair discrimination and areas of potential conflict of interest.

In phase III, the HeLP track provides the opportunity to apply and assimilate understanding gained in phases I and II as well as demonstrate (through reflective writing) the ability to (1) consider, apply, and reflect critically on ethical, legal, and professional aspects of clinical care in particular cases; (2) reflectively consider values of different people that are likely to be encountered in the course of medical practice; (3) respond appropriately to actual or potential clinical errors and adverse incidents; and (4) apply and reflect critically on ethical and legal responsibilities to patients. Finally, phases IV and V will prepare students for clinical competency and provide them with opportunities to explore ethical considerations and practices that underlie and support good medical practice. Students are expected to be able to apply their understanding, especially in the ability to integrate ethical and legal analysis of actual clinical encounters with clinical knowledge and skills, propose action or decision based on this synthesis, and display professional attitudes and behaviors consistent with the requirements of the medical profession.

In addition to the HeLP track, a number of complementary ethics programs are conducted by YLLSOM and supported by the Centre for Biomedical Ethics. In phase II and during clinical postings in phases III and IV, a number of medical specialties have related inputs on ethics that are directed at specific clinical concerns. For instance, there will be ethical components in the foundation courses on clinical skills and patient-based programs in phase II. The knowledge, skills, and attitudes that are developed in phases I and II will be revisited and reinforced in these clinical settings.

In devising modes of teaching and assessment, a key strategy in the HeLP track has been to relate specific learning outcomes with matching methods of assessment as progression through an ascending pyramid of knowledge-habituation-action that reflects knowledge, ethical sensitivity and reflection, and ability to act with clinical competence (Campbell, Chin, & Voo, 2009: 277–278). By this approach, teaching is most intensive in phases I and II, which is directed at raising the level of knowledge and understanding, and is mainly conducted by way of lectures and tutorials. In phase I, there are 12 h of lectures and 8 h of tutorials over a period of 34 weeks of instruction. In phase II, this is followed by 11.5 h of lectures and 3 h of tutorials over a period of 25 weeks of instruction. Some lectures are conducted with standardized patients in interactive sessions, where students are divided into smaller groups to increase the opportunity of engaging with these patients. Assessments are incorporated into the continuous and year-end assessments of the YLLSOM, so that modified essay questions in ethics will be included in selected continuous assessments and the final examination.

In phase III, students are required to complete a short reflective essay on professionalism after their clinical posting. This exercise is intended to encourage application and assimilation of knowledge and understanding from phases I and II through habituation, especially in critical thinking, ethical awareness, and empathy. For phases IV and V, lectures on ethical issues in specific areas of medicine are

conducted as a part of the combined teaching sessions to enhance clinical ethical competency. Ethical issues addressed include bereavement and dying, iatrogenic injury, advanced medical directive and human organ transplantation, and relationship with the pharmaceutical industry.

While there is no single agreed best approach to teaching ethics and professionalism, the HeLP track reflects widely accepted view that "ethics education should be fully integrated both horizontally and vertically with the clinical curriculum so that students can experience and appreciate the centrality of ethics to clinical practice," in hope of producing doctors that are "reflective, responsive and self-regulating" (Campbell et al., 2009: 279).

Apart from the HeLP track, the CBmE manages a program directed at training HECs or clinical ethics committees (CECs), known as the Clinical Ethics Network for Training, Research and Support (or CENTRES). This program was initiated by the MOH in 2009 to facilitate dialogue among the different HECs or CECs and to develop their capacity in clinical ethics consultation. The CBmE was appointed to manage this initiative and to develop a one-stop online repository of resources (www.centres.sg) and an online forum to stimulate discussion and knowledge sharing. In the first two phases of this initiative (which was completed in March 2011), the CENTRES initiative has been successful in obtaining an understanding the needs and challenges that HECs or CECs have been confronted with through needs and operations analyses and a web survey. Regular workshops have also been organized to develop capacity in ethical decision-making on a range of issues in clinical ethics, and a quarterly newsletter has also been launched.

Stem Cell Research and the Beginning of Life

The first set of recommendations published by the BAC is on human stem cell research and reproductive and therapeutic cloning (Bioethics Advisory Committee, 2002a). These recommendations include proposals for stringent regulation of human embryonic stem cell research in Singapore and the legal prohibition of reproductive cloning, which was taken up by the legislature with the enactment of the *Human Cloning and Other Prohibited Practices Act* in 2004. As with other major scientific jurisdictions, the legislation imposes a 14-day limit so that research involving a human embryo is allowed up to that point in development. Embryology is relied upon as justification for this standard as public consultation showed that there was no consensus among the main religious groups in Singapore as to when "personhood" could be said to begin (Ho, Capps, & Voo, 2010). On this basis, one could perhaps conclude that at least in ethical policy, human life begins from 14 days of embryonic development or when the "primitive streak" becomes evident. From a legal standpoint however, it has been argued that the law is much slower in recognizing when life begins, since, for instance, a pregnant woman has the discretion to terminate her pregnancy up to 24 weeks from conception (Singapore Statutes, 1985b). Similarly, the common law relating to inheritance and the penal code attribute legal "personhood" at a much later stage of fetal development (Kaan, 2010).

Eggs, Tissues, and Human-Animal Combinations

Following the publication of these recommendations, scientific developments in relation to cloning and induced pluripotent stem cell technology necessitated continuing review of Singapore ethical policies on stem cell and cloning technology. A review of the recommendations published in 2002 was formally undertaken in 2007, with the focus on ethical, legal, and social issues arising from the procurement and use of human eggs for biomedical research and on research involving human-animal combinations. Apart from scientific developments, review of these areas was considered to be necessary following the scandal from the unethical procurement of eggs in South Korea and, more importantly, from revisions to ethical policies and guidelines in the United States, Australia, Canada, and a number of European countries such as the Britain and Denmark. Recommendations relating to the donation of human eggs for biomedical research were published by the BAC at the end of 2008 (Bioethics Advisory Committee, 2008), after public feedback was received on various issues presented in a consultation paper between 7 November 2007 and 7 January 2008 and at a public forum on 11 November 2007. Another consultation paper was distributed for public discussion and comment on research involving human-animal combinations between 8 January and 10 March 2008. In September 2010, the BAC published a set of recommendations that permit the creation and use of cytoplasmic hybrid embryos and animal chimeras in research on a strictly regulated basis. It further recommended that a single national body be established to review and monitor all stem cell research involving human pluripotent stem cells or human-animal combinations conducted in Singapore (Bioethics Advisory Committee, 2010).

The BAC was also responsible for a series of recommendations which served to systematize ethical governance of research using human tissue. The report on "Human Tissue Research" was published in November 2002 to provide a set of national ethical guidelines to be applied uniformly by all persons conducting human tissue banking and biomedical research using human tissue in Singapore (Bioethics Advisory Committee, 2002b). The ethical principles embodied in the guidelines include the primacy of the welfare of tissue donors, the need for informed consent and confidentiality, respect for the human body, and sensitivity toward the religious and cultural perspectives and traditions of tissue donors. Taken together with its report on egg donation, the BAC communicates a strong stance against commodification of the human body (or any part thereof).

Genetics and Reproductive Technologies

Ethical governance of genetic research was formulated at two different junctures: at the point where genetic information is derived through various means of testing and in the management and use of the information itself. The report on genetic testing and genetic research served to operationalize a number of internationally recognized ethical principles in the local context (Bioethics Advisory Committee, 2005).

These ethical principles relate to the voluntary and informed basis of genetic testing, special care and responsibility when vulnerable persons are tested, and ethical conduct of human genetic research, among others. Specific ethical considerations have also been set out by the BAC in relation to five types of genetic testing, many of which can have profound influence over reproductive choices and reproduction. Preimplantation genetic diagnosis and preimplantation tissue typing are reproductive technologies that can be ethically practiced in Singapore but on a regulated basis. As for prenatal genetic diagnosis, the BAC states that it should be limited to serious medical disorders and must not be applied for the selection of desired traits or gender. Due to safety concerns arising from germline genetic modification, the BAC did not think it should be clinically applied. The recommendations in this report and those in the report on egg donation, taken with a set of directives of the MOH on assisted reproduction (MOH, 2006b), constitute the governance framework for reproductive technologies in Singapore.

Given the difficulty in interpreting genetic test results correctly, there has been considerable emphasis on genetic counseling before and after testing. In addition, the BAC indicates that genetic testing should generally be conducted through a qualified healthcare professional and that predictive health information should not be offered directly to the public. The personal nature of genetic information was more fully deliberated on in a further report published by the BAC on informational use in biomedical research (Bioethics Advisory Committee, 2007). The report proposes legal protection of personal information in biomedical research and sets out a number of considerations that could better safeguard privacy and confidentiality concerns in biomedical research. Similar to developments in the UK, the BAC recommends that a moratorium on the use of predictive genetic information for insurance purposes to be introduced and for employer access to such information to be limited, unless it is appropriate to address imminent workplace health and safety concerns. The recommendation of the BAC to provide disease registries that employ personal information in public health research on firm legal footing was taken up in legislation with the enactment of the *National Registries of Diseases Act* later that year.

Infectious Diseases

The regulatory framework directed at preventing the introduction and spread of infectious diseases dates back to 1976, with the enactment of the *Infectious Diseases Act* (Singapore Statutes, 2003b). New provisions were added with the outbreak of severe acute respiratory syndrome (SARS) in 2003 and its aftermath. These provisions relate to quarantine imposition and administration (including the more efficient imposition of social distancing measures), compliance with disease control measures, and handling of deceased persons (Singapore Statutes, 2003a). In essence, they enable strong state interventions in response to potential and actual public health emergencies posed by serious infectious diseases, of which SARS, yellow fever, and the plague are so categorized. This regulatory framework

proved to be robust during the outbreak of influenza A (H1N1) in 2009, although the pandemic was mild compared with the pandemics of 1918 (Spanish flu) and 1957 (Asian flu) (Lim, 2010: 860–861).

Apart from the three serious infectious diseases, 30 other infectious diseases are listed as requiring the MOH to be notified by medical clinics, clinical laboratory, and healthcare professionals and establishments of any person suspected to be suffering from or is a carrier of any of these infectious diseases (Singapore Statute, 2003b: Section 6 and First Schedule). The regulatory framework further enables the implementation of public health surveillance programs as well as the imposition of medical examination and treatment, when necessary. In 2008, the legislation was amended to include specific provisions directed at controlling the spread of HIV (Singapore Statutes, 2008a). The number of residents in Singapore reported with HIV or AIDS steadily increased from 2 persons in 1985 to 4,845 persons in 2010, of which 2,319 persons are asymptomatic carriers, 1,137 have or have had AIDS related illnesses, and 1,389 have died (Ministry of Health, 2011a: paragraph 1 and Table 1).

As the transmission of HIV in Singapore was found to be mainly through unprotected sex with an HIV-infected person, this legislative change places a greater responsibility on individuals whose sexual behavior puts their spouses or partners at risk of contracting the disease. Under Section 23 of the legislation, a person who has reason to believe that he or she has been exposed to a significant risk of contracting the disease must undergo HIV testing to ascertain his or her health status before the sexual activity. Otherwise, his or her partner must be informed of the risk of contracting HIV. The rationale behind this requirement is to encourage communicative openness between partners, condom use, and regular HIV testing, although the efficacy of this policy has yet to be fully ascertained. Since the legislative amendment came into force, a number of HIV-positive individuals have been convicted for not obtaining prior voluntary agreement to accept the risk of contracting HIV (through informed consent), following complaints made by their partners with whom they have had unprotected sex. Broader systemic challenges to HIV testing remain, of which mandatory notification of HIV-positive status to health authorities, as well as social discrimination and high cost of medical interventions, is the most likely concern among at-risk individuals. The government has since introduced a number of measures to address these concerns, including the launch of public education initiatives, extending financial assistance (via Medifund) to needy citizens who require HIV treatment (including medications), and allowing the use of funds in the national medical savings account (i.e., Medisave) to purchase approved drugs for HIV/AIDS (Ministry of Health, 2010b, 2011b).

Public Health

A major public health initiative has been to limit the amount of tobacco use in Singapore. Legislation to control smoking of tobacco in public places was introduced in 1970, and a tobacco tax was imposed in 1972. Since that time, a series of

regulatory measures and social programs have been introduced (see www.hpb.gov.sg/smokefree/). More recent policy measures that have been implemented include requiring health warning labels to be affixed to the outer packaging of tobacco products and prohibiting tobacco advertising, promotion, and sponsorship, as well as future innovative tobacco products (Singapore Statutes, 2011). In addition, a number of "softer" approaches have been adopted. These include the establishment of a peer-led program, working with grassroot communities to identify and implement localized solutions; launch of an initiative to recognize active tobacco control advocates in the business community (such as operating smoke-free premises) and the launch of a mainstream campaign involving a supportive network across the island to encourage smokers to make a personal pledge to quit. Between 1992 and 2010, smoking rate has fallen from 18.3 % to 14.3 %, and the current aim is to reduce smoking prevalence to below 10 % by 2020 (Health Promotion Board, 2012).

Apart from tobacco control, the Health Promotion Board (HPB) has established a number of programs directed at increasing the quality and years of healthy life among Singaporean citizens. These include health and dental services for school children, promoting physical activity, childhood injury prevention, screening for breast and cervical cancer, myopia prevention, and workplace health promotion. Public education through various means has been directed at AIDS, mental health, nutrition, and osteoporosis, among others. The HPB was established as a statutory body in 2001 with the key responsibility of implementing national health promotion and disease prevention programs.

Transplantation Medicine and Organ Donation

Organ transplantation and donation are strictly regulated activities. Under the *Medical (Therapy, Education and Research) Act* (MTERA; Singapore Statutes, 1985a), a person with the requisite legal capacity may pledge to donate his or her organs upon death for therapy (including transplantation), education, or research. Where such a pledge has not been made prior to death, the relatives of a deceased person are empowered to make the donation. However, the removal of designated organs for the purposes of transplantation is primarily regulated under another statute, the *Human Organ Transplant Act* (HOTA; Singapore Statutes, 2005). It provides that a kidney, heart, liver, and cornea may be transplanted upon the death of a Singaporean citizen or permanent resident who is 21 years of age and above and of sound mind. Such a person may opt out of this regime by lodging an objection with the MOH, although he or she will lose priority as a potential organ recipient to another person who has not opted out of the system. There is no age limit to being an organ donor or recipient.

Under the HOTA regime, living donor organ transplantation is allowed, provided that the donor has provided legally effective consent and the specified organ is removed in a hospital with the written authorization of the transplant ethics committee (TEC) of the hospital. Under the guidelines of the MOH (2009c), a TEC

has the responsibility of evaluating applications for living donor organ transplantation. Generally speaking, a TEC must be reasonably certain that the proposed donation is altruistic and that consent has been obtained without any fraud, duress, or undue influence. The decision of the TEC must be unanimous, having also taken into account considerations of public interest and community values (Singapore Statutes, 2004c). In addition, paired matching is permitted under HOTA, whereby a donor can be paired with a compatible recipient in order for another recipient of the donor's choice to receive an organ from another living donor or have priority in selection. Training for TEC members is provided by the CBmE.

Commercial dealing in organs is strictly prohibited under HOTA, although reimbursement for costs and expenses reasonably incurred in the course, and as a result, of the donation is allowed. Such costs and expenses include cost of the medical procedure, domestic help or childcare, loss of earnings, and short- or long-term medical care as a consequence of the donation. The judiciary gave effect to this policy stance when it meted out deterrent sentence on a vendor who attempted to arrange the sale of a kidney by an Indonesian man to a local recipient. Justice of Appeal VK Rajah explains the policy rationale (Wang Chin Sing case: 871–872): "While these middlemen often claim to be providing a useful service to the desperately ill, the truth of the matter is that they are usually purely inspired by unbridled avarice to maximise their financial returns from each transaction. Left unchecked, these middlemen can cause immeasurable harm to the parties involved (particularly the donors) as well as indelibly tarnish the standing of the medical community, which may be (unwittingly) drawn into this intricate web of deceit . . . in Singapore as the law now stands, any middleman who seeks to secure for himself any form of commercial advantage has absolutely no legitimate role to play in the process of donor or organ matching and transfer."

Traditional Medicine

Traditional Chinese medicine (TCM) is the most common and well-accepted form of alternative medicine in Singapore. Since 2000, the TCM Practitioners Board has been established under the TCM Act (Singapore Statutes, 2001b) to register TCM practitioners, accredit TCM institutions, and ensure that an acceptable level of ethical standards is observed (Traditional Chinese Medicine Practitioners Board, 2006). Unlike "western" medical practitioners, it is not mandatory for a registered TCM practitioner to take up professional indemnity insurance, since most TCM practice is not particularly invasive. Even then, a significant number of complaints have been made against TCM practitioners, mainly relating to professional misconduct and negligence. One case is related to a colonic cleansing treatment that a TCM practitioner introduced to his patient (*Lim Poh Eng* case, 1999). Due to the improper administration of the treatment and to inappropriate follow-up by the TCM practitioner, the patient developed extensive gangrene of her anal canal, which left her with the permanent loss of her rectum and consequently having to wear a colostomy bag indefinitely. During the trial, the High Court held that

a practitioner of TCM would be held to the standard of a reasonable TCM practitioner, and not of a "western" practitioner, and that a common standard of negligence applied to both civil and criminal cases. On this basis, the TCM practitioner was found to be criminally negligent. In addition, the TCM Act, and the ethical and professional standards promulgated thereunder, has extraterritorial effect in that a registered practitioner can be prosecuted for professional misconduct committed overseas (*Huang Danmin* case 2010).

End-of-Life Care and Advance Care Planning

A general lack of discussion of prognosis and mortality between patients and their physicians concerning the treatment of advanced cancer has been observed in the USA, Japan, and a number of European countries (Harrington & Smith 2008). Perhaps attributable to varying degrees of this deficiency, patients have unrealistic expectations about treatments and treatment outcomes, particularly if they are never told or are not told accurately about their health condition. Even when told, they may not believe information about benefits and risks of treatment. A study by Jacinta Tan and Jacqueline Chin showed that some of the challenges that confront end-of-life care in Singapore do not differ significantly from other countries (Tan & Chin 2011). However, cultural understandings of the meaning of information for patients and families and decision-making patterns within different communities are critical forms of knowledge that inform the framing of practical guidance on what, how, to whom, and by whom information disclosures are to be undertaken in healthcare settings.

End-of-life care has been rendered more complicated by modern technology that can prolong life in the final stages of a terminal condition. If it is envisaged that extraordinary life-sustaining treatment may be required, any patient who is 21 years of age and above, with the requisite mental capacity, may create an advance medical directive (AMD) to refuse such treatment. As a legal document, the AMD becomes effective when the patient subsequently loses mental capacity to refuse treatment and death is imminent. To be effective, the AMD must be completed in the prescribed format and signed by the patient in the presence of two witnesses before it is lodged with the Registrar of AMDs. One of the two witnesses must be the patient's doctor, while the other witness must have attained at least 21 years of age. Both witnesses must not have any vested interests in the patient's death.

In practice, very few Singaporeans have created an AMD for a number of reasons. First, the AMD has a very restricted scope of application as "extraordinary life-sustaining treatment" has been narrowly defined as "any medical procedure or measure which, when administered to a terminally ill patient, will only prolong the process of dying when death is imminent, but excludes palliative care" (Singapore Statutes, 1997: Section 2). In other words, the AMD will typically only be of relevance at the very end of the treatment. By that time, both the medical team and the family members of the patient may decide to cease intrusive medical

interventions on the basis of medical futility. Second, it is often unclear if a patient has made an AMD, as it is an offense for any person who has or will be likely to have the medical care of the patient to ask or otherwise enquire of the patient as to whether an AMD has been made or otherwise of an intent to do so. In addition, it is an offense to require or prohibit the making of an AMD as a condition for being insured or for receiving medical or healthcare services. Of course, the medical team may seek guidance from the family members of the patient, but the latter may not know or remember if an AMD has been made. Even if there is such a directive, family members often do not know if the patient has revoked the AMD or otherwise changed his or her mind after the directive was made. Third, many Singaporeans consider it culturally inappropriate to discuss end-of-life matters with family members. Where the patient is an elderly person or a legal minor, it has often been difficult to discern the patient's true wishes. Medical decision-making for these groups of patients has often been made collectively by families and, sometimes, by family members on behalf of the patient (Tan & Chin 2011: 9–10). Tan and Chin explain that elderly patients, for instance, may regard this passive involvement as an expression of altruistic sacrifice, assessing other financial needs to be more pressing (Tan & Chin 2011: 14–6).

The limitations of AMDs contributed to a shift in emphasis from making advance directives to advance care planning (ACP). In a guidance issued by the NMEC, ACP has been defined as "a voluntary process of discussion about future care between an individual, their care providers (irrespective of discipline) and often those close to the individual, should the individual become seriously ill in the future and be unable to make decisions, and/or communicate their wishes to others. Even if the individual is still able to make his wishes clear at the point when he requires the care, ACP would facilitate the decision to be made. ACP may include clarifications on the individual's wishes and concerns, important values and personal goals of care" (NMEC, 2010: 2, paragraph 11). To better realize the ethical goal of patient autonomy, proper and adequate communication is given considerable emphasis in ACP. Unlike the AMD regime, ACP endeavors to provide a broader basis for medical decision-making, particularly in its recognition of the inevitability of family involvement. The guidance states: "With more parties involved, disagreement may occur. One reason may be that the decisions made by the individual do not adhere to dominant culture. Sufficient time should be provided for discussions between individuals and their family members to acknowledge and respect the goals, values and wishes that the individual chooses" (NMEC, 2010: 12, Annex B).

Mental Capacity and Mental Health

A similar philosophy is evident in the Mental Capacity Act (MCA; Singapore Statutes, 2010), which came into operation on 1 March 2010. This regime attempts to balance personal autonomy in decision-making with safeguarding the person's best interests in the event that he or she lacks mental capacity to decide. The

legislation makes clear that mental capacity (or the lack thereof) cannot be assumed only on the premise that a person has a particular medical condition but must be assessed on a case-by-case basis, applying five statutory principles (Singapore Statutes, 2010: Section 3). In general, a person lacks mental capacity to make a specific decision at the time it needs to be made when he or she is unable to understand, remember, or weigh information relating to decision-making or to communicate the decision. The legislation also creates a new statutory form of power of attorney known as the lasting power of attorney (LPA). This is a legal document that allows a person who has attained 21 years of age, with the requisite mental capacity, to appoint one or more persons (donee(s)) to act and make decisions on his or her behalf, including the provision or refusal of consent to continue healthcare treatment or participate in clinical trials (Singapore Statutes, 2010: Sections 22, 26 and 29). However, a donee is precluded from making certain decisions including treatment for sexual sterilization, abortion, organ removal, or the gifting of the body (or any part thereof). In addition, the donee does not have the power to make or revoke an AMD, or to refuse life-sustaining treatment or treatment required to prevent a serious deterioration in the patient's condition. In the absence of an AMD, the doctor must these medical decisions in the best interests of the patient (Office of Public Guardian, 2008: 33–44; Singapore Statutes, 2010: Section 6; Tan & Chin, 2011: 38–39).

Neither the AMD nor the MCA regimes apply to persons under the age of 21 years. Generally speaking, a person below the age of 21 years is regarded as a legal minor, although legislation may specify otherwise. For instance, the law recognizes certain contracts entered into by a person who has attained the age of 18 years to be legally binding (Singapore Statutes, 1999a: Section 35). In most cases however, the consent of a parent or guardian is required as they are primarily responsible for the care and welfare of their child or young person. Parental or guardianship authority is not absolute, as any action taken or decision made concerning a legal minor (including receiving medical treatment or participation in a clinical trial) should invariably be in his or her best interests (Singapore Statutes, 2001a: Section 3A). Failing which, state procedures may be invoked to protect the interests of the legal minor (Ministry of Community Development, Youth and Sports, 2005). Although it is not a settled law in Singapore as to whether a legal minor can provide legally valid consent if he or she has sufficient understanding and intelligence to comprehend the nature and consequences of receiving medical treatment, for instance, English common law (Gillick case) serves as persuasive authority to at least require the active participation of such a child or young person in the informed consent process.

Apart from the regulatory frameworks that are in place, the government has announced various measures to meet the challenges of a growing and aging population. Under the National Mental Health Blueprint that was implemented in 2007 (Chong, 2007; MOH 2010), core services for mental health conditions were strengthened to enhance early detection and treatment of children with mental health issues and to train school counselors to better manage these children. Community psychogeriatric programs have also been introduced to

provide home-based mental health services for the frail elderly. In 2012, the MOH announced the government's plan to develop a new community-based mental health plan to complement its hospital-based services (MOH, 2012b). A key initiative under the plan is to integrate specialist-led multidisciplinary teams with primary care services, with the goal of improving access to care for mental health patients. These teams will be supported by more specialized setups to focus specifically on dementia patients. Counseling and psychotherapy services will also be expanded in the community to increase the capability of general practitioners to assist patients with mild to moderate mental conditions such as anxiety and depression. Mental health services have also been made more accessible in terms of cost. Qualified individuals are entitled to subsidized treatment at community hospitals (or polyclinics) for schizophrenia, major depression, dementia, and bipolar disorder. The use of Medisave funds is now allowed for outpatient treatment of these conditions as well as for inpatient psychiatric treatment. Besides these initiatives, the HPB will continue with mental health education and promotion efforts, which are directed at unfair discrimination and stigmatization of people with mental health illnesses. Within the profession, clinical practices relating to schizophrenia, bipolar disorder, and depression have also been evaluated and systematized (MOH, 2007a, 2011c, 2011d, 2011e).

Palliative Care

Another area that policymakers have given much attention to is palliative care. In 2011, a national strategy, commissioned by the MOH, highlights a number of changes that are necessary to enhance the provision of palliative care needs in Singapore and provides recommendations to ensure the sustainability of service offerings and use of nonpalliative care specialists and physician substitutes (Lien Centre for Palliative Care, 2011). In particular, the strategy maps ten goals directed at areas of service development, training and research, and public education and awareness. The recommendations for the national strategy for palliative care have been accepted by the government, and a taskforce will be set up to study it in greater detail (Pang, 2012). Since then, several measures have also been announced to render intermediate and long-term care services more affordable, including financial assistance to better support care for the elderly at home and in the community (MOH, 2012b).

Future Challenges

The last decade witnessed considerable developments in all three domains of bioethics in Singapore. Many contentions and challenges that have surfaced will continue to demand ethical and regulatory attention in the foreseeable future. Already, policy orientation is beginning to shift in anticipation of the healthcare

needs that a silvering population will present. With a population that is more educated, affluent, and mobile, greater demands on the medical profession, public health initiatives, and healthcare delivery in general are expected. Certain services that have been on the periphery of healthcare are likely to become more commonplace and controversial. Take for instance plastic surgery or cosmetic medicine. In a recent incident, the death of a heavily sedated liposuction patient from asphyxia highlights ethical and regulatory conundra that are expected to grow over time (Lum, 2012). The issues of cost, necessity, and accessibility that such services present find no ready solution.

Significant investment in biomedical research has also been made in the past decade. One can perhaps deduce that new biomedical technologies and medicines, along with innovative interventions, will generate many ethical challenges. In addition, the growing emphasis on industrial collaboration, translational medicine, and other market-oriented research practices will exacerbate conflicts of interest (especially financial) concerns. Even if new guidelines are promulgated, it is questionable if such a measure is in itself capable of meeting this challenge (Campbell et al., 2010; Ho et al., 2010; Krimsky, 2006).

Conclusion

This chapter has considered the establishment of an elaborate ethics governance framework through the collaborative work of the MOH, the BAC, and CBmE. To be sure, the account provided is not exhaustive, as other agents (such as those concerned with research involving animals and environment protection) have also actively contributed to this framework. However, this chapter has focused on developments since the year 2000 that have shaped bioethics in medical practice and education as well as biomedical research. While there are still many challenges ahead, no society has had to work in isolation. Instructive experiences and resources have been generated across all domains of bioethics and jurisdictions. They suggest that clarity of ethical goals, open communication, and earnest engagement, along with reflective and socially responsible conduct, will offer a reliable way forward.

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Vasil Gluchman, Adela Blahová Lešková, Júlia Klembarová, Alexandra Smatanová, Katarína Komenská, Rudolf Novotný, and Natália Kotorová

V. Gluchman (✉) • A.B. Lešková • J. Klembarová • A. Smatanová • K. Komenská
Institute of Philosophy and Ethics, University of Prešov, Prešov, Slovakia
e-mail: gluchman@unipo.sk; leskova.blahova@gmail.com; j.klembarova@gmail.com; smatanova.a@gmail.com; katarina.komenska@yahoo.com

R. Novotný
Faculty of Health Care, University Hospital, University of Prešov, Prešov, Slovakia
e-mail: novotny.r@fnsppresov.sk

N. Kotorová
University Hospital J. A. Reiman, Prešov, Slovakia
e-mail: kotorova@fnsppresov.sk

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Introduction

Due to significant developments in biotechnologies, biomedical research, and medicine in general, the present world, especially Europe, is witnessing a huge increase in interest in bioethics. This, however, often brings about new questions and problems with regard to the differences in understanding and actual approaches, that is, values, principles, and norms of bioethics. Many of those problems, which have been the subject of polemics and arguments in the world for many years, are now, little by little, being discussed on a professional level also in Slovakia (and in Central Europe). In Slovakia, medical, political, and ideological approaches dominate in the discussions and polemics in question; the interest and involvement of philosophers and ethicists is not very significant.

However, the UNESCO Chair in Bioethics at the University of Prešov is trying to develop a platform for an exchange of opinions and become a coordinator of a number of activities for the professional community. That means providing opportunities for meetings of medical professionals, biologists, health-care professionals, and other natural scientists on the one hand and representatives of philosophy, ethics, theology, and other humanities on the other. This chapter on bioethics in Slovakia is one of the results of the UNESCO Chair in Bioethics and cooperation among different groups of Slovak bioethicists.

Bioethics Development

When and How Did Bioethics Start?

The birth of bioethics in Slovakia can only be dated as far back as 1989. Philosophers although were concerned of these issues before. All there was before was experiments in natural science, especially biology, stating that there are also ethical aspects to life. The isolation of Slovakia from the course of events in the scientific world was the reason why the emergence of bioethics was delayed. It was also caused by political and ideological barriers caused by dividing the world into two contradictory political and ideological camps, which prevented prompt responses to new trends in biomedical research, medical practice, health care, as well as philosophy and ethics. It was not until after 1989 that a free exchange of information started and scientists, as well as philosophers, ethicists, and theologians, could freely express their opinions on intellectual stimuli in the world and also reflect upon them in the Slovak environment.

Who Were the Major Instigators?

The Western (European as well as American) bioethical tradition had a significant influence on the forming of bioethics in Slovakia. At the very beginning, the establishment of bioethics in Slovakia was shaped by specialists in medical and

natural science, such as Jozef Glasa, Ladislav Šoltés, Marta Kollárová, Ľubica Lacinová, and Ján Ďačok. These were later joined by philosophers, ethicists, and theologians, such as Peter Sýkora, Vasil Gluchman, Mária Nemčeková, Eva Smolková, Peter Volek, Zuzana Kiczková, Daniela Kovaľová, Adela Lešková Blahová, Lenka Bohunická, Igor Kišš, and others, as well as the lawyers Branislav Fábry and Ivan Humeník, and specialists from other areas (Glasa et al., 1999; Kovaľová, 2004; Lešková Blahová, 2010).

What Have Been the Major Concerns Over Time?

Medicine and nursing (and, within their scopes, especially medical and nursing ethics) have received most attention. Problems in claiming human rights and values in health care in the form of respecting patients' rights (patients' informed consent, information confidentiality, patients' autonomy, physical and mental integrity, palliative care), the issues of euthanasia and dignified death, organ transplants, instrumentalization of man in medical research, the issue of conscience (in health-care staff), as well as evaluating the relationship between the doctor or the nurse – the patient – the patient's family members, activities of (bio)ethical committees, etc., are at the forefront (Bilasová et al., 2008; Nemčeková et al., 2008, 2004).

Another large subject area in bioethics is formed by issues of gene technology, biotechnology, reproductive and regenerative medicine, which, however, in the Slovak environment are reduced to an ethical and moral discussion on the matter of the beginning of human life, and related issues regarding determining the moral (and, consequently, legal) status of the human embryo, abortion, cloning, the moral aspects of eugenics in the form of preimplantation and prenatal genetic diagnostics or the gender selection in one's future baby, and also research on human embryos or human embryonic stem cells, among others (Hrkút, 2009; Jemelka, Gluchman, & Lešková Blahová, 2008; Sýkora, 2010; 2008). A fair amount of attention is paid to methodological and metaethical issues of bioethics (Gluchman, 2009, 2008a, 2008b, 2005a, 2005b; Sýkora, 2008; Smolková, 2006; Lešková Blahová 2010).

A special category of bioethics in Slovakia is made up by environmental ethics (as part of bioethics), dominated by the following philosophers: Eva Smolková, Zlata Androvičová, Eva Odlerová, Ľubov Stekauerová, Dušan Špirko, the culturologist Ivan Dubnička, and others, who actively applied environmental theories in Slovak circumstances (Jemelka & Lesňák, 2008; Jemelka et al., 2010).

What Resources Have Been Developed?

Several codes of ethics on a national level have been established, such as the deontological code of the Slovak Health Chamber (1992, 1993, 1996, 1998), codes of ethics for nurses and midwives (part of Act No. 311/2002 Coll., Enclosures No. 1 and 2), codes of ethics for doctors and dentists (Enclosure Act No. 219/2002), codes of ethics for health-care staff (part of Act No. 578/2004 on health-care providers,

Enclosure No. 4), Charter of patients' rights in the Slovak Republic (2001), codes of ethics for the pharmaceutical industry in Slovakia (2004, 2006, 2008) (Glasa, 2009).

Conferences and symposia focused on bioethics are more and more common. Scholarly journals, treatises, and university course books are being published. An increased interest in bioethics is equally obvious, especially in the area of reproduction rights, also in NGO–civic pro-life movements and associations supporting Christian values are being founded, such as Forum for Life (Fórum života), the Centre for Bioethical Reform (Centrum pre bioetickú reformu), Yes to Life (Áno pre život), Community of Life (Spoločenstvo života), etc., as well as nongovernmental nonprofit pro-choice organizations, such as the Slovak Family Planning Association (Spoločnosť pre plánované rodičovstvo) and Pro choice (Možnosť voľby).

What Steps Have Been Taken?

After 1989, the political approach to bioethical and medical issues was the first to change, resulting from development of bioethics in the world, which was also reflected in legislation (still in Czechoslovakia, or the Czechoslovak Federation, i.e., until the beginning of 1993, when the country was divided into two independent republics: the Czech Republic and the Slovak Republic) regarding health care, the option for churches to take part in pastoral care in hospitals, etc. Further steps followed relating to the foundation of the Central Bioethical Committee (1990) and other committees in health-care institutions. Following the experience of developed western countries, courses of bioethics, or medical ethics, started to be included in curricula at medical faculties. These were, however, often taught by people lacking the appropriate education in ethics, or bioethics, that is, medical doctors, priests, or even Christian laymen interested in ethics and bioethics. It was not until 1995 when a broader infrastructure started to be created and attention started to be paid to bioethics at more universities. The second half of the 1990s saw the first ethics teacher training courses at faculties of humanities as well as training of other specialists in ethics, including bioethics.

Current Bioethics Infrastructure

Teaching Bioethics at Universities

After 1989, and especially in the second half of the 1990s, the first specialized scientific research and educational departments were founded, as well as other university departments, where courses in bioethics are taught (be it a narrower or a broader conception of bioethics) at all levels of university education within various specializations and study programs. At the same time, these departments carry out research activities in this field. With regard to the above, the following departments should be mentioned: the Department of Ethics at the Faculty of Arts, University of Prešov; the Department of General and Applied Ethics at the Faculty of Arts, Constantine the Philosopher University in Nitra; the Department of Ethics

and Applied Ethics at the Faculty of Humanities, Matej Bel University in Banská Bystrica; the Department of Applied Ethics at the Faculty of Arts, Pavol Jozef Šafárik University in Košice; the Department of Ethics and Moral Philosophy at the Faculty of Arts, University of Trnava; the Department of Medical Ethics at the Medical Faculty, Slovak Medical University in Bratislava; and the Department of Bioethics and Pastoral Medicine at the Faculty of Health Care, Catholic University in Ružomberok. Bioethics is also taught at all medical and health-care faculties in Slovakia.

Bioethics Committees

Up until 1989, there were no ethical, or bioethical, committees in Slovakia, at least not in the modern conception of the term. The Central Ethics Committee founded at the Slovak Ministry of Health Care (since 2005 under the name the Ethical Committee of the Slovak Ministry of Health Care, operating as a national bioethical committee) was not established until 1990 (Glasa et al., 1999). The process of institutionalization of bioethics in Slovakia also leads to the foundation of the Slovak Board for Bioethics at the Slovak UNESCO Committee (2004), the Ethical Committee for the Pharmaceutical Industry in Slovakia (2004), as well as the formation and activities of (bio)ethical committees, boards, and councils on a regional and local level (at research and health-care institutions).

Expert Bodies/Centers

In 1992, the first specialized scientific research and educational department (focused on the development of medical ethics, bioethics, ethics of nursing, and ethics of public health care in Slovakia), the Institute of Medical Ethics and Bioethics, was founded as a joint department of the Slovak Health Care University and the Medical Faculty at Comenius University in Bratislava (with Jozef Glasa as the chair). The institute is also known for issuing the international bilingual (Slovak–English) scholarly journal Medical Ethics and Bioethics (Medicínska etika & Bioetika – 1994, editor in chief Jozef Glasa). The year 2002 saw the foundation of the Institute of Social Medicine and Medical Ethics at the Medical Faculty, Comenius University in Bratislava. Later on, in 2008, the Centre for Bioethics at the Department of Philosophy, Faculty of Arts, St. Cyril and Method University in Trnava (with Peter Sýkora as the chair) was established. Undoubtedly, the foundation of the UNESCO Chair in Bioethics at the Faculty of Arts, University in Prešov (Vasil Gluchman being the chair) in May 2010 was a significant event. Hereby, the Department of Ethics at the Faculty of Arts, University of Prešov, which is its center, now ranks among exclusive UNESCO Chairs worldwide, dealing with research and education in bioethics as the only department of its kind in Central Europe. Publishing the international journal *Ethics and Bioethics (in Central Europe)* (2011, editor in chief Vasil Gluchman) is among the activities of this department.

Relevant Legislation

In contrast to other European countries, Slovak legislation regulating moral and ethical issues in biomedicine, such as in reproductive and regenerative medicine, medical genetics, and biomedical and biological research, is fragmented in many cases. With regard to the given areas of biomedicine, there are no special laws, or a particular biomedical law, to regulate them. This area is partly contained in several national laws, or legislative rules and regulations, as well as in general legal enactments regulating the protection of person (such as the civil code). The Health Care and Services Act in particular could be mentioned, regarding their provision (Act No. 576/2004 Coll.), their providers (Act No. 578/2004 Coll.), and their extent and payment (Act No. 577/2004 Coll.). There is also the Nursing and Midwifery Act (No. 311/2002 Coll.), the Medical Profession Act (No. 219/2002), the Medicines and Medical Devices Act (No. 140/1998 Coll.), the Public Health Service Act (No. 126/2006 Coll.), etc. The issue of genetically modified organisms appears to be an exception from this area, which, in Slovak legislation, is embedded in a special act (No. 151/2002 Coll.), the act on the use of genetic technologies and genetically modified organisms (Glasa, 2009; Lešková Blahová, 2010). The above acts apply at present, as amended by rules and regulations made by the Slovak government, while certain legal acts are adopted from European associations and the European Union. In a great number of cases, nonbinding or advisory international acts on a worldwide or European level are respected (such as UN and UNESCO statutes and agreements). In general, the Slovak Republic is a country with conservative, or restrictive, biopolicy (Humeník, 2008; Lešková Blahová, 2010).

Public Debate

After 1989, the most prominent topics of discussion in Slovakia regarding bioethics were abortion and the rights of unborn children. It was especially the Christian Democratic Movement (Kresťansko-demokratické hnutie) and other Christian organizations or NGOs that tried to tighten the wording of the abortion act, which originated back in the 1960s. It was presented as a remnant of the totalitarian past. Despite the fact that a majority of the population of Slovakia adhere to Christianity, the efforts of Christian democrats gained sufficient support neither publicly nor in the parliament, which meant that Slovakia kept a relatively liberal abortion law. Another significant topic which dominated the first 5 years of this millennium was the issue of conscientious objection and its legislative embedding, which would, for instance, allow doctors to refuse to perform an abortion or in vitro fertilization, should they conscientiously object to it. It was not in this instance either for the present liberal legislative to be made stricter, in spite of the actions of the Christian democrats who, in protest, resigned from the government, which resulted in early parliamentary elections in 2006.

Major Bioethical Issues and Discussions

Beginning of Life

The issue of the beginning of human life is undoubtedly very prominent in Slovak bioethical discussions. One of the reasons is that it impacts a number of biomedical branches, such as medical and molecular genetics (and especially genetic testing and gene therapy as part of it), regenerative medicine (especially at the level of cell therapy), reproductive medicine (with regard to moral issues of abortion and assisted reproduction), and biomedical research (research using human embryos and embryonic stem cells). The problem of determining the beginning of human life (in connection with determining the ontological, or metaphysical, status of human beings) predominantly lies in whether it is possible to attribute to a human embryo the full moral status of a human person or whether it is supposed to be perceived as a "mere" stage in human development, which could be used for the moral "justification" of its instrumentalization in medicine or scientific research. These and related issues are, in Slovakia, usually considered through the eyes of theology, medicine, law, and, to a lesser extent, secular philosophy and ethics. It is due to the powerful Christian cultural background of the country that the moral theological and methodological perspective dominates among the professionals. Secondarily, it is also caused by a low level of interest among secular professionals (bioethicists) in speaking about moral issues of this kind. This is one of the reasons why Slovakia is a rather conservative country, bioethically (Lešková Blahová, 2010).

When determining the moral status of the human embryo, and the related issue of respecting the moral value of human life and human dignity, the principle of potentiality remains the predominant argument in theological ethics (especially for personalist theories). According to this principle, the human embryo is a potential human being/person, who, thanks to this argument, deserves respect and protection from the very beginning and, consequently, in all stages of its development, which means that any instrumentalization of man is refused. Secondarily, the above-mentioned principle also refers to the genetic and numerical continuity of the developmental stages of man (Balák, 2009; Glasa & Glasová, 2002; Volek, 2006, 2007, 2008). It, however, meets criticism from secular philosophers and ethicists, regarding the issue of the numerical identity of man, or a reexamination of the ontological status of the human embryo (a scholarly polemic between Peter Volek and Peter Sýkora).

Among the Slovak professionals, there is also a less prominent but more liberal bioethical approach to the presented issue, especially identified with the secular philosophical–ethical tradition, in the form of the argument of rationality concerning lack of rational abilities in case of human embryo. Still, one cannot speak of any extreme form of liberalism, allowing (and not judging as an immoral action) any, be it insufficiently justified, instrumentalization or willful destruction of the human embryo in (bio)medicine. This is more of a compromise position in solving the given issue. With regard to the moral status of man, a so-called gradualist position is mentioned, more precisely, a gradualness in respect for the dignity of human life.

In simple words, this means that the moral status of man increases gradually with the rational abilities of the human organism, which are a prerequisite for its moral competence. This allows the given principle to morally justify the instrumentalization of a human being (not a person) in medicine and science. For it to be marked as morally acceptable, adequate respect toward human dignity befitting the particular developmental stage of the human being in question and a sufficient relevance or justness of such actions have to be present (Gluchman, 2005b, 2008c; Kišš, 2004; Lešková Blahová, 2010; Sýkora, 2006, 2008). Consequently, the bioethical debate moves to the legal sphere, where the legal status of the embryo is considered, for example, by Branislav Fábry and Ivan Humeník (Fábry, 2007).

End of Life

Neither euthanasia nor patient-assisted suicide (PAS) is legal in Slovakia. Health-care professionals have to act in accordance with the code of ethics (Paragraph 80 1d, Act No. 578/ 2004 Coll.). Euthanasia is illegal and considered a criminal act. Likewise, PAS or any suggestion, information, or instruction given by a physician on how to commit suicide is considered a criminal act. This raises important ethical questions. Terminally ill patients often ask their physicians about other options, and sometimes, they decide for STED (stop eating and drinking). If the physician does not inform the patient on how to proceed, this procedure can be truly painful, uncomfortable, and filled with suffering. Moreover, the patient in question can be declared incompetent, and the relationship between the patient and the physician can worsen. However, with adequate care and advice from the physician, it can lead to a peaceful death where the patient's fundamental needs are fulfilled. The question remains as to how well Slovak physicians are trained in listening to their patients' wishes at the end of their lives, how "culturally competent" and how ethically sensitive they are. Unlike in many European countries, there is no public debate about euthanasia or PAS in Slovakia. A significant issue connected to the end of life is that of withholding and withdrawing treatment. Patients have the right to reject all lifesaving treatments, medicine, and interventions, provided they are legally responsible for all the consequences of such a decision. Thus, a physician acting in accordance with the patient's wishes cannot be legally prosecuted. How about those cases when the patient is no longer able to express his wishes or is declared incompetent to make such decisions? Mostly, physicians agree that futile treatment ought to be discontinued. However, who should decide when and whether the treatment is futile? What about such cases when the patient's wishes and the physician's decision are in conflict? It is important to respect the patients' desire and their right (also the right of their families) to decide on where they want to spend their last moments. The patient has the right to refuse certain treatments (such as surgery, drugs, and chemotherapy), if he feels it does not help him, but, instead, subjects him to unnecessary pain and suffering. There is also a major influence from the Catholic Church, which strongly refuses euthanasia as a solution to great suffering in the final phase of life.

Health and Disease

Slovak ethicists often reflect on the matter of health and disease as an issue of quality of life. This helps to understand the problem of health in its complexity, and at different stages, tendencies to define the concept of health and disease in the holistic and normative view are not direct but, still, obvious (Bilasová et al., 2008). Lately, an original Slovak ethical theory, the ethics of social consequences (ESC), has attempted to deal with bioethical issues. Lately, the original Slovak ethical theory, ethics of social consequences (ESC), tries to engage itself with bioethical issues. As one of the outcomes of this interest might be considered the concept of health in which ethics of social consequences inspires itself by the holistic theory of health of Lennart Nordenfelt. The initial understanding of health within ESC is that health is (a) something good and, in this way, a moral goal and (b) an instrument which helps other life goals to be reached. A more detailed analysis of the concept of health shows a parallel with the holistic theory of health in that they both consider health an ability to fulfill vital goals. ESC agrees that the ability to fulfill one's goals reflects the quality of life. What ESC adds to the discussion is the importance of understanding the ability to set these vital goals as a kind of moral skill that has to be developed by a moral agent.

Health-Care System

The health-care system stands for all interferences by society (government, community, institutions, and individual members of society) in the matter of health and disease. Public health and the health of all members of the society are its main value and aim. Health is in this matter defined as something beneficial to society and as one of the conditions in which society can work successfully and can actively develop itself. In Slovakia, main roles and characteristics of the health-care system are defined in legislation (Act 576/2004). From an ethical viewpoint, the goals of the Slovak health-care system are based on fundamental moral principles: reduction of suffering, respect for the dignity and rights of others, prevalence of good over bad (or minimization of malice if the action cannot guarantee an overall prevalence of good), and production of positive social consequences, based on principles of humanity and justice (Gluchman, 2003; Komenská, 2011). The health-care system in Slovakia is a social system charged with guaranteeing the health of its members and with increasing the quality of their lives. The health-care system is a complex system created not only by health-care professionals but also by a well-organized system of institutions, organizations, and individuals who cooperate to reach their common goal. However, some of the bioethical problems are ineffectiveness of the health-care system in Slovakia as well as its latent corruption especially within public hospitals.

Traditional Medicine

In the sixteenth century, one could find healing-oil makers in the mountainous parts of Slovakia who used the healing power of herbs. In 1771, Jan Barvírek-Tonsoris

wrote the first Slovak printed book *Sana Consilia Medica or Medical Health Advice* (*Sana Consilia Medica aneb zdravá rada lékařská*) on traditional healing. Ľudmila Thurzová was a traditional healer whose educational work culminated in 1963 in the publication of *The Mini Atlas of Healing Herbs* (*Malý atlas liečivých rastlín*). At present, there are approximately 2,000 traditional healers in Slovakia. The number is inaccurate, as healers do not need a license to provide health care. Psychotronicists, herbalists, and chirotherapists all declare to be traditional healers. Chirotherapy is a measure, which, in Slovakia, should only be performed by medical doctors. There is no legal adjustment in the Slovak Republic referring to the status of healers. A healer does not need to have any medical erudition and can practice without restriction. According to Act No. 578/2004 Coll., healers are not health-care workers. The 2006 Criminal Code classifies harm to one's health as a criminal act committed by an offender who, in spite of not having appropriate specialized health-care skills, pursues health care and causes harm to one's health by an unprofessional or careless act. The ethical conflict relates to the undefined legal and professional status of traditional healers in Slovakia. Traditional healers are not obliged to prove their education and are not legally obliged to maintain confidentiality. Act No. 578/2004 Coll. states that a health-care worker must not encourage any other person to perform such acts which are permitted to be carried out by health-care workers only. The law does not prevent a medical doctor to be a traditional healer at the same time. The activity of healers is not inspected. By course of the WHO and EU resolutions, the Slovak Medical University in Bratislava founded the Institute of Traditional Chinese Medicine (Ústav tradičnej čínskej medicíny – ÚTČM) in 2010 as its executive organ. The activities of ÚTČM are based on the philosophy of traditional Chinese medicine (TCM) and its components, that is, acupuncture, physiotherapy, kinesthetic therapy, massage, and diet therapy. By its existence, the institute validates the use of TCM and its theories in health care as well as research in Slovakia. Acupuncture is part of health care, and its content was defined and approved by the Slovak Ministry of Health Care in Act No. 576/2004. At present, there are approximately 600 trained doctors–acupuncturists in Slovakia. Its particular application in the area of diagnostics, treatment, and prevention as well as physiotherapy is, however, problematic, as the major aim is not only to suppress illnesses but also to strengthen one's health with the aim of rationalizing the overall treatment and preventative measures as well as effectively saving health-care costs. It is necessary to monitor the validity of some traditional techniques as well as to test and inspect physiotherapeutic products. Likewise, there is a need to systematically inform health-care workers and the public about TCM.

Genetics

Bioethical issues of genetics, especially on the level of molecular and medical genetics, are, in the Slovak environment, reduced to medical, philosophical–ethical, theological, or legal bioethical discussion on preimplantation and prenatal genetic diagnostics (regarding measures within assisted reproduction). To a lesser extent,

contemplations on the ethical and moral aspects of gene manipulations (gene engineering) with regard to man emerge, mostly with human sex cells or embryos and fetuses. In this matter, one can often encounter polemics on the morality of genetic improvement human beings in the form of genetic interference into the human genome (gene therapy) on both the level of the individual and the species or on the eugenic threats of genetics. All this reasoning is perceived in the context of philosophical–ethical or theological reflection on (non)crossing the borderline of naturalness (natural order of things), interfering in human nature, (dis)respecting the moral value of human life and dignity, determining the moral status of a human embryo, etc. In most cases, these are mere informative articles. There are only few authors who stand out, who try to form their own evaluative analytical outlook regarding selected methodological (philosophical–ethical) standpoints, such as Peter Volek, Igor Kišš, Peter Sýkora, Adela Lešková Blahová, and others (Kišš, 2006; Lešková Blahová, 2010; Sýkora, 2010, 2006, 2008; Volek, 2009). Since Slovakia is a country with conservative, or even restrictive, biopolicy, a dismissive approach toward controversial measures within medical, or molecular, genetics is not surprising.

Reproductive Medicine

Moral issues of reproductive medicine in Slovakia are restricted to a discussion on selected measures of assisted reproduction, possibly, stretching to reproduction rights of man (especially human reproduction autonomy). The most common reasoning is directed toward morally controversial consequences of artificial and so-called unnatural creation of human embryos for the purposes of assisted reproduction, and, consequently, the matter of their genetic testing and possible selection, such as the gender of the future baby (preimplantation genetic diagnostics and prenatal genetic diagnostics in later stages of prenatal development). Other polemics are carried out about treating so-called excess human embryos in the form of their further keeping (cryoconservation), liquidation or disposal (killing), and adoption or usage in biomedical research (with regard to the isolation of embryonic stem cells). The issue of multifetal pregnancy reduction (in cases of assisted reproduction) also emerges to a considerable extent and, by effect, a more notable matter of acceptability of abortion in general. Again, these measures are evaluated in the context of acting for/against (human) nature, or the natural order of things, (non)attributing a human embryo a moral status, and (dis)respecting moral values of human life and human dignity or thoughts on their (in)humanity. Assessing moral issues of reproductive medicine is primarily supported (if at all) by the methodology of moral theology and, to a lesser extent, secular philosophy and ethics. It must be stated that the discussion on practical moral issues of reproductive medicine is still carried out on a rather theoretical ethical level (reasoning on the beginning of human life) with low potential for moral application and, only to a minimum extent, on a specialized scholarly level. The moral applications can be found only in the works of Igor Kišš, Vasil Gluchman, and Ján Hrkút (Gluchman, 2005b, 2008c; Hrkút, 2006, 2007, 2009; Kišš, 2006, 2004).

Medical Research

Slovak professional bioethical community mostly regards the level of clarifying fundamental theoretical methodological, or metaethical, issues (also) related to (bio)medical research. Two areas of thought can be recognized. The first level of rather medical or legal reflections is concerned with the participation of human subjects in research (especially the issue of acquiring their voluntary and informed consent, acting for the benefit/good of participants in biomedical research and assessing the resulting risks, or protection of personal information). Many a time, it concerns the level of giving information on basic human rights in clinical research, reaching out to those carrying out the research. In a broader context, specialists (mainly in medicine, natural science, and law) speculate about the competences of ethical committees who evaluate the ethical and moral acceptability of such research (Humeník, 2008; Magulová, 2005). With regard to this, deeper ethical reflections on (non)respecting the moral value of human life and human dignity, physical and emotional integrity, and safety and justified interest of research participants or (in)human and (ir)responsible actions by scientists/doctors are virtually lacking. The other area of bioethical discussions concerns assessing research performed on human embryos. Research on human embryos and embryonic stem cells, or so-called lines of human embryonic stem cells, probably causes the greatest controversy, in spite of the fact that this type of biomedical research is illegal in Slovakia. It is often perceived in the context of the (im)morality of (therapeutic and reproductive) human cloning (Glasa & Glasová, 2001). Only a small number of views get to a deeper level of ethical reasoning on the instrumentalization of man and disputes about actions which do (not) maintain the moral value of human life and dignity and are (un)natural (artificial, antinatural) and (in) human. In relation to this, a compromise approach of certain authors, such as Igor Kišš, Peter Sýkora or Adela Lešková Blahová, and others, can be mentioned (Kišš, 2006; Lešková Blahová, 2010; Sýkora, 2010).

Public Health

The following five areas are a priority for Slovak public health care: chronic conditions (predominantly cardiovascular diseases, tumors, and obesity), infectious diseases, influence of the environment on health, smoking, and alcohol. PHA (Public Health Organisation) is in charge of coordinating activities on a national level in the area of public health care, which is a contributory organization of the Ministry of Health Care. PHA controls 36 regional institutes of public health care on a national level; it monitors infectious diseases and, if required, takes action in the protection of life and the improvement of health. In 1993, *health advisory clinics* were founded as an integral part of the *offices of public health care* with the aim of giving advice on risk factors, healthy diet, giving up smoking, physical activity, mental health, and managing stress. In order to increase awareness, a great number of conferences, seminars, courses, and educational workshops are

organized regarding health protection (such as World Health Day, World Environment Day, International Day against Drug Abuse, World Food Day, World No Tobacco Day, and World AIDS Day). *Offices of health care* monitor the living conditions of children and the young; they sustain health by means of programs promoting healthy lifestyle (focused on the issues of smoking, healthy diet, drugs, HIV/AIDS, and sex). Offices of public health care (in cooperation with the Ministry of Environment and other sectors) monitor risk factors in the area of environment and health care. Prevention and screening programs in Slovakia are covered by the SHI. The aim is to create a society-wide effective system of measures focused on reducing the incidence and prevalence of the most serious heart conditions and vascular risk factors, as well as on reducing morbidity and mortality rates of the most serious cardiovascular conditions – ischemic heart disease, chronic heart failure, and sudden cardiac death.

Infectious Diseases

The pivotal strategy in the prevention of infections in Slovakia is maintaining high levels of vaccination. Slovakia has had a vaccination program since 1986. It is focused on elimination of infections, predominantly in children. The Slovak national immunization program is realized in compliance with the WHO goals for all countries in the twenty-first century. Consistent administration of this program managed to significantly improve and maintain a low or zero incidence of diseases preceded by vaccination. In 2007, Slovakia reached vaccination levels between 98.1 % and 99.5 %. Vaccination is of primary importance in the care of pediatricians. In 2007, there was no incidence of infantile paralysis, diphtheria, or morbilli. The epidemiological situation with regard to the incidence of infectious diseases in 2010 can be evaluated as favorable. The situation was satisfactory especially with regard to diseases prevented by vaccination, with the exception of pertussis (whooping cough), the incidence of which significantly increased in 2009. In 2010, 1,929 cases of all types of viral hepatitis were registered in Slovakia, which was 1 % less than in 2009. VH-C dominated among the chronic forms – 221 cases, that is, 67.8 %. An increase (by a factor of 2.3) was only observed in the acute form of VH-C. After several years, 1 case of VH-E was documented, imported from Vietnam. In comparison to 2009, an increase (by a factor of 1.2) in diarrheal diseases with explained etiology was observed. Between January 1, 2010, and December 31, 2010, 125 cases of SARI (severe acute respiratory infection) were reported. From 125 reported cases of SARI, 27 (21.6 %) patients died. From the total number of deaths, the pandemic virus A (H1N1) was confirmed in 14 patients.

Transplantation Medicine and Organ Donation

In Slovakia, transplants are restricted to two types, kidney transplants and, to a lesser extent, heart transplants. Slovak specialists in the field of transplantation

medicine achieve great results in the above areas. Neither liver nor lung transplants are performed. A lack of organ donors is, however, a frequent problem, which is often connected to a conservative Christian viewpoint among the public concerning the dead body and the option to donate organs in order to save a life, or lives, of others. Christian Churches are not directly against organ donation; they, however, take a dismissive standpoint toward organ sale, as, in their opinions, the significant ethical and moral effect of altruistically helping a sick person is lost.

Emerging Technologies

In the past 20 years, the situation in Slovak health care has considerably improved, with regard to the newest lifesaving technology as well as technology enabling early diagnosis of life-threatening diseases. Slovak health care, however, suffers from a serious lack of finances provided from the state budget or public resources, which is why it significantly lags behind developed Western European countries in the area of new technologies. So far it has not been possible to pursue any reforming steps which would provide greater space for the introduction of private funds in hospitals. These are, to a large extent, at the hands of the state, or, in some cases, regulated by self-governing regions. They, however, do not have enough resources for their development, sufficient financial evaluation of the staff, etc. On the other hand, nontransparent public procurement for purchases of expensive medical equipment and technology is a serious ethical and moral problem. Thus, state financial resources are wasted or ineffectively handled, and health institutions are continuously in debt.

Intensive Care

In the past decades, scientific and medical findings on treating life-threatening diseases have substantially improved. At the same time, medical equipment and technology used for saving human lives has significantly improved; however, limited financial resources available in health care in Slovakia as well as in other Central and Eastern European countries are still a serious problem. This is true, to the same extent, for intensive care units, where doctors as well as other health-care workers have to solve moral dilemmas regarding effective use of drugs, medical technology, and other equipment in treating patients living risky lifestyles, such as alcoholics and drug addicts, and, on the other hand, when it is necessary to save lives of young people who have been in accidents, patients with chronic conditions, and so on. The situation in the Slovak health service, including intensive health care, at the end of 2011 is further complicated by doctors going on strike and handing in their notice in protest to the health-care reforms of Iveta Radičová's government regarding privatization of hospitals (in an effort to prevent hospitals from falling further into debt). Furthermore, doctors in hospitals have requested pay rises. Patients have, thus, come to be doctors' "hostages" in their effort to maintain the status quo or improve their own financial situation.

Palliative Care

The Slovak Ministry of Health defines the concept of palliative care in accordance with the WHO definition of palliative care (2002). This means that the concept of palliative care in Slovakia is focused on symptom management, pain, and suffering relief. The only legal option for terminally ill patients is the provision of opiates that neither prolong nor shorten their lives. Caring for patients is multidimensional (bio-psycho-social), and thus, the caring team consists of specialists from various fields. Moreover, palliative care not only involves care for the patient alone but also for the family members. The problem is that, in Slovak hospitals and health-care institutions, spiritual care is usually only provided by a clergyman. Therefore, many patients reject it merely because they are afraid of being forced to convert. This is why the lack of humanist workers and specialists trained in spiritual care represents an urgent problem which needs solving. Palliative care can be delivered in hospices (patients over 65 years of age), specialized wards in hospitals, or at home. The first palliative care ward in Slovakia was established at the National Institute of Oncology in 1995. *The Hospice of Mother Teresa* (*Hospic Matky Terezy*), the first hospice in Slovakia, was established in Bardejovská Nová Ves (Eastern Slovakia) in 2002. Nowadays, there are a few hospice services available in several towns in Slovakia. Nevertheless, hospice care is not financed by the government but by nongovernmental organizations. Apparently, this financial support is not sufficient, and people have to pay to stay in such institutions. Not all people can, however, afford to spend their last days in these institutions. The fact that supply and demand are not equal, as there are not enough palliative care establishments in Slovakia, is also a problem. Since 2006, palliative medicine has been officially recognized in Slovakia as a new field of medical study. This is considered a major success.

Care for the Elderly

In Slovakia, the population of elderly people with chronic conditions makes up a quarter of the overall population. Health care provided to patients older than 65 years of age is called geriatric care and is aimed at prevention, diagnosis, rehabilitation, and nursing of elderly patients. Care for the elderly is available in geriatric outpatient wards, geriatric hospital wards, and in long-term care wards. The insufficient number of beds for elderly patients is another pressing concern. On average, there are two beds per 10, 000 inhabitants and one geriatric outpatient ward per 10, 000 inhabitants over 65 years of age. Moreover, these are usually understaffed. From the above facts, it can be inferred that care for elderly patients is inadequate and the elderly are not sufficiently informed about their situation due to the unsatisfactory number of specialized geriatric clinics. Elderly people are not often adequately informed, and thus, their physicians cannot be aware of their wishes about possible future treatment, or where they would like to die, since the elderly do not always keep these matters in mind. Specialized physicians and those in homes for the elderly, geriatric hospital wards, and nursing homes should help

elderly patients think about their future and find out what their ideas about life and death are. However, as those are not always available, elderly people can end up in conditions they never wished for. Even if the specialized care giver and care are provided, the question should be asked whether physicians and nurses are adequately trained to care for the elderly and to provide them with the best possible care. The fact that the elderly usually only receive a small pension and that treatment is rather expensive, as is residential stay in a private home for the elderly, causes another problem. The Ministry of Health Care and the Ministry of Labour, Social Affairs and Family do not seem to be able to make a decision as to who should be responsible for the matters of the elderly. Therefore, a solution of these problems has been hindered. At the same time, the elderly usually enjoy contact with their GPs, and since, in Slovakia, patients do not pay any fee for visiting their GP, these visits are not controlled, and many patients think of GPs as a possibility for some social contact. Thus, GPs who are not specialists in geriatric care often have to surrogate the role of a psychologist or a social worker.

Chronic Diseases

In Slovak bioethical discourse, the issue of chronic diseases is mostly reflected in case studies of specific diseases, such as cancer and AIDS, or conditions like Down's syndrome or from a particular point of view (Nemčeková et al., 2004). Most theoretical aspects regarding specific characteristics of chronic diseases and conditions are not defined. Ethical and moral problems such as autonomy, freedom and its absence, decision-making capacity, and ability to fulfill one's social role and function are reflected in philosophical and ethical discussions; however, they are absent with regard to chronic diseases. The most prominent chronic health difficulties in Slovakia are an increasing incidence of cardiovascular conditions, tumors, respiratory diseases, allergies, and fatal accidents. From the total number of deaths, cardiac and vascular conditions and cerebral vascular diseases have for a long time been the most common. At present, more people are dying of circulatory system diseases than of all types of tumors. According to the 2005 WHO/EURO data, Slovakia is in the third (out of 34 European states) of those countries with the highest death rates. In general, between 1981 and 2005, Slovakia registered the lowest decrease in death rate due to circulatory diseases. In Slovakia, neither the number of new acute coronary incidences nor the number of strokes is decreasing. Diabetes mellitus, as one of the most significant risk factors, is associated with a two- to four-times higher mortality and morbidity with regard to cardiovascular conditions. A dramatic increase in cardiovascular complications in diabetics is partly due to insufficient regulation of glycemia but especially to coincidence of hypertension and dyslipidemia. Ischemic heart disease is a disabling and deadly disease, killing over 15, 000 people in Slovakia yearly. In the past 10 years, Slovakia has seen a minimum decrease in the most serious risk factors connected to cardiovascular conditions in the population. Such high prevalence in the Slovak population results from a very low level of their regulation. According to the overall

findings, as much as 68 % of women and 78.4 % of men are at risk. The incidence correlates highly with age, gender, the level of education, and the region of Slovakia, while the best results were found in the population of large towns and the worst in the regions of Southern and Eastern Slovakia. These findings also concern dietary habits. Ethical and moral issues concern especially unhealthy lifestyle of the Slovak population and lack of permanent public health-care information concerning reasons of chronic diseases as well as shortcomings in primary and secondary education about the harmfulness of smoking, using alcohol, and drugs.

Psychiatric Care

Specialized psychiatric outpatient departments, general hospitals with psychiatric departments, specialized hospitals (psychiatric hospitals, centers for treatment of drug addiction, psychiatric treatment institutions), psychiatric day-care centers, psychiatric treatment facilities, home care agencies, community-based psychiatric facilities, crisis centers with mobile team units, and so on are all examples of institutions in Slovakia providing services to people with mental disorders, with the main aim of providing necessary health care based on their specific needs. In 2004, the National Programme of Mental Health was approved by the Slovak government, with the following goals (for the period 2005–2015): reduction of the stigma associated with mental disorders, development of home care agencies, development of crisis intervention services, and development of mental health programs. In spite of these efforts, it is important to emphasize that psychiatric care in Slovakia is undervalued and does not meet the actual needs of society. For instance, insufficient capacity as well as poor material and technical facilities of particular psychiatric institutions could be mentioned. From the geographical viewpoint, an unevenly and insufficiently developed network of psychiatric care facilities represents another negative feature with regard to psychiatric care in Slovakia. Furthermore, patients with mental conditions sometimes become victims of discrimination based on the permanent stigma and prejudice present in society. They are seen as unpredictable, unreliable, or dangerous. The stigmatization of mental conditions often results in handicapped people not searching for help (from a psychologist or a psychiatrist) refusing help and advice from family members. Consequently, their health deteriorates and can lead to social seclusion. That is why it is necessary to uphold the dignity of these people and enhance the value of psychiatric care and services in this field. Such aspects as the stigmatization of mental conditions and its negative view in society can be defined as the main reasons for the slow development of psychiatric care in Slovakia (in comparison to countries in Western Europe).

Pediatric Care

Slovak pediatrics is of a very high standard; it has especially expanded in the past 30–40 years. Pediatricians achieve excellent results in the vaccination of children

against infectious diseases. Vaccination of children against these diseases exceeds 90 %, which means that the health situation of the youth in Slovakia with regard to the incidence of infectious diseases has improved in general. In the past, a considerable number of newborns, or children of preschool age, died of these diseases. On the other hand, parents' resistance to compulsory vaccinations is emerging, stating that, in a certain part of the child population, unwanted side effects to vaccination occur. Most doctors, however, caution that the health benefits of vaccination in the population outweigh possible unwanted side effects. Nevertheless, compulsory vaccination in children has come to be an area of ethically questionable lobbying by pharmaceutical companies toward pediatricians, which might be seen as a latent form of corruption. Dealers of pharmaceutical companies offer many benefits for medical doctors (including pediatricians) in order to prescribe their vaccines, for instance, they offer them free participation in medical conferences in tourist resort destinations, holidays, etc.

Emergency Care

The emergency service has a long-standing tradition in Slovak health care, although its technological level still lagged behind the world standards in the recent past. Lately, the situation has significantly improved, especially at the beginning of the twenty-first century, due to some reforms in the Slovak health-care system and investment by the government with regard to improving the standards and technological equipment in providing emergency care. A significant role was played by the introduction of private funds in the operation of emergency services and the fact that the state's, or public health-care institutions', monopoly in providing emergency service in various regions of Slovakia ended. Nevertheless, ethical, or moral, doubts arise regarding the transparency of the selection process of emergency service providers in individual parts of Slovakia, since, many a time, they change after the parliamentary elections and a change in the government.

General Practice

The standards of general practitioners in Slovakia are considerably high, which is related to the health-care system and the network of general care centers, established in the past 50–60 years in the entire Slovakia, in every village, and, naturally, in every town, where specialist doctors are available. A lack of general practitioners in economically poorer regions in Slovakia is an issue, and more difficult access to general practitioners in mountainous parts of Slovakia can also be considered a weakness. In the near future, a lack of dentists might be a serious problem in general, and especially in peripheral regions of Slovakia, which is related to high financial demands for the equipment of a dental clinic and the insufficient financial remuneration of their vocation. A certain ethical and moral problem regards latent corruption related to the prescription of more expensive

drugs produced by certain pharmaceutical companies, which, similarly, increases the operational expenses of Slovak health care and decreases its efficiency and, by effect, the quality of provided health care. Slovak health-care system lacks enough financial sources and majority of public hospitals are in permanent debt; however, due to strong pharmaceutical lobby, it is impossible to approve an efficient act concerning prescriptive policy in Slovakia. Slovak hospitals very often buy too much expensive medical drugs and units because a system of public procurement is ineffective.

Health Promotion and Education

Most vascular diseases can be prevented, and, according to the WHO background data, even a moderate decrease in blood pressure, obesity, level of cholesterol, and tobacco usage could decrease the incidence of cardiovascular diseases by more than a half. The goal of the European Heart Health Charter is to considerably lower the death rate to cardiovascular diseases in each European country. In 2006 and 2007, the government authorized two strategic documents: the National Alcohol Action Plan – regarding the problems of 2006–2010 and the National Tobacco Control Programme. The principles included in the World Health Declaration and the 2005 Luxembourg Declaration, also approved and signed by the Slovak Ministry of Health in 2007 in Bratislava, state that health is a fundamental human right. Everybody has the right to the highest standard of mental and physical health. Each country has the responsibility and the sovereign right to implement recommendations, while respecting differences among individual regions, ethical values, and culture and while taking internationally recognized human rights into consideration. The health-care system is no longer focused on treatment but rather prevention. This change results from the essential principles for health sustenance published in the Ottawa Charter (1986), as well as in the European Heart Health Charter (2007). The goal is to create a positive society-wide atmosphere for the intensive, efficient, and long-term education of population, as well as to enhance the education of medical doctors, with the aim of improving therapy especially in arterial hypertension and dyslipidemia. A solution to this joyless situation in Slovakia lies in a holistic understanding of health with a systemic approach based on prevention. Theoretical holistic models, as they are known in health care, offer philosophical and pragmatic solutions to health-care workers as well as the public. Research into the causes, pathogenesis, clinical manifestations, and complications of cardio- and cerebrovascular diseases is a fundamental priority in biomedical research.

Scientific and Professional Integrity

In Slovakia, medical doctors in general have a strong social status and respect given by their qualification and, in most cases, also by their great approach to their patients,

mainly perceived as suffering human beings. On the other hand, manifestations of paternalism are quite frequent, especially toward elderly patients or from elderly doctors. Corruption in health care seems latent in the cases of, for example, nontransparent public procurement and purchasing of medical and information technology and services and in prescribing more expensive drugs. The public steps doctors take at present (in 2011) directed against any reforms in Slovak health care (including privatization of state hospitals with the aim of preventing hospitals from falling further into debt) do not help their professional integrity nor do the efforts to have their pay increased, which is, from the viewpoint of the economic situation in Slovakia, seen as unfair by a considerable proportion of the public and media.

Relations with Industry and Donors

Another serious ethical and moral problem facing the Slovak health-care system is the pervasive influence of pharmaceutical companies and companies mediating the purchase of medical supplies and technology necessary for health-care operation, which is manifested by state hospitals consistently falling further in debt. Equally serious is the issue of the functioning of state hospitals, whose management changes after every parliamentary election, and governing political parties are rarely interested in their privatization. The medical trade union presents the same approach, which, by effect, preserves the existing condition and could lead to serious problems in the functioning of Slovak health care in the future. The ownership terms regarding many private health-care institutions, hospitals, or pharmacies are not clear either. On the other hand, private health-care institutions (including hospitals) often function better than state institutions.

Future Challenges

Bioethics Infrastructure

In Slovakia, important legislation in bioethics is often lacking. Therefore, attention should be paid to this area in the future, as well as to increasing the level of training of members of bioethical committees, especially in the knowledge of ethical and bioethical fundamentals. At the same time, attention should also be paid to providing education in bioethics at medical faculties and universities. It would be desirable to introduce lessons focused on basic information in bioethics at secondary schools. These would be taught by qualified specialists in bioethics (who would also be competent in the basics of ethics).

New and Emerging Issues

There is a great amount of work ahead in Slovakia in the area of public discussion on a number of ethical issues (e.g., abortion, euthanasia, embryo stem cell research,

therapeutical or reproductive cloning, and biobanks), which are being dealt in the world. However, specialized scholarly and academic debate is, in Slovakia, often absent or rather poor. It could be presumed that new specialist forums for discussions and presentations of opinions, such as the UNESCO Chair in Bioethics or the journal "Ethics and Bioethics," can significantly enhance an exchange of opinions and a search of optimum solutions to the above issues, which would be accepted by a considerable proportion of the specialist as well as lay public in Slovakia.

Opportunities

Another opportunity for further development of bioethics in Slovakia is cooperation with UNESCO (Bioethics Section, Social and Human Sciences Sector) in Paris and contacts with other UNESCO Chairs in Bioethics in the world, especially with the UNESCO Chair in Bioethics at the University of Haifa (Israel). Cooperation with other like-minded departments in Central European countries, especially in the Czech Republic, Poland, and Hungary, is equally significant. For the development of bioethics in Slovakia is very significant to create a platform for discussion among different approaches to bioethics (for instance, medical, legal, philosophical, ethical, sociological, and theological) and to start public discourse on the topical bioethical issues in contexts with discussions in the world. The next step is to improve bioethical education especially in medical faculties and universities as well as among medical doctors, nurses, and health-care workers.

Conclusion

In the past 20 years, Slovakia has made considerable progress in bioethics. Still, a great amount of work is ahead in the area of cooperation in creating policies, legislation, increasing the quality of bioethical committees' function, improving the situation in bioethics education, as well as discussing bioethical topics and contemporary issues with the scholarly and lay public. This requires greater openness and cooperation among medical doctors, health-care workers, scientists, philosophers, ethicists, theologians, lawyers, and other specialists dealing with bioethics in Slovakia. It is supported by the Slovak Research and Development Agency, contract No. APVV-0432-10.

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South Africa

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Anton A. van Niekerk

Bioethics Development

When and How Has Bioethics Started?

Whereas medical ethics, in the guise of the Hippocratic tradition with its famous oath, is arguably one of the oldest disciplines in the Western intellectual tradition, bioethics, as we know and practice it today, has mostly been a product of the aftermath of World War II. In South Africa during the first half of the twentieth century, "discussions on medical ethics. . .largely took place within the framework of the authoritarian, paternalistic behavior expected of professionals supposedly

A.A. van Niekerk
Centre for Applied Ethics, Stellenbosch University, Matieland, South Africa
e-mail: aavn@maties.sun.ac.za

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adhering to the Hippocratic Oath and similar codes" (Benatar, 2004, p. 564). In this respect, South Africa resembles most other Western countries, even though it is widely regarded as a developing country. South Africa is often referred to as a "microcosm" of the rest of the world in the sense that it has distinct similarities with both developed and developing countries. The first document on medical ethics in South Africa was written by Guy Elliot in 1954 and was based on his experience of deliberations on ethical matters by the Medical Association of South Africa (MASA). This document dealt mainly with ethical codes, professional secrecy, advertising, the conduct of consultations, fees, and financial matters and only very briefly with abortion, sterilization, and the ethics of investigative medicine (Elliot, 1954; Benatar, 2004, p. 564).

Bioethics was particularly stimulated in the course of the 1960s, internationally and also in South Africa. The rise of medical technology (such as the "Scribner shunt," i.e., the first instance of renal dialysis, accomplished in 1960 by Dr. Belding Scribner on his patient Clyde Shields – the ethical problem that this yielded had largely to do with the question as to which patients acquired preferential access to this technology) and the concomitant power over disease that it conferred upon doctors had much to do with this. More powerful technologies inevitably gave rise to questions about access; for the first time, people became really struck by the reality of "the doctor as judge of who shall live and who shall die" (title of a book by the German theologian Helmut Thielicke, 1976). An event in the South Africa of the 1960s, in turn, also generated new concerns of a bioethical nature, namely, the first heart transplant by Christiaan Barnard on Louis Washkansky on 3 December 1967 – an event that, apart from its overt significance in the history of medicine, was responsible for renewed reflection on the definition of death and the resultant emphasis on brain function, rather than cardiopulmonary function, as the significant and morally definitive indication of death. Following this event, a number of conferences, mainly organized by theologians, on medical ethical issues took place in South Africa in the 1960s and 1970s, but they led to very little public or professional debate in the country (Benatar, 2004, pp. 564–565).

At this time, bioethics was not yet regarded as a separate subject in the medical curriculum. To the extent that ethics received any attention in medical training, it was believed that it ought to be taught perfunctorily and informally "at the bedside."

Although the events just referred to no doubt also played a significant role in the rise of bioethics in South Africa, the struggle against apartheid and discrimination – respectively, the struggle for the acquisition of a culture of constitutionalism, human rights (enforced by law), and an open, democratic society – also played a pivotal role in the rise of bioethics, particularly in the 1970s and 1980s of the twentieth century. This will be dealt with in somewhat more detail in the next section.

Who Have Been the Major Actors/Forces?

As a discipline, bioethics was first systematically taught at the medical schools of the University of the Witwatersrand (Wits) and the University of Cape Town (UCT)

from the early 1980s onward. At Wits the teaching responsibility was mainly carried by a human geneticist, Prof. Trefor Jenkins. At UCT, the pioneer was Prof. Solomon R. Benatar, head of the Department of Medicine and a versatile physician with training in a number of medical specialties. To this prowess, he energetically added bioethics from the beginning of the 1980s and created a Bioethics Centre at UCT that became the vehicle of both the bioethics teaching program as well as a host of other activities that continue to this day. Benatar must be regarded as not only the true pioneer but the main driving force of bioethics in South Africa since the 1980s. Besides his numerous publications, Benatar was the first chairperson of the National Health Sciences Research Ethics Committee of South Africa (more about this below), and he is also a former president of the International Association of Bioethics. Bioethics teaching, let alone research, took a significantly lower profile at the other South African universities until the beginning of the 1990s.

Formal qualifications in bioethics in South Africa are mostly a product of initiatives of the 1990s. At Stellenbosch University, Prof. Anton van Niekerk (a philosopher, not a physician) created a Centre for Applied Ethics with a Unit for Bioethics in 1990 and designed a master's program in bioethics from 1996 onward (it is still offered and creates much interest). Many of the students that completed this program are today visibly active in bioethics research and training in South Africa and abroad. Prof. Willem Landman at the University of the Western Cape also developed an interest in bioethics in the course of the 1980s. He moved to the Department of Humanities at the Brody Medical School of East Carolina University in the USA in 1994 where he attained full tenure before returning to South Africa in 2000 to set up the Ethics Institute of South Africa, which will be discussed in the next section. The next section will also address the more concerted training programs in biomedical research ethics that came into being in the course of the first decade of the twenty-first century.

The first full-time position in the Wits faculty for teaching bioethics was created about 15 years ago, when Prof. Udo Schuklenk was appointed there. He took responsibility for undergraduate training and also created a postgraduate program that was offered online. He has since left South Africa and is currently teaching bioethics at the Philosophy Department of Queen's University in Canada. The teaching programs at Wits are continuing under the auspices of the Steve Biko Centre for Bioethics. During his stay in South Africa, Schuklenk also created the Blackwell-published journal for bioethical issues in the developing world, *Developing World Bioethics* that he has edited since 2001, initially with Willem Landman.

Bioethics, however, did not only gain interest because of the work of individuals. A train of events related to the death of Steve Biko, one of the best-known martyrs for freedom during the struggle against apartheid, also played a pivotal role in sensitizing people to bioethical issues in the course of the 1980s.

The Biko history can only be fully understood and its relevance for bioethics only adequately appreciated against the background of the reality of apartheid, South Africa's notorious system of racial discrimination and oppression that was

only overturned when the country became a democracy in 1994 under the leadership of Nelson Mandela. Apartheid, which blossomed between 1948 and 1994 when the National Party was in power in South Africa, was a political and sociocultural system that institutionalized racism and racial discrimination. Under apartheid, black people had no vote and were excluded from any significant political power. The races in South Africa were socially separated, and blacks were systematically discriminated against by means of the Population Registration Act (in terms of which whites and blacks were identified as such), the Group Areas Act (which enforced separate residential and business areas for the different races), and the Mixed Marriages Act as well as Article 16 of the Immorality Act, in terms of which marriages between black and white were prohibited and sexual intercourse between members of different races was criminalized. There was strict separation of schools, with blacks receiving patently inferior education, and in the labor market, they could at best operate in jobs that required little formal education. Blacks were expected to move to so-called ethnically based "homelands" where they could execute political rights, but these covered hardly 13 % of the landmass of South Africa and were utterly underdeveloped areas with little or no potential for agricultural, economic, or sociopolitical development. The "homelands" were also never recognized by the outside world as politically legitimate or sustainable entities.

Steve Biko was a medical student and a pivotal leader of the Black Consciousness Movement in the 1970s in South Africa – a movement that espoused the philosophy that black people should take pride in who and what they are, despite the dehumanization of apartheid to which they were daily exposed, and should take responsibility for their own liberation. He was taken into custody in Port Elizabeth because of his dissemination of these ideas. In the process, he was tortured and received patently inadequate medical care. He sustained a very serious head injury that was not diagnosed by the physicians who, in collusion with the apartheid authorities (notably the then South African Police), paid lip service to examining him. He consequently was thrown naked, with only a hard rug to lie on, into the back of a Land Rover and driven about 750 miles to Pretoria Central Prison, where he died unattended in his cell the next day, 12 September 1977. His death was immediately world news. The questions regarding how he died and the cause of death were deliberately ignored by the South African government, and the significance of his death was rudely downplayed, particularly by the then minister of justice, Mr. Jimmy Kruger, who, in a speech in parliament, made the notorious statement that "Biko leaves me cold."

What makes the Biko history particularly significant for the history of bioethics in South Africa has to do with the responses to the circumstances surrounding his death by the organized medical profession in South Africa. The South African Medical and Dental Council (SAMDC) – the body that at that time registered and disciplined all healthcare professionals – refused to act against the doctors (Lang and Tucker) who (mis-) treated Biko. This caused a national and international furore. Consequently, a small group of medical doctors, led by Prof. Frances Ames, Philip Tobias, and Trefor Jenkins (all from Wits University), took the

SAMDC to court for neglecting their duty in this regard, and this led to a supreme court injunction against the SAMDC, resulting in a reversal of its previous decisions and the imposition of disciplinary action against the guilty doctors.

In a recent publication, the significance of the Biko affair for the rise of and interest in bioethics in South Africa was formulated as follows by Van Niekerk and Benatar:

> [T]he Biko affair, and the way in which it highlighted the importance of a moral orientation in the practice of medicine, directly contributed to a re-organization of the institutionalized medical profession in South Africa. Greater attention to ethical responsibilities toward prisoners, detainees, and hunger strikers was another gratifying response to the Biko case (Jenkins, 1987, 1988; Benatar, 1988, 1990; Kalk and Veriava, 1991). The public confession of guilt by the district surgeon who bore major responsibility for Biko's medical care, emphasized the need to maintain professional independence in the face of state security and other coercive pressures. . .[T]ogether with an event such as the Soweto uprising of June 1976, Biko's death made it clear that all rhetoric from government leaders about the intended justice of the homeland system, and other alleged feats of apartheid, was bogus, that the system was morally corrupt, and that its demise was merely a matter of time. At the same time, it highlighted the depths to which a society can sink when gross violations of human rights occur and are tolerated. It is no exaggeration to claim that the Biko affair, together with other factors, played an important role in sensitizing the country at large about the dire need of a culture of human rights in South Africa. The Bill of Rights that today introduces the South African Constitution (finalized in 1996) is therefore, in a special way, a testimony to the important lessons learned in South Africa from the Biko affair, and from the canons of medical ethics. In this sense it can be argued that the Biko affair was also a very significant turning point in South African history, and an illustration of the social and political impact that a severe violation of medical morals had on South African society. (Van Niekerk & Benatar, 2011, pp. 138–139)

What Have Been the Major Concerns over Time?

In the previous section, mention was made of the fact that it was only in the 1980s that bioethics attained systematic and sustained attention from academicians in South Africa, followed by a flurry of activities and a growing range of outputs in the course of the 1990s and the first decade of the twenty-first century. In addition, there was a discussion regarding the way in which collusion with the apartheid regime by senior and authoritative members of the medical profession in the 1980s resulted in bioethics mainly focusing on the issue of medical professionalism and justice in the access to and administration of healthcare.

The *Proceedings of a UCT Faculty of Medicine Symposium*, held in July 1991 and published in 1992, give an indication of the kinds of issues and concerns at the forefront of bioethical reflection in South Africa up to that point. The main contributors to the published proceedings were philosophers. Allen Buchanan and Dennis Thompson were invited from abroad, whereas Willem Landman, André du Toit, and David Brooks made up the South African philosopher contingent. Other contributors were Solly Benatar, Cedric de Beer from Wits, the theologian Willem Saayman, and the medical sociologist Dingie van Rensburg. Most of the

contributions were on the issue of the alleged right to healthcare as well as the most advantageous health system for a South African society that, at that time, was in transition and would elect its first democratic government within 2 years of publication. Another theme that was addressed was the growing AIDS epidemic and its ethical ramifications, as well as isolated papers on hospital ethics and the issue of the withdrawal of life support from terminally ill patients.

In the first half of the 1990s, the newly created Unit for Bioethics, part of the Centre for Applied Ethics at Stellenbosch University, also organized a range of annual conferences on, at that time, topical issues in bioethics. These topics were the status of prenatal life, the moral problems provoked by the AIDS pandemic, genetic manipulation (as it was then called), and the issue of healthcare as human right. Four books were published as the outcome of these conferences (which were well attended). Contributors included philosophers (Anton van Niekerk, Willem Landman, and Johan Hattingh), physicians (Jacques Kriel and Pierre de Villiers), lawyers (Andreas van Wyk and Lourens du Plessis), sociologists (Dian Joubert), and theologians (Etienne de Villiers, Danie du Toit, and Daniel Louw). It is clear from these initial activities that bioethics was, from the beginning, approached in a multidisciplinary manner.

HIV/AIDS grew in prominence as a major issue in the course of the 1990s and the first decade of the twenty-first century, mainly because of the controversy surrounding the government's apparent inertia toward the problem and the way it seemed to spiral out of control. The issue of HIV/AIDS in South Africa will be more fully addressed later on in the section concerning "Infectious Diseases".

The 1990s also saw significant developments in connection with abortion and euthanasia as traditional bioethical issues. The year 1996 saw a new, revolutionary abortion law (the "Choice on Termination of Pregnancy Act"), which overturned South Africa's archaic statutory position on abortion into one of the most liberal dispensations available in the world. As regards euthanasia, a comprehensive investigation was undertaken by the Law Commission in the latter half of the 1990s and brought to completion by a comprehensive report and provocative recommendations. This report, which was tabled in parliament, has not succeeded in drawing any significant response from the government to this day. These two events shall be dealt with in more detail in section "Major Bioethics Issues and Discussions".

Topics that have come to dominate bioethical reflection in the course of the past decade have been again HIV/AIDS but also biomedical research ethics (including the issue of benefit sharing in research ethics in the developing world) as well as global health ethics.

What Resources Have Been Developed?

South Africa's Medical Research Council (MRC) set up an ethics committee that, since the late 1970s, formulated guidelines for medical research. This was in response to a need for guidelines in the South African context that would complement the adherence to universally authoritative, yet less specific guidelines such as

the Belmont Report, the Nuremberg Code, and the Declaration of Helsinki. The first two editions of these guidelines (1979 and 1987) were small, pocket-sized volumes. They were followed by a much more comprehensive revised edition in 1993 which was also, with permission, extensively based on reports from the Royal College of Physicians of London. Up to this point, the guidelines were contained in a single volume. The MRC ethics committee, under the leadership of Prof. Peter Cleaton-Jones of Wits, again oversaw a comprehensive revision of these guidelines, which resulted, shortly after the turn of the century, in the publication of five separate books of guidelines. They all have the overarching title of *Guidelines on Ethics for Medical Research*, and the five more specific themes are (1) general principles, (2) reproductive biology and genetic research, (3) the use of animals in research, (4) the use of biohazards and radiation, and (5) HIV vaccine trials. Some of South Africa's most eminent bioethicists and medical scientists and researchers contributed to this work.

Since the publication of these five volumes, the South African Health Professions Council (the follow-up of the former SAMDC referred to earlier in connection with the Biko incident) also published guidelines for good clinical practice.

A significant number of books in the field of bioethics have been published by South African bioethicists. A few of the more recent titles may briefly be mentioned. The first is Solly Benatar's most recent book *Global health and global health ethics*, a volume he edited with Gillian Brock and which was published by Cambridge University Press in 2011. This year (2011) also saw the publication of a comprehensive introduction to bioethics, titled *Medical Ethics, Law and Human Rights*, edited by Keymanthri Moodley and published by Van Schaik. Moodley and Sudeshni Naidoo also published a book *Ethics and the Dental Team* in 2010. Ames Dhai and David McQuoid-Mason of the Steve Biko Centre for Bioethics similarly edited a book with the title *Bioethics, Human Rights and Health Law: Principles and Practice*, published by Juta (2010). Anton van Niekerk and Loretta Kopelman edited a volume titled *Ethics and AIDS in Africa: The Challenge to our Thinking*, published by David Philip in South Africa and Left Coast Press in the USA in 2006. Mention must also be made of Solly Benatar's penetrating chapter titled "Ethical challenges for health care in South Africa" in HCJ van Rensburg's comprehensive volume *Health and Health Care in South Africa* (Van Schaik, 2004).

South African bioethicists publish in journals all over the world. A South African bioethics journal has recently been created and has the title *The South African Journal of Bioethics and Law*. It is edited by a team of no less than 12 people. *The South African Medical Journal*, however, also regularly publishes articles and letters of a bioethical nature. Mention has been made of the journal *Developing World Bioethics*, currently edited by Udo Schuklenk and Debora Diniz. Although published by Blackwell in Britain and not specifically South African, this journal has attained a certain popularity in South African bioethical circles and mostly addresses issues that are quite pertinent to the South African context.

The Internet nowadays offers a series of networks in which South African bioethicists often participate. A recent and quite active example of this is the Bioethics International Facebook Network.

No specific society for bioethics has been created in South Africa, although an ethics society was set up a number of years ago but was found to be unsustainable. South African bioethicists seemingly prefer to attend and contribute to international societies and conferences, notably those of the International Association of Bioethics. Solly Benatar (an ex-president) and Anton van Niekerk have served as board members of the latter international society.

What Have Been the Steps/Measures Taken?

Reference has been made to policies with bioethical ramifications that have been put into place (like the Abortion Act of 1996) and the Law Commission Report on the possibility of voluntary active euthanasia in 1998 – a report that has not yet been acted upon in South African legislation. A number of constitutional court cases related to end-of-life care as well as to justice in the distribution of healthcare have taken place, of which the best known is that of *Soobramoney versus the Minister of Health in Kwazulu-Natal* (1997), the first in which the court had to adjudicate on the universal constitutional right to medical treatment as against the problem of an underresourced healthcare system. Mr Soobramoney was a terminally ill patient who required access to renal dialysis but was refused access by Addington Hospital in Durban because he did not meet the eligibility criteria. The hospital argued that, in the light of the overwhelming demands on this treatment facility, the chances of less ill patients benefiting considerably more from the treatment than Mr Soobramoney were significantly better. The constitutional court ruled in favor of the hospital.

A measure of order and coherence among a disparate number of policy documents related to a variety of medical treatments and research was restored with the promulgation of the new National South African Health Act (No. 61 of 2003). This act is important for a wide variety of measures that it now regulates. For the field of bioethics, mention must particularly be made of its provisions for medical research as well as the creation and accreditation of research ethics committees via the National Healthcare Ethics Research Committee (NHERC). Both of these aspects will be dealt with in more detail later in this chapter. Ethics committees for both clinical overview and research review are currently quite pervasive in South Africa. Much has also been achieved in terms of setting up teaching programs in bioethics at most of the healthcare training facilities in South Africa, even though the outcome of these efforts is currently somewhat uneven. This will be discussed in more detail in the next section.

Current Bioethics Infrastructure

Teaching of Bioethics at University and Other Levels

The teaching of bioethics in South Africa mainly occurs at two levels: that of tertiary education in the health and biological sciences and at the level of

continuous professional development of health workers registered at and accredited by the South African Health Professions Council (SAHPC). The second level will be discussed before moving to the first.

For more than the past decade, the SAHPC has required mandatory continuous professional development (CPD) for all health workers registered under its authority and auspices (medical doctors, dentists, psychologists, nurses, physiotherapists, and occupational therapists). Each health professional has to score a number of annual points for such CPD. For most of these professions, a tally of 10 CPD points for bioethics training needs to be scored by each individual annually. Separate sessions or seminars for ethics training are therefore set up regularly, whereas it has now also become customary to have a special plenary on ethics at every large healthcare conference that is organized in the country. The hope is that this CPD ethics training might to an extent compensate for the lack of sufficient ethics education characteristic of particularly an older generation of healthcare workers in South Africa. The author of this article has been involved in a wide variety of these activities over the past decade. Greater, though arguably not adequate, ethical sensitization has developed in healthcare circles because of these initiatives.

Whereas bioethics training at universities (particularly medical schools) was sparse in the 1980s, much progress has been made ever since. Bioethics has gradually been introduced into the undergraduate training of healthcare workers in the course of the 1990s, but full curricula have only been developed in the first decade of this century. No fully-fledged departments of bioethics or of medical humanities have been created in the medical schools in South Africa, and likewise, no fully-fledged chairs in bioethics have been established. What has rather occurred is that centers or units for applied ethics or bioethics have been established at universities such as UCT, Stellenbosch, Wits, and Kwazulu-Natal. These centers undertook ethics education as part of their brief, but they originally developed as centers for research and service delivery. Nowadays, particularly at the four mentioned institutions as well as the medical schools of the Universities of Pretoria and to a lesser extent the Free State, full curricula in bioethics have been developed and are being taught, mostly by staff in the medical school and often assisted by philosophers. The book edited by Keymanthri Moodley and mentioned earlier (*Medical Ethics, Law and Human Rights*) gives an adequate idea of the type of curriculum contents that, for example, is being taught at the medical school of a university such as Stellenbosch. The idea of bioethics as a fully-fledged subject with equal status to that of the other medical disciplines (as occurs, e.g., at some universities in the USA, such as East Carolina University) and taught in every year of medical training has not been seriously entertained in South Africa.

This also raises the question about who trains the trainers. Not all efforts at developing postgraduate training programs in bioethics in South Africa have been successful, though a number have been attempted. UCT created a master's in bioethics that was abandoned after a few years, because of other developments in research ethics training that we will deal with shortly. The same is the case for an online master's that was attempted at Wits. Wits Medical School currently offers a master's in medical sciences in bioethics. The best known and attended of these postgraduate

general programs in bioethics has, however, been the two-year master's in philosophy in bioethics that has been offered by Stellenbosch University's Philosophy Department and Centre for Applied Ethics since 1996, still continuing with ever-growing numbers. (The structure of the program is changing slightly from 2012 onward due to new directives about master's degrees by the South African Department of Higher Education.) A total of about 80 bioethicists have been trained through this program, and many of them occupy influential positions in healthcare faculties and other academic structures in South Africa and abroad. A small number (about 12) of the students who completed this program successfully have gone on to attain PhDs in bioethics, most of them at Stellenbosch University.

Thus far, we have predominantly addressed general bioethics training at under- and postgraduate level. Over the past decade, postgraduate training in specifically biomedical research ethics has become very important and prominent in South Africa. Van Niekerk and Benatar write in this respect:

> As in the rest of the world, clinical research has become a major enterprise (and an instance of big business) in South Africa, and, increasingly, in other parts of Africa. In their chapter on health research in South Africa in the 1999 edition of the *South African Health Review*, Mbewu and Mngomezulu write that, for many years prior to democracy, South Africa has been regarded as a "researcher's 'paradise' . . .because of its first world technology alongside a third world captive population, largely unprotected by codes of conduct and with extremely poor human rights protection" (Mbewu & Mngomezulu, 1999, p. 370). Consequently health research done in South Africa and other African countries was often not submitted to rigorous ethical scrutiny in a manner that would have been required in developed countries, and the benefits (if any) of which were often not made available to the populations amongst which the research was originally done. A lot of what is currently done in bioethics in South Africa deals with capacity building in research ethics, in particular capacity to participate in the ethical review of research protocols. Research – including the research initiated and executed by multi-national conglomerates in the developing world – prima facie always has a beneficial intent. Yet, these multi-national corporations at the same time have commercial, profit-seeking agendas that do not always operate with altruistic intent and to the demonstrable benefit of research subjects in these countries. Bioethics therefore faces a special responsibility not to be hi-jacked by those same agendas, and to exercise its morality-seeking responsibility with real integrity. (Van Niekerk & Benatar, 2011, p. 144)

In view of this need to thoroughly train actual and potential members of research ethics committees or institutional review boards for the informed execution of their responsibilities, two networks or initiatives were formed, namely, the International Research Ethics Network of Southern Africa (IRENSA), under the leadership of Prof. Solly Benatar in Cape Town, and the South African Research Ethics Training Initiative (SARETI) under the (eventual) leadership of Prof. Doug Wassenaar of the University of Kwazulu-Natal (in collaboration with colleagues at the University of Pretoria). Both these initiatives applied for grants by the Fogarty Foundation of the National Institutes of Health in the USA, and both applications were successful. In the IRENSA initiative, apart from the South African multidisciplinary contingent of faculty members, lecturers from abroad such as Peter A. Singer from Toronto and Len Doyle from London became actively involved in the teaching. IRENSA offered a postgraduate diploma in international research ethics, and SARETI a master's degree.

In the case of the IRENSA program (which ran for 8 years, from 2003 to 2010, with one renewal of the grant), a total of 244 students – many from African countries besides South Africa – applied for the program; 97 were admitted to the program and 79 completed the training. Generous bursaries were allotted to the successful applicants that enabled them to attend three annual lecture series. They were also expected to complete a practicum. There can be no doubt that the training done in this course will, in due course, have a very significant effect on the quality of work done by research ethics committees in South Africa and on the continent of Africa. A highly informative (though unpublished) *Impact Report* on the IRENSA program became available in the course of 2011. It contains information of the student intake and success as well as reports from the trainees, the countries, and the institutions involved and a range of reflections on their experience in the program by members of the faculty.

Recently, another application to the Fogarty Foundation for a similar program offered by the Centre for Medical Ethics and Law in the Health Sciences Faculty of Stellenbosch University has been successful. This initiative is called Advancing Research Ethics Training in Southern Africa (ARESA) and also takes the form of a one-year postgraduate diploma. The principal investigator is Prof. Keymanthri Moodley, director of the center, assisted by a co-PI, Dr. Stuart Rennie from the University of North Carolina (Chapel Hill), as well as a multidisciplinary team of lecturers. The first intake of students occurred in 2011.

Bioethics Committees

The original bioethics committees in South Africa are the ethics committees of the Medical Research Council and of Wits University, both of which were fully operational in the course of the 1980s. Mention has already been made of the series of *Guidelines for Medical Research* that were published over three decades by the MRC committee. In the course of the 1990s, research ethics committees that take the responsibility of an ethics review of all new research proposals that are undertaken by researchers of a particular institution have been created by all the universities that are engaged in healthcare research. The work of these institutional committees has progressively increased over the years, and there are currently serious concerns about their sustainability across the board (particularly at large institutions with high volumes of research) without due compensation to members or without significant additional investment in administrative support for the work done by members who are mostly ordinary academics burdened with many other responsibilities.

It has in South Africa, as elsewhere in the world, increasingly been accepted that any research involving human beings, even if the research is not strictly of a medical nature, requires ethical scrutiny, particularly in terms of issues such as confidentiality and the informed consent of research participants. The result is that we are also increasingly seeing research ethics committees making their appearance in faculties of humanities and social and economic and/or business

sciences as well as the faculty of education. The treatment of animals requires such committees in faculties of science, veterinary science, and agriculture, whereas the issue of the possible impact of research on the environment has also resulted in such committees being set up in faculties such as science and engineering.

Ethics committees also occur in institutions that are not strictly academic. The South African Medical Association has set up an ethics committee, and ethics committees are increasingly being created at a number of hospitals in South Africa, mainly for consultation regarding morally problematic clinical situations. A research body such as the Council for Scientific and Industrial Research (CSIR) currently has an ethics committee.

This proliferation of ethics committees raises the question as to the capacity for service on the committees. The relatively recently promulgated South African Health Act (2003), referred to earlier, has created an oversight body that is supposed to take care of this problem. In terms of this new act, this body is known as the National Health Sciences Research Council (NHSRC), which is strictly speaking not an ethics committee itself but a national policy-making body that is appointed by and reports to the Minister of Health. This council is expected to accredit and register all legitimate ethics committees in the country and even to act as the final court of appeal for researchers who are unhappy about the decisions of the committees to which they originally submitted their protocols. How exactly this latter alleged function of the NHSRC is to be executed is nevertheless unclear. Other questions also prevail about the exact brief of this new structure.

Expert Bodies/Centers

Mention has already been made of Centres for Applied Ethics and Bioethics that have been created at the universities of Cape Town, Stellenbosch, and Wits. At the academic level, these three centers represent the center of gravity in terms of academic work in the field of bioethics in South Africa.

The establishment of the Ethics Institute of South Africa (EthicsSA) in the course of the year 2000 was, in addition, a significant step taken in fostering an ethical business and healthcare culture in South Africa in recent times. The organization was established as the outcome of a comprehensive feasibility study, in the course of 1998–1999, by the Merck Company Foundation (facilitated by the Ethics Resource Center in Washington, DC) and the South African Medical Association (SAMA). The aim was to set up an ethics center, molded along the lines of similar institutions that the former two organizations have set up in other parts of the world. SAMA's involvement had the effect that the center, set up in 2000 as a consequence of the work of a steering committee of which the author of this chapter was a member, initially concentrated on ethical issues in the healthcare sector of South Africa. Willem Landman, earlier professor of philosophy and medical ethics at the University of the Western Cape and East Carolina University in the USA, was appointed as first CEO, a position he held until 2009, when he retired (he continues

as an executive director). Prof. Deon Rossouw, previously from the University of Pretoria, was subsequently appointed as the next CEO.

EthicSA is an independent, Section 21 (nonprofit) company that initiates and supports ethics-related activities. It has a small management team and a board consisting of business people, academics, and professional persons. Its offices are situated in Hatfield, Pretoria. Income is generated through grants, services, and a membership program. The organization has progressed from 100 % dependence on grant income in 2000 to becoming self-sustained at present.

EthicSA's vision is one of an ethical South Africa. Its mission has, from the outset, been ethics advocacy. To this end, it provides thought leadership, does research, offers training, and provides support services. It works in partnerships with the public and private sectors, academia, and the professions. It promotes and advances ethical practices in South Africa (and Africa) in the professions, business, and public policy. To this end, ethical standards are set and resources are provided to meet those standards in the public and private sectors.

In its first 3 years, EthicSA completed four major research projects, all of which attracted wide media attention but, importantly, also led to significant efforts by interested parties to address the practical ethical challenges highlighted in the research reports. Research projects in medical ethics focused on the ethics of the business practices of South African medical doctors, the Chris Hani Baragwanath Hospital in Soweto, and the Universitas Hospital in Bloemfontein. In 2003, the organization published a research report on the state of corporate ethics management and programs in 53 top companies listed on the JSE Securities Exchange.

EthicSA's specific current activities include:

- Encouraging public debate on ethical issues
- Initiating and facilitating ethics research
- Contributing to ethics education and training
- Producing ethics publications
- Facilitating the development and implementation of codes of ethics
- Conducting organizational ethics assessments (audits)
- Setting ethical standards and developing public policy

EthicSA has facilitated a considerably heightened ethics awareness in the country. In terms of its visions and mission, it is a unique organization, and its situatedness as an independent, nongovernmental organization (NGO) outside of the academic departments that deal with ethics creates an opportunity of a unique quality of appeal and sensitization to ethical concerns in the South African populace at large.

Major Bioethics Issues and Discussions

Beginning of Life

Before 1996, South Africa had an extremely conservative dispensation as far as the possibility of abortion was concerned. Abortion was only allowed when the

mother's life was endangered by continued pregnancy, when the pregnancy was the outcome of rape or incest, when the fetus suffered from severe congenital disease, or when continued pregnancy would cause severe mental disease. This dispensation was dramatically changed by the promulgation of a new law, officially called the Choice on Termination of Pregnancy Act (Act 92 of 1996), in the direct aftermath of South Africa's becoming a democracy in 1994. As a result of this act, South Africa nowadays has one of the most liberal abortion dispensations in the world. In terms of the act, abortion on demand is, without conditions, possible for the first 12 weeks of pregnancy. Healthcare workers may refuse to do the procedure on the basis of conscientious objections but are then compelled to refer the patient to a healthcare worker who will perform the procedure. There is no age restriction on the woman that requests an abortion. Children must be counseled and advised to inform their parents but are free not to do so. The father of the fetus (if known) does not have to be informed. When the pregnancy is between 12 and 20 weeks, abortion is still possible on request if certain indications apply, one of which being that abortion is permissible if the birth of the child would disadvantage the pregnant woman financially. This makes abortion up to 20 weeks de facto possible under this law in South Africa.

End of Life

The following quote from Van Niekerk and Benatar summarizes the situation in this regard adequately:

> In South Africa, no form of "active euthanasia" in the sense of active assistance in bringing about death is legal in the clinical situation. Withholding treatment in situations where the treatment is futile and death is inevitable has been defended in South Africa (Benatar et al., 1994b) and is legally permitted. The "new South Africa" has seen a seemingly provocative reinvestigation of this position on assisted death. At the time following the adoption of South Africa's new constitution (1996), the South African Law Commission launched a comprehensive research project on this issue and brought out a report.
>
> While this report and recommendations of the Law Commission were tabled in parliament more than 10 years ago (1998), and its recommendations were widely reported and commented on in the press. . .there has been no further effort by the government of the day to take these recommendations further in terms of legislation.
>
> The earlier referred-to status quo, therefore, still prevails on this issue in South Africa. Whereas it is fair to surmise that bioethical teaching, reflection, and discussion might well have contributed significantly to the formulation of the Law Commission's report. . .the absence of further action and legislation bears testimony to the limited impact of bioethics in South Africa as far as this issue is concerned. (Van Niekerk & Benatar, 2011, pp. 140–141)

Healthcare System: Access to Healthcare

South Africa has a two-tiered healthcare system, namely, a private system and a public system. About 80 % of the population is served by the public system and

20 % by the private system. The situation is, however, considerably reversed when it comes to the utilization of resources. More than 60 % of all resources spent on healthcare in South Africa are spent in the private sector which caters for only 20 % of the population. That means that less than 40 % of resources are spent in the public sector, catering for 80 % of the population. Also less than 15 % of South Africans have medical insurance (in the sense of membership of medical aid funds). The cost of healthcare in the private sector makes such insurance imperative.

The palpable injustice of this dispensation is to a significant extent a remnant of the apartheid system and is therefore widely not regarded as sustainable. The ANC government has, in the past year, announced that it is moving forward with its intention to create a national healthcare system which will, in principle, make effective healthcare (what the package will be is still unclear) accessible for all South Africans. The idea apparently is that everybody will be compelled to contribute to this system according to means and that people who have the resources will still be able to access additional insurance that will transcend the package of coverage that the new system will make available to all.

What remains unclear is exactly how this new system will be financed and when it is foreseen that it will come into operation. Up until now, the idea of such a new national system has not run into serious opposition, even from the ranks of private healthcare providers. That situation might change as more detailed plans for the new system become public in the near future.

Traditional Medicine

South Africa's African social context is such that traditional medicine still plays an important role among many communities in the country, particularly those in rural areas (although urban Africans quite often supplement their adherence to Western healthcare with the occasional visit to and advice from a traditional healer). It does sometimes happen that effective care is thwarted by ill-advised practices or potions recommended by traditional healers. Often, however, their advice and forms of care do not cause clear-cut harm.

A practice that has been explored over the past decade is the possibility of cooperation between traditional healers and Western doctors, particularly as far as HIV/AIDS treatment is concerned. Success has been achieved in training such healers in the basic aspects of HIV diagnosis and utilizing them to channel potentially HIV-positive patients to centers of Western care after a visit to the traditional healer.

Infectious Diseases

For many years, mainly during the second half of the 1990s and the first half of this century's first decade, bioethical discussions in South Africa were dominated by the HIV/AIDS pandemic. The history of this syndrome's first appearance in the early

1980s, its initial association with men who have sex with men and drug abusers, the eventual realization that it spreads even more rapidly through unprotected heterosexual intercourse, and its eventual devastating occurrence and preponderance in sub-Saharan Africa where 10 % of the world's population carries 70 % of the world's burden of HIV/AIDS disease, is well documented. Amidst these alarming findings, it also became clear that South Africa was the country with the highest number (in absolute terms) of HIV infections; at one stage, this figure was 5.1 million, which amounted to 21 % of the adult population of the country. Until fairly recently, the indication also was that as many as 80,000 children were infected annually and that there were 200,000 infected children under the age of 15 in South Africa.

The ethical problems associated with the HIV pandemic seemed endless. Should infection warrant notification of the state? Should there be mandatory testing, particularly given the problems of effective surveillance? Should infecting another person without revelation of one's status be criminalized? Is it warranted to discriminate against infected people, particularly in the workplace? What are the human rights of HIV-positive individuals? How is the stigma associated with the disease to be overcome? Is it morally justifiable to make condoms available to children? Is it morally warranted to do research on children with HIV/AIDS? Is it morally in order to experiment with cheaper drug regimens against placebo in Africa, given that, for a long time, the minimum standard of care was nothing at all? Is it morally in order to violate intellectual property concerns in order to produce cheaper HIV/AIDS drugs in the developing world? The list goes on and on.

What, however, complicated the South African debate very considerably during the indicated time was the attitude of policymakers at the highest level of government. The impression was often created and several times reinforced that pivotal people in government, such as the then Minister of Health, did not accept that AIDS was caused by a retrovirus, that established medical science about the development and treatment of the condition was suspect, and that it should be replaced by treatments designed by people who were generally regarded as quacks by the healthcare establishment. There was, in particular, extreme reluctance to make antiretroviral treatment for the condition available at state health facilities, even when it became clear that some large pharmaceutical companies, who were often suspected of exploiting the pandemic for the sake of profit, were willing to provide the drugs free of charge or at greatly reduced prices. This caused an uproar, and the government was taken on in the streets and in the highest court of South Africa by an activist group called the Treatment Action Campaign under the spirited leadership of Zachie Ahmat. The conflict between the healthcare profession and the government came to another head when Dr. Thys von Mollendorff, superintendent (i.e., chief medical officer and administrator) of a prominent hospital in Nelspruit in the province of Mpumalanga, agreed to make his facilities available for the provision of antiretroviral treatments for rape victims. He was, as a result, fired by the then Minister of Health of Mpumalanga in 2001 for contravening official government policy on the provision of antiretroviral treatments. The incident is

indicative of the enormous obstacles that hindered the effective management of the pandemic for a considerable period in South Africa's recent history.

Governmental resistance to the medically justified treatment of HIV/AIDS has luckily abated in the past few years. There does not seem to be any more governmental denial of the problem, and the provision of proper treatment has now become part of official government policy. South Africa's widespread poverty and the difficulty of people living with HIV/AIDS in the rural areas to reach proper healthcare facilities nevertheless remain enormous challenges for the effective combating of the pandemic. What also remains a serious shortcoming in South Africa's approach to this crisis is the absence of an imaginative prevention campaign along the lines of successful initiatives as were seen in countries like Uganda, Sierra Leone, and Thailand.

Van Niekerk and Benatar write in this regard:

> Education about safe sex and about the use of condoms are important aspects of the thrust against HIV/AIDS, but these are not remotely sufficient to overcome deeply entrenched suspicion of such advice that interferes with procreation and that goes against centuries of socially-accepted and psychologically-driven sexual practices in other cultures. Failure to recognise the pervasive social, economic, behavioural and political aspects of HIV/AIDS – both in terms of its origins and its control – is self-defeating. The complexity of the scientific endeavour required to understand the pathobiology of the disease and to develop appropriate treatment is more than matched by the complexity of understanding and dealing with the social underpinnings of HIV/AIDS and other plagues (Van Niekerk, 2002), locally and globally (Benatar, 2002b).
>
> The example of anti-smoking campaigns illustrates the difficulty in achieving behavioural change even for acquired habits with only mild addictive effects. The greater challenge of achieving change in relation to such basic drives and needs as sexual relations should not be underestimated – and especially when interacting with people whose social and sexual mores differ and who may be suspicious of the underlying motives of "educators" (Van Niekerk, 2002). The programme of action against HIV/AIDS in South Africa includes culturally sensitive education, information and behavior change strategies and vaccine development, but the impact of these will take many years to become manifest. A comprehensive programme will also need amplification by definitive and convincing political and cultural action to dispel the regrettable denial that surrounds HIV/AIDS, and by significant social and economic progress. (Van Niekerk & Benatar, 2011, pp. 143–144)

Future Challenges

As is well known, healthcare as such is not necessarily the major contributor to a healthy population. Clean water, balanced and healthy nutrition, and clean sanitary facilities are much more important. The provision of these in a developing country such as South Africa is a major challenge that also needs to reflect far more in the bioethics research of the future. As far as healthcare itself is concerned, the effective treatment of serious infectious disease such as HIV/AIDS and tuberculosis, as well as achieving such treatment within a context wherein the majority of people have better access to sustainable healthcare services, remains the major challenge in South Africa.

In as far as healthcare will in the future increasingly be provided on the basis of genetic information and will thus be much more population based, the challenge in Africa is to assess the extent to which such new treatments can be relevant for specifically African needs.

Summary and Conclusion

Bioethics is not nearly as big a subject in South Africa as it is in the USA or Britain. However, since the 1980s, there has been a sustained growth of interest in as well as the practice of bioethics in South Africa. A serious breach in basic bioethical practice (i.e., the death of Steve Biko) played a major part in unleashing the (eventually successful) forces of liberation and democratization in the history of this country. The impact that HIV/AIDS has had and continues to have on South African society creates a host of bioethical issues that need to be consistently addressed. South Africa is a favorite spot for biomedical research, and this has also posed the challenge of training people effectively for service on research ethics committees that have to review this research, protect vulnerable populations, and insist on channeling benefits of such research back to local communities. In this sense, bioethics plays a major role in development of the biomedical sciences and thus in the fascinating unfolding story of late-arrived democracy in South Africa.

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Spain

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Miguel Angel Sanchez-Gonzalez and Lydia Feito Grande

Bioethics Development

When and How has Bioethics Started?

A Precursor: Pedro Laín Entralgo

The work of Pedro Laín Entralgo (1908–2001) was an important precedent for many of the themes that bioethics has subsequently covered.

Laín Entralgo created an influential School of History of Medicine and Medical Humanities, as Chair of History of Medicine at the Complutense University of Madrid. Influenced by the thought of José Ortega y Gasset (1883–1955) and Xavier

M.A. Sanchez-Gonzalez (✉) • L. Feito Grande
School of Medicine, Complutense University of Madrid, Madrid, Spain
e-mail: migsan@med.ucm.es; lydia.feito@med.ucm.es

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Zubiri (1898–1983), he developed a philosophical anthropology that successfully incorporates the disciplines of Biology, Physiology, and Neurology.

Laín wanted to help solve the problems of the medicine of his time by developing a system of medicine both scientific and personal, which would be part of his theory of the relationship of doctor and patient. One of his best-known works happens to be *The Doctor-Patient Relationship*: *History and Theory* written in 1964. Five years later, he published a synthesis of his ideas in *Doctor and Patient* (Laín, 1969), which is perhaps his most known work and has been translated into other languages. In this work, Laín asserts that "medical friendship" is the affective link in an ideal medical relationship. Medical friendship is a mode of unilateral relationship of aid that puts the physician in direct contact with the other person. The patient participates in this relationship with trust and confidence, while the doctor brings benevolence and beneficence. This medical friendship is essential to making diagnoses and personalizing treatments.

Lain Entralgo still had time to join in debates promoted by the new discipline of bioethics. He participated in the conference on "*Changing values in medicine*" which took place at Cornell University, Ithaca, New York, in 1979. At this conference, he presented a paper entitled: "*What does the Word Good Mean in Good Patient*?" Interestingly, his ideas were hailed as the highest exponent of the old paternalistic tradition; but he was also criticized for not openly acknowledging the autonomy and rights of patients. (Childress, 1979).

Despite such criticism, the humanistic ideas of Pedro Laín and the school he created, as currently represented eminently by Prof. Diego Gracia, have been a powerful stimulus for many current developments in bioethics.

A Triple Source for the Spanish Bioethics with International Links

There were three different and independent origins for the Spanish bioethics with direct international links.

The first was Francesc Abel S.J. who was a friend and disciple of André Hellegers. Abel attended the Kennedy Institute in 1972, where he stayed more than 3 years. He returned to Barcelona with the idea of establishing an institute of bioethics based on the model of the Kennedy Institute. Since 1975, he conducted a seminar on bioethics attached to the faculty of theology in Barcelona. This initial workshop was established in 1984 as a private foundation with the name of *Institut Borja de Bioètica*, within the accommodations offered by the Society of Jesus. Beginning in 2000, this program was integrated into the Ramon Llull University and directed by the jurist Núria Terribas. In addition, Francesc Abel organized the first Committee on medical ethics, within Hospital Sant Joan de Déu in Barcelona. This program was started in 1976 and still operates today.

The second milestone that reflects the movement of international bioethics in Spain is represented by Javier Gafo, S.J. Gafo majored in bioethics in the Gregorian University of Rome with his doctoral thesis in moral theology on "Abortion and the Beginning of Human Life," published in 1979. Appointed Professor and Chair of Bioethics at the Faculty of Theology at the Pontifical University of Comillas, he

began to convene annual seminars on various subjects in 1986. These seminars have continued and gathered almost all Spanish professionals interested in these issues. Gafo has been an important source of editorial and educational activities. After the death of Gafo, his Professorship was directed successively by Jorge Ferrer, S. J., Julio Martínez, S. J., Juan Masiá, S. J., and Javier de la Torre.

The third important scholar with contacts in American and international bioethics was Diego Gracia Guillén. As a disciple of Laín Entralgo and Xavier Zubiri, and after doing postdoctoral studies in Germany, he conducted his first research in the fields of history, philosophy, and medical anthropology. His direct contact with American bioethics began in 1986, through the bioethicist James Drane, who was a visiting scholar in his department (Drane, 2009). Thus, they both began to teach the first course in bioethics that was offered at the Complutense University. In 1987, accompanied by the same Drane, Gracia visited the main centers of Bioethics and Medical Humanities that existed in United States and met their most important leaders. Upon his return, Diego Gracia began to implement a teaching and research program as chair in the Complutense University. Through his teaching, Gracia has gathered a large number of professionals and exercised considerable influence both within and outside of Spain. During all this time, the work of Diego Gracia has been assisted by Miguel Angel Sánchez González, as a Professor in Gracia's department. This Miguel Sanchez, physician and philosopher, had been a fellow at the Center for Clinical Medical Ethics of the University of Chicago in 1988.

Who Have Been the Major Actors/Forces?

Pioneers in the 1970s and 1980s

The first two decades of bioethics in Spain were dominated by the personal initiatives of the three ground breaking individuals mentioned above. This section provides more detail on each.

Francesc Abel i Fabre S. J. (1933–2011) was a physician who specialized in obstetrics and gynecology. With a degree in theology and sociology (with specialization in demography and population), he was also a priest and member of the Society of Jesus.

He was the cofounder of the *International Study Group on Bioethics* (1980–1994); the *Societat Catalana Bioètica* (1990); and the *European Association of Centers of Medical Ethics* – EACME – (1985). He was also a member of the Committee of Bioethics of Catalonia.

The Borja Institute of bioethics founded by Abel in 1975 was the first Bioethics center in Europe. Gifted with an excellent specialized library, this Institute has been an important focus and promoter of bioethical dialogue in Spain, organizing courses, conferences, round tables, publications, and research projects. Since 1996, this center has also offered a MA degree in bioethics.

Javier Gafo Fernández S. J. (1936–2001) was licensed in biology, philosophy, and theology. He was also priest and member of the Society of Jesus.

He was a member of the Theological Commission of the Episcopal Commission of the Doctrine of the Faith of the Spanish Episcopal Conference, and an expert of the Commission of the Congress for the "Study of fertilization in vitro and artificial insemination" (1985). He was part of the National Commission on assisted human reproduction (1997), the Committee of experts in bioethics and cloning (1998), and the Committee for the study of the status of human embryo (2000).

Above all, the editorial activity carried out and promoted by Javier Gafo as chair is perhaps the most voluminous in bioethics in Spain. In 1997, this activity culminated in the creation of a M.A. degree in bioethics.

Diego Gracia Guillén (1941–present) is a physician, specialized in psychiatry. He also has a degree in philosophy. As professor of the history of medicine at the Complutense University of Madrid, he also directs the Institute of Bioethics of the Foundation of the health sciences.

In 1988, Gracia launched at the Complutense University the first M.A. of bioethics in the Spanish language, which up to now has graduated nearly 300 professionals. Between 1996 and 2003, Gracia also headed a M.A. degree in Latin America which conducted concentrated classes during the summer months. He was invited to do this by the authorities of the regional program on bioethics for Latin America and the Caribbean under the sponsorship of the *Pan American Health Organization*.

It can be said that Diego Gracia is the main person who introduced a secular view of bioethics in Spain, while remaining anchored in the European cultural tradition and incorporating the most recent international developments in the field of bioethics (Gracia, 2009). Indeed, the contribution of Diego Gracia has been not only to import an American form of bioethics, but also to enrich and reformulate it from Spanish and European intellectual tradition that he knows well, as director of the Institute of Philosophy "Xavier Zubiri."

One of his early theoretical contributions was the contemplation of the principles of bioethics as a result of the convergence of three traditions: an ancient tradition within the medical profession and two other legal and political traditions that had been kept outside of medicine. He also devoted his efforts in finding a foundation for a bioethics that, rather than limiting itself to the resolution of conflicts, can also advance as an ethic of responsibility. In his search for these foundations, he studied methods of decision making and suggested a method based on deliberation (Gracia, 2003).

New Important Authors in the 1990s

Gradually other actors from different fields entered the field of bioethics.

The contribution of the jurist Carlos Romeo Casabona and his team in the Chair of Law and Human Genome of the University of Deusto is remarkable in the field of law. Maria Casado and her group at the *Observatory Bioètica i Dret* of the University of Barcelona and Javier Sánchez Caro and his group in Bioethics and Law in the government of the Autonomy of Madrid, are also making significant contributions.

The field of moral philosophy began to react to bioethical issues from the publication by Adela Cortina in 1993: "*Applied ethics and radical democracy*" which advocates for a deliberative model. This was a challenge for the academic

philosophy that was joined, among others by Victoria Camps, Margarita Boladeras, Javier Sádaba, Teresa López de la Vieja, and José María García Gómez-Heras.

In the field of theology, theologians ready to intervene in the democratic and pluralistic bioethical debate, advancing their point of view among other approaches, should be distinguished from scholars entrenched in dogma and papal Magisterium, who seek to impose their thesis. In addition to the already mentioned representatives of the Society of Jesus, Javier Elizari and Marciano Vidal have excelled among the theologians open to the public debate. Advocates of a militant bioethics in favor of traditional religious positions, on the other hand, tend to have some relationship with conservative church groups and be integrated into the Spanish Association of Bioethics and Medical Ethics (AEBI). The reputable group led by Gonzalo Herranz at the University of Navarra also has a relationship with these latest positions.

The physician and former socialist deputy Marcelo Palacios, author and draftsman of legislation and propositions of law which have been important for bioethics deserves special mention. In 1997, he founded the International Society of Bioethics (SIBI).

It is also important to cite the work of professionals trained by Diego Gracia and his team; including physicians as Azucena Couceiro, Javier Júdez, and Benjamín Herreros who have produced good research and teaching, and Pablo Simon, professor and coordinator of courses of bioethics in the Andalusian School of public health (Granada). Among bioethicists also trained by Gracias's team, there are psychologists, as Javier Barbero, specializing in spiritual accompaniment, and philosophers as Lydia Feito who since 2008 has been incorporated into the Group of the Complutense University, where she directs a research seminar in bioethics.

What Resources Have Been Developed?

Bioethics associations at the national and regional levels have been created. Among them: the *Asociación de Bioética Fundamental y Clínica* (ABFyC) which represents a pluralistic and nonreligious bioethics, in the wake of Diego Gracia's teaching; the *Asociación Española de Bioética y Etica Médica* (AEBI), more devoted to a catholic bioethics; and the *Sociedad Internacional de Bioética* (*SIBI*), of international scope, founded in 1996 at the proposal of Marcelo Palacios.

Some bioethics journals are being published. Among them: *Cuadernos de* Bioética which is the official journal of the Asociación Española de Bioética y Etica Médica (AEBI); *Labor Hospitalaria*, edited from 1948 by the Hospitaller Order of Saint John of God; *Bioética & Debat*, published by the Instituto Borja de Bioética; and more recently *Debatica*, which is the journal of the Sociedad Andaluza de Bioética.

A good number of bioethics books have been published in Spain during the last decades. The outstanding *Fundamentos de Bioética* (*Foundations of Bioethics*), written by Diego Gracia in 1989, opened the road and were followed by many others (Gracia 2004, 2012). Francesc Abel wrote a history of bioethics in 2001. The Chair of Bioethics in Comillas has published more than 60 books on numerous

topics. The Institute of bioethics in the Health sciences Foundation, together with the College of Medicine, has elaborated several guides on ethics for clinical practice. Romeo Casabona has directed the edition of an *Encyclopaedia of Bio-law and Bioethics*: (2011). More recently, Miguel Sánchez González has written a manual for health care students (2012).

What Have Been the Steps/Measures Taken?

After the death of Franco in 1975, the army and the Church began to lose their traditional sociopolitical influence. This was the start of a process of acceptance of pluralism and search of a minimal civil ethics.

In the political and legislative arenas, the 1978 Constitution introduced a liberal democracy protective of human rights. Since then, liberal and utilitarian moral approaches have been gaining ground. The international movement of bioethics, by being in concert with those trends, could enter Spain and find fertile ground at an opportune moment. In fact, much of the legislation enacted during the past three decades originated from liberal channels similar to those of English-speaking countries. Nevertheless, one can find exceptions to this trend, for example, in the discussions about the beginning and the end of life, dominated by the most conservative sectors of Spanish society.

In 1984, the so-called Palacios Committee was created by the government for study of the problems associated with the new techniques of assisted reproduction.

In 1992, the Ministry of Health created an Advisory Committee to assess and report to the Minister on matters scientific, ethical, professional, and social research and health care.

The biomedical Research Act 14/2007 established the *Comité de Bioética de España* (*Bioethics Committee of Spain*), as an independent body with consultative status on matters relating to the ethical and social implications of biomedicine and health sciences.

Current Bioethics Infrastructure

Teaching of Bioethics at University and Other Levels

There has been a struggle between different sectors and University departments on teaching bioethics.

At most Spanish universities, with the exception of the Complutense University, departments of History of Medicine have not shown much interest in bioethics. On the contrary, they have tried to neutralize it as a threatening competitor of the social sciences that they were teaching.

Legal medicine departments have more systematically tended to assume the role of teaching bioethics within universities, although confusing it at times with health law or with the more traditional medical deontology.

Finally, individual initiatives have also proliferated, endorsed by teachers motivated by their own convictions or their ecclesial linkages.

In this context, it is not uncommon to find teaching programs in bioethics without orientation in international bioethics, that sometimes focus on legal reductionisms or are noticeably inspired by faith-based beliefs.

Nevertheless, it can be said that bioethics has been established, albeit in unequal fashion in all training programs of the health professions, especially among doctors and nurses at undergraduate level. At the level of postgraduate training, the offering of bioethics programs is large and growing.

Today in Spain many postgraduate programs are offered. The oldest one is the Master on Bioethics at the Complutense University of Madrid (UCM). The Comillas Pontifical University and the Borja Institute of bioethics have also been offering a master degree on bioethics for a number of years.

Bioethics Committees

At the present moment, there are clinical and research committees in virtually all public hospitals. At the national level, there is the *Comité de Bioética de España* (*Bioethics Committee of Spain*), which was already mentioned above.

Expert Bodies/Centers

As for groups or institutions who are working on issues of bioethics, there are too many to list here. Only some of them can be mentioned: the Borja Institute of Bioethics, the Chair of bioethics of the faculty of theology in the Comillas Pontifical University, the Chair of law and human genome of the University of Deusto, the Department of Biomedical Humanities at the University of Navarra, the Observatory of Bioethics and law directed by Prof. María Casado in El Parc Cientific of Barcelona.

Some institutes and schools are offering regular bioethics courses. It is worth noting the *training course for trainers* offered by the Institute of Bioethics in the Health sciences; and the courses of the Andalusian School of Health.

Relevant Legislation

The last democratic *Constitution* of 1978 established the current legal framework. After the Spain's entry into the European Community in 1986, the EC's directives should be transferred to the legal system.

In Spain, a Royal Decree of 1978 introduced the *first legislation on clinical trials*, which stated the need to establish Research Ethics Committees in hospitals. In 1990, the Act on Medications (*Ley del medicamento*) was adapted to the directives of the European Community.

The *Act of extraction and transplant of organs*. (*Ley de extracción y trasplante de órganos*) was enacted in 1979. This act established a system of presumed consent for the removal of organs after brain death, unless the deceased had expressed their opposition. In practice, however, authorization for the removal of organs continued to come from the family. Subsequently, Spain has come to be the country with the highest rate of donations. Nonetheless, this result seems to depend mostly on the system of detection and collection of organs which implemented the Spanish National Transplant Organization (ONT).

In 1985, the Socialist Government enacted a *Law of decriminalization of abortion* (*Ley orgánica de despenalización del aborto*) in three cases: serious risk to physical or mental health of the woman, rape, and malformations in the fetus. This Act was in force until 2010, when a new *Organic Law of sexual and reproductive health and voluntary interruption of pregnancy* (*salud sexual y reproductiva y de la interrupción voluntaria del embarazo*) was promulgated. This law transformed the previous law of cases into a law of time limits, where the termination of pregnancy is free until the 14th week of gestation. In 2012, the new conservative People's Party government announced his intention to return to the model of the 1985 Act.

The *General Law* of *health* (*Ley General de Sanidad*) in 1986 introduced among other things, the first Bill of Patient's Rights, based on the recognition of patients' autonomy and the need of informed consent.

In 1988, Spain was one of the first countries to enact a law on *assisted reproduction* (*Ley de Reproducción asistida*). That law was expanded in 2006 with the *techniques of assisted human reproduction Act* (*Ley sobre técnicas de reproducción humana asistida*). These laws recognize the right of any woman over the age of 18 to avail of these techniques regardless of their marital status or sexual orientation.

Also enacted in 1988 was a *law on organ donation and use of embryos and human fetuses or their cells*, *tissues or organs* (*Ley de donación y utilización de embriones y fetos humanos o de sus células*, *tejidos u órganos*). This act authorizes the procurement and use of biological structures from dead embryos for the purposes of diagnosis, therapy, or research. At the same time, this act prohibits any modification of healthy human genetic material; the use of embryos or their cells for the manufacture of cosmetic products; the extraction of cells for purposes other than prenatal diagnosis; and experimentation on live embryos, except in the case of nonviable embryos.

The Act of 1994, which established the legal regime of *the contained use*, *voluntary release and marketing of genetically modified organisms* (*utilización confinada*, *liberación voluntaria y comercialización de organismos modificados genéticamente*), in order to prevent risks to human health and the environment, incorporated the substantive rules of the European Community directives into the Spanish law. These standards have been now put into another law in 2003 that bears the same title.

The protection of experimental animals began with a Royal Decree in 1988 on the *protection of animals used for experimental and other scientific purposes*

(*protección de los animales utilizados para experimentación y otros fines científicos*). This decree introduced a system of centralized control following the British model. In 2007, the currently still existing *law for the care of animals, in their exploitation, transport, experimentation and sacrifice* (*Ley para el cuidado de los animales, en su explotación, transporte, experimentación y sacrificio*) was adopted.

Of special importance was the *Convention for the protection of human rights and the dignity of the human being with regard to the application of biology and medicine* (called *Oviedo Convention*) signed in 1997 and ratified by Spain in 1999.

To complete the picture, the most recent laws must be highlighted: the *Organic law of 1999 on Personal data protection* (*Ley Orgánica sobre Protección de Datos de Character Personal*). The *Basic Law of 2002, regulatory of the autonomy of the patient and of rights and obligations in the field of information and clinical documentation* (*Ley básica reguladora de la autonomía del paciente y de derechos y obligaciones en materia de información y documentación clínica*). The *Act of 2003, on cohesion and quality of the national health system*. (*Ley de cohesión y calidad del Sistema Nacional de Salud*.) And *the Act of 2007, for research in biomedicine* (*Ley de Investigación Biomédica*).

Major Bioethics Issues and Discussions

Some discussions (Sánchez-González, 1997) have been related to the cultural and political peculiarities of Spanish society, among them:

1. *Rationalism* versus *empiricism*: *the need of foundations and the search for a model of European Bioethics*

Since the beginning of the Modern Age, rationalistic and idealistic philosophical systems have dominated in Continental Europe. These systems have had a totalizing character, one which is thoroughly systematic and deductive. Meanwhile, empiricism, emotivism, and pragmatism have dominated in English-speaking countries. These differences lead to certain differences in ways of thinking.

First, there are differences in the area of law. Continental Europe emphasizes the importance of the statute. In English-speaking countries, on the contrary, jurisprudence is given much more space. In Europe, there is a tendency toward universal codification which presupposes that all particular situations can be predicted, and a legal deductivism according to which problematic cases must be judged according to their degree of fit with preestablished substantive norms. In all of this, to the influence of systematic rationalism one must add the presence of *iusnaturalism*. This legal doctrine recognizes the preexistence of a Natural Law as the source of law and morality. This natural law can be known rationally and integrated into a legal code in deontological and axiomatic form. The resulting legal framework privileges the idea that all conflicts can and must be previously regulated with certain substantive legal contents which leave little space to individual judgment. This way of thinking is less concerned with who is to decide than with what is to be decided.

All of the foregoing translates into the priority in Spain of the criteria of best interest in decision making and in the practical nonexistence of substituted judgment.

Among the consequences of this latter mentality is support for the concept of medically indicated treatment and for any other formula which permits doctors to discover the best interests of patients. In the United States, on the contrary, certain defenders of patient's rights, such as R. Veatch, have rejected the concept of medically indicated treatment as one which is irremediably charged with value judgments (Veatch, 1991).

Additionally, in the area of moral philosophy, continental European thought tends to consider insufficient an ethics which is merely casuistic and procedural. Instead, it attempts to establish norms which have some universal and substantive content.

Hence, the continental criticism of Anglo-Saxon bioethics for its proceduralism and casuistry as well as the attempts to find a more solid foundation. To fill these perceived gaps, the Spanish bioethicists have participated in the search for a European or Latin model of bioethics (Rendtorff & Kemp, 2000).

2. *Importance of virtue versus rights*, (Gracia, 1993), *giving way to peculiarities in the way of understanding informed consent and the doctor-patient relationship*

Philosophical ethics began in the Greek Antiquity as a reflection on the virtues which human beings can cultivate. The first ethical systems were primarily efforts to discover what type of person one should be. These systems relegated the study of the actions a person should undertake to the second level, because it was understood that a person with a good character would know the right thing to do in each case. The end of ethics was *eudaimonia*, that is to say, human excellence, which brings about the happiness of the moral agent.

During the Renaissance one finds the beginnings of a new moral tradition based on the concepts of rights and duty in Central Europe. The importance of these concepts culminated in the works of the eighteenth century Enlightenment, and became predominant in the Protestant countries of Central and Northern Europe as well as in the British Islands.

Despite these changes in others parts of Europe, the ancient concepts of vice and virtue have persisted with relatively more force in the Mediterranean understanding of morality. The persistence of these concepts can be seen in the importance that is given to character qualities in these countries: honor, fame, nobility, courage, sincerity, trustworthiness, generosity, and friendship, among others. The Mediterranean citizen expects much from his family and friends. It is understood that true friends and family have virtues which predispose them to help and favor each other. And this same citizen tends to place a similar confidence in the virtues of his physician. He requires, before all else, that his physician be trustworthy, compassionate, and capable of friendship (Laín, 1964). And he considers only secondarily the information which he receives from his doctor. The Mediterranean thinks that, if he can trust his doctor, such information is not pivotal. If he cannot trust his physician, such information is useless. He also thinks that little can be accomplished by demanding his legal rights. In fact, here

there are relatively few cases instituted by patients against their doctors, and the practice of medicine here is much less defensive. When there are complaints, they are usually related to a bad doctor-patient relationship. A patient, who has been well served from a personal point of view, will hardly ever denounce his doctor.

In Mediterranean societies, the doctor and the family have a greater role. Their authority seems less arbitrary, because they are supposed to incorporate a whole set of shared communitarian beliefs and values. Physicians understand that they should play a role of protecting and counseling the sick. In this model,, the ethics of the physician is to assume the right attitude as well as the obligations imposed on him by the profession. At the same time, the corresponding virtue for the sick person is to obey the doctor who possessed the necessary virtues.

To sideline a physician in the decision-making process and/or to reduce him to a mere transmitter of information could erode his professional virtue and his human motivation. In addition, to marginalize the family would damage the habitual dynamic of social relations within the community. Thus, the doctor and the family are two factors in the decision making which should not be ignored.

3. *Stoicism versus utilitarianism*: *and the corresponding tendency to assimilate and reduce the ethics to law*

Of all ancient ethical doctrines concerning virtue, Stoicism has left the biggest mark on the Mediterranean countries, and this impression has been the biggest in Spain and the Spanish speaking countries.

Happiness for the stoic is found in the serenity of the spirit independent of material goods and the adversities of fortune. It is a happiness that is reached by limiting one's necessities and dominating one's passions.

Philosophic stoicism has resurged periodically in Europe. It permeated Roman law and Christian moral theology. It resurged with force in the fifteenth century and was intermingled and confused, with Christian asceticism. Above all, it became important in Spain where it inspired great works of literature and mysticism. Spanish stoicism introduced the themes of meditations on death and the vanity of worldly enterprises. This stoicism accompanied the height of the Spanish empire and it is the philosophy which seems most to have found its place in the Spanish soul (Zambrano, 1987, 1994). Its influence can be detected in four cultural attitudes which, for the moment, continue to be widely shared by Hispanic people. First, there is a peculiar disdain for consumer goods, an attitude which considers frugality as the most important virtue. This attitude is contrary to the modern consumerist mentality. Next, stoicism proposed a certain way of understanding happiness, according to which happiness is to be found in inner states of spirit and in relationships with others, rather than in the enjoyment of material commodities. Thirdly, stoicism contributed to the development of a peculiarly anti utilitarian approach to problems which at times can even lead a Hispanic person to disregard practical solutions. In Spain today it is still frequent to think that utilitarianism and pragmatism are directly opposed to ethics. Fourthly, stoicism is accompanied by a particular distrust of the individual ego and a suspicion of the private. For the wise stoic, always attempting to ascertain the universal nature of things, there was

nothing private. The individual self, differentiated from others, was precisely the enemy to be defeated. Perhaps, this last attitude has led Spaniards to give less importance to privacy and to be more concerned with egalitarianism.

There are, however, two aspects to which stoicism could perhaps make a contribution. First, stoic meditation on the dignity of life and death permit one to better accept limitations upon therapeutic efforts in extreme cases. Secondly, the ascetic value accorded to the renunciation of the individual self and its desires makes it easier to accept a culturally shared definition of therapeutic futility.

The tendency to equate ethics with a natural law which obliges all may also be related to the Stoic legacy. And that natural law should be reproduced in statutory laws or mandatory codes of conduct. This explains the prevalence of deontological codes throughout the South of Europe, where health care professionals are more constrained by the professional rules than by the rights of patients. At the same time, the patient has a duty to improve his health and follow the instructions of the physician. This model of ethics in southern Europe, contrasts with the liberal model of Western Europe (UK and the Netherlands) which is based on rights, and with the model of social welfare which is more characteristic of the Nordic countries (Dickenson, 1999).

4. *Political statism versus Citizen Initiatives*: *The difficult liberalization of Spanish political life*

The Greco-Roman political tradition was centralist and based on the state. It tended to concede little importance to spontaneous social dynamics and citizen initiatives. In Continental Europe, it can be said that the common good has been more important that individual liberty. And the European emphasis has been placed more on the social than on the individual.

This tradition is even greater in Hispanic countries. Spain through the political work of the Catholic royalty was the inventor of the modern absolutist State at the end of the middle Ages. It has had a great tradition of political absolutism throughout the modern era and into the contemporary one. No wonder that within this tradition there was a major political centralism, as well as religious dogmatism and a certain moral dictatorship over the individual. Nor is it surprising that, overall, there was less of a tradition of democracy and citizen's liberties. Hispanic countries have had a strong sense of independence against foreigners but a weak sense of individual rights. Thus, the Spanish, perhaps, place too much faith in state politics and political leaders.

In Spain patient's rights have been imposed and advanced almost exclusively by the State. They have not entered by way of common law jurisprudence, nor have they been the result of progress of public opinion or citizens' demands upon the state. Instead, patients' rights have been the results of a legislative act by the state which has implanted them through statutory laws and codes. In Spain, patients' rights were first legally established by the 1986 General Health Law (Ley General de Sanidad). Only since then has a process of implementation been initiated.

This outlook can lead to a weakened respect for individual differences and choices. Of course, this is no excuse for the failure to recognize the right of individual autonomy. On the contrary, this should serve to put more emphasis upon the need to actively promote individual rights and options. The existence of customs contrary to citizen participation should serve to remind one that it is necessary to encourage greater social debate.

On the other hand, it might be said that there is a greater tendency to accept socially established criteria which are publicly recognized as reasonable. There is perhaps a greater disposition toward the acceptance of professional leadership in the establishment of standards. Institutions should not ignore this possibility for shaping public opinion, although, they will certainly have to exercise this leadership by encouraging greater social participation among citizens and fostering open social debate.

5. *Greater sensitivity to justice than to autonomy*: *Prominence of the conflicts between justice and efficiency*, *and debates about health systems*

Philosophical views concerning justice are undoubtedly much older than the very concept of individual autonomy. For Aristotle, as one example, justice was the sum of all the virtues:

> "*We call just that what produces or preserves happiness for the political community. . . This kind of Justice is not a part of virtue*, *but rather the whole virtue*." (Nichomaquean Ethics, 1129b and 1130a).

Throughout almost all of the modern era the liberal political tradition has had relatively little strength in Spain. Since the second half of the nineteenth century it has been counterbalanced by a greater force of workers' social movements.

At the present moment European governments take charge of what in other countries belongs to the realm of private enterprise. Healthcare systems are mostly financed or directly run by the state. In these systems of collectivized assistance, problems of justice go to foreground. When all health services are free, users aspire to obtain the maximum service possible. It can be said that in Spain the most frequent requests are not made to forgo treatments but rather to secure their application.

Taking into account what has been said up to this point, it is no wonder that in Spain the interest in justice is stronger that the interest in individual autonomy. There seems to be a strong belief that no isolated act has purely individual consequences and that any decision in a public health system could affect the whole of the system.

It is to be expected that the growing problem of health costs will make it ever more necessary to take issues of justice into consideration; and these considerations of justice will require the establishment of treatment standards, as well as minimum and maximum levels of assistance,

6. *Persistence of traditional positions*: *discussions about the beginning and the end of life*

The importance that the Roman Catholic Church has had in the history of Spain still can be detected in the willingness of some sectors to enforce positions emanating from the ecclesiastical Magisterium. This explains the prolonged debate in Spain

about the ethical aspects of the beginning of life, such as contraception, assisted reproduction and, especially, the termination of pregnancy.

Debates over the end of life have also proliferated, particularly over treatments which may shorten life, such as withdrawal of treatments, euthanasia, assisted suicide and, more recently terminal sedation.

Future Challenges

1. *Redesigning the thematic agenda*

The bioethical topics discussed in Spain should not be a mere echo of those achieved in other areas. The initial impetus of bioethics in North America was the extension of the civil rights movement. Spanish bioethicists need to be faithful to their own sensibilities and peculiar ethical traditions and know how to respond to the most pressing problems.

Bioethics research and education must not fail to cultivate two essential thematic areas. First they have to examine healthcare justice, reflecting not only the national situation, but echoing also the needs of the global justice affecting developing countries, and especially Latin America. Secondly, bioethics must achieve the global and ecological perspective that Potter advised since its inception. Environmental and sustainable development issues are essential to preserving the quality and sustainability of one's life.

2. *Practicing a pluralistic bioethics in the middle of the two temptations*: *Legalism and confessionalism*

Bioethics in Spain will have to learn to sail between the Scylla of legal reductionism to which lawyers and forensic pathologists subscribe and the Charybdis of theological reductionism by those who try to use bioethics as a way to enforce their own faith-based and more or less conservative ideals.

3. *Finding a space for interdisciplinary bioethics within institutes of humanities*

As yet university departments of history of medicine, social sciences and medical anthropology have not been very favorable toward the cultivation of bioethics, not only for reasons of curricular competition, but because those departments, as it has been pointed out by Diego Gracia (2009), usually consider themselves as scientific and as such they are used to working with empirical facts but not with values.

Institutes of Medical Humanities need to be created independent, and yet with good links to the departments of social sciences, law, and theology.

4. *Developing educational strategies on all educational levels*, *and mechanisms of implementation of bioethics*

It would be necessary to develop models of training in bioethics more unified and coherent on all educational levels.

Knowledge of bioethics should be disseminated to all citizens, to respond to the practical vocation of bioethics, developing procedures for modification and improvement of medical practices.

The increasing importance of bioethics at various educational levels and the active work of a good number of specialists foretell a good future for bioethics in Spain.

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Sri Lanka

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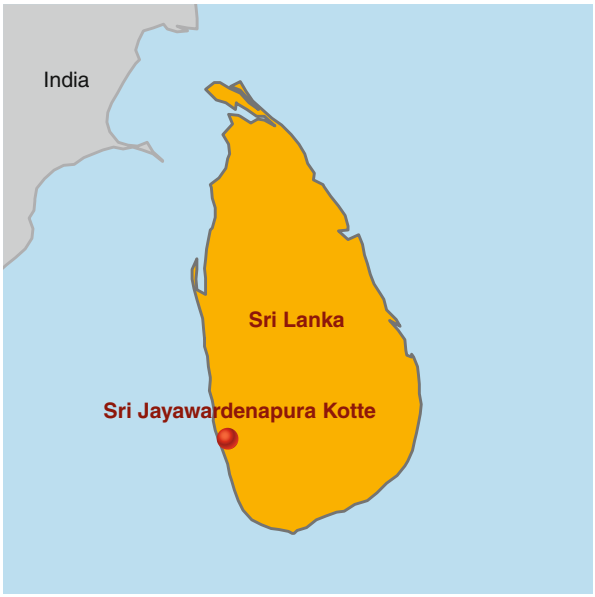
Anoja Fernando



Bioethics Development

When and How Has Bioethics Started?

Historical Background

According to the definition given by UNESCO (2005), the modern discipline of bioethics deals with the "ethical issues raised by medicine and the life and social sciences as applied to human beings and their relationship with the biosphere, including issues relating to the availability and accessibility of scientific and

A. Fernando
Chairperson National Committee on Ethics in Science and Technology, National Science Foundation, Colombo, Sri Lanka
e-mail: anojaf@yahoo.com

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technological developments and their applications" (UNESCO, 2005, General Provisions, Article 1 – Use of Terms, Item 18, p. 3).

However, historical sources reveal that the ethical concerns, policies, and practices which existed in Sri Lanka in ancient times are remarkably consistent with the modern concept of bioethics. The moral and ethical dimensions of issues such as life and death, medicine and the healing arts, and man's relationship with other living beings and the environment were closely influenced by the predominant cultural and religious beliefs existing at the time. From the third century BCE until the advent of Western colonizers in the sixteenth century CE, the predominant influence on the cultural and religious ethos in Sri Lanka was Buddhism.

Buddhism was founded in India in the sixth century BCE by Siddhartha Gautama, who was known as the Buddha after attaining enlightenment. Buddhism was introduced to Sri Lanka (circa 250 BCE) during the reign of King Devānampiya Tissa, by missionaries led by Thera Mahinda, sent by the Mauryan Emperor Aśoka in North India, who had embraced Buddhism after experiencing the horrors of war. Sri Lanka was ruled by its own kings from the sixth century BCE until 1815, when the British annexed the Kandyan kingdom. This long reign of kings is described in Sri Lankan Pali chronicles, such as the *Mahāvamsa* (fifth to sixth century AD) and the *Culavamsa*, which together with the lithic inscriptions left by the ancient kings, and the archaeological remains of ancient hospitals, provide a record of Buddhist influences on health, medicine, man's relations with nature, and the duties of kings towards their subjects in these areas. The epigraphical edicts of Emperor Aśoka in India (third century BCE) refer to hospitals in India as well as in Tambapanni, i.e., Sri Lanka (Fernando, 2005). The morality preached by Aśoka was imbued with the Buddhist values of compassion, moderation, tolerance, and respect for all life (Dhammika, 1993). Aśoka was considered as a perfect example of the Buddhist ideal of a Universal Monarch (Seneviratna, 1994), and kings throughout the ancient Buddhist world were encouraged to emulate his style of government as the ideal.

Buddhist views on ethics in medicine, as stated in the *Vinaya Pitaka*, show a remarkable similarity to the Hippocratic code of ethics. In Buddhism, provision of hospitals, medicine, and food for the sick were considered to be highly virtuous deeds, accruing much merit to the doer. This was the force that drove the kings to construct hospitals in ancient Sri Lanka (Uragoda, 1987). "It is to Gautama and his followers that we owe, apparently, the hospital idea" (BMJ 1928 Editorial, p. 541). George Parker, in his 1927 Thomas Vicary Lecture, says "Thus from before 500 BC downwards Buddhist hospitals were perpetually being built," and "In Ceylon and Burma they seem to have been ubiquitous" (Parker, 1928, pp. 41, 39). In ancient Sri Lankan society, the practice of *karunā* (compassion) and the resulting *ahimsā* (non-malfeasance) were predominant in guiding the meritorious actions of both king and commoner in the areas relevant to "bioethics."

Karuna and *ahimsa* were reflected in Buddhist society's treatment of animals and the environment as well. It is recorded in the ancient chronicles (*Mahāvamsa*, Chapter XIV) that there was a systematic philosophy of conservation dating back to the time of Thera Mahinda's visit circa 250 BCE, when he first preached to the King of Sri Lanka. "*O great King! The birds of the air and the beasts on the earth*

have an equal right to live and move about in any part of this land as thou. The land belongs to the people and all living beings; thou art only the guardian of it" (Weeramantry, 2000, p. 18). This is one of the earliest illustrations of the principle of trusteeship. Buddhists should not destroy any living thing, nor cause others to do so. This precept of abstaining from killing was followed by many kings whose edicts laying down rules for the protection of animals have been inscribed on stone (Uragoda, 1994). Sri Lankan society for the most part did not eat meat until the introduction of Western influences from the sixteenth century onwards.

Respect for nature and the environment is reflected in the treatment and uses of water and other forms of life in ancient Sri Lankan culture. At the World Future Council held in Hamburg in May 2007, Judge C. G. Weeramantry, former Vice President of the International Court of Justice, described the Buddhist perspectives on the interrelationships between all living beings and the environment. Quoting from the Buddhist scriptures, the Pali Canon or the *Tripitaka*, he demonstrated how Buddhist teachings and Buddhist kings have been in the forefront of pioneering laws on environmental protection since ancient times. The numerous moral principles described in the scriptures included protection of trees and other organic life, protection of the environment, goodwill towards all forms of life, rejection of anthropocentrism in favor of ecocentrism, the unity of the human family, the interdependence of all entities and events, and the emphasis on coexistence with other species and groups, rather than their conquest (Weeramantry, 2007).

Judge Weeramantry also advanced another theory that modern international law has much to gain from the wisdom of the past, when he cited the ancient hydraulic civilization of Sri Lanka as an excellent example of the concept of sustainable development. This civilization recognized the need for developing agriculture and, according to the ancient chronicles, built stupendous irrigation schemes using superior technology for the "benefit of the country" (Weeramantry, 2000, p. 17) and "out of compassion for all living creatures" (Weeramantry, 2000, p. 17), while ensuring the protection of the environment at the same time. Felling of forests was prohibited, animals were protected in sanctuaries, and royal edicts decreed that not even a drop of rainwater should be allowed to flow into the ocean without being made useful to man (Weeramantry, 2000).

With the advent of the Portuguese in 1505 and the Dutch in 1656, who successively occupied the Maritime Provinces, and finally of the British in 1796, who ruled the entire country from 1815 to 1948, Sri Lankan society changed from being predominantly Sinhala-Buddhist (with Hindu roots) to a multireligious, multicultural society. With the introduction of Christianity and Western medicine, the scientific community was introduced to a medical ethics having a Christian (or "Western") morality as its model (Fernando, 2005). Hunting animals for sport was introduced by Western colonizers from the sixteenth century onwards and was very popular with the British in the nineteenth century (Uragoda, 1994).

As pointed out by many writers, there are some fundamental differences between the Western model of ethics and the Buddhist and Hindu (indigenous) ethics (Arsecularatne, 1998). Professor Hyakudai Sakamoto (1999) has drawn attention to the contrast between the Asian ethos of "a holistic harmony" and the

"dualistic individualism" of the West (Sakamoto, 1999, p. 194). In Western ethics, the importance of the individual (individual autonomy) is considered fundamental in decision making, while Buddhism emphasizes an individual's duties over his rights. This is exemplified by the *Dasa Raja Dhamma*, or the ten duties of a king, where Buddhism specifies certain basic virtues for rulers. In addition to the virtues such as generosity, morality, and nonviolence, an ideal king (or government) was expected to protect not only the people but quadrupeds and birds and also protect trees and other organic life, as part of his duties.

During the 500 years of colonization by Western powers, the predominantly Sinhala-Buddhist society in Sri Lanka had gradually become a multireligious, multicultural society. With the achievement of independence in 1948, the regular election of democratic governments has made it possible to introduce some of the more admirable bioethical concepts and practices which existed during the times of the ancient kings of Sri Lanka. Since independence, every Sri Lankan citizen has been entitled to free education in State schools and universities and free health services in government hospitals. Hunting of animals is prohibited; protection of fauna and flora is encouraged by legislation, and many wild life sanctuaries and protected nature reserves have been established. There are many lessons in bioethics to be learned from Sri Lanka's ancient history.

Modern Era

Professional ethics: The Sri Lanka Medical Council (SLMC) is a statutory body established for the purpose of protecting health-care seekers by ensuring the maintenance of academic and professional standards, discipline, and ethical practice by health professionals who are registered with it. The Ceylon Medical Council (CMC) was established by the Medical Council Ordinance No. 24 of 1924 and replaced by the Sri Lanka Medical Council by the Medical (Amendment) Act No. 40 of 1998 when the title was substituted for "Ceylon Medical Council." As presently constituted, the Council has representatives from medical faculties of the state universities as well as from professionals in the state and private sector (Sri Lanka Medical Council, www.srilankamedicalcouncil.org). An Ethics Committee was formed in 2001 to consider ethical issues.

The SLMC, being the regulatory body for registered medical and dental practitioners in Sri Lanka, is responsible for maintaining professional and ethical standards. Guidance on professional ethics is circulated to all registered practitioners at regular intervals. The SLMC guidelines on ethical conduct, produced by their Ethics Committee in 2003, were updated in 2009 (Sri Lanka Medical Council, 2009). Advice on serious professional misconduct, advertising, and writing of medical certificates are issued separately. All newly qualified medical practitioners are required to take a modern version of the Hippocratic Oath prior to full registration with the SLMA. In 2005 the SLMC produced a "Provisional Code of Practice for Assisted Reproductive Technologies."

Several other Professional Colleges and Associations (e.g., Sri Lanka Medical Association, Sri Lanka Association for the Advancement of Science) also have ethics committees to deal with ethical issues.

Teaching of Medical Ethics: There are eight Faculties of Medicine in Sri Lanka. The departments of forensic medicine in all the Faculties of Medicine have always included the teaching of professional ethics in their undergraduate syllabus (Babapulle, 1992). Medical ethics as a separate subject was introduced into the curricula of most Sri Lankan medical schools in the 1980s, and some faculties have well-developed courses. The Faculty of Medicine in Colombo, established in 1870, is the oldest medical school in Sri Lanka. A formal course on medical ethics was introduced in 1994, and, with the new medical curriculum introduced in 1996, teaching of ethics was incorporated into the Behavioural Sciences Stream spanning the entire 5 years of the medical course (Jayakody & Kasturiaratchi, 1999).

S. N. Arseculeratne, Emeritus Professor in the Faculty of Medicine, University of Peradeniya, has for many years highlighted the need to take cultural relativity into account when teaching medical ethics to Asian undergraduates and has advocated the use of innovative approaches to teaching ethics (Arseculeratne & Babapulle, 1996). He has described the relationship between culture, ethics, and medical education and suggested how ethics could be made more relevant to medical students in Sri Lanka by incorporating an "indigenous ethics" into medical education (Arseculeratne, Simpson, Premasiri, & Kumarasiri, 2008).

In the Faculty of Medicine, University of Ruhuna, ethics was introduced to new entrant students during the History of Medicine lectures from the very inception in 1981. A short formal course on medical ethics, comprising lectures, case presentations, and discussions, was introduced in 1995, at the beginning of the 3rd year, just before the students commenced their clinical work in the hospital. In addition, clinical ethics teaching was introduced in the wards during the final year of the 5-year medical course when the students did their hospital clerkships with the professors in the four main disciplines – Medicine, Surgery, Pediatrics, and Obstetrics and Gynecology. In order to increase the relevance of medical ethics for our students, some innovations were introduced in 2005 in the Faculty of Medicine, University of Ruhuna. One method was to include Asian medical ethics drawn from the indigenous systems of medicine which have existed for many years in India and Sri Lanka. The other innovation was the introduction of Medical Humanities in October 2005 (Fernando, 2008).

Postgraduate teaching of medical ethics is a more recent development. The Postgraduate Institute of Medicine (PGIM) is the only institute that is responsible for the specialist training of medical doctors in Sri Lanka. It is a national institute attached to the University of Colombo and is internationally recognized with "equivalence" of recognition by the Royal Colleges of the United Kingdom. The PGIM works in close collaboration with the Ministry of Health, the Faculties of Medicine in the state universities, and the Professional Colleges. It has a Board of Management which comes under the Senate of the University of Colombo and functions through several Boards of Study for the different disciplines.

Formal ethics teaching for doctors following postgraduate degree courses in the different fields of medicine is currently gaining popularity. Ethics teaching was first introduced as part of Research Methodology Courses conducted by the PGIM for postgraduate trainees in some of the disciplines that included a research component

in their degree course, e.g., pathology, microbiology, and community medicine. Research ethics thus became an integral part of such courses. Most of the degree courses conducted by the PGIM taught topics on medical ethics at various points in their syllabus (e.g., informed consent, end of life issues), but not as a separate module. The number of courses that include a formal ethics component is still very small. The MD in Medical Administration course introduced a 15-h module on ethics in 2010. It is anticipated that more postgraduate degree courses at the PGIM will incorporate ethics into their formal curricula.

Research ethics: Institutional Ethics Review Committees (ERCs), dealing with the review and approval of research protocols, have been established in all the Medical Faculties of Sri Lanka, commencing in the late 1970s in the older Medical Faculties of Colombo and Peradeniya. The newer faculties in Galle, Jaffna, Kelaniya, and Sri Jayawardenepura established ERCs in the 1980s. Ethics Review Committees were also established in other organizations such as the Sri Lanka Medical Association (in 1999), the Medical Research Institute (MRI), the National Institute of Health Sciences (NIHS), and a few of the larger hospitals (Jayakody & Kasturiaratchi, 1999; Dissanayake, Lanerolle, & Mendis, 2006). Each ERC conducts training programs and workshops on research ethics for their members and for researchers.

The ERC of the Faculty of Medicine, Colombo, established in the late 1970s under the deanship of Professor S. R. Kottegoda, is the oldest Ethics Review Committee in Sri Lanka. It was surveyed and evaluated by the Forum for ERCs in Asia and the Western Pacific (FERCAP) in 2009 and became the first ERC in Sri Lanka to be recognized by the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER) – a worldwide network of independently established regional fora for ethics review committees, health researchers, and invited partner organizations supported by the TDR program of the World Health Organization. The ERC of the Faculty of Medical Sciences at the University of Sri Jayawardenepura also gained SIDCER recognition in 2012.

The Ethics Review Committee of the Faculty of Medicine, University of Colombo, has been very active during the past few years and has conducted several national workshops and training programs on research ethics for doctors and researchers from all over Sri Lanka. It also organized the "Ethical and Regulatory Aspects of Clinical Research Course" conducted by the Bioethics Department of the National Institutes of Health (NIH), Maryland, USA, via live video conferencing, for the first time in 2008.

The Forum for Ethics Review Committees in Sri Lanka (FERCSL) is a forum of ERCs in Sri Lanka, convened under the Sri Lanka Medical Association. Originally formed in 2004, the forum became more firmly established, with its own constitution, in 2007 Sumathipala et al. (2010). It has the objective of fostering an improved understanding and implementation of ethics review of biomedical research in Sri Lanka. FERCSL strives to achieve its goal through the following activities:

1. Improving communication among member ERCs
2. Organizing meetings and symposia

3. Stipulating Guidelines and Standard Operating Procedures for member ERCs
4. Facilitating training and education opportunities for members of ERCs
5. Coordinating communication and responses on the subject of ethics review of biomedical research with the WHO, UNAIDS, CIOMS, UNESCO, and other international organizations involved in fostering ethics review

The Colombo Faculty ERC, together with FERCSL, produced Guidelines for Ethics Review Committees (Forum for Ethics Review Committees in Sri Lanka (FERCSL), 2007) and Guidelines for Ethics Review of Animal Research (Forum for Ethics Review Committees in Sri Lanka (FERCSL), Ethics Review Committee, Faculty of Medicine, University of Colombo, 2009). FERCSL members regularly conduct workshops on research ethics for its member ERCs and for researchers with the aim of improving their knowledge and performance.

The Senior Scientists Forum of the National Science and Technology Commission prepared a very useful document titled "A Guidebook on Research Ethics" in 1995 with a view to assisting all those involved in scientific research to maintain a high standard of professionalism. The document describes the responsibilities, commitments, and obligations of individual scientists as well as laboratory ethics.

The Institute for Research & Development (IRD), an independent nongovernmental organization promoting multidisciplinary research, has conducted courses on research ethics and bioethics, in 2003, 2007, and 2009/10, as part of their program on awareness raising and capacity building in research. The IRD organized a consensus generation meeting on disaster research and ethics from a developing world perspective in 2007, and a working group (Regional WGDRE*)* funded by a Wellcome Trust grant produced a draft guideline for disaster research and ethics: Statement on Ethical Issues in Disaster-Related Research – a Developing World Perspective, 2007 (Sumathipala et al., 2010).

Bioethics: Professional ethics, medical ethics, and research ethics, as described in the previous sections, are fields familiar to most medical students and doctors in Sri Lanka and have a recent history going back several years. The modern discipline of Bioethics, on the other hand, which evolved from medical ethics in response to advances in biomedicine and technology, has a broader definition, describing an interdisciplinary field including the life sciences, the environment, health, and health care. Bioethics is a relatively new field in Sri Lanka, and began to attract attention at the beginning of the new millennium. The evolution of bioethics from medical ethics and the challenges faced in the new century were highlighted in a presidential address at the Sri Lanka Medical Association in 2001(Fernando, 2001).

A National Bioethics Committee (NBC) was established at the National Science Foundation (NSF), Sri Lanka, in August 2003, at the request of the Sri Lanka National Commission for UNESCO. The National Science Foundation, coming under the (then) Ministry of Science and Technology, was identified as a suitable focal point for bioethics in Sri Lanka by the Sri Lanka National Commission for UNESCO. The establishment of the Committee thus complied with Article 19 of the UNESCO Universal Declaration on Bioethics and Human Rights, which states that "independent, multidisciplinary and pluralist ethics committees should be established, promoted and supported at the appropriate level."

The main aims of the newly formed National Bioethics Committee (2003) were:

- To publicize (and help implement) UNESCO and other international declarations on bioethics, and liaise with the UNESCO International Bioethics Committee
- To formulate guidelines for emerging issues in bioethics
- To network with Institutional Bioethics Committees in Sri Lanka
- To promote concerns for human dignity and human rights in research
- To consider ethical issues related to all living organisms in the field of biology

Under this last broad category, the Committee identified the need to inculcate ethical attitudes, by teaching and training at an appropriate level, to be of real importance. In keeping with these aims, the activities of the National Bioethics Committee during the first four years of its existence were concentrated on two broad areas: Bioethics Education and Bioethics Regulation (Fernando & Fernando, 2009). Thus, unlike most national bioethics committees in other countries, our committee became involved in teaching bioethics from the start.

At the inception, the NBC was chaired by the then Chairman of the National Science Foundation, who is a research scientist. According to the UNESCO Guide, recruitment of members could be based on one or more of the four criteria – expertise, representativeness, experience, and integrity. In recruiting members to serve on the committee, the National Science Foundation was restricted by the fact that there are no professional bioethicists in Sri Lanka. (In the West they are usually philosophers and/or theologians.) Therefore its members were recruited mainly from a representative viewpoint and for their experience in the field of medical ethics. There were members representing the Ministries of Health and Justice and the national medical and scientific associations, among others. Special efforts were made to include people with a legal background in view of the activities planned. Subsequently, members were handpicked for their interest and experience.

At the beginning, progress of the NBC was rather slow, mainly due to governance issues at institutional and national levels. In November 2004, the membership was reconstituted and during the next few years many activities were carried out through a number of subcommittees. The number of meetings during this period averaged 10 meetings per year.

In March 2008 the NBC was replaced by the National Committee on Ethics in Science and Technology (NCEST), widening the scope of the committee. The need for a committee with wider terms of reference was highlighted by the NBC itself and became a reality after a long period of gestation. The new committee, at the beginning, had a Bioethics Subcommittee to continue the work already begun by the earlier NBC. Among the Terms of Reference for the National Committee on Ethics in Science and Technology (NCEST) are the following:

1. Recommend programs or activities for communication of ethics in science and technology issues to relevant stakeholders as appropriate.
2. Facilitate activity to enhance understanding and debate on ethics related to science and technology among researchers, students, and the general public.

3. Advise the NSF on priority issues to be communicated to policy makers.
4. Identify ethical issues related to
   - All aspects of research and development and develop a code of ethics for research grantees of the NSF
   - Technology development and propose necessary measures to address same.
5. Guide and support the NSF to work as the focal point for UNESCO Bioethics and ethics of science and technology programs.
6. Advise the NSF to respond in a timely manner to national and international ethical issues related to science and technology.
7. Coordinate, collaborate, and cooperate with other institutions and agencies on national, regional, and international activities related to ethics in science and technology.

Who Have Been the Major Actors/Forces?

The National Science Foundation (NSF), which came under the Ministry of Science and Technology, took the initiative to establish the National Bioethics Committee (NBC) in 2003, and, later, the National Committee for Ethics in Science and Technology (NCEST) in 2008. The Sri Lanka National Commission for UNESCO was responsible for identifying the NSF as the institution where the NBC could be located.

Prior to the introduction of bioethics as a distinct discipline, and the establishment of a National Bioethics Committee, the faculties of medicine in Sri Lanka played the leading role in the field of medical ethics, both in the teaching of medical ethics to medical undergraduates and in establishing research ethics committees in Sri Lanka. However, these activities did not extend beyond the medical profession. Even after ethics review committees had been established in the medical faculties in the early 1980s, there was a significant lack of awareness among hospital doctors on the need for ethical review of research (Kottegoda, 1988). As far back as 1991, the predecessor of the National Science Foundation, called the Natural Resources, Energy and Science Authority (NARESA), appointed a committee to develop ethical guidelines for research in the different scientific disciplines, including biomedical research on humans, animal experimentation, and social science research. The guidelines produced in 1992 failed to gain publicity among researchers and did not develop into National Guidelines.

Long-established professional associations such as the Sri Lanka Medical Association (SLMA), the Sri Lanka Medical Council (SLMC), and the Sri Lanka Association for the Advancement of Science (SLAAS) have played an important role in providing ethical guidance for doctors and scientists through their ethics committees. The work of the SLMC in maintaining the professional and ethical standards of registered practitioners has been described earlier.

The Sri Lanka Medical Association (SLMA) established in 1887 as a branch of the British Medical Association is the oldest medical association in Asia and

Australasia and has always given high priority to ethics. In 1995, its Ethics Committee produced a Patients' Charter, called the Declaration on Health, and also developed Ethical Criteria for the Promotion of Medicinal Drugs and Devices in Sri Lanka in 1996. This has been revised subsequently. The Ethics Committee of the Sri Lanka Medical Association (SLMA) during the past decade has encouraged the establishment of Ethics Committees in the other professional colleges and also facilitated joint meetings and seminars on ethics. The SLMA has also consistently promoted the teaching of ethics by regularly including it in their Continuing Medical Education (CME) programs. More recently, the SLMA initiated discussions among relevant institutes to explore the possibility of introducing Clinical Ethics Committees (Hospital Ethics Committees) in some of the bigger hospitals.

The Sri Lanka Medical Association, the University of Colombo and the National Science Foundation, Sri Lanka, successfully co-organized and hosted the 12th FERCAP International Conference and General Assembly, "Development, Ethnicity, Culture and Ethical Health Research" from 18 to 21 November 2012, in Colombo, Sri Lanka.

Sri Lanka Association for the Advancement of Science (SLAAS) is the premier organization of scientists in Sri Lanka. The Ethics Committee of SLAAS is a statutory committee which has the power to take action against its members who violate the code of ethics. The National Health Research Council (NHRC) and the Drug Regulatory Authority (DRA) of the Ministry of Health have also encouraged and extended their support towards activities in the field of research ethics and medical ethics. The Postgraduate Institute of Medicine (PGIM) has regularly conducted research methodology courses for their postgraduate students, and research ethics is always included in these programs.

What Have Been the Major Concerns Over Time?

The major concerns have been the lack of national laws, regulations, and national guidelines for research ethics and for the practice of the newer technologies in medicine and science, such as assisted reproductive technologies and newer genetic technologies. Where applicable, the general laws have been used as a point of comparison. For example, the Transplantation of Human Tissues Act, 1987, regulates the donation of human organs for specified purposes. The application of this Act can be extended to research relating to the human gene, although the human gene is not specifically mentioned in this Act.

There is an urgent need to regulate assisted reproductive and genetic technologies in Sri Lanka. Regulation of the transfer of genetic material and data also needs attention. Conduct of clinical trials of drugs is increasing steadily in Sri Lanka with the advent of Contract Research Organizations (CROs) and requires regulation in order to ensure ethical compliance as well as scientific quality.

The members of Ethics Review Committees need to be trained more comprehensively in ethical review, and the ERCs supported with more resources to enable

the ERCs to reach the standard required to gain SIDCER recognition. The inability to monitor research projects after giving ethical approval remains a serious problem among all the ERCs. A central research ethics committee having a broad mandate and power to deal with policy and problematic ethical issues at a national level is also desirable.

What Resources Have Been Developed (e.g., Books, Programs, Media, Networks, Societies)?

UNESCO Grant to NSF

In 2007, the National Bioethics Committee was awarded a grant under the UNESCO Participation Program to develop bioethics in Sri Lanka. This grant was used to conduct several teacher-training workshops on bioethics education for science teachers in universities and schools. Part of the grant was utilized to obtain several publications on bioethics, some of which were distributed to the university libraries in Sri Lanka while most of the publications were kept in the NSF library.

Forum for Ethics Review Committees in Sri Lanka (FERCSL)

FERCSL is composed of members of ERCs in Sri Lanka. Many members of the faculties of medicine and the SLMA have undergone training in research ethics, both locally and internationally. They provide a pool of expertise for training of researchers and other ERC members in Sri Lanka. A few also act as resource persons in the training and survey programs of FERCAP (Forum for ERCs in Asia and the Western Pacific) conducted in other Asian countries. FERCSL together with the ERC of the Colombo Faculty of Medicine produced Ethics Review Committee Guidelines (FERCSL, 2007) and guidelines for ethics review of research proposals involving animals in Sri Lanka (FERCSL, 2009). Some of the ERCs in Sri Lanka have developed Standard Operating Procedures for their Ethics Review Committees.

Individual Institutes

In addition to the two organizations mentioned above, other institutes and centers, such as the faculties of medicine, SLAAS, the PGIM, the professional colleges, and the Institute for Research & Development (IRD), have developed their own resources.

What Have Been the Steps/Measures Taken (Policies, Legislation, Infrastructures, Teaching Programs, Committees, etc.)?

Bioethics Regulation

Human Reproduction and Genetics Act (HURGA)

The practice of assisted reproduction was fast developing in Sri Lanka in the early part of the present decade and proving to be popular with childless couples. Around

2004 the Sri Lanka Medical Council (SLMC) identified an urgent need for regulation of assisted reproductive technologies (ART) in Sri Lanka. As a first step, the SLMC published "A Provisional Code of Practice for Assisted Reproductive Technologies" (SLMC, 2005). This was based on the Code of Practice relating to the 1990 Human Fertilisation and Embryology Act of the UK and a report of the National Science and Technology Commission of Sri Lanka (NASTEC): New Genetics and Assisted Reproductive Technologies in Sri Lanka: A draft National Policy on Biomedical Ethics (Jayasekera et al., 2003).

In the year 2006, the NBC undertook the task of drafting legislation that would underpin the SLMC Code of Practice for ART. A decision was taken at the outset to widen the scope of the Act such that it would cover genetic technologies as well. Using the 1990 UK Human Fertilisation and Embryology Act as a model, a joint committee composed of members from the NBC, members of the Sri Lanka Medical Council who had been involved in producing the Code of Practice, and experts from the legal and ART fields drafted the Human Reproduction and Genetics Act (HURGA), the principal aim of which is to establish a Human Reproduction and Genetics Authority in Sri Lanka. This Authority will oversee and regulate all forms of Assisted Reproductive Technologies and the introduction and practice of Genetic Technologies, both in the research and clinical spheres. It is a comprehensive Act that deals with the responsibilities of practitioners, the procedures that are permitted, and also provides for the inspection and approval of the clinics and laboratories where both ART and genetic technologies are practiced. The draft is now ready for wide public consultation, where it would be circulated among medical and scientific professionals, interest groups, and the general public to seek their views (Fernando & Fernando, 2009).

One of the expert committee members who was involved in drafting HURGA has recently reiterated the urgent need for enacting regulation of ART in Sri Lanka (Seneviratne, 2011).

National Policy on Human Genetic Material and Data for Sri Lanka

In October 2003 the General Conference of UNESCO adopted the International Declaration on Human Genetic Data. Article 1 defines the aims and scope of this declaration. The aims include ensuring the "respect of human dignity and protection of human rights and fundamental freedoms" in the collection and use of biological samples containing genetic data and goes on to state, inter alia, "to set out the principles which should guide States in the formulation of their legislation and their policies on these issues (and) form the basis for guidelines of good practice in these areas for the institutions and individuals concerned."

This declaration came to the attention of the Sri Lanka Medical Association in 2003 during the period when drafts were circulated for comment, at a time when the SLMA ethics review committee was aware of the importance of this subject. In February 2004 the NBC produced a draft set of guidelines based on this declaration titled "Guidelines – Biological Samples and Human Genetic Data: Collection, Processing, Use and Storage." This was done to bring into sharper focus the issues dealt with in the Declaration and to facilitate exploring

how Sri Lanka should respond and what needed to be done to meet its obligations as required by the Declaration. The draft was sent for scrutiny and comment by members of the Ethics Review Committees and the Solicitor General's Department – that is, the office of the Government's chief legal officer. The latter consultation was necessary as many of the recommendations in the guidelines depended on what was prescribed by Sri Lanka's laws. It was revealed that very few laws existed in Sri Lanka that dealt with the issues covered by the Declaration, and the draft guidelines. It was therefore seen to be necessary to consider new legal enactments to adequately deal with the issues involved.

The NBC thereupon commissioned a law academic to review regulatory legislation in relation to human genetics – both in the fields of clinical application and research – in selected countries that had relevance to Sri Lanka. The legislation existing in five countries – India, Japan, Thailand, the United States of America (USA), and the United Kingdom (UK) – was studied (Watson, 2007). The selection of countries was based, partly, on the availability of their legislation on the World Wide Web. Having identified the lacunae in the Sri Lanka laws and the subject areas that have to be addressed, the NBC (and later the NCEST) at the National Science Foundation was ready for a series of meetings with wide representation to decide on policy in relation to these subjects, before recommending them to the Government for adoption and thereafter for the introduction of new legislation.

At a discussion held in September 2010 between members of the National Health Research Council of the Ministry of Health, the Bioethics Subcommittee of the National Committee on Ethics in Science and Technology (NCEST), and the Sri Lanka Medical Association, consensus was reached as to the urgent need for national regulations in the field of human genetic material and data. Accordingly, a drafting committee comprising members from all three institutions developed a draft National Policy on Human Genetic Material and Data for Sri Lanka as a preliminary step, which is now ready for finalization after stakeholder meetings held in 2011 and 2012.

Bioethics Education

The National Bioethics Committee (NBC) established in 2003 decided to concentrate on activities promoting bioethics education as one of its priorities, in keeping with *Article 23* of the UNESCO Universal Declaration, which states "To achieve a better understanding of the ethical implications of scientific and technological developments, in particular for young people, States should foster bioethics education and training at all levels and encourage dissemination of information about bioethics."

The NBC felt that teaching of medical ethics is adequately covered by the medical faculties and decided to concentrate on the science-based faculties in our universities (i.e., Faculties of Natural and Applied Sciences, Agriculture, and Veterinary Medicine). During the early period, between 2005 and 2008, the NBC conducted several introductory teacher-training workshops for university teachers and secondary school teachers from all over the island, with funding from the

Ministry of Science and Technology. Despite the uncertainties of travel in Sri Lanka at this time due to the prevailing war with the terrorists, there was enthusiastic participation from university academics from all parts of the country, including the North and the East (Fernando & Fernando, 2009).

In 2007, the National Bioethics Committee of the NSF received a grant from UNESCO, to further develop the bioethics teaching program in Sri Lanka. Several comprehensive teacher-training programs were conducted in 2008. In addition to several one-day workshops, a 2-day residential workshop was conducted for university science teachers with the help of a resource person from the University of Durham in the United Kingdom.

In addition to several Train-the-Trainer workshops on bioethics education conducted for university science teachers, other workshops were conducted on *Introduction of bioethics in secondary schools* and *Humane Ethics in the Care, Use and Study of Animals* for secondary school teachers, *Current issues in bioethics & biomedical research* for Medical and Dental faculty researchers, and the *Establishment of Research Ethics Committees in Science Faculties* as well as *Developing guidelines for research on animals* for teachers from the science-based faculties.

Current Bioethics Infrastructure

Teaching of Bioethics at University and Other Levels

Teaching Medical Ethics

Medical ethics teaching at undergraduate level is fairly well established in most of the medical faculties. However, the duration and content of the courses are not uniform among the faculties. At postgraduate level, ethics teaching is less formally organized although a few courses have introduced separate modules on ethics. Research ethics is fairly well covered at both undergraduate and postgraduate levels, and is frequently dealt with in workshops and continuing medical education programs.

Teaching Bioethics

Teaching bioethics at university level (other than in the medical faculties) is less well organized. A few science faculties have introduced the subject at undergraduate level.

The National Bioethics Committee (2004–2008) initiated teacher-training activities to promote the introduction of bioethics in the science-based disciplines in universities. This initiative is being continued by the National Committee on Ethics in Science and Technology at the National Science Foundation.

Bioethics was also introduced in government secondary schools through the National Institute of Education.

Bioethics Committees

The need to reflect and act on the ethical, legal, and social dimensions of modern advances in science and biotechnology resulted in the establishment of many kinds of bioethics committees around the world. These committees can be described as falling into four categories, according to their goals, and the level at which they function, national, regional, and local, as described in the UNESCO booklet *Establishing Bioethics Committees – Guide No. 1*. In practice, however, some of these committees could function at more than one level, e.g., Research Ethics Committees, and they could also have a combination of goals:

1. Policy-Making and/or Advisory Committees (PMAs) – at national level
2. Health-Professional Association Committees (HPA) – at national and regional levels
3. Health Care/Hospital Ethics Committees (HECs) – at local and institutional levels
4. Research Ethics Committees (RECs) - at many levels

The following types of bioethics committees are present in Sri Lanka.

Policy-Making and/or Advisory Committees (PMAs)

The need for a National Committee was fulfilled in 2003 with the establishment of the National Bioethics Committee at the National Science Foundation, which came under the Ministry of Science and Technology. This committee was replaced by the National Committee on Ethics in Science and Technology in 2008. The Ministry is now called the Ministry of Technology and Research.

Health-Professional Association Committees (HPA)

Some of the older Health Professional Associations such as the Sri Lanka Medical Association and the Sri Lanka Medical Council have had Ethics Committees for many years, while others are in the process of establishing such committees.

Research Ethics Committees (RECs) or Ethics Review Committees (ERCs)

In Sri Lanka, Research Ethics Committees, dealing with the review and approval of research protocols, have functioned for the past 25 years or so in all the Medical Faculties of the universities. Research Committees have also been established in other organizations, such as the Sri Lanka Medical Association and the Medial Research Institute (MRI), and in some of the larger hospitals, for this purpose.

Health Care/Hospital Ethics Committees (HECs)

In Sri Lanka, no Hospital Ethics Committees have been established in any of the government hospitals, although one functioned for a few years in a private hospital. In 2011, the Sri Lanka Medical Association took the initiative to introduce the concept of Hospital Ethics Committees in Sri Lanka, but as yet, no Hospital Ethics Committees have been established.

Expert Bodies/Centers

There are no associations or societies devoted specifically to bioethics. As yet, there are no Departments of Bioethics in any of the universities in Sri Lanka. The National Committee on Ethics in Science and Technology (NCEST) at the National Science Foundation (formerly the National Bioethics Committee) is the only body involved in the wider discipline of bioethics at a national level. Teaching of medical ethics and research ethics, however, is undertaken by several centers in Sri Lanka, including all the Faculties of Medicine, the Postgraduate Institute of Medicine, the professional medical organizations including the Sri Lanka Medical Association, and the Institute for Research & Development (IRD).

Relevant Legislation

There is no legislation on bioethics at present.

Public Debate Activities

There is no regular forum for the public debate of major ethical issues. Whenever any policies or potential regulations are drafted by professional organizations or academic bodies, stakeholder meetings are convened to obtain public opinion and publicity will be given in the media.

The draft acts prepared by the National Committee on Ethics of in Science and Technology will be discussed at stakeholder meetings including members of the public before being finalized.

Others

The Ethics Committee of the Sri Lanka Association for the Advancement of Science (SLAAS) initiated an annual meeting/oration, on a topic related to ethics, in memory of the late Professor S.R. Kottegoda, who was a Past President of the Association and who encouraged the development of research ethics and research ethics committees at many scientific institutions. These annual meetings/orations have continued without a break since 1997, and provide a suitable forum for the dissemination of ethical issues relevant to Sri Lanka (Arsecularatne, 1998).

Major Bioethics Issues and Discussions

Beginning of Life

There are no specific laws concerning the beginning of life except for the law prohibiting abortions. In Sri Lanka, an abortion is only permitted if the pregnancy

threatens the life of the mother. There is also not much public canvassing to change the existing law either. Respect for human life is considered to be paramount among all the religions in Sri Lanka although paradoxically, a large number of illegal abortions are carried out under different names.

End of Life

End of life ethical issues are not issues that generate a lot of controversy in Sri Lanka. Unlike in the West, where patient autonomy is paramount, in Sri Lanka, as in most other Asian countries, while informed consent is routinely obtained for most procedures, the wishes of the family are also given a lot of consideration by doctors with regard to end of life ethical issues, such as life-sustaining interventions and withholding/withdrawal of life support. Living wills and advance directives are not common. Euthanasia is illegal.

Health and Disease

There are no major ethical issues in this area. Sri Lanka is proud of the free health service provided to all its citizens who wish to avail themselves of this service. Private health care is also available to those who can afford it. Ethical issues may arise in the allocation of scarce resources in an equitable manner in the state hospitals. Some of the very expensive drugs such as cytotoxic drugs may not be available for free in the state sector hospitals. On the other hand, many drugs issued free to patients are not utilized properly simply because they are given free.

Health-Care System, Access to Health Care

Sri Lanka has a history of successful health action at relatively low levels of per capita expenditure since independence and is often praised by the World Health Organization for its achievements in the public health domain. Sri Lanka has the best health indices in South Asia, on par with some of the richer countries in the region. Citizens of Sri Lanka have high literacy rates and enjoy the benefits of universal access to free health care and free education up to university level. These achievements are mainly due to the socialist policies of successive governments democratically elected since gaining independence from Britain in 1948.

Many of the older infectious diseases have been eradicated, and the public is generally satisfied with the quality of and access to health care provided by the State. Private health care and hospitals are also available to those who can afford it.

In 1996, the Ethics Committee of the Sri Lanka Medical Association produced a Patients' Charter, called the *Declaration on Health*, which spells out some of the rights (and obligations) of the people. The aim was to produce greater understanding of health-related issues by the people, leading to further improvement of

the health of the people as well as closer cooperation among all categories of health professionals, the State, and society in general.

Traditional Medicine

Approximately 50 % of the population of Sri Lanka utilizes traditional/indigenous medicine, which system is recognized as an essential partner in the health-care services of the country. Practitioners of traditional medicine have been encouraged to conduct research on indigenous medicines together with Western qualified doctors, and this has resulted in a more scientific research outcome as well as recognition of the products by drug regulatory authorities. Practitioners of traditional medicine are also included as members of research ethics committees that review research protocols. This has led to better cooperation and understanding between the practitioners of the two systems of medicine in the country.

One of the problems in this area is the illegal export and smuggling of valuable herbal preparations out of the country. This not only deprives the country of an important source of income, but local researchers are also deprived of the opportunity of developing new medicinal drugs and the benefits resulting from the intellectual property rights that should accrue to them.

Genetics

Lack of effective regulations for the exportation of human genetic material is known to be a serious problem in the country. The Transplantation of Human Tissues Act No 48 of 1987 states in its preamble that the Act provides for the donation of human bodies and tissues for therapeutic, scientific, educational, and research purposes and the removal, use, and preservation of such tissues. Although there is no specific mention of genetic material, theoretically, genetic materials that are parts of tissues are covered by this act, and their use for any of the preceding purposes is covered by the provisions as well.

In view of the tremendous technological advances in the field of genetics and the various ethical concerns resulting from the accelerated growth in genetic research and services, it was agreed that specific national policies and regulations in the field of human genetic data are desirable. It was decided to draft a National Policy on Human Genetic Material and Data as a preliminary step prior to the formulation of legislation. This draft policy was discussed at stakeholder meetings held in 2011 and 2012 and is now ready for finalization.

Reproductive Medicine

The practice of assisted reproduction is well established in Sri Lanka. There is little public debate about ART in Sri Lanka, the issue being generally kept very private. There is also not much publicity given to this field in the media, possibly due to

cultural factors. Currently there is no legislation on ART, the practitioners of ART being guided by self-imposed ethical guidelines. As a first step, the SLMC published "A Provisional Code of Practice for Assisted Reproductive Technologies" (SLMC 2005). An Act to provide regulations for assisted reproductive medicine and genetics has been drafted (Human Reproduction and Genetics Act (HURGA)).

Medical Research

Research protocols involving humans and animals have to be submitted to an independent recognized Ethics Review Committee for approval before commencement of the research. While research ethics is taught to medical undergraduates and postgraduates at some point in their career, and the need to obtain ethical approval is emphasized, the only way to ensure that this is done is to insist on evidence of approval when presenting or publishing the research findings. Most academic bodies and journals have begun to do this.

All clinical trials in humans conducted in Sri Lanka are required to be registered in a Clinical Trials Registry. The Clinical Trials Registry of the Sri Lanka Medical Association is recognized as a Primary Registry by the World Health Organization. All clinical trials on new drugs conducted in Sri Lanka are also required to be registered with the Drug Regulatory Authority of the Ministry of Health, where a special Sub Committee on Clinical Trials (SCOCT) has been established to approve such clinical trials.

There has been a gradual increase in the number of clinical trials being conducted in Sri Lanka, often as multicenter global trials with foreign/pharmaceutical industry funding. The introduction of Contract Research Organizations (CRO) into the country is also anticipated. It has therefore become necessary to ensure that such trials are conducted according to international standards of Good Clinical Practice (GCP). Since the existing regulatory framework for clinical trials do not meet these standards, a Clinical Trials Act has been drafted by the Ministry of Health to provide regulations for the conduct of clinical trials of drugs and other interventions, conforming to international standards as well as existing Sri Lankan law. An increase in foreign/industry funded research also indicates a need for properly functioning ERCs in the country. There is an obligation on the part of the sponsors/government to ensure the proper functioning of the ERCs by providing the necessary funds and resources.

"Guidelines on Stem Cell Research and Therapy" have been developed by the Ethics Review Committee of a private hospital where such research is being planned. This area need to be discussed and debated in ethics fora.

Public Health

Sri Lanka has a very good system of public health and is often praised by the World Health Organization for its achievements in eradicating many diseases such as polio, leprosy, and malaria.

Infectious Diseases

Sri Lanka has done very well in controlling and even eradicating some infectious diseases. The country has been praised for its excellent immunization program for children. There are no ethical issues in this area.

Transplantation Medicine and Organ Donation

The first renal transplantation operation was carried out in 1985, using a kidney from a living related donor. Since then, over 1,000 successful renal transplantations have been carried out in Sri Lanka. Antirejection drugs are provided free of charge at National Hospital of Sri Lanka, Colombo, and at the two specialized transplantation centers in Colombo and Kandy. Renal transplantation using a kidney from a brain-dead donor was done for the first time in 1995. In Sri Lanka the most common and accepted type of donors are living relations of the patient. Non-related altruistic donors are also becoming common. The ethical issue here is to prevent an altruistic donor from becoming a commercial one. The Human Tissue Transplantation Act of Sri Lanka in Section 17 outlaws the sale of organs (Sheriffdeen, 2011).

Sri Lanka has recently expanded its organ transplant services by adding liver transplantations to the already existing kidney transplant program. The existing "Transplantation of Human Tissues Act" is inadequate to deal with all the new developments, and a new Act or a revision of the existing one is desirable.

Emerging Technologies (Nanotechnology, Information Technology, etc.)

Nanotechnology (NT)

The National Science Foundation, Sri Lanka, is participating in a joint project with India and Pakistan to develop a regulatory framework for nanotechnology-related activities in the respective countries. This project is funded by the IDRC. One of the five components of the project is "Ethics of Nanotechnology." Under this component, a code of ethics for nanotechnology-related activities in Sri Lanka and ethical guidance for researchers in nanotechnology have been developed.

Intensive Care

The PGIM had introduced a Diploma in Critical Care Medicine. The course work for this degree includes an ethics module which deals with end of life and emergency medicine ethics.

Palliative Care

Except at the main cancer hospital, facilities for the terminally ill are not commonly available. Such patients are usually looked after at home with great difficulty. This is partly due to religious and cultural reasons. Hospices and similar institutions should be established and attention paid to the development of palliative care.

Care for the Elderly

Geriatrics is also not a well-developed specialty in Sri Lanka. However, the population of Sri Lanka is rapidly aging, due to increasing life expectancy and improved health care. This is an area that needs attention.

Chronic Diseases

No specific ethical issues.

Psychiatric Care

The mental health-care facilities in Sri Lanka are gradually increasing although there is a dearth of qualified psychiatrists to cope with the patient load.

Pediatric Care

No specific ethical issues.

Emergency Care

Free treatment at all state hospitals is available to all citizens and noncitizens as well.

General Practice

No specific ethical issues.

Health Promotion and Education

The Ministry of Health has a department dealing with this area and programs have been introduced in schools as well. No specific ethical issues.

Scientific and Professional Integrity, Conflict of Interest, and Corruption

These issues are dealt with in several guidelines and codes of conduct applicable to the professionals and scientists. The Sri Lanka Medical Council provides "Guidelines on Ethical Conduct for Medical and Dental Practitioners" registered with the SLMC. A Professional Code of Ethics for Scientists was developed by the National Committee on Ethics in Science and Technology (NCEST) in 2010. The Organization of Professional Associations of Sri Lanka also produced a code of ethics titled "General Principles and Guidelines of Ethical Conduct for Professionals" in 1995. SLAAS has a very comprehensive set of ethical guidelines for research.

Relations with Industry and Donors/Sponsors

Industry sponsorship plays a major role in the academic activities of the professional medical associations. Ensuring ethical practices during sponsorship is the responsibility of the association and its ethics committee. In 1996, the Sri Lanka Medical Association produced a booklet "Ethical Criteria for the Promotion of Medicinal Drugs and Devices in Sri Lanka." This was based on the WHO document "Ethical Criteria for Medicinal Drug promotion." These criteria have been accepted by the medical, dental, and veterinary professions, as well as the pharmaceutical manufacturers and traders in Sri Lanka.

Future Challenges

In the Field of Bioethics Infrastructures (Need for Legislation, Ethics Committees, Ethics Education, etc.)?

Legislation

The Clinical Trials Act that has been drafted should be finalized and enacted. Ethical guidelines for biomedical research on humans should be developed, ideally by the Ministry of Health, so that all researchers in Sri Lanka could follow standard guidelines. This would also make it easier for ERCs to review and approve research protocols in a uniform manner.

Ethics Committees

While there are several Ethics Review Committees (ERCs) evaluating and approving research proposals, they do not have statutory powers nor the resources or infrastructure to monitor the research or take action against unethical research on humans. A central Research Ethics Committee could be established to deal with these important functions, as well as to decide on policy issues. The existing Ethics Review Committees (ERCs) need financial and other support from the Ministry of Health in order to increase their efficiency in reviewing, approving, and monitoring

research protocols in human biomedical research. Another urgent need is to initiate the establishment of Hospital Ethics Committees. The initiative for this should come from the Ministry of Health.

Ethics Education

Currently, most of the activities are concentrated in the teaching of medical ethics and research ethics to medical undergraduates and postgraduates. Doctors and academics trained in ethics are available to conduct courses and workshops with financial support provided mainly by the World Health Organization. Currently there are no degree programs or ongoing courses in bioethics in Sri Lanka. Short courses in bioethics are conducted infrequently by some institutes such as the National Science Foundation. The medical faculties concentrate on teaching medical ethics and research ethics. The establishment of University Departments of Bioethics is desirable. A UNESCO Chair in Bioethics established in a recognized state university with experience in teaching medical ethics would be a stimulus for the further development of bioethics in Sri Lanka.

In the Field of New and Emerging Issues?

The National Bioethics Committee (subsequently the National Committee on Ethics in Science and Technology) of the National Science Foundation has drafted the Human Reproduction and Genetics Act (HURGA) and the National Policy on Human Genetic Material and Data for Sri Lanka. It is hoped that these two drafts could be finalized and implemented as legislation in the near future.

The National Science Foundation has also taken the initiative to develop a National Policy on Nanotechnology for Sri Lanka. It is now in the process of finalizing a regulatory framework for nanotechnology-related activities. This includes ethical guidelines for research in nanotechnology and a code of ethics for application of nanotechnology in Sri Lanka.

Recently, Sri Lanka expanded its organ transplant services by adding liver transplantations to the already existing kidney transplant program. There is also an increasing demand for the transfer of human biological material and data from Sri Lanka to other countries, ostensibly for research purposes, giving rise to several ethical issues. The existing "Transplantation of Human Tissues Act, No 48 of 1987" is inadequate to deal with all the new developments and a new Act or a revision of the existing one is desirable.

Any Other Problems and Opportunities for the Further Development of Bioethics in the Country?

Lack of funds to conduct courses and training workshops is a major constraint for the development of bioethics in Sri Lanka. To develop bioethics as a discipline, the

governmental institutes and bodies currently involved in bioethics activities in Sri Lanka would need to attract financial support from funding agencies such as UNESCO, the Wellcome Trust, the Nuffield Council on Bioethics, and similar international bodies. There should be more commitment and enthusiasm from the educational institutes in Sri Lanka for the teaching of bioethics.

The small group of experts and academics currently working in the field of bioethics should create more awareness among other academics and professionals, as well as the general public about the need for discussion and debate on bioethical issues. They should also impress upon the government the necessity of enacting necessary laws and regulations to support the development of bioethics in Sri Lanka.

Summary and Conclusion

The need for teaching medical ethics to undergraduates is accepted by all the medical schools in the country. However, the content and methods vary from faculty to faculty and need to be improved. Teaching of medical ethics at postgraduate level has already started and will eventually be formalized.

The bioethics teacher-training program started in 2005 by the National Bioethics Committee needs to be continued with the ultimate aim of introducing bioethics into the curricula of all science-based faculties in the universities and also in secondary schools. In this regard, it would be useful to promote the establishment of at least one university department of bioethics.

Researchers in the field of medicine, at both undergraduate and postgraduate level, are familiar with the principles of research ethics and obtain approval from ERCs before commencing their research. This awareness should be extended to other areas of research. Ethics Review Committees reviewing biomedical research in humans function adequately at present but need to be strengthened by providing them with more support to enable all ERCs to attain the high standard necessary to gain recognition by FERCAP/SIDCER. National guidelines for ethical research should be developed, in order to achieve standardized procedures of giving ethical approval for research.

Bioethics activities in Sri Lanka could also benefit by drawing inspiration from its ancient history and the influence of Buddhism on many areas and issues of bioethical relevance. The words of Judge C.G. Weeramantry, spoken at the World Future Council held in Hamburg in May 2007, would be a fitting conclusion.

"In the result Buddhism offers us a range of powerful concepts for the protection of the long-term future through such principles as interdependence, universalism, moderation, trusteeship, environmental protection, environmental education, sustainable development and a consciousness of the rights of future generations. Buddhism's infinite treasury of wisdom cannot any longer be neglected without damage to the human future" (Weeramantry, 2007).

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Switzerland

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Gaia Barazzetti, Alberto Bondolfi, Samia Hurst, and Alex Mauron

Introduction

This chapter describes the development and the current status of bioethics in Switzerland with special emphasis on the historical evolution and the social and cultural contexts that have shaped the debate in the country. Medical ethics

G. Barazzetti (✉)
ETHOS-Interdisciplinary Ethics Platform, University of Lausanne, Lausanne, Switzerland
e-mail: gaia.barazzetti@unil.ch

A. Bondolfi
Faculté de théologie, University of Geneva, Geneva, Switzerland
e-mail: alberto.bondolfi@unige.ch

S. Hurst • A. Mauron
Institute for Biomedical Ethics, University of Geneva, Geneva, Switzerland
e-mail: Samia.Hurst@unige.ch; Alexandre.Mauron@unige.ch

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developed in the late 1970s and was progressively institutionalized in the following decades through the establishment of ethical committees, guidelines for health care professionals, academic training in medical schools, and ethical consultation in Swiss hospitals.

Over the past three decades, discussions within academia, policy making, and the public arena have resulted in the adoption of regulations on several bioethical issues. As elsewhere in Western Europe, major issues of discussion include abortion and the status of prenatal life, assisted suicide, end-of-life care, organ transplantation, reproductive technologies, ethical issues of genetic technologies, and protection of human subjects of research. Nevertheless, these issues have a considerable bearing on Swiss public debate because of the system of semi-direct democracy, in which citizens can be called upon to vote on legislative proposals or on challenges to parliamentary bills. Decentralized governance, cultural and confessional differences, as well as the value placed on individual choices have largely influenced discussions, laws, and practices regarding many bioethical issues outlined in this chapter.

Bioethics Development

When and How Has Bioethics Started?

Certain aspects of ethical issues in medical care were part of graduate courses of moral theology and forensic medicine before the existence of bioethics as a distinct field. From the 1970s, medical ethics began to be considered as a specific field grounded in philosophical ethics and dealing with normative questions in medical practice and research.

In 1979, the Swiss Academy of Medical Sciences (SAMS) (http://www.samw.ch/en/News/News.html), founded by medical schools and health care professions, set up a SAMS Central Ethical Committee (http://www.samw.ch/en/Ethics/CEC.html) in charge of establishing guidelines on controversial issues in medical practice. Over time, some of these guidelines have acquired binding authority, either through endorsement by the Swiss Medical Association (http://www.fmh.ch/index.html) as part of the professional code of physicians or by being referred to by laws or by case law. In the following decades, academia progressively took an interest in ethics, in general and medical ethics in particular. Progressively, Swiss universities established chairs in ethics within philosophy departments and medical schools.

Who Have Been the Major Actors/Forces?

Switzerland is a multicultural federal republic with a system of semi-direct democracy where governance is strongly decentralized. This is also reflected in bioethics. The major actors in the field are as follows:

– The Swiss Academy of Medical Sciences (SAMS), based in Basel

- The Zurich University Centre for Ethics (ZUCE) (http://www.ethik.uzh.ch/index_en.html).
- The Institute for Biomedical Ethics (IEB) (http://www.unige.ch/medecine/ib/accueil.html) at the University of Geneva.
- More recently, the University of Basel's Institute for Biomedical Ethics (IBMB) (http://ibmb.unibas.ch/) and the University of Lausanne's ETHOS – Interdisciplinary Ethics Platform (http://www.unil.ch/ethos/page60109_en.html).

In December 1998, the Swiss National Advisory Commission on Biomedical Ethics (NEK-CNE) (http://www.bag.admin.ch/nek-cne/04236/index.html?lang=en) was set up as an independent, extra-parliamentary deliberative body, with the mission to promote public debate and advise policymakers on ethical issues in the field of biomedical research and practice. The Federal Ethics Committee on Non-Human Biotechnology (ECNH) (http://www.ekah.ch/en/index.html) was established the same year as an independent expert committee to advise authorities on ethical issues of nonhuman biotechnology and gene technology. Ethics commissions providing advice for clinical practice are increasingly present in Swiss hospitals.

The Confederation also established the Centre for Technology Assessment TA-SWISS (http://www.ta-swiss.ch/en/) with a view to investigate the social impact of new technologies and advise the Parliament and the Federal Council on controversial technologies. Research in the field of biomedical ethics is mainly sustained by the Swiss National Science Foundation (SNSF) (http://www.snf.ch/E/Pages/default.aspx) through various forms of financial support to academic institutions and individual researchers and through national programs on specific topics. Among nonacademic institutions, the Brocher Foundation (http://www.brocher.ch/pages/default.asp?lang=en) supports research on ethical, social, and legal issues of biomedical technologies.

The Swiss Society for Biomedical Ethics (SGBE/SSEB) (http://www.bioethica-forum.ch/content/e_SGBESSEB.php) – a multidisciplinary, multilingual, and non-confessional association of scholars and practitioners joining various ethical perspectives and a pluralistic approach to bioethical issues – promotes research and training in bioethics (see section "What Resources Have Been Developed (e.g., Books, Programs, Media, Networks, Societies)?" below).

What Have Been the Major Concerns Over Time?

During the 1990s, the Swiss debate was characterized by lively public discussions on ethical dilemmas related to genetics, reproductive technologies, and end-of-life care. Beside these major topics, the bioethical debate within academia, policy making, and the public arena has focused on organ transplantation, the protection of human subjects of research, experimentation on animals, abortion, and the ethical status of human prenatal life, the prevention of infectious diseases, and patient rights.

What Resources Have Been Developed (e.g., Books, Programs, Media, Networks, Societies)?

Numerous publications in the field are produced at the local level in the various linguistic regions of the country. In addition, several resources in bioethics have been developed at the national level. The Swiss Academy of Medical Sciences (SAMS) and the Swiss Medical Association promoted the publication of a textbook of biomedical ethics discussions and regulations in the country (Bondolfi and Müller, 1999).

Since the early 1990s, the universities of Zurich and Geneva initiated formal bioethics courses for medical students. Until 2006, the Swiss Society for Biomedical Ethics (SGBE/SSBE) has organized a summer school for health care professionals and researchers who did not have the opportunity to have training in bioethics during their education. Every 2 years since 2005 and annually since 2009, the SGBE/SSBE organizes workshops where research projects are presented and discussed.

Two main book series on bioethical research in Switzerland are published in German and French by Schwabe editions in Basel within the collection *Ethik und Recht* and by Georg editions in Geneva within the reader's collection *Controverses en éthique*. The SGBE/SSBE publishes the journal *Bioethica Forum* (http://www.bioethica-forum.ch/e_index.php), as well as a collection of thematic essays in French and German entitled *Folia Bioethica*.

What Have Been the Steps/Measures Taken?

Over the past three decades, Switzerland has adopted regulations on several bioethical issues, such as reproductive technologies (http://www.admin.ch/ch/d/sr/c810_11.html), genetically modified organisms (http://www.admin.ch/ch/d/sr/c814_91.html), research on human embryonic stem cells derived from spare embryos (http://www.admin.ch/ch/d/sr/810_31/index.html), human genetic testing (http://www.admin.ch/ch/d/sr/810_12/index.html) including prenatal testing and newborn screening, and organ transplantation (http://www.bag.admin.ch/transplantation/00694/01739/index.html?lang=de). A new law on biomedical research on human subjects will soon become effective (http://www.bag.admin.ch/themen/medizin/00701/00702/07558/index.html?lang=de), and a far-reaching revision of the civil code will make advance directives recognized on a federal level in 2013 (http://www.ejpd.admin.ch/content/ejpd/de/home/themen/gesellschaft/ref_gesetzgebung/ref_vormundschaft.html).

Whereas the cantons hold legal prerogative in the field of health care policy, on most of the issues listed above, the Confederation enlarged the scope of its power, otherwise limited to infectious disease control. Giving the Swiss Parliament the authority to enact laws on additional topics requires a change in the Constitution, which in turn requires that citizens be called upon to vote. In the last 30 years, this happened regularly on many issues regarding medical practice and research.

It should be noted that abortion and assisted suicide are regulated by the Swiss criminal code and that no specific legislation on these practices has been

introduced. In particular, Articles 118–120 of the code authorize abortion on demand in the first trimester and on medical indication thereafter, and Articles 115 and 114 legally condone assisted suicide for altruistic reasons and outlaw "murder on demand by the victim" or voluntary active euthanasia.

The Swiss law on epidemics dates back to 1974 and has never been amended over time. During the AIDS pandemic, no specific standards were introduced, although information campaigns were strongly supported by public authorities to prevent the spreading of the disease in the country.

Besides the regulatory activity of the Confederation, the Swiss Academy of Medical Sciences (SAMS) regularly provides recommendations and guidance for health care professionals on various topics relevant to medical practice and research as outlined above.

Current Bioethics Infrastructure

Teaching of Bioethics at University and Other Levels

The teaching of bioethics is currently present in all the faculties of human and veterinary medicine, in some faculties of sciences, and in many bachelor- and master-level training programs for health professionals. The Swiss Academy of Medical Sciences (SAMS) is compiling a complete list of teaching institutions and programs. The federal law defining training for the medical profession requires academic programs to include courses on the ethical aspects of the professional activity, with a view to develop students' personal skills and social competences. Although education in bioethics is compulsory for medical students, training programs can be defined by universities with a high degree of autonomy.

Bioethics Committees

Research involving animals or human participants needs to obtain clearance from an ethics committee, as is the case in all countries recognizing international ethical principles of biomedical research. A new federal law on biomedical research on human subjects will come into force by 2014. Until then, the ethical review of research protocols and the establishment of ethics committee fall under the jurisdiction of cantons. At present, cantons where universities have faculties of medicine have set up cantonal ethics committees, organized in various subcommittees covering different research fields. Where no faculty of medicine exists, an inter-cantonal ethics committee is established, with the exception of Ticino where the cantonal committee was created because of intense research activities in the canton and because of its geographic isolation.

In addition to ethics committees for the review of research protocols, clinical ethics committees are present in almost half of all Swiss hospitals to provide ethical consultation to health care professionals (Hurst et al., 2008). The functioning of each clinical ethics committee is regulated by its statute.

Expert Bodies/Centers

At the national level, two ethics committees exist in Switzerland to promote public debate and advise policymakers on ethical issues: the Federal Ethics Committee on Non-Human Biotechnology (ECNH) examines ethical issues of biotechnological interventions on plants and animals, whereas the Swiss National Advisory Commission on Biomedical Ethics (NEK-CNE) considers ethical and health policy issues in the field of biomedicine.

Relevant Legislation

The relevant Swiss legislation in the field of bioethics is detailed in section "What Have Been the Steps/Measures Taken".

Public Debate Activities

In Switzerland, public discussion of bioethical issues is largely determined by the political agenda set by the Parliament. However, the system of semi-direct democracy, in which parliamentary bills can be called into question, new laws can be proposed, and constitutional amendments can be passed by popular vote, have a considerable bearing on public debate activities in the country. Bioethical issues that are currently under discussion in the public debate include the following:

- The use and reimbursement of reproductive technologies, especially preimplantation diagnosis.
- Various issues in environmental ethics, especially the regulation and use of genetically modified organisms.
- The relevance of further regulating the legal practice of suicide assistance, and/or of legalizing voluntary euthanasia.
- The application of patient rights within the health care system.
- The costs of the Swiss health care system and the ethical and health policy issues relating to access to health care.
- Ethical issues of direct-to-consumer genetic testing.

Major Bioethics Issues and Discussions

Beginning of Life

Within academic discourse, dilemmas surrounding the ethical standing of human prenatal life and reproductive technologies are discussed largely in the same terms in Switzerland as elsewhere in Western Europe, and controversies run along similar lines. Nevertheless, these issues have been particularly visible in Swiss public life on account of the system of semi-direct democracy, in which citizens are regularly

called upon to vote on legislative proposals or on challenges to bills adopted by Parliament. In the last two decades, this occurred a number of times for topics relevant to this section. In 2002, Parliament adopted a far-reaching reform of criminal law as regards abortion, basing the protection of embryos and fetuses on a "gradualist" view of their moral status – the view according to which the appropriate protections grow, as it were, along with it. This made Swiss criminal law much more liberal than the (nominally) conservative status quo. Conservatives and certain religious circles gathered the requisite number of signatures to put the issue before the people, but their challenge to a liberal abortion law was resoundingly defeated (72.2 % votes were in favor of the new law; a competing proposal to prohibit abortion in most situations was defeated by 81.7 % of votes).

The ethics and politics of reproductive technologies as well as related issues such as research using human embryonic stem cells show a far more complex picture. Broadly speaking, Swiss legislation on reproductive technologies rests on the paradigm of application within a nuclear family, recognizes an individual's right to know her biological ascendency, and has strictly banned the production of embryos for any purpose other than implantation. At the same time, however, research is highly valued, and this extends to human embryonic stem cells. In the early 1990s, a fairly restrictive constitutional amendment was adopted (Article 119 of the Constitution) with strong popular support at the time. Among other restrictions, oocyte donation, embryo donation, and preimplantation genetic diagnosis (PGD) were outlawed, as were the production of more than three embryos in vitro per cycle of fertility treatment; keeping frozen spare embryos for an ulterior treatment cycle was also forbidden. In the early years of this century, a bill softening these prohibitions in order to make human embryonic stem cell research possible was put to the popular ballot and accepted (66.4 % "yes" votes). Among other elements, this new law establishes a requirement for parental consent for the use of surplus embryos in human embryonic stem cell research (Porz, Bürkli, Barazzetti, Scully and Rehmann-Sutter, 2008). The climate of public opinion on these issues seems to have changed. The prohibition of PGD is currently challenged, and a correspondingly revised legislation is being discussed.

End of Life

The Swiss debate on end-of-life care can be traced back to the 1960s. Discussions were nourished by philosophers, theologians, and health care professionals, confronting new dilemmas of end-of-life care raised by medical progress. There are many publications on the topic in Switzerland, although this literature is relatively fragmented due to its multilingual character. Early discussion on end-of-life care centered on a medical decision to limit life support of a dying person. Eventually, this decision was not enacted, but it brought about an energetic debate on withdrawing medical care at the end of life. In the wake of this discussion, the Swiss Academy of Medical Sciences (SAMS) drew ethical recommendations that allow doctors to withhold futile treatments to dying patients. Issued in 1976, the SAMS guidelines have been regularly reviewed as the debate on end-of-life care in

the country continued to evolve (revisions were published in 1981, 1988, 1995, and 2004). The analysis of the successive versions of the document shows a growing consensus on the moral wrongness of futile medical care.

Besides issues of end-of-life care, the practice of assisted suicide has been extensively discussed in the country (Pfister and Biller-Andorno, 2010). Assisted suicide is legally condoned by Article 115 of the Swiss criminal law if the motive is altruistic, and it can be performed by nonphysicians (Hurst and Mauron, 2003). The viewpoint of the SAMS on assisted suicide has changed over time. While the 1995 revision of the SAMS guidelines (Available at http://www.samw.ch/de/Ethik/Richtlinien/Archiv.html) stated that assisted suicide is "not a part of medical activity," the last version of the document (Swiss Academy of Medical Sciences, 2004a) acknowledges that a conscientious decision by a doctor to assist suicide should be respected. During the last few years, the political discussion has focused on whether to regulate both assisted suicide and voluntary euthanasia by law. In June 2011, the Parliament decided to maintain the status quo.

Discussions about palliative care and advanced directives were less controversial and have rapidly reached a general consensus. Palliative care is promoted and sustained by the Confederation and the cantons. Advanced directives, which already exist in several cantons, are recognized on a federal level by a revision of the Swiss civil code, as of 2013.

Health and Disease

In Switzerland, coverage by medical insurance is based on the presence of disease and the indication for medical treatment, making the definition of what constitutes disease, or not, a key element. Excluded areas include long-term care, viewed as required by old age rather than disease, but also contraception and fertility treatments, both of which are considered lifestyle choices rather than health issues. More recently, coverage for vision correction in childhood has been excluded from coverage: based on statistical frequency, it was argued that it was normal and thus not a health condition.

Health Care System, Access to Health Care

The Swiss health care system is a universal coverage system based on an individual mandate for the purchase of state-regulated but privately managed health insurance, with subsidies toward this purchase for lower income groups (Gagnebin and Sprumont, 2009). Voluntary additional insurance can be purchased by individuals who so choose; it covers greater comfort and choice of provider in hospitals, as well as certain interventions not covered by basic health insurance such as travel insurance or some forms of alternative medicine. Despite universal coverage and a very well-funded health system with dense regional access, barriers to access exist. The most visible one is a high rate of

out-of-pocket payments, which have been shown to lead some persons to forgo needed care (Wolff, Gaspoz and Guessous, 2011). Moreover, as outlined above (see section "Health and Disease"), coverage under basic insurance is predicated on interventions targeting disease, making the definition of what constitutes disease, or not, a key element. Dental care is also excluded from health care coverage. Rather than being based on a link between dental care and personal behavior in the prevention of dental disease, however, this exclusion is based on early requests by dentists to be excluded from what they viewed as obligations linked to their interventions' inclusion under the basic health insurance mandate.

Coverage for alternative medicine has been the object of a long-standing debate in Switzerland, where some forms of alternative therapy have originated and where several have been in use for a long time. Coverage of medical interventions is legally predicated on the intervention being "effective, appropriate, and efficient." Thus, one part of the discussion regarding alternative medicine has centered on its effectiveness. Despite a negative recommendation by the official commission on health coverage, however, the exclusion of these forms of alternative medicine proved so unpopular that they were covered despite not being proven effective.

Moreover, discussions regarding the possibility of excluding marginally beneficial interventions have taken place (Zimmermann-Acklin, 2005). These have been politically difficult and hence sporadic.

Traditional Medicine

As outlined above (see section "Health Care System, Access to Health Care"), coverage for alternative medicine has been the object of a long-standing debate in Switzerland, where some forms of alternative therapy have originated and where several have been in use for a long time. Several forms of alternative medicine – phytotherapy, homeopathy, Chinese traditional medicine, neural therapy, and anthroposophic medicine – are practiced by physicians with officially recognized courses of training. Coverage of medical interventions, however, is legally predicated on the intervention being "effective, appropriate, and efficient." Thus, one part of the discussion regarding alternative medicine has centered on its effectiveness. Despite a negative recommendation by the official commission on health coverage, however, the exclusion of these forms of alternative medicine proved so unpopular that they were covered despite not being proven effective.

Another part of the discussion has centered on the place of alternative medicine in medical training. Since 2009, Switzerland is required by its Constitution to "take alternative medicines into account". Although it is not entirely clear what this might mean for medical schools, it is broadly accepted that making students critically aware of alternative medicines and their claims will be the main application of this law in universities.

Genetics

Discussions about human genetics in Switzerland cover a wide range of topics, as it is the case elsewhere: from presymptomatic and susceptibility testing to DNA fingerprinting for criminal investigations; from disclosure and confidentiality of test results to gene therapy. A *Federal Act on Human Genetic Testing* (http://www.admin.ch/ch/e/rs/c810_12.html) was enacted in 2004 to regulate human genetic testing in the country.

Ethical and science policy issues that have been extensively discussed in the Swiss context have centered on the use of genetically modified (GM) crops in agriculture and on the commercialization of GM food, ensuing from the lack of specific regulations and transparent authorization procedures. For nearly 15 years, from the first field experiments in the early 1990s to the moratorium for GM crops that was passed in 2005, the debate spread out across the country in the form of a controversy about safety and environmental risks. The controversy was triggered by the action taken by ecologist groups who proposed an initiative for a restrictive regulation of various aspects of GM food, including patenting and commercialization. In response, molecular biologists organized protest marches in defense of new genetic technologies, also supported by pharmaceutical companies. Farmers concerned about the coexistence of traditional and genetically modified crops also called for a careful consideration of environmental and economic impacts of GM crops onto the small-size Swiss agriculture. The spreading controversy forced public authorities to accelerate the process of planning regulations. A directive on the labelling of food containing GM organisms was enforced in 1996, and the Federal Ethics Committee on Non-Human Biotechnology (ECNH) was set up in 1998 to examine ethical issues of developments in gene and biotechnology with a view to assess their impacts on humans and the environment. The ECNH should work in cooperation with the Swiss Expert Committee for Biosafety (SECB) (http://www.efbs.admin.ch/en/index.html) to review experimental protocols of GM crops field experiments and to inform the Federal Office for Environment (FOEN) (http://www.bafu.admin.ch/index.html?lang=en) in charge of giving the final clearance. The initiative proposed by ecologists was eventually voted in 1998 and rejected by a majority of the electorate (66 %). This result did not close the controversy in the country, which turned to be focused on field experiments. Notwithstanding the approval of the SECB and the favorable evaluation from several scientists, between 1999 and 2001, the FOEN repeatedly denied authorization of field experiments on the basis of the precautionary principle. The decision of the FOEN was contested by scientists who considered field experiments essential to their research work, which was conducted under a national research strategy on biotechnology financed by the Swiss National Science Foundation (SNSF). This crisis in national science policy was the consequence of various ethical and social issues of GM food that were still under discussion in the public debate. Indeed, in the course of the controversy, the evaluation and management of risks has evolved from a model where decision making is restricted to a qualified group of experts and policy makers,

to a model of public negotiation of risks (Audétat, November and Kaufmann, 2005). Although the agenda for discussion was initially focused on potential risks of GM food, the widening controversy contributed to democratize and enrich the public debate, which eventually included economic, environmental, and health-related issues of genetically modified crops (Kaufmann et al., 2004).

In 2005, a referendum was held to decide whether or not to prohibit the use of GM plants for a period of 5 years. The majority of the voters accepted the five-year moratorium, which was later extended to November 2013. The ostensible purpose of the moratorium was to provide time for evaluation of potential benefits and risks of GM plants, as well as their social acceptability. To this end, a national research program was implemented by the SNSF (NRP 59) (http://www.nrp59.ch/e_index.cfm). Since the empirical part of this research necessitates field testing of GM plants, and since such tests raise fierce opposition by legal and illegal means, it is doubtful whether this research program will provide enough results to inform public policy on this matter.

Reproductive Medicine

Discussions regarding reproductive medicine in Switzerland have centered on what should be allowed on the one hand and what should be covered by health insurance on the other. Broadly speaking and as outlined above (see section "Beginning of Life"), Swiss legislation on reproductive technologies rests on the paradigm of application within a nuclear family and recognizes an individual's right to know her biological ascendency.

As regards abortion, the Swiss Parliament adopted a reform of criminal law in 2002, basing the protection of embryos and fetuses on a "gradualist" view of their moral status – the view according to which the appropriate protections grow, as it were, along with it. As outlined in section "Health and Disease," contraception and fertility treatments are generally excluded from health coverage, as both are considered lifestyle choices rather than health issues.

Medical Research

International principles and guidelines are applied to research with human subjects in Switzerland. Swiss law makes explicit reference to the ICH guidelines for Good Clinical Practice, and Swiss Academy of Medical Sciences (SAMS) recommendations (http://www.samw.ch/de/Ethik/Richtlinien/Archiv.html) refer to the declaration of Helsinki. Specific issues have nevertheless been raised in the Swiss context, in particular, since the first project for a federal law on research with human subjects was put to public consultation in 2006. Three issues have been the object of particular debate.

First, the scope of protections for human subjects of research outside of biomedical sciences is controversial. On the one hand, it is difficult to see how the area of

research where human subjects incur risks should make a difference to the protection they are given. On the other hand, ethical codes and oversight bodies are often younger, fewer, or even nonexistent in fields other than biomedical science. When it came to defining the required protections' scope of application, the authors of the law project rejected application based on the discipline or professional group of the investigators as too difficult to define exhaustively and too likely to include research involving no risk to human participants. They also rejected application based on the degree of risk, based on the lack of bodies competent to review such research outside the scope of biomedicine. They defined the scope of protection, which includes ethics committee review, based on two criteria (Duetz and Gruberski, 2009):

1. Research on human disease and the development and functioning of the human body, where the term "disease" is understood broadly and includes psychological health impairments.
2. A risk threshold based on the possibility of harm to human dignity and personal integrity: This is defined by the exclusion of research on in vitro embryos, anonymous biological material, and anonymously obtained or completely anonymized health-related data.

Second, federalism has led to decentralized review of multicenter studies even within Switzerland, and coordination of ethics review by different ethics committees has proved difficult. Recently, the working group of Ethics Review Committees has implemented a rotating centralized review to facilitate multicenter review.

Third, the interface between research with animals and research with human subjects is a particular point of tension in Switzerland. Research with animals is particularly strictly regulated in Switzerland, based on a constitutional clause protecting the integrity of living organisms – or the "dignity of creatures" in the German version. The "dignity" of animals is explicitly different from human dignity: it means that animal interests must be considered in the balance of risks and benefits but can nevertheless be subordinated to greater human interests (ECNH, 2008). In practice, application predictably remains difficult. In 2008, a decision to stop two experiments on monkeys was upheld by the Swiss Supreme Court based on the uncertainty and distance of the expected clinical applications in view of the burden imposed on nonhuman primates. As such decisions illustrate, the appropriate thresholds to apply in balancing human and animal interests remain controversial.

Public Health

Ethical issues in public health tend to cluster around three main issues: tensions between public health efforts and individual self-determination, questions regarding legitimacy and appropriate decision makers, and difficulties in distinguishing public interventions for the prevention of disease on the one hand and the moralization of health on the other. In Switzerland, a strong focus on individual self-determination, combined with the cantonal organization of many aspects of the health care system, has tended to make concerted public

health efforts more difficult. Antismoking campaigns, for example, have tended to focus on individual efforts rather than on limits to the availability of tobacco. It is only when it became clear that smoking was harmful to others that bans on smoking in public spaces were implemented. Information campaigns for organ transplantation have also been criticized for focusing on neutrality and avoiding any appearance of promoting organ donation. This focus on individual self-determination extends to the prevention of infectious diseases, with very few mandatory vaccinations and some resurgence, for example, of measles as one consequence. During the beginning of the AIDS pandemic, public health interventions struck many as signalizing a shift away from the moralization of sexuality as advertisement for condoms were used in public spaces to promote effective protection. More recently, however, health itself has tended to risk becoming moralized as part of prevention campaigns aimed, for example, at the prevention of smoking or obesity.

Infectious Diseases

As outlined above (see section "What Have Been the Steps/Measures Taken"), the Swiss law on epidemics dates back to 1974 and has never been amended since. At the beginning of the AIDS pandemic and during concerns regarding avian flu outbreaks, no specific standards were introduced, although information campaigns were strongly supported by public authorities to prevent the spreading of the disease in the country. As outlined under Public health, however, a strong focus on individual self-determination, combined with the cantonal organization of many aspects of the health care system, has tended to make concerted public health efforts in prevention more difficult. This focus on individual self-determination extends to the prevention of infectious diseases, with very few mandatory vaccinations and some resurgence, for example, of measles as one consequence.

Transplantation Medicine and Organ Donation

In 2004, the Confederation adopted a federal law on organ transplantation. Before that date, this practice was regulated by the directives of the Swiss Academy of Medical Sciences (SAMS) (Available at http://www.samw.ch/en/Ethics/Guidelines/Archive.html) and by 15 different cantonal laws. Notwithstanding the new federal regulation and the information campaigns for the promotion of organ donation, the practice is limited by the significant shortage of organs available for transplantation. There are important differences in the attitude of Swiss citizens with regard to transplantation. The paucity of cadaveric donations in the country has contributed to increase the number of transplants from living donors, a practice strictly regulated by the new federal law. According to the current legislation, explicit consent to organ donation should be given by persons before death or should be witnessed by family members after death.

The Confederation mandated the SAMS to draw recommendations for clinicians on both the definition of brain death and the procedures to assess it. The SAMS regularly updates these directives (Updated versions are available at http://www.samw.ch/en/Ethics/Guidelines/Currently-valid-guidelines.html).

More recently, the Swiss Parliament has discussed the adoption of an implicit consent to organ donation. The Swiss National Advisory Commission on Biomedical Ethics raised several concerns on the ethical implications of this measure for medical practice.

New legal provisions have been introduced on allocation of organs available for transplantation, with a view to establish stringent eligibility criteria for patients on the basis of urgency and efficacy. At present, the practice of xenotransplantation, which was extensively discussed as an alternative to organ transplantation, has been progressively abandoned and eventually prohibited by law due to the high risks of transmission of zoogenic pathogens.

Emerging Technologies

Discussion of new emerging technologies in Switzerland is mainly, although not exclusively, focused on nanotechnology. Similarly to what happened in the case of the GMO controversy, the agenda for discussion is dominated by concerns about risks and safety of nanoparticles. This approach is manifested in the national research program founded by the Swiss National Science Foundation (SNSF) to investigate impacts of biomedical and environmental use of nanomaterials (NRP 64) (http://www.nfp64.ch/E/Pages/home.aspx), as well as in the initiatives launched by the Federal Office of Public Health (FOPH) (http://www.bag.admin.ch/index.html?lang=en), such as the platform for public dialogue NANO and the *Precautionary Matrix for Synthetic Nanomaterials*, a method to assess potential risks of the production of nanomaterials.

Very recently, some arenas of discussions have been developed, such as the following: the publifocus organized by the Centre for Technology Assessment TA-SWISS (http://www.ta-swiss.ch/en/projects/nanotechnologies/); the newsletter published by the Innovation Society, an independent consulting company based at the Technology Center of the Federal Institute of Materials Science and Technology in St. Gallen (http://www.innovationsgesellschaft.ch/index.php?page=93); and *Nanopublic* (http://www.unil.ch/nanopublic/page32013.html), the nanotechnologies and society interdisciplinary platform aiming at fostering dialogue between the Swiss nanotechnology stakeholders.

Intensive Care

Discussion of ethical issues in intensive care has focused on questions raised at the end of life and on admission criteria in triage situations. It is generally accepted in Switzerland that competent patients have a right to refuse medical interventions, including life-sustaining measures. Consequently, withholding and withdrawing

therapy is an accepted part of medical practice. It is further accepted that futility, the absence of hope that an intervention will bring sufficient benefit to the patient to warrant the burden to that patient, can justifiably ground a decision to withhold or withdraw medical interventions. One consequence is that, among patients who die in Swiss intensive care units, a significant number does so following a decision to limit life-sustaining measures. Such decisions are usually based on consensus within interdisciplinary teams, on agreement with competent patients, and in the case of incompetent patients on discussions with family members regarding what the patient would have wanted. A revision of the Swiss Civil Code, giving greater representation power to family members of incapacitated patients, should result in a shift toward greater participation of families in such decisions in the near future.

Issues arising in the allocation of intensive care beds have been minimized by nationwide coordination among intensive care units. As indications for intensive care grow, however, such issues have been increasingly debated at the local level.

The Swiss Academy of Medical Sciences (SAMS) published guidelines on ethical issues in intensive care in 1999 (SAMS, 1999). Separate guidelines for the treatment of severely premature newborns have been regularly updated by the Swiss Society for Neonatology.

Palliative Care

As outlined in section "End of Life", discussions about palliative care and advanced directives have rapidly reached a general consensus. Palliative care is promoted and sustained by the Confederation and the cantons. Advanced directives, which already exist in several cantons, are recognized on a federal level by a revision of the Swiss civil code, as of 2013.

Care for the Elderly

Although discussions on care for the elderly are similar in Switzerland and other countries, four issues can be noted. First, the medical specialty of geriatrics or gerontology is rather new in clinical medicine, and in Switzerland, it has faced difficulties in identifying its specificities in clinical settings. As clinical approaches in gerontology tend to be rather different from those in other areas of medicine treating elderly patients, this has meant that ethical issues in the care of the elderly have varied with the clinical setting. Second, discussions of ethical issues in old age have tended to focus on practical clinical issues (Monod, Chiolero, Büla and Benaroyo, 2011), such as adapting medical interventions *to* old age, how to define the proper aims of medicine *in* old age, attempting to avoid both critiques of "agism," or doing too little, and concerns that medicine is doing too much. Third, antiaging medicine has been a focus of research, and this has led to considerable discussions regarding ethical issues raised by medical enhancements. Fourth, as in many other western countries, issues are raised by the coverage of elder care.

As resource constraints meet rising needs, concerns have also been voiced that the elderly could become a population particularly vulnerable to unjustified rationing. In Switzerland, coverage by medical insurance is based on the presence of disease and the indication for medical treatment. Dependence for the activities of daily living is not considered a disease, and thus it is not covered by insurance. Any such costs are paid out of pocket by individuals, with state help available for those who become indigent as a result. Although this still affects a minority of the population aged >85, its unpredictability has led to calls to extend insurance to cover long-term care. Tensions arising between the costs which this would involve and the requirements for solidarity in facing old age are an ongoing debate.

Ethical guidelines for the care of dependent elderly patients were published by the Swiss Academy of Medical Sciences (SAMS) in 2004 (SAMS, 2004b). They focus on issues including appropriate care, continuity of care, interdisciplinary collaboration and collaboration with family members, advance directives, informed consent, decisions for incapacitated patients, adaptation of prevention, acute care, rehabilitation and palliative care to old age, and end-of-life issues.

Chronic Diseases

Issues related, among others, to access to health care and indications for palliative care do arise in the context of chronic diseases, they are not different from those outlined in the sections "Health and Disease, Health Care System, Access to Health Care, Traditional Medicine" above.

Psychiatric Care

All the main issues raised in other areas of medicine are also raised in psychiatric care. A further focus has centered in Switzerland on whether suicide assistance should be allowed in the case of competent patients suffering from psychiatric diseases. In 2006, a Swiss Supreme Court ruling established that suicide assistance could be allowed in the case of competent psychiatric patients on the strict condition that their wish to die be well-considered, durable, and free of any outside influence based on an expert psychiatric evaluation. Controversies on this topic, however, are still ongoing.

Pediatric Care

Various issues outlined in the above sections are also relevant to pediatric care (Kind, 2009). In the Swiss context, it should be noted that the threshold which allows a patient to make her own decisions regarding health care is not adulthood but decision-making capacity regarding the choice at stake. "Mature minors" who are patients in Switzerland can thus consent to – or refuse – medical interventions, including life-saving interventions. Specific laws require additional parental

consent in cases where greater protection is necessary – such as consent for participation in research – and in some cases, minors are excluded from particularly risky altruistic medical interventions entirely – such as live donation of solid organs. Such cases, however, are exceptions. Competent minors' consent is also required to divulge any confidential information to their parents or other guardians.

Emergency Care

Aside from a brief attempt in 2007 to exclude illegal immigrants from emergency care, which was swiftly rejected by the Swiss Supreme Court, the Swiss National Advisory Commission on Biomedical Ethics (NEK-CNE), and Swiss health care providers in their practice, no specific ethical issues have been raised in Switzerland regarding emergency care.

General Practice

All the main issues raised in other areas of medicine are also raised in general practice. More recently, policy issues regarding general practice, such as the usefulness of a gatekeeper role within the health care system or the importance of increasing the attraction of general practice for young physicians, have been increasingly debated within the health policy discussion. Moreover, Switzerland is a destination country in the global medical brain drain, which clearly raises ethical issues far beyond those which have been addressed to date.

Health Promotion and Education

See section "Public Health" above.

Scientific and Professional Integrity, Conflict of Interest, Corruption

Issues of scientific fraud and other breaches of scientific integrity have regularly surfaced in Swiss academic life, as is the case elsewhere. Beginning in the 1980s, there was increased controversy and dissatisfaction about the informal manner with which these cases were traditionally handled by academia. In particular, the lack of clear procedural rules meant that investigations of alleged scientific misconduct by academic authorities were easy targets for legal challenge. This led universities and the Swiss Academies of Arts and Sciences (http://www.swiss-academies.ch/en/index/Portrait.html) to adopt more detailed, formal regulations. The Swiss Academy of Medical Sciences (SAMS) released a set of regulations on scientific integrity in 2002 (SAMS, 2002). This document defined the nature and scope of scientific misconduct in biomedical research and perhaps even more importantly, established a detailed procedure to investigate

accusations of scientific misconduct. The document was in line with similar guidelines on this topic issued by various national and international bodies (e.g., European Science Foundation – US Office of Research Integrity: *Research Integrity: global responsibility to foster common standards* (http://www.esf.org/index.php?id=4479). These guidelines were influential in getting universities to develop their own framework for issues of scientific integrity, by adapting the rules that had evolved in the context of medical faculties and biomedical research institutes to a broader range of scientific and scholarly fields.

In 2007, the Swiss Academies of Arts and Sciences issued a memorandum in which they define basic principles and offer to help research institutions in setting up specific rules and procedures. This was followed by setting up a permanent commission on scientific integrity, which issued a much more detailed document in 2008 delineating ethical principles and procedural rules (Swiss Academies of Arts and Sciences, 2008). The principles tend to go beyond the "FFP core" (fabrication or falsification of research results, plagiarism) familiar to Anglo-American researchers and include attitudinal goals concerning, for instance, the role model provided by senior researchers, the importance of quality vs. quantity of research output, and the responsible use of the constitutionally guaranteed freedom to do research. The procedural rules involve a four-pronged organization of integrity protection. This includes an ombudsperson who deals with initial complaints and may arbitrate minor cases and an integrity protection commissioner who selects a suitable fact-finding panel to conduct the inquiry and, in case solid evidence of misconduct is found, passes the results to a decision-making panel to whom authority to decide the case has been delegated by the dean, university president, or director of the research institution. This somewhat complex system was felt to be needed in order to guarantee due process and the presumption of innocence as well as protecting whistleblowers and safeguarding relevant evidence.

Relations with Industry and Donors/Sponsors

The relationship between the pharmaceutical industry on the one hand and academic biomedical research and medical practitioners on the other has special significance in Switzerland. Some of the largest pharmaceutical companies in the world have originated in this country, where they still maintain their headquarters and a significant proportion of research and manufacturing facilities (for how long is unclear). This means that the pharmaceutical industry enjoys a great deal of political influence, for instance in negotiating drug prices with Swiss health authorities. It also entails a strong presence of industry in postgraduate medical education and academic medicine. As regards medical research, this close connection between academia and industry is not always, or necessarily, problematic. In fact, during the "golden age" (roughly from the 1950s to the 1980s), when biomedical advances quickly resulted in the availability of whole classes of important new drugs, this relationship was quite constructive and useful. In recent decades, however, important global changes have affected

both sides of this divide. As a result, it has become more and more apparent that the primary interests of universities, industry, and public health are often at odds with each other. The old "cozy" relationship came increasingly under fire, and it was again the Swiss Academy of Medical Sciences (SAMS) which took the lead in setting up regulations to deal with these issues. Its guidelines on this subject were initially greeted with skepticism and controversy but are now firmly established (SAMS, 2005). These include not only general principles but also specific and practical rules, especially as regards industry-initiated or industry-supported grand rounds and postgraduate training sessions.

One industrial sector that poses a unique challenge to scientific integrity and public health is the tobacco industry. Several world companies involved in cigarette manufacturing have established their headquarters in Switzerland, where they happen to be beyond the reach of American and European law. They enjoy a position of enviable privilege and influence, with dismal consequences as regards scientific integrity (University of Geneva, 2004; Diethelm et al., 2005) and health policy, as evidenced by the fact that Switzerland is one of the few countries that has not ratified the WHO tobacco convention.

Other: Addiction

Since 1994, Switzerland has had a rather unique policy on illegal addictive drugs, based on a fourfold objective: prevention, therapy, risk reduction, and repression. Risk reduction entails the setting up of "injection rooms," where persons addicted to opioids can inject themselves in safe conditions and, more controversially, the provision of heroin under medical supervision to prescreened, highly dependent drug users (foundation Sucht Info Schweiz: http://www.suchtschweiz.ch/de/themen/). From its onset, this program was considered experimental and involved continuous evaluation of its efficacy in improving the health and social integration of long-term drug users. This attracted a great deal of attention and often skepticism on the domestic and international scene. In a sense, this reaction is understandable since the pragmatic and evidence-based Swiss approach is inherently alien to the "moral crusade" which often energizes the "war on drugs" on a global scale. This risk reduction policy was confirmed by a majority of Swiss voters in a referendum held in 2008. Recently, the Swiss experiment has been viewed more sympathetically from abroad, as the failure of a purely prohibitionist stance is increasingly and more openly discussed internationally.

Future Challenges

The ongoing debate on eligibility criteria for patients to be listed for organ transplantation and the paucity of organs available in the country show that cultural forces and individual preferences have important impacts on the implementation of health care policies and need to be carefully examined. This debate shows that the authority

of the state to deal with health policy issues through nudge campaigns aiming to affect individual choices should be reconsidered. However, it also raises the question of whether the state can endorse some ethical perspective or should be neutral on bioethical issues. Further discussion is needed to develop a richer understanding of the societal implications of individual choices and of the role of the state in this field.

Although the Swiss health care system guarantees a universal coverage based on individual health insurance, the increasing rate of out-of-pocket payments has raised ethical concerns regarding barriers to access to needed care. The concept of personal responsibility that fuels the ethos of health care coverage needs to be reconsidered to prevent the state-regulated but privately managed health insurance system from producing health care inequalities in the country.

A significant proportion of academic biomedical research in Switzerland is funded by pharmaceutical companies, and even modest changes in the pharmaceutical industry may have important consequences on medical research and practice. Therefore, future challenges also include the discussion of ethical issues in the governance of biomedical research in the country.

Since Switzerland has developed an outstanding environment for technological innovation and industrial development in the life sciences, it is likely that issues related to science policy, both on the national level and internationally, will become more urgent in the near future.

Summary Conclusions

The Swiss debate over controversial bioethical issues in the country is characterized by the coexistence of academic expertise on the one hand and of public participation in the discussion of possible solutions on the other. Occasionally, public engagement has influenced the roadmap for regulation, as was the case for genetically modified plants.

Over the last decade, scholars in the field of bioethics have progressively abandoned the role of exclusive experts in the field and have turned into participants into a wider debate involving multiple competences and varied public actors. Most importantly, however, direct democracy, decentralized governance, and the value placed on individual choices have largely influenced debates, laws, and practices regarding many bioethical issues.

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Syrian Arab Republic

86

Ghiath Alahmad

Introduction

Even though all societies share many ethical values and agree on many ethical principles, each of them has a unique point of view due to their differing political, economic, and social structures and different historical events and circumstances. Syria, as a Middle Eastern country, has a rich history.

While discussions about ethical issues in Syria are on the rise, there are still very few studies on the subject. In this chapter, different situations regarding bioethics in Syria will be explored, by first studying the social and economic conditions under

G. Alahmad
King Abdullah International Medical Research Center, King Saud bin Abdulaziz University for Health Sciences, Riyadh, Riyadh, Saudi Arabia
e-mail: ghiathalahmad@hotmail.com

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which they arise. The major bioethics issues and discussions in Syria will be addressed. The related activities of different governmental institutes are explored such as the Ministries of Health and Higher Education and nongovernmental offices that also have an interest in bioethical issues.

Background: Syrian Society and Culture

As a start, an overview of Syrian culture and society is given, including the political and economic circumstances that may affect the development of bioethics. Then, the growth of bioethics in Syria is generally explored. Three different hot topics are investigated as examples of the Syrian method of deliberating about bioethics.

All people in the Middle East are strongly connected to history. Historical events and peoples' heritage form a vital part of the daily life of the community. While all nations share many characteristics and history, two categories of Arabic societies can be recognized. The first kind of society became a center of culture, civilization, and the sciences shortly after the establishment of an Islamic state 1,400 years ago. This society lasted until the First World War, when these countries started to fall, one after the other, under European colonization; they fell under the direct influence of the quick technical and civil developments of Europe. These countries include Syria, Iraq, Egypt, and others. The second kind of society does not have the same rich scientific history and suffers from the direct delegation of foreigner workers. These countries, most of which are Gulf countries, continued to use Islamic judicial systems.

The regimes differ between the two groups; while the systems were a hereditary monarchy for the second group, the countries of the first group fell under dictatorial regimes, which came after the military coups that have occurred since the middle of the past century. Since the beginning of 2011, the countries of the first group have witnessed a movement of revolt through what is called the Arabic Spring, which led to a change of government for many of these countries and the establishment of democratic regimes in Tunisia, Egypt, Libya, and Yemen, most probably followed by Syria in the near future.

From an economic point of view, Syria did not directly benefit economically, politically, or culturally from the great oil discoveries in the neighboring Gulf region during the middle of the twentieth century. Instead, Syria started to lose its importance due to the dictatorial political system and its economic needs. The cultural center in the Middle East started to move from its old centers in Damascus and Cairo to new centers in Riyadh, Kuwait, and Dubai. This change became obvious during the last two decades of the previous century and the beginning of the twenty-first century and was a result of the huge economic jumps in the Gulf region and the crisis and economic needs in other countries like Syria.

Syrian society has a mixed and rich structure. Different Islamic sects can be found, including various Christian denominations, Jews and many other diverse and special ideological disciplines (Abduh, 2003; Alzarkah, 1995). Sunni Islam, however, remains the major religion in Syria (Alzarkah, 1995), encompassing nearly 72 % of the population. Regardless of this mixed structure in Syrian society, the

social and cultural habits and thoughts are similar across all the Syrians groups. It is remarkable that the social ethics and morals of many Syrians have undergone extensive changes due to historical and social responses.

Bioethics in Syria

Even with a common history and similar religious, social, and ethical links, there are many differences between the Middle Eastern countries, and these differences are related to each country's societal structure and economic development. Syria is a country with a rich history and an extensive civilization that was formed by the mixing of many ethnic groups, people, and religions. Unfortunately, the economic growth of Syria is not very good, and there have not been any great oil discoveries like in the Gulf area.

Syrians, like many other Middle Eastern citizens, are religious people. The majority are Sunni Muslims, with other Islamic groups contributing to the minority. Christians make up 8–10 % of Syrians (المركز اللبناني للدراسات الاستراتيجية The Lebanese Center for Strategic Studies, 1985; Central Intelligence Agency [CIA], 2011). These groups are used to living together, as they have for hundreds of years, and practicing their beliefs freely (Alsebaee, 1999).

The model of Syrian society and historical developments affect Syrian judicial law, including laws that are related to medical practice issues. Many resources were used when creating Syrian judicial law in 1949 (decree 84 in May 18, 1949), including Islamic jurisprudence, French law, and Egyptian law (Alzarkah, 1995).

Foundations of Bioethics in Syria

Bioethics, as a field of science, is still very new in Syria; the National Bioethics Committee was only established in 2003 through an initiative of UNESCO. The committee consists of seven members from many specialties (medicine, law, religion, and the sciences) (Saleh, 2007). Another committee was proposed by the Syrian Ministry of Health (MOH) in the same year. In 2005, Damascus University established an ethics committee. In the same year, a presidential decree was issued for the initiation of the Higher Commission for Scientific Research. This decree sets the principles and rules that guarantee that research be conducted ethically (Higher Commission for Scientific Research, 2006). In 2008, a special research committee was established according to this decree. This ethical research committee is independent from the National Bioethics Committee. However, all of these committees are still new and have not yet been activated. No research ethics code, national guidelines, or Good Clinical Practice (GCP) exist in Syria at this moment. The Helsinki Declaration and the International Organizations of Medical Sciences (CIOMS) guidelines are the resources that have been chosen by the research

committee of the MOH to be the references for the ethical standard for conducting clinical research. Some local ethical committees have judicial ground. These committees are consulted to resolve the different cases and ethical problems of different types of organizations and associations.

Five years ago, bioethics was included in the undergraduate curriculum of Damascus University, and the subject is being studied from ethical, legal, and religious perspectives (Saleh, 2007). Because Syria is part of the Arabic and Islamic region, it helps to make informal decisions for some Islamic and Arabic institutes like the Islamic Organization for Medical Sciences, the Islamic Jurisprudence Assembly, and the Arab League Educational, Cultural, and Scientific Organization. *Many* fatwas have been issued by these organizations.

Other deliberations on bioethics are made through conferences and discussions held by government institutes such as the Ministry of Health, the Ministry of Higher Education and the Syrian Medical Association. The first symposium was focused on the medical, legal, and religious aspects of effeminacy surgery and sex change and was organized by the Medical Association in Syria in Damascus on 2002 (Saleh, 2007). In May 2005, a bioethics in the Arabic World Symposium was held in Damascus; about 24 scientific papers were discussed. The Syrian American Medical Association has also made very good efforts to promote bioethics discussions. American doctors of Syrian descent are trying, through an annual convention, to educate the Syrian medical community about the advances in the bioethics field (Alshammas & Affof, 2006). Similarly, a workshop about organ transplantation was conducted by the Syrian Medical Association on 2003, with the participation of people from different specialties including Muslims and Christian researchers, lawyers, and medical doctors. The Syrians and the French doctors held their first meeting on bioethics 2003, which included important topics such as a symposium on organ transplantation and a seminar on the moral repercussions of research into stem cells (Saleh, 2007). Furthermore, there have been many books written by religious scholars about medical issues from Islamic and Christian points of view. These books are very popular and are widely accepted, as most people trust religious scholars. The books of Prof. Mohammad Said Al-Buty, one of the most famous scholars of the Islamic world, are a good example, like his book titled: "مسألة تحديد النسل وقاية وعلاجاً The issue of birth control in prevention and treatment" (Albouti, 1988).

Major Bioethics Issues and Discussion

Many bioethical issues receive public interest and debate in Syria; however, the most frequent bioethical talks and discussions concern two issues: reproductive technologies and organ donation. The recent developments in bioethics could be understood by elaborating on these two issues using reproductive technologies as an example of an attempt to harmonize Islamic jurisprudence and law and organ transplantation as an example of the need for regulation and the effects of economic crises. Besides these two issues, reproductive technologies and organ donation,

another issue starts to take a significant position in the public concerns that is the honor killing. In fact, honor killing is a controversial issue, and it is an example of the conflict between religion and social customs.

Honor Killing

Honor killing is a crime in which a victim is killed by one or more of their close relatives because they were caught having sex outside the family system. The claim, then, is that this killing was to "maintain the honor" of the family.

While the main reason for honor killing is usually for having sex outside of marriage, there are also other less frequent reasons, such as marrying a man from another religion or another sect. In many cases, there is no sex at all; the woman is just seen alone with a man. The sensitivity of these reasons varies across different regions of the world.

Some writers consider honor killing a kind of "communion" of a human provided by the family members to the surrounding community to achieve the desired behavior of women in accordance with the values and customs of that society (Syrian Women Observatory [SWO], 2009). It carries a clear message from the killer and his family: "We are clean, we have taken out the reason for your refusal of us, please accept us again, we are similar and like each other." This reasoning explains the overt ritual of the murder when it is performed in a public place in rare cases. Other families' women show their happiness for this familial purification.

Therefore, calling the act an honor killing is used to distinguish it from other kinds of crimes by connecting it to the reason for killing: the preservation of honor.

Honor crimes are committed in many parts of the world but mostly in Islamic countries, especially Afghanistan, Pakistan, Iran, Jordan, and Syria, due to the popular belief that Islam supports this murder because of the legal protection provided in some of these countries for the killers if they prove that their motive was "honor."

Usually, honor killing does not take this name except in countries that have some kind of legal protection that lightens or exempts the killer from punishment, as is the case in countries such as Syria and Jordan. In Syria, there are two legal articles that give honor killers a lighter punishment of "not less than 2 years imprisonment for murder": Article 584 and Article 192 of the Syrian Penal Code. However, some scholars argue that there is no legal protection for those who commit honor killings because there are many conditions that must be met for the excuses to be valid, such as the element of surprise and the intention of killing. Consequently, anyone who kills or injures any female, sister, wife, or girl, because she is secretly married, married to a man of a different religion, ran away with her lover, committed adultery with another man (who is married or not), or practiced prostitution is not excused from or receives a lighter punishment (Misk, 2010).

Usually, honor killings are linked to the religion of Islam, but the experience of several organizations that work against these crimes, including the Syrian Women Observatory, has shown that people who commit these crimes follow different religions. Scholars of different religions, including Islam, stress that their religion

rejects these types of crimes, asserting that the right of retribution is an exclusive right of the government and that no individual has the right to exact revenge. Muslim jurists say that nothing can be called an honor killing. One Muslim scholar, Dr. Tawfeeq Ramadan Al-Buty, says: it is a crime (killing), resulted from another crime (adultery). It deserves lightening the punishment. But he has not the right to kill (Alnasher, 2010).

There have been efforts in other countries against honor killing. In Syria, a campaign entitled the National Campaign against honor killings was launched by a private group called Women of Syria in September 2005 and continues to this day. This campaign aims to repeal the two articles, Article 548 and Article 192, of the Syrian Penal Code that allow for the reduction of the punishment to at least 2 years. Recently, some people in Syria have tried to bring this issue up for public debate (see: Syrian Women Observatory (http://nesasy.org). Others oppose such debate and consider the issue to be exaggerated (Misk, 2010). The statistics released by the Syrian Interior Ministry state that in 2010, there were 249 cases of honor killing in Syria. This equates to 1 crime per 100,000 people (the Syrian population is 21 million) (Alawsat, 2011).

The Syrian government recognizes these crimes and held a national conference in October 2008 entitled the National Meeting on honor crimes, which concluded with important recommendations aimed at opposing these crimes of honor in Syria.

Other countries also contribute to the fight against these crimes. Jordan, Turkey, Pakistan, and Tunisia have canceled any legal excuse for honor killing.

Honor killing is a controversial issue: it is and remains a crime. We do not see any legislator, jurist, or writer who considers it to be anything else. Activists are concentrating on trying to change the laws that lessen the punishment for honor killing rather than on simply educating people. The idea is that anyone who would commit an honor killing would do so regardless of the punishment. Studies show that 80 % of honor killings are performed in rural areas where there is less education (Alawsat, 2011). Increasing public awareness about human rights, justice, respect, and humanity can help make this change.

Family Planning/Reproductive Technology

There are many labels used for the policy that aims to reduce the population growth in Syria. The common label among people is the term birth control, followed by the less popular term, birth planning. Those who contribute to the implementation of this policy prefer to use the term family planning, as it is more general, more comprehensive, and not limited to only birth control but also includes the concept of reproductive health in general. However, the most important reason to adopt the label of family planning is to hide behind it to avoid arousing religious people who reject the idea of birth control altogether. There are many questions about the feasibility of this policy, which is still in the beginning stages in Syria.

Some say that interest in this matter goes back to the 1970s, following the release of the census results in 1970, in which the rate of population growth was 3.6 %,

which resulted in the formation of government committees. In 1974, the Syrian Family Planning Association was established, but this did not prevent the granting of a family medal to all families with more than 12 children until late 1986 (Albuni, 2008). Moreover, the government continued granting incentives to mothers to have more children.

The situation remained unchanged in terms of the number of children in families until 2002, when a decree was released that explicitly indicated the number of children for which the mother will be granted maternity leave and that referred to the Syrian Commission for Family Affairs that was developed in the same year. Family planning policies are no longer restricted to the government alone but are also influenced by the Family Planning Association and the Syrian Commission for Family Affairs; the Ministry of Health and the Women's Union also play a role. There is a consensus among the members of all of these parties to call the issue family planning and not birth control. They find family planning and birth control two different issues, even if they have the same results.

The Family Planning Association claims that it is working in accordance with the religious and social values of Syria. There are 19 clinics that follow the guidelines of the association in all provinces; the clinics implement the policy of the association and distribute various family planning methods such as birth control pills, IUDs, and condoms. There is also a mobile clinic that tours the 20 villages in the countryside of Damascus and provides services. The Family Planning Association intervenes in the interests of young girls and gives advice to raise awareness among them.

The primary health care unit of the Ministry of Health has several programs under the name of reproductive health including family planning, care for the pregnant, the early detection of cervical cancer, and emergency obstetric care. It does not advocate birth control or a reduction of the population, but it instructs parents to leave an interval of 3 years between children, for example, so that they are able to secure a decent life for each child. The Ministry of Health centers across the country distribute family planning methods. This year, these methods are being distributed free of charge to citizens, in cooperation with the United Nations Fund.

There are some difficulties regarding family planning in Syria because of the different social, religious, and cultural backgrounds.

Religion and Family Planning

There is no doubt that the Islamic religion rejects the idea of birth control, much like the Christian religion does, as is stated in the first chapter of Genesis: "and God blessed them and said unto them, Be fruitful and multiply, and fill the earth and subdue it." This is further reflected in the principles of Pope Pius II, which state that a clean marriage is a marriage that produces children without interruption or regulation.

There is a great deal of talk about the opposition to birth control in Islam, but another school of thought states that there is a call for family planning in Islam, citing three Quranic verses that call for birth planning and show that breastfeeding should be conducted for two full years. There are also a few prophetical traditions that confirm that the companions of Prophet Mohammed were ejaculating outside

of the woman (isolation العزل is the expression used in the prophetic tradition). They said: we ejaculate outside, while the Quran was delivered, and the Prophet did not prevent isolation. Institutions that are interested in birth control in Syria attempt to mobilize the position of religious jurists for their purpose because of the importance of the jurists in influencing people's opinions. However, the dominating opinion among the jurists, which is what is taught to the public, is that reproductive technologies cannot be used for birth control unless under the guise of family planning, such as leaving 3 years between every birth, or in cases of risk to the mother. Permanent methods to prevent pregnancy, like tubal ligation, are not allowed.

Numbers

Reports issued by the Syrian Commission for Family Affairs, a commission that records data on the Syrian population, show that the rate of population growth has declined and it is currently at 2.45 %, after a period of significant growth that was not met with a similar growth in economic performance. In a study on the attitudes and beliefs of women toward family planning issues, the current rate of use for methods of family planning in Syria is 73 %. This percentage exceeds the 60 % percent that was hoped to be achieved by the year 2015. The study was conducted with 10,000 married women at the age of reproduction from rural and urban areas.

Some researchers question the 73 % statistic and believe that the figure was drawn from the results using multi-indicators and that the true percentage is 58.3 %. The UNDP report of the United Nations regarding poverty in Syria reported that the number of women who engage in family planning in Syria is less than 46 % and that 25 % of women do not use any method of family planning.

A study by the Syrian Commission itself showed that 43 % of women want to have more children and the average number of desired children is 4.89. However, 17.5 % of women who have recently had a baby say that they are not willing to get pregnant again very soon, and 9.2 % of pregnant women are not pleased that they are currently pregnant.

Laws

All of the involved agencies, the Syrian Family Planning Association, the Syrian Commission for Family Affairs, and the Women's Union work under the risk of punishment by law through a number of articles. Articles 523 and 530 prevent the advertising, sale of goods, acquisition of goods, or facilities for the use of family planning methods. Furthermore, Law No. 23 of 1998 associates the use of family planning methods with an exposure to sanctions. In 2002, 22 women were convicted of the offense of preventing pregnancy. Article 523 and Article 208 state that methods leading to the prevention of pregnancy or an offer to use them for prostitution to prevent pregnancy will be punished by imprisonment for 1 month to 1 year and a fine of 100 Syrian pounds.

In article 524, anyone who sells, offers for sale, or acquires for the purpose of selling any material intended to prevent pregnancy shall be punished with the same punishment.

Thus, theoretically, the application of these laws could lead to the punishment of the Ministry of Health, which oversees the distribution of family planning methods, as well as the Syrian Women's Union, but these laws are so rarely enforced that many family planning workers have not even heard of the laws. Some believe that these legal articles do not actually constitute an obstacle as they are never enforced, but people still fight for their repeal. However, the government has not responded to such appeals, and these laws are still intact today.

The rate of population growth in Syria is one of the highest in the world but has declined from 3.30 % in 1993 to 2.45 % in 2004. There is no proof that this reduction is the success of the policies enacted to decrease the population growth; the pressure from the current economic conditions may be stifling to Syrian citizens, preventing them from having a greater number of children and forcing them to resort to using birth control.

Even though the sale of contraceptives is not legally allowed, many local officials and authorized organizations are doing just that; there are about 15 centers that are working without any legal frame. However, people in Syria are mostly following the jurisprudential rules that were released by the Islamic institutes and scholars regarding the use of all new reproductive technologies that state that they allow them for family planning but not for reducing the number of births. They argue that the population density in Syria is just 112 people per km^2, which is considerably less than the density in the UK, Germany, France, and many other countries (United Nation, 2009). They contend that concentrating on improving the economy can solve the problem of the increasing population.

Organ Transplantation

The subject of organ transplantation and donation is a highly sensitive issue because of the economic and social aspects and the concerns about health and humanity.

There is an active global trade in this area that lures some weak people to deviate from the nobility and honor of medicine to the extortion and brokerage of these organs for large sums of money. There is a growing black market for organ trafficking and a stock exchange to rival the prices of oil and gold. While most families are still reeling from the high costs of the transplant and from the difficulties involved in finding a suitable donor, they now also have to contend with the dangers posed by the impact of this rush.

There is a trend in many developing countries, including Syria, to regulate organ transplantation and to give it legitimacy and legality. Kidneys are the most common used organ on transplantation.

Kidney transplantation began at two centers in Syria in December 1985. The first was at Al-Mowasat, a university hospital in Damascus, where 501 kidney transplants were conducted from living donors to relatives through 2003. The second center was at the Tashrin military hospital in Damascus, where about 216 cases of kidney transplantation have been performed. In 2001, the Ministry of Health

Table 86.1 Kidney transplantation in Syria

	Kidney transplantations in Syria		
Year	Inside	Outside	Total
1998	53	130	183
2003	225	12	237
2007	335	1–2	336–337
2008	252	70	322

established a center for kidney transplantation in the Kidney Hospital which is located also in Damascus. Overall, 214 kidney transplants from living donors, to both relatives and nonrelatives, have been performed there through 2003. Only 10–15 % of all kidney transplants occur in the private sector.

The overall number of patients who have had a kidney transplant in Syria and were still alive at the end of 2003 is 1,320, 70 % of which were males and 30 % were females. This number includes 28 patients who had a second kidney transplant. There are about 100 transplants performed outside Syria every year in India, Iraq, and Egypt; transplants that are performed in these areas may be complicated by blackmail, brokerage, and the wasting of money, on top of other surgical and internal complications including the transfer of malaria or AIDS.

The rate of kidney transplants in the Syrian population by the end of 2002 was 11 transplants per one million people. Considering that the incidence of chronic renal failure in Syria is about 65–70 patients per one million people each year, it can be concluded that the rate of transplantation is still below the normal limit, which is not acceptable, and that the reason that this number is so low is that the kidneys had to be taken solely from living donors who were relatives of the patients between 1985 and mid-2002. In 1998, 130 kidney transplants were conducted outside Syria (like Egypt and India) and 53 were conducted inside. In 2003, there were only 12 transplants performed outside and 225 inside Syria, and in 2007, there 2–3 cases outside and 335 cases inside Syria. The effects of new laws that were developed can be easily recognized by comparing the 1998 statistics with the 2003 and 2007 statistics and show the effects of new laws that were developed, especially those that allowed for the taking of kidneys from nonrelated live donors. In 2008, the prime minister issues a new decree that limited kidney transplantation to governmental hospitals only and increased the number of governmental centers for transplantation from three to eight. The effect of this decree was that the number of transplantations decreased to 252 inside and increased to about 70 outside Syria (Akroosh, 2010) (see Table 86.1).

After kidney transplantations, cornea transplantations are considered to be the most common type of transplantation in Syria; the last statistics published in official journals in 2008 state that there were 1,200 cornea transplants, and there were about 1,500 cases by 2010. All of these corneas were donated by the international tissue bank TBI or the ORBIS organization.

Other kinds of organ transplantations, including liver, pancreas, and heart, are still not very common in Syria. There is a plan to establish a center for organ donation, but such a plan is still in the beginning stages (Alasaad, 2010).

Organ transplantation, transfer, and donation in Syria are governed under Law No. 31 of 1972 and the amended law No. 43 of 1986. This law and its amendment were issued to encourage people to donate their organs to save the lives of other people who are in need, but it seems this purpose has not been achieved. On the one hand, the practical application of these laws resulted in a lack of donations received during that period. On the other hand, a global organ trade began, creating a significant risk for patients who were in need of a transplant and did not have enough money, to the extent that some of them died for lack of the organ they needed. These factors led to a push to intervene and amend the provisions governing organ transplantation, to encourage donors, and to facilitate procedures in a way that matched the accelerated scientific progress in this area, especially as it became possible to store organs in special banks until it they are needed. A new law on transplantation and donation, No. 30, was promulgated on 11/20/2003. On 11/7/2004, a new regulatory decision, No. 73/T, was made that contained instructions governing organ transplantation. It regulates the mechanism and conditions of the transplantation to ensure the safety, health and dignity of both the donor and the recipient and to keep this good noble work as a humanitarian exchange. This new law will help in controlling the hidden black market in two ways. Firstly, it states to punish anyone who violates the provisions of the new law on organ transplantations with imprisonment from 6 months to 2 years with a fine of 5,000–10,000 Syrian pounds. Secondly, organ trafficking was not punishable earlier; this new law fills this gap, making organ trafficking punishable by imprisonment with hard labor (between 3 years and 15 years) with a fine of 50,000–100,000 Syrian pounds.

Organ transplantation is a serious problem in Syria due to the gap between the need for organs and available organs. Sixty-five to seventy patients per one million people need kidneys each year, while only 11–12 kidneys are available per one million people each year. The black market can manifest itself in many ways, including fliers full of compassion and propitiation that are pasted on walls, on the streets, and near hospitals or even through hidden agreements that are mediated by a surgeon. These situations may result in harmful outcomes when the transplantation is performed by an unqualified doctor, in unsuitable circumstances or in unprepared hospitals. It is estimated that one kidney from a live donor costs 15,000 American dollars (Gusen & Alsubeh, 2006).

The laws issued in 2003 and 2004 were a great step toward regulating transplantation and controlled, to some degree, some of these unethical practices, but they were unable to prevent organ trafficking completely. Many changes are still needed to further control the issue, such as allowing for transplantations from dead people with new regulations and a new definition of brain death. Organs taken from dead people can help solve these problems and increase the number of available organs.

It is notable that this black market exists despite the many fatwas from Islamic institutes and scholars that have forbidden organ selling. There is some doubt whether these fatwas are known to the public, so it is a good idea to make these Islamic opinions that allow for organ transplantations and that prevent organ selling known to the public. These opinions include those of individuals, like those that

have been written by many Muslim scholars, and the institutional fatwas, especially the fatwas of the International Islamic Fiqh Academy and the Fiqh Council (Muslim World League), to help create a good and suitable environment and culture for organ donation. In the future, policies may exist that state that everyone is a donor unless he or she refuses, which will open a new discussion in this debate.

Future Challenges

Without a doubt, Syrians have gone through many painful events since February of 2011. The killing of thousands of Syrians, including doctors and other health care providers when Syrians began their movement for freedom and democracy as a part of the "Arabic Spring," will deeply affect the future life of a variety of Syrian groups. This is expected to initiate radical change in the structure of Syrian society following over 40 years of dictatorial ruling.

The current unrest has disrupted the normal daily life of people scientifically, economically, and socially, which will deeply affect biomedical issues in the coming years. Typical bioethical dialogues regarding issues such as organ transplantation and medical research do not capture the interest of Syrians at this stage of unrest. Other issues take precedence, including how to survive, excruciation of arrested people, how to obtain proper treatment, and offering protection to doctors as wounded civilians and the doctors treating them have become a target of the regime. This has led to a new phenomenon of having primary and hidden clinics for providing emergency procedures for civil victims (Daniel, 2012). This is necessary because a doctor treating the wounded is considered the same as the holder of a bomb by the Syrian regime (Agence France-Presse [A. F. P], 2012).

The future of Syria is ambiguous. However, an optimistic look might argue that this transient period of unrest will lead to a democratic government, similar to that seen in other countries of the "Arabic Spring." In this case, many Syrian immigrants who spent decades of their life in different regions around the world would likely return home, bringing their diverse backgrounds, cultures, and experiences, to mix with the people that remained inside Syria. All of this, in addition to the economic investments expected by the Syrians and others, would likely lead to cultural, economic, and social richness and build suitable ground for dialogue and debates regarding vital bioethical issues. On the other hand, a dual effects and cooperation might develop regarding such bioethical issues among Syria and the surrounding countries in the region, through some activities arranged by some parties, like the Regional Office for the Eastern Mediterranean of World Health Organization WHO and the Maryland University which organizes yearly workshops in research ethics in different countries in the Middle East through the "Middle East Research Ethics Training Initiative (MERETI)."

The issues of organ transplantation and family planning are expected to remain the main biomedical issues in Syria in the future. Additionally, increased interest is

expected for issues such as in vitro fertilization, premarriage testing, medical research, and storing of genetic materials. Autonomy and justice are expected to have an increased value for both the public and bioethicists in case the current unrest leads to democracy.

Conclusion

The social, economic, and historical circumstances of Syria have led to the development of a special vision about some vital issues. Although the Syrian view matches the international view regarding many issues, Syrians take interest in some issues that are not considered very important in other countries.

Although there have been notable efforts by some government and nongovernment parties regarding bioethical issues, a clear failure is recognized, especially in the field of medical research, as there were no national guidelines regulating clinical research. Organ donation, even with the very important laws from 2003 to 2004, still requires greater regulatory efforts to prevent the sale of organs on the black market. The new national center for organ donation that is planned will play an important role in this regard. Debates on reproductive technologies and honor killing highlight the importance of raising public awareness about human rights and human dignity.

Confronting the future challenges of these issues will require a large number of qualified Syrian researchers in the field of bioethics who understand the nature of Syrian society, its economic circumstances, and its social structure. Cooperation between these bioethicists, jurists, politicians, economists, and socialists is vital if Syria wants to match the huge international developments that are occurring in the field of bioethics.

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Turkey

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Berna Arda and M. Volkan Kavas

Introduction

When and How Has Bioethics Started?

The very first academic bioethics discussions were devoted to issues regarding the beginning of life. The 2827 numbered law, promulgated in Turkey in the year 1983

B. Arda (✉) • M.V. Kavas
Department of History of Medicine and Ethics, School of Medicine, Ankara University, Sihhiye, Ankara, Turkey
e-mail: arda@medicine.ankara.edu.tr; volkankavas@yahoo.com

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about population planning, stipulates the right to medical abortus with the consent of the parents until the tenth week of pregnancy (Law on Population Planning 1983). The spouse's consent for a married woman is also required in the case of an abortion. The consent of the spouse should also be obtained for both male and female sterilizations (the bylaw related with abortion 1983). In the mentioned regulations, "mother's health" was put as the core element by the legislator. Feminist ethics today emphasizes "maternal rights" implying that during determination periods in medical abortion and usage of prenatal diagnostics methods, the main determinant should be the woman. "Mother's sovereignty" and "fetus' benefit" seem to be the main conflicting issues regarding abortion. However, while treating this topic, "benefit of the society" emerges as another important parameter to be taken into consideration, even though it is rarely addressed. As time progresses, a woman's sovereignty on her body and sexuality becomes much more important than the benefit of society due to feminist influences. Today, maternal rights are always thought of along with the concept of "inside uterus property rights." Therefore, it is crucial that the medical team communicates with all family members, starting with the candidate's mother; the couple should be well informed about the situation since their consent shall be determinative and required for further actions.

Other early bioethical discussions in Turkey focused on research ethics (Oğuz and Arda 1991). In 1988, the usage of a plant abstract (Nerium Oleander, NO) by a physician for cancer therapy as an application of folk medicine instead of standard scientific treatment methods has triggered a public discussion. The efficiency of NO extract in cancer patients, the place of such "alternative" methods, and the harmful side effects of these sorts of tools were the main discussion points. On one hand the rights of the subjects and on the other hand the limits of social responsibility of scientific activity have been discussed. As a result of these efforts, the very first ethics committees concerned with the biomedical trials were established in Turkey in the early 1990s.

Usage of prenatal diagnostic methods for sex determination, professional attitude of the physician on the human rights topics, medical ethics issues to do with vulnerable groups, publication ethics, patient rights, and physician rights are the main topics that have been discussed since 1990s.

Who Have Been the Major Actors/Forces?

Turkey belongs to the upper-middle income class among the income classes defined by the World Bank. With respect to scientific expenditure, Turkey is one of the two Muslim countries that are comparable with other countries. Another point to emphasize is that while the member countries of Islam Conference Organization (ICO) have maintained or even regressed in scientific output for the last 20 years, Turkey, which had only 500 scientific publications in 1988, has increased that number to more than 16,000 today. Despite a lack of rich petroleum resources, Turkey has been the most successful member of the ICO, which has been attributed to the 1923 revolution during which a secular state was

established. Another important point is the presence of female academicians at a rate of 30 % in Turkish universities (Butler, 2006; Giles, 2006).

Considering the infrastructure in the country, the research process has been the most important factor in the field of ethics. Especially after the 1980s, a lot of biomedical research has been started in Turkey. Since the period of 2000–2008, 1–3 % of all trials in Europe were conducted in Turkey. Most of them (92 %, $n = 416$) were interventional and the rest (8 %, $n = 34$) were observational. Fifty-five percent of these trials were Phase 3 drug trials (Gülen 2010). The research potential and infrastructures of the country, full membership candidacy to the European Union, and legislative necessities are main factors underlying these results.

What Have Been the Major Concerns Over Time?

Informed consent has become one of the most significant topics in daily medical practice and biomedical research; it covers two main domains: medical treatment and medical research. The first regards the acceptance of the medical interventions by the patient who will undergo them after being informed about the content, risks, and benefits of the diagnostic, the treatment methods, and their alternatives. The latter is about guaranteeing that a participant, whether they are ill or healthy, is fully informed about interventions applied to their body for research purposes. Due to some specific features of the cultural base in the country, such as paternalism, and problems arising from the transformation of the healthcare system mostly according to market needs (such as the fact that doctors have less time to spare for each patient, work harder, and have less professional independence), obtaining informed consent is becoming more difficult for healthcare professionals. Since the emergence of bioethics debates, important progress has been made in terms of informed consent. The necessity of informed consent in both daily therapeutic practices and research processes of medicine has gained indisputable acceptance. Reasons for this result vary; however, the fact that this issue has been emphasized in medical education over the years and took place in medical legislation early enough may be considered the most effective factor. Currently, comprehensive, written, and signed consent forms are used before invasive interventions, surgical operations, and research projects. Many medical specialty associations have prepared informed consent forms taking special interventions and practices of their fields into consideration. Yet it should not be ignored that this dimension of the patient-physician relationship is a continuous process, which must be verbal as well, and should not be diminished merely to the scope of written forms.

What Resources Have Been Developed?

Most of the medical schools with a medical ethics department have books related to undergraduate medical ethics education. These books usually contain the main ethical issues and are updated periodically (Arda, Oğuz, & Şahinoğlu Pelin,

1999; Sarı et al., 2007). There have been a lot of translated books and guides from English to Turkish for scholars and general readers (Carmi, 2003; Harris, 1998; United Nations Educational, Scientific and Cultural Organization [UNESCO], 2008a, b, 2010; Veatch, 2010).

The Turkish Bioethics Association (TBA) was established in Ankara in 1994 as the very first society in the field. Due to its authority of representation, all ethics scholars were recognized by the state in 1999, when it was authorized to use name of the country. The main objectives of TBA are to contribute to the development and education of bioethics and to improve its connections with healthcare disciplines. TBA organizes biannual symposia on bioethics and since 2001 has also organized the national congress of medical ethics, as well as courses on medical ethics and conferences on special issues. TBA has published a number of books and reports, mostly the proceedings of symposia and congress (see www.tbd.org.tr).

The Society for Medical Ethics and Medical Law was established in Istanbul as the second professional society in 2004. It has organized periodical national and international conferences, expert meetings, and seminars and has published most of the proceedings of these academic events. The aims of this society are to promote scientific research, support education of medical ethics and law, and provide international scientific relations in the field of the medical ethics and law (see www.teth.org.tr).

The Ethics Committee of the Turkish Medical Association (ECTMA) is another body working on bioethical themes. The ECTMA was founded in Ankara in February 1994. The composition of the ECTMA is multidisciplinary. The members are academicians from different fields, such as Medicine, Nursing, Philosophy, Medical Sociology, and Law. The meeting frequency is twice a month. These meetings are closed to the public, but press announcements have been made. The committee strives for consensus and has produced reports during its activity period. The opinions of ECTMA are prepared in a way to cover a lot of different topics, such as organ and tissue transplantation, sex determination, electroconvulsive therapy usage, and hunger striking (Arda 1996; www.ttb.org.tr). There have also been a few published studies related to this nongovernmental ethical body (Akşit & Arda, 2003; Anonymous, 2008, 2009a; Arda et al., 2004).

There are two important periodicals: Turkiye Klinikleri Medical Ethics and Law and History Journal (started in 1993 with the name of Medical Ethics, and after 2000 the name changed to Medical Ethics, Law, and History) (see http://tipetigi.turkiyeklinikleri.com). The other journal is the Turkish Annual on the Studies of Medical Ethics and Law.

What Have Been the Steps/Measures Taken

Turkey has been a democratic, secular, unitary, constitutional republic since 1923. The Republic of Turkey is a parliamentary representative democracy. The constitution governs the legal framework of the country. The constitution was changed in the years of 1924, 1961, and 1982.

Health was among the priorities set by the founders of the Republic of Turkey. This is why one of the first laws issued by the Turkish Grand National Assembly, founded on April 23, 1920, during the years of the Turkish War of Independence, was the law to establish the Ministry of Health. With this law, health services were accepted as a public service conducted by a ministry of the state (Arda, 2012).

There are a lot of international conventions ratified by Grand National Assembly of Turkey, such as UN Conventions on the Elimination of all Forms of Discrimination against Women and the Rights of the Child and Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine of the Council of Europe. According to the article 90 of Turkish constitution:

> Ratification of the treaties concluded with other countries and international organizations on behalf of the Republic of Turkey shall be subject to adoption by the Turkish Grand National Assembly of a law approving the ratification. . . .. International agreements duly put into effect shall have the force of law and no appeal to the Constitutional Court can be made with regard to these agreements on the grounds that they are in contradiction to the Constitution. In conflicts between international treaties concerning basic rights and freedoms and national laws, priority will be given to the international treaties. (Anonymous, 1982)

This Convention for Human Rights and Biomedicine is an integral part of the Turkish legal system. The Oviedo Convention was ratified according to article 90 of the constitution by the Grand National Assembly on December 3, 2003, and the law on the "Convention for the Protection of the Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Law on the Approval of the Ratification of the Convention on Human Rights and Biomedicine No. 5013" was put into effect with the publication in the official paper No. 25311 on December 9, 2003 (Anonymous, 2003, Katoğlu, 2005, Uygur & Sancar, 2005).

The Additional Protocol to the Convention on Human Rights and Biomedicine, concerning biomedical research, has also been ratified and published in official gazette in 2011 (Anonymous, 2011a).

The presence of the medical ethics and deontology classes in undergraduate medical education as compulsory courses seems to have some advantages. After the 1990s, classical medical education has been modernized in terms of its content and methods. In 2002, with the emergence of the National Core Curriculum (NCC) project, the aim and learning objectives of undergraduate medical education have been determined on the national level. To determine the objectives of undergraduate medical education for Turkey, clinical and basic science, knowledge, skills, and attitudes relevant to bioethical topics, such as physician-patient relationship, patient privacy, and patient autonomy, have been defined and classified. A total of 1,610 cognitive, 428 psychomotor skills, and 247 attitudes have been named. Thus, the core curriculum defined is not just a set of diseases, conditions, and symptoms. The major outcome of this work initiated an atmosphere of collaboration and understanding between different medical schools in Turkey. This process has led to the development of a National Core Curriculum which contains ethical issues and targets as well (Kemahlı et al., 2004).

Ethics committees (ECs) are important entities because they regulate the steps taken for biomedical trials, most of which are authorized by the Ministry of Health. According to the regulation, ECs must be comprised of between 7 and 15 members. At least one of these members must be a non-healthcare professional and one must be a jurist. The majority of the members must consist of healthcare professionals holding a doctorate or medical residency degree. The EC must meet in order to perform a scientific and ethical assessment of the trial protocol, the design and suitability of the trial, the inclusion and exclusion criteria, the suitability of investigators, the adequacy of the trial sites, the methods and documents used to inform the subjects, and the consent obtained from trial subjects, as well as any other aspects pertinent to the trial. In doing this, the EC must try to ensure that the subjects' rights, safety, and well-being are protected. The EC ensures that the study is conducted and monitored according to the regulations. According to the Implementing Regulation on Clinical Research, different sorts of ethics committees have been defined. There are ECs for Drug Clinical Trials, ECs for Bioavailability/Bioequivalence Trials, ECs for Non-drug Clinical Trials, and ECs for Clinical Trials (Anonymous, 2011b).

As different sorts of ECs, hospital ethics committees, university ethics committees, or ad hoc ethics committees have also been organized mostly in order to conserve and defend patient rights in different contexts. The EC on sexual determination in Ankara University School of Medicine is one of the successful examples working in a multidisciplinary way for long years (Öcal et al. 2010). These committees also play an important role in resolving ethical conflicts, analyzing the bioethical cases, and proposing action choices to relevant parties.

Current Bioethics Infrastructure

Teaching of Bioethics at University and Other Levels

In Turkey, within the medical school tradition, duties and responsibilities of the physician have always been a part of the curriculum since the first quarter of the nineteenth century. Currently, it is a *sine qua non* for undergraduate medical education, too. In 1961, "medical deontology" and "history of medicine" were accepted together as one specialty branch in medicine in Turkey (with the statement of October 13, 1962 and number: 5/1789; Official Gazette No. 10942, Code of the Medical Profession). This situation lasted until 2002, the year the MoH changed the concerning regulation. After 1981, when the legal changes related to the university system of the country took effect, the main characteristics constituted the final transition from the concept of "deontology" to "medical ethics." Drastic changes have occurred in lecture contents. Today, any student receiving his/her training at any medical school in Turkey has to take a "medical ethics" course and pass (Arda, Oğuz, & Şahinoğlu, 2009). Medical ethics

education is an indispensable part of undergraduate medical education according to the National Core Curriculum (Kemahlı et al., 2004).

It is possible to find the details of all the courses related with ethics in the database study GEOBS (Global Ethics Observatory) on Database3 (see www.unesco.org). Totally, 35 ethics teaching programs, undergraduate and postgraduate level, have been documented from Turkey: 29 are about medical ethics, 4 about bioethics, 1 about environmental ethics, and 1 about science ethics. Thus, medical ethics teaching has a central role in the field of bioethics (Arda, 2011).

The undergraduate curriculum of the other health sciences, such as dentistry, pharmacy, veterinary medicine, and nursing, also contains similar courses to the ones mentioned above. There have been a few courses related to ethics in some other fields, such as law, engineering, biology, and environment, on the postgraduate level (master or doctorate programs) of some universities (see www.unesco.org).

Bioethics Committees

Despite some deficits, for example, the absence of a national bioethics committee, legislative instruments concerning research as well as ECs are available in Turkey (Arda & Aydın, 1995). The very first ECs were founded in the early 1990s according to the rules of the Regulation on Medical Research in 1993.

There has also been a bioethics specialty committee under the UNESCO National Commission of Turkey (see www.unesco.org.tr). This committee was founded in 2000 for the purpose of following international developments in the area of bioethics and adapting to them under the duties of the National Commission. The main aims are to increase the public and individual awareness, to remind professionals of their responsibilities regarding the protection of human dignity in research and practice of biomedical sciences, to create an environment for discussion with diverse participation, and to improve bioethics education in Turkey at every level through consultation meetings and workshops. The committee organized meetings such as rotating conferences in bioethics, ethics experts meetings, and workshops. The committee has also finalized the Turkish translation of the three declarations published by the International Bioethics Committee of UNESCO.

Expert Bodies/Centers

Medical ethics departments of the schools of medicine, UNESCO Philosophy and Human Rights Chair in Maltepe University, non governmental organizations in the field, like Turkish Bioethics Association (TBA) and Society for Medical Ethics and Medical Law, are expert bodies mostly originated from academic area.

Relevant Legislation

In the Turkish juristical system, there are many legislative regulations which can be associated directly or indirectly with bioethical themes. The concerning major legal instruments are as follows:

- Civil Law, Law No. 4721
- Turkish Penal Code, Law No. 5237
- Law on Turkish Medical Association, Law No. 6023
- Law No. 2238 on the Procurement, Preservation, Grafting, and Transplantation of Organs and Tissue
- Law on Population Planning, No. 2827
- Law on the "Convention for the Protection of the Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Law on the Approval of the Ratification of the Convention on Human Rights and Biomedicine No. 5013"
- Medical Deontology Regulation
- Implementing Regulation on Patient Rights
- Implementing Regulation on Clinical Research

Public Debate Activities

The congresses of medical ethics, medical law, and bioethics serve as a discussion platform in academia. Bioethics issues are also occasionally debated in popular publications regarding medicine or news portals, daily newspapers, and on national radio and television channels. The contribution of civil associations such as some active medical chambers and HAYAD (society for patient and patients' relatives' rights) to this process is worth mentioning (see www.hayad.org.tr). At the end of the 2000s, physician's ethical responsibility in hunger strike cases (Arda, 2002, Oğuz & Miles, 2005) and the social responsibility of scientists – against the backdrop of the Dilovası case (Tuncer and Özen, see www.ttb.org) – have been important issues in recent debates.

Major Bioethics Issues and Discussions at the Moment

Beginning of Life

From the perspective of feminist bioethics, the 1983 Law on Population Planning is considered an important women rights acquisition. Elective abortion can be held only with the woman's consent. Thus, a secondary consent of the partner is not necessary. There are two main sides regarding the issue of abortion: those who defend the embryo's right to live by claiming with traditional and religious approaches that life is holy and it begins from the first moment of fertilization and those who assert that a woman is the only subject who can decide freely about

her body and her life. The social and economical status of women in Turkey should be taken into consideration while handling this subject.

End of Life

One critical problem seems to be that there is a general ignorance among professionals, academics, and the public about end-of-life issues. This topic is one of the least debated aspects of clinical ethics in Turkey. Moreover, there is no comprehensive data portraying the situation to undergraduate students in medical school, but it is thought that education programs about systematic end-of-life issues are very little or mostly none. Studies focusing on the attitudes of medical professionals toward the dying patient are increasing in number, even though the pace of such initiatives is far from satisfactory.

Euthanasia is forbidden in Turkey by law which often leads to contradictory clinical situations. Physicians might feel forced to continue treatment which is known to be futile and only helps extend the dying period of the patient which might be full of suffering for him/her and his/her relatives. Although not legal, what is usually preferred in such cases is to withdraw the treatment and discharge the patient, if the person can receive adequate palliative care at home.

Health and Disease

"Socialized healthcare services" have been abandoned gradually since the 1980s, and the healthcare system has been left to the dynamics of a free-market economy. This process is almost completed, suggesting that healthcare services are treated as goods to be sold to citizens who ask for them by private companies but not provided by the state with the people who need them. One of the most prominent examples of this process is the total elimination of health centers by January 2010 all over the country. These health centers would usually be financed by the government from the state budget and provided both preventative and therapeutic services together on a population-based regional scale. The medical team working in a health center was supposed to be responsible for monitoring the health status of all individuals from birth to death living in the territory of the concerning center and taking necessary measures to improve it. Preventing diseases was acknowledged as the top priority. Although it seems to be a big responsibility at the moment, healthcare workers were motivated to work that way in the context of that time, most likely because the socioeconomical substructure was suitable for collective work, unlike today's context promoting individualism.

Since the early 1980s, all governments attempted to polish therapeutic services while devaluing preventative ones by applying several policies which prepared today's conditions. Limiting the budget of health centers, terminating national vaccine production, and unjust allocation of healthcare professionals throughout the country are some examples. Through the 1980s and the 1990s, the approach of

"treating diseases after they occur" was intensely advocated by politicians and stakeholders, either explicitly or implicitly, and thus, almost all investments in healthcare made both by the state and private sectors were based on this understanding.

In line with this trend, the commercialized healthcare system, whose final aim was to turn health services to complete subject to free-market economy, has been established step-by-step for the last 30 years. When a person is ill, he/she would have to undergo the appropriate treatment for his/her illness. Obviously, this is more profitable but not cheaper than preventing the person from diseases. With this plan, incomes were privatized and costs were publicized. The enormous increase in recent years in the number of medical examinations, applications to emergency services, and sales of medications and medical technologies in Turkey can be explained when this trend is taken into consideration.

An ideological turn was also achieved parallel to this process. The "health" concept has gone through a dramatic change. While on one hand, "health" was promoted as a "demand" of individuals rather than a "basic need" of people living in interaction in a community, on the other hand it was isolated from its social determinants and diminished to individuals' own responsibility by all the governments since the 1980s. Unquestionably, AKP (Party for Justice and Development), which has been in power for the last 10 years in Turkey, was the most eager and powerful of all governments striving for this end. Thus, "health" has happened to be redefined without a holistic look. A natural consequence of this trend was the growth of medications and the medical technologies market.

Healthcare System, Access to Healthcare

The transformation of the healthcare system in Turkey from a state-funded and organized structure toward a fully market-oriented one can be considered the most crucial bioethics issue. This issue has covered a large part of the bioethics agenda in Turkey for almost a decade, not only because of its critical consequences on financing, provision, quality of and access to healthcare services in short term, and on the community's health parameters in long term but also because of the irreversible changes in values accompanying this process. Professional bodies such as Turkish Medical Association, unions such as Union of Health and Social Service Workers, some political parties and journalists, and writers and scholars from various disciplines have produced a great deal of literature on this issue and have mostly taken a negative stance toward it.

The transformation of healthcare has had two main components: not only has the previous system been gradually destroyed and replaced with the new one, but also new definitions for key concepts, such as "the state's social responsibility" and "right to healthcare," were suggested and a great deal of money and effort has been spent to make this conceptual transformation widely accepted. The first can be determined as the "structural change," which includes the emergence of new models for providing healthcare services, establishing institutions for financing and

regulating the "health market," and marketization of state hospitals and making relevant legislation. The latter is aimed at changing the thinking of people, an ideological turn, which served to create expectations compatible with market economy on behalf of the community and newly attributed identity for healthcare professionals as well as patients and individuals who are in need of healthcare services.

The transformation of the healthcare system, which has been implemented dramatically and drastically in the last 10 years, is about to be completed by the beginning of 2013 in terms of legislation. However, it seems that relevant structural change will take more time. Eventually, the organization of healthcare management will be decentralized, health institutions belonging to the state will be either completely privatized or made subject to free health market dynamics, the Ministry of Health's (MoH) responsibilities of financing and managing, and serving free, equal, and quality healthcare to every citizen will be reduced to a mere health market-regulating function. The state's social security institutions' coverage will also be narrowed gradually, giant health corporations and chains will continue to be supported by state resources, and medical education will be commercialized. Hence, while an increasing number of healthcare professionals will be losing their job security, their income security, and professional independence, individuals will have to pay either directly or through other mechanisms such as contribution margins or private heath insurances for every healthcare service they need to get. It is not hard to foresee that, on a very general scale, "health" will turn into a commodity, to be bought and sold, and "patients" will be customers buying services necessary for the quality of his/her own life.

When overlooking the historical epoch of social services in Turkey since the foundation of the modern republic in 1923, it is seen that free and equal access to healthcare has always been problematic. If one accepts providing every citizen with equal and quality healthcare services as a supreme ethical ideal, then starting from the foundation of Turkish Republic, which is said to be the point in history when the Turkish modernization broke through, this ideal has never been achieved. It is not surprising, as it is argued by many authors, that it is only possible if the political authority aims to provide these services for free as well. Although during the period of "socialized healthcare services" lasting from the early 1960s to the mid-1980s, Turkish citizens experienced practices in the health sector closest ever to the ideal mentioned above, being a capitalist state, Turkey has never had a free and universalized healthcare system.

Nevertheless, parallel to the "globalization" process and application of neoliberal policies, Turkey began to lose whatever practices, institutions, and understandings were inherited from the period of "socialized healthcare services." Accordingly, the "right to free, equal, and quality healthcare" was replaced by the promotion of "healthcare as a commodity." With the marketization of the healthcare system, it has been widely claimed that the idea that the state can provide with every citizen free, equal, and quality healthcare services, both therapeutic and preventative, was neither possible nor necessary. Once it was widely accepted that healthcare could not be free and cannot be equally provided anymore, then it was not that difficult as it

was 30 years ago to convince people that it can be treated as a commodity whose quality was variable according to where it is sold and for what price.

The commercialized healthcare system does not improve but limits access to equal and quality healthcare services. Before the neoliberal policies, healthcare services used to be brought to people's living spaces, for example, to their homes, working sites, and schools, through several mechanisms, such as working site doctors, first-step preventative services, health-scanning programs, and periodical region-based vaccinations. Today, these policies have mostly been abandoned. People are supposed to find their way to a health institution when they are sick or when they are in need of healthcare. In addition to that, a decree law was recently passed, including regulations for a completely market-determined healthcare system (see www.resmigazete.gov.tr, Anonymous, 2011c). According to this law, people will have to pay an extra payroll tax in order to have the right to benefit from "basic health assurance package" provided by the state. The content of this package is unknown yet. Moreover, they will start paying a "share" for every box of medication they receive and per examination session when they see a family physician. Hospitals will not serve for free either, but there will be diversity in prices, since health institutions will be classified and graded according to the level of accreditation they have. It is not hard to anticipate that stakeholders will invest more money where they expect more profit. Thus, it is anticipated that while health corporations will concentrate in some regions, some other parts of the country will have to be content with worse quality low-grade healthcare institutions.

Traditional Medicine

The most recent decree law (663 No.) regulating the provision of healthcare services recognizes practices called "traditional, supplementary, or alternative medicine" as a part of modern medicine and, thus, claims that such practices can be done in hospitals with the permission of the MoH. Traditional medicine and relevant practices have always been considered a research area within the history of medicine discipline. However, for quite a long time, ethicists have claimed that integrating such practices into the current healthcare provision system without any scientific inquiry on their reliability and validity is inconsistent with the scientific fundamentals of modern medicine. Apparently, this issue necessitates a bioethical evaluation with broad participation of scholars from the field, medical professionals, historians, and such.

Reproductive Medicine

Sperm and egg donation is prohibited by law in Turkey. However, allowing non-married women to utilize these methods has been an issue of hot debate. Besides the fact that the number of eggs to be transferred is strictly stated in Healthcare Practice Notification (SUT) and Medical Help Practice Notification (BUT), being

married is an absolute necessity to be eligible for such methods on the legal context. For that reason single women or irregular couples, such as homosexual or lesbian, have no right to use such artificial reproductive technologies. Limitations of the transfer number have been based on the scarcity of economic resources, and only the first transfers have been afforded by national health system. This limitation has been discussed by clinicians and found unrealistic.

Medical Research

Ethical aspects of medical research have occupied a considerable place on the public agenda recently. Especially, directions about funding and conducting research ethics committees have been changed frequently, and uncertainty prevailed until very recently. During the last 2 years, the MoH has put several regulations into rule. Configuration, rules of working procedures, and scope of research ethics committees happened to be the topics of disagreement between authorities. For example, TMA litigated one such regulation, since it used to limit the autonomy of TMA to elect its own representative who would have taken part in central RECs. When observed closely, this process has given the general impression that MoH does not want to leave the final decision especially about drug and medical technologies researches to local RECs. According to the most recent legislation, dated August 19, 2011, if an REC is not approved by MoH inspectors, then it cannot examine medical research about medications and medical technologies. The applicants whose research is approved ethically and scientifically by an approved committee must be directed to the MoH, so that they can get a second approval there to be able to start conducting their research.

Public Health

The period of 1960–1985 is worth mentioning, during which "socialized healthcare services" were implemented and generalized throughout the country to some degree (though not fully). There was a common understanding that providing every citizen with just, equal, and free healthcare was the duty of the state in that era. Despite their numerous defects and flaws they embodied, "socialized healthcare services" policies affected public health figures positively. However, problems such as regional inequality in access to health remained the same.

Starting from the beginning of the 1980s, the marketization operation in healthcare continues parallel to marketization of all social sectors. Under neoliberal policies apart from a small portion of the population, people are said to be deprived of adequate housing possibilities, balanced nutrition, systematic basic health education, sports facilities, cultural activities, and, last but not least, preventative healthcare services. In a world under the dominion neoliberal policies, which are actually shaped according to the wills of world capitalists, people are forced to migrate to bigger cities for work; since they have lost their job insurances, they have

to change their jobs frequently if not completely unemployed; and natural environment has been destroyed in rural areas in order to create new domains to be exploited, and urban spaces have been drastically transformed for profit under the name of "urban renewal."

In relation to public health, two processes work together against the best interest of majority of people: (1) The transformation of living and working conditions of the community for profit – this brings about a total destruction of social and natural measures to improve the secondary determinants of health. For example, in many factories, workers have to work without necessary measures and substructure, which would otherwise protect them from the possible harms of the job they are doing. They also work without insurance, for long hours up to 10–14 h a day, for very little money, under stress and humiliation. They can barely earn their living. The unemployment rate is quite high as well (around 19 %). Similarly, people are to leave their hometowns and migrate to the ghettos of big cities for work, where they are deprived of healthy living conditions. It is becoming more frequent that working class peoples' houses are taken from them by the state under a policy called "urban renewal." Only those who can afford the high prices can move to their new flats, which are said to be healthier. However, this claim is proved to be very suspicious with the reports of Union of Chambers of Turkish Engineers and Architects. (2) The destruction of preventative health services.

National public health figures might be suggestive about the consequences of these policies. However, these figures should be examined in terms of short-term and long-term consequences. It is widely accepted that displays, such as death at birth rate and mother death rate, cannot be observed in short term. The early data shows that the number of people seen by a doctor has increased since 2002. Similarly, there seems to be a decrease in death at birth rate. However, the reliability of these findings is controversial. It is difficult to obtain such comprehensive results of healthcare policies in a short time, namely, in several years. At least a decade is needed to obtain the first reliable data about public health displays. The effects of HTP on the general health status of people can only be anticipated to worsen but is not known yet.

Infectious Diseases

With the decentralization and opening up the health sector to free-market economy, it is claimed by public health scholars that it will be either very difficult or impossible to control infectious diseases. As a matter of fact, epidemics of previously eradicated, limited, or controlled contagious diseases were seen again in the last decade. These epidemics seemed confined to certain regions, for example, malaria was determined in southeast and cholera in some small cities. However, as with the case of tuberculosis, some diseases appeared again in big cities, like Ankara or Istanbul, especially in suburban areas.

The stigmatization of people with AIDS also continues to be a problem. Apart from a limited number of campaigns calling out particular groups, such as medical students

and healthcare professionals, to promote awareness about the syndrome, very few or no constant programs have been implemented aimed at the general public.

Transplantation Medicine and Organ Donation

Organ donation has always been a problematic issue. First, the number of donors is generally very limited and far from meeting the need of waiting lists. Second, it is observed that the religious beliefs have a retentive effect on many people about donating their organs. Third, the way the national media treats this issue might have some undesirable consequences, and thus, should be analyzed morally. News about transplantation medicine and organ donation is usually given with news of criminal deaths or death of young people. The main discourse in such news is benevolence, which is often served too dramatically, and far from being prudent, lacking scientific and systematic information on organ donation programs. Thus, the way the issue of organ donation is treated in the media is far from educating people on a conscious level, rather it is committed only by means of personal conscience. Fourth, the government tends to use this issue to propagandize how successful they are in their health policies. Recently, composite tissue transplantations, such as face and/or extremity transplantations, have been made very frequently in some big university hospitals. The MoH spared quite a big budget for these operations, since these interventions are totally free of charge but very expensive. Some cases were lost due to the risk of the composite tissue transplantations. The controversial aspect of this latest policy is that while the government seems to be proud of itself for its so-called worldwide successes in organ transplantation, it does not implement campaigns or education programs, to promote organ donations or support non-composite organ transplantation operations, while thousands of people are queued on the waiting lists. Fifth, Turkey is said to be on the conjunction point of organ trafficking routes; however, this issue has never been brought to the public agenda or discussed in front of public conscience by policymakers. Sixth, the government plans to establish organ transplantation centers which would serve on an international level. These centers are said to be established on health-free regions, where corporations would invest on healthcare sector completely unaffiliated with national legislation. This attempt seems to have undesirable consequences, since it might lead to the emergence of an organ market on international level and birth of an organ transplantation tourism industry.

Emerging Technologies

Today, medicine cannot be thought of apart from the high-technology products. Emerging technologies bring about both new possibilities and risks. Therefore, having a leading power on the development of new technologies becomes critical in order to control the risks/benefit ratio in favor for the second. However, Turkey

cannot produce its own biomedical technology consistent with its national necessities. Similarly, since Turkey has no national science policy, it has no national technological investment program either. Such initiatives are under the control of international corporations. This results in being subject to technological advancements rather than having a say in steering them.

Technological products are continually served to the healthcare market. Being a conscious consumer, as individuals or institutions, becomes critical in order to evaluate which products meet the current primary needs and which do not. With the marketization of healthcare, needs and other motivations such as maximizing the profits often contradict. Developing a critical approach to this issue seems to be an important task for bioethicists.

Lastly, the emergence of genetically modified organisms (GMOs) and their entrance into the food market should be analyzed carefully. There are also serious concerns about the possible negative biological effects of GMOs on national agriculture and animal breeding. GMO technology, which is said to be more efficient than the previous production techniques, is under control of international power groups, such as monopolies investing the GMO technologies, market, and industry. The fact that the GMO industry imposes itself over Turkey's national agriculture sector is another aspect of this issue, which is subject to hot debates.

Intensive Care

Unfortunately, this issue is one of the topics hardly debated. However, subjects such as "medical futility," "advance directives," "consent for organ donation," and "proper supervision of intensive care units" are in need to be examined and discussed in depth. "Which cases are to be accepted as futile, and what is to be done with them?" or "how to get the advanced directives for the patients under intensive care conditions?" are questions awaiting to be answered. Bioethicists in Turkey must work with neurologists, oncologists, surgeons, nurses, anesthesiologists, rehabilitation specialists and technicians, and administrators, in taking the very first steps in order to discuss and improve intensive care implementations.

Palliative Care

There seems to be no consensus among concerning parties on how palliative care should be conducted and improved. In addition, this issue is not a hot topic of bioethics discussions. Research focused on the needs and concerns of terminally ill patients, and their relatives are very few in number. Although the MoH currently covers medical expenses of terminally ill patients in state or university hospitals, there is no comprehensive scanning study about programming, standardization, and priorities of palliative care in the country. Bioethicists might play an important role in filling this gap, fostering efforts to organize palliative education programs in collaboration with clinicians, such as oncologists, surgeons, and rehabilitation practitioners.

Care for Elderly

There has been an increase in the aging population over recent decades. This fact necessitates taking measures. The most prominent issues seem to be (1) lack of social support mechanisms, (2) stigmatization, and (3) providing the elderly with medical care.

The limited official social support systems that had existed before have now been gradually abandoned and taken over by the private sector. The quality of state intuitions, where elderly people are cared for free, has been gradually corrupted, while the number of "quality" private companies providing elderly care services has increased. This becomes problematic because many people will not have access to these services. Luckily, it is a common tradition to take care of the elderly within the family. However, research on the quality of life and social support of elderly people is very limited.

Stigmatization does not seem to be a common problem in Turkey, as elderly patients are treated as patients from other age groups in hospitals. Nevertheless, some specific aspects of the professional relationship with the elderly are in need of attention. The participation of elderly people in daily social life is quite limited, due to a lack of necessary measures such as appropriate conditions for transportation, facilities where they can be productive and active, convenient areas for socialization, clean environment, as well as support mechanisms enabling them live more independently.

Medical care for the elderly is expected to be the subject of greater problems in the near future with the recent regulations transforming the healthcare system completely to a free-market economy. Elderly people usually have complicated medical problems and, thus, need intense, multidimensional, and time-consuming medical care, which can be expensive. Since care will not be covered by the state anymore, it is not unreasonable to anticipate that only a small portion of elderly people will be able to benefit from such medical care in a fully marketized system.

Chronic Diseases

Cardiovascular diseases, endocrinological diseases, and diseases related to physical medicine are the most common chronic diseases in Turkey. The quality of care for chronically ill patients and the timely access to chronic care need to be examined ethically.

General Practice

Informed consent has become one of the most significant topics in daily medical practice. Since obtaining informed consent has become one of the routine activities in medicine, it is necessary to add this subject to the medical curriculum.

The "family physicians" system, an important branch of Health Transformation Program (HTP), basically meant the marketization of first-step healthcare services. The first practices started in 2004 in some cities as a pilot study. In January 2010, the system was broadened to the whole country. With the system, the "health centers" structure and "healthcare teams" that were supposed to protect and improve the health condition of the population for which they are responsible were abandoned. Instead, it was claimed that first-step services were to be conducted by "family physicians," who are motivated for their own profit as they work under pay for performance. The "family physician" is considered responsible for both preventative and therapeutic services, as well as other expenses, such as the wage of employees, the rental costs and maintenance of the "family health centers" where they serve healthcare. The main character of the system is to attach individuals, not families, to physicians. Physicians have to compete with each other in order to catch up with the minimal number of patients registered, otherwise, their wages decrease. Public health scholars and experts from TMA anticipate that this system will have severe consequences. Primary healthcare services might not be conducted properly which would create severe problems by means of preventing diseases and improving living conditions of people. Besides, they claim that it would be harder to maintain the basic intrinsic values of the physician-patient relationship, such as trust, benevolence, and fidelity, because the physician would become a "seller," and the patient would become a "buyer."

Health Promotion and Education

The main determining factor, marketization of healthcare services, has also affected health promotion and education negatively. This aspect can be examined under two main branches: (1) promotion of "better health" toward general public and (2) medical education.

Parallel to the trends turning health to a commodity and destroying preventative healthcare services, a more systematic and comprehensive health promotion toward the general public, which used to be conducted by the state to some extent, has been gradually abandoned. Instead, health promotion campaigns and television programs or medical advertisements filled this gap. The promotion campaigns have usually been supported or organized directly by private hospitals, drug companies, and/or medical technology corporations. As people started to be seen as potential customers, these organizations began to function mostly as advertizing facilities. Medical advertisements have been used frequently through mass media with the same goal. As known, promotion campaigns are not systematic and are usually done for a group of people (not the whole community) for a limited period of time. Information provided by campaigns and in TV programs or advertisements are criticized by professionals because they are not thought to be based on scientific data.

The reorganization of medical education according to free-market conditions is an important component of this process. The commercialization process in the healthcare sector suggests that medical education will be left gradually to monopolies and will be privatized or marketized by public-private partnership policies in the near future. This can also be inferenced from the enormous increase in the number of private medical schools all over the country. State medical schools have been in financial difficulty, as their budget previously supplied from the Treasury was reduced. Therefore, they had to behave like a company, in order to sustain physical continuity and educational quality. Moreover, in the last 10 years, a lot of private medical schools were established. The Council of Higher Education has implemented policies toward limiting the administrative autonomy of medical schools in terms of the curriculum, the number of undergraduate students, and the student fees. Also, it is observed that the content of education is to be determined according to the working circumstances after school, namely, for the purpose of creating the type of physician who can adjust to the market conditions. While perspectives associating the medical profession with values, such as equality, public benefit, and social justice, are being abandoned, the education process is changing with the purpose of creating more submissive, competitive, individualistic, timid, and less quizzical healthcare professionals.

Relations with Industry and Donors/Sponsors

It is a well-known fact that many scientific activities in the medical arena were held with the sponsorship of the drug and medical technologies industry. Drug companies have supported many scientific gatherings, medical congresses, symposiums, etc., and financed research in several medical subdisciplines. Moreover, representatives of these companies have had continuous contact with clinical physicians through various methods. Many argue that there is enough evidence to substantiate that the industry has a remarkable effect on the conduct and even the results of many research studies (Gottlieb, 1999; Hensley & Abboud, 2004; Ibia et al., 2010; Lexchin, Bero, Djulbegovic, & Clark, 2003; Melander, Ahlqvist-Rastad, Meijer, & Beermann, 2003; Wahlbeck & Adams, 1999). Some authors even claim that if there is any relationship with the industry, it is intrinsically unethical (Civaner, 2006). Nevertheless, it is promising that recently this issue has been studied and discussed more often than before when representatives of scientific authorities, such as medical specialty societies, and the majority of researches considered it mostly normal and inevitable. “Conflict of interest” is another problem. Although both the TMA and the MoH have declarations about principles regarding the just conduct of relationships of physicians and researchers within the medical industry, this issue is not supervised strictly in Turkey. Relations with drug companies have been perceived as legitimate within the medical society, even though this issue has been criticized by several bioethics scholars and discussed to some degree in a few studies examining the moral

aspects of physician-drug company relationships. Initially, researchers should be asked to declare that they have no conflict of interest while conducting medical research and presenting their results. Necessarily, bioethics scholars should also focus on this issue more intensely.

Future Challenges

In the Field of Bioethics Infrastructures

The standardization of ethics education on the undergraduate and postgraduate level as well as the establishment of an autonomous and interdisciplinary national bioethical committee seems to be the major challenges for the near future. Relating to the undergraduate ethics education in Turkey, although it is mandatory in approximately 75 medical schools, standardization is necessary in terms of curriculum, teaching methods, and competence of scholars. This effort will make it possible to reach the aims expressed in the National Core Curriculum as well. The foundation of a national advisory bioethics committee, which would work independently and autonomously on this issue in order to create a discussion platform in the light of national priorities and needs, would help solve relevant problems on both cultural and social bases.

In the Field of New and Emerging Issues

In Turkey for the last 20 years, new sci-tech tools have been invading the daily life. For that reason, creating awareness in public opinion on commercialization of life and preventing acts of populism seem important. Despite paternalistic trends in the cultural context, there has been important progress in obtaining informed consent. However, protecting patient privacy has always been a problematic aspect of this process due to the bureaucratic procedures in health reimbursement systems.

The protection of vulnerable groups, such as minors, mentally handicapped, immigrants, and refugees, is another important issue regarding the right to access to healthcare for all of society.

Other Problems and Opportunities for the Further Development of Bioethics

Ethics as a basic field for humankind necessitates a free discussion environment and open inquiry. Most of the time, a suitable normative base is maintained after a prolific and fruitful discussion. All relevant parties of the society should find the opportunity

to express their own opinion through such a discussion process. During the preparation of new legislation, common and widespread debate processes have not been realized; it seems to be an important point in the way of democratization which is related to the expression of bioethics in daily life (Arda, 2009).

Summary Conclusion

Bioethical debates seem to follow two main interrelated paths: (1) the increasing necessity to answer questions arising from structural changes in healthcare in accordance with the marketization process of social services and, thus, to redefine current concerns about what the future is going to be like and (2) bioethicists' growing interest toward medical law and vice versa. This distinction also reflects the two dimensions of marketization in healthcare: a vivid confusion about conflicting values and efforts to constitute legislative regulations necessary for a new paradigm. While bioethicists have been reluctant to define and examine the former, they are often called for providing moral ground for new legislations with regard to the latter.

The marketization process, which started by the beginning of 1980s and gained speed during the last 10 years, is about to be completed by the first half of 2013. In terms of the healthcare system, a structural transformation necessitated a coherent ideological framework. In short, healthcare services have been commercialized, health institutions have been privatized substantially, and healthcare professionals have been forced to leave their previous rights, such as employment assurance, income assurance, and professional independence, and accept working under circumstances of a new health market economy.

How justifiable it is to replace previous values with new ones, which have been promoted as intrinsic to inevitable trends of the "new world order," is a question currently underlying many discussions of the field of bioethics. Parallel to this comprehensive paradigmatic transition from the understandings and institutions of social state to those of a complete free-market economy state, moral conflicts on the macro-level have happened to cover a great portion of the bioethics agenda. They have been widely challenged by professional bodies, unions, practitioners, and also scholars from other disciplines, such as law, sociology, and public health. Limitation of free access to healthcare, growing inequalities between different social classes and regions by means of basic parameters about health, implementation of pay for performance and flexible working models in the healthcare sector, decentralization of the healthcare system, emergence of public-private partnership, giant hospital-chain enterprises, etc., are some examples to the components and results of HTP. Parallel to this comprehensive paradigmatic transition from the understandings and institutions of social state to those of a complete free-market economy state, moral conflicts on a macro-level have happened to cover a great portion of the bioethics agenda.

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Ukraine

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Svitlana Pustovit and Liudmyla Paliei

Introduction

Bioethics in Ukraine as in many post-Soviet countries has been developing in the context of preceding millennial experience. From the 1970s to 1980s, Soviet scientists got involved in research of the ethical dimensions of science, techniques, medicine and biology, the relationships between values, science, and society. Along with foreign scientists, they came to underline the hazards of modern science and technologies as well as the need for development of philosophical fundamentals

S. Pustovit (✉) • L. Paliei
Philosophy Department, The Shupyk National Medical Academy of Post-graduate Education, Kyiv, Ukraine
e-mail: pustovit-svetlana@rambler.ru; l_paliei@ukr.net

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and ethics of science and technology. Ethics of science was discussed within the frame of biophilosophy proposed by Soviet philosopher I.T. Frolov (Frolov & Yudin, 1986; Pustovit, 2009).

Until the early 1990s, the term "bioethics" had been used only as a scientific term; the content of bioethical principles had been interpreted in the light of social values and collectivistic ethics. Personality, individual autonomy, and dignity as well as freedom of choice had remained subordinate to social priorities (Frolov & Yudin, 1986). Therefore, the society had lacked constructive criticism of the traditional paternalism of medical ethics and the ethics of Hippocrates. Any "nonacademic" approach (including religion) to the problems of ethics and the values of science had been rejected.

However, the ideas of cosmism (harmony of society, nature, and the cosmos) were developed in the Soviet Union. A concept of the evolution of humankind suggested by Academician V. Vernadsky gained popularity. According to these views, the planet is at the beginning of a new evolutionary stage of its development – the noosphere or sphere of reason, where scientific thought plays a crucial role (Vernadsky, 1991). Therefore, the concept of global bioethics as comprehensive ethics and philosophy, proposed by the American scientist V.R. Potter, found a fertile ground for development in the post-Soviet countries including Ukraine.

In 1991, Ukraine became an independent state. Implementation of a neoliberal model of social development in Ukraine in the early 1990s led to significant losses in social guarantees and a decline in civil rights. The systems responsible for securing national interests in the area of economics, education, health care, ecology, and property management turned out not to be effective enough to provide social protection of the population. The income gap polarized the society into the extreme rich and the extreme poor. The health care and ecology standards decreased owing to reduction in budget support. Infringements of basic constitutional provisions concerning social orientation of the state, its major responsibility, namely, securing fundamental rights and freedoms of the citizens, caused emerging national security challenges and threats.

It was apparent that the present system of health care and environment protection needed to be changed in the light of new democratic values and priorities, protection of man's fundamental rights and freedoms.

More than 10-year experience with bioethics in Ukraine led to the implementation of global bioethics ideas and principles into education, medical legislation, health-care practice, clinical trials, and environment protection.

Bioethics Development

When and How Did Bioethics Start?

Until 1991, Ukraine had been part of the USSR; therefore, originally its scientists had investigated philosophical problems of biology, medicine, and ecology in relation to Soviet philosophy and the Marxist paradigm. After the breakup of the

USSR and the appearance of new independent states, society faced difficult tasks of development of new legal frameworks and ethical principles in the field of medicine, health care, environment protection, and social politics.

In the last 10 years, bioethics, after having been a section of philosophy of science in the past, has turned into a fast-developing area of public discussion, interdisciplinary studies, social practice, and education. The social movement committed to ideas of bioethics propagation and implementation of its principles into practice has been developing.

Since November 1995, when Ukraine became a permanent member of the Council of Europe (CE), Ukrainian representatives have been working actively at the Steering Committee on Bioethics at the CE. In the framework of this activity, Ukraine participated in the development of all international bioethics documents including the Convention of Human Rights and Biomedicine (Oviedo, 1997).

On 25–29 September 2000, the First Ukrainian-British Bioethics Symposium, organized and sponsored by Kyiv Research Centre REAL, the Ukrainian Association on Bioethics (UAB), the Shupyk Kyiv Medical Academy of Post-graduate Education, University College and Guys Hospital of London University, Whitefield Institute, and Green College of Oxford University, was held in Kyiv.

Who Have the Major Actors/Forces Been?

In 1998, the National Committee on Bioethics at the National Academy of Sciences of Ukraine (NASU) was established on UNESCO's recommendation. Later it was transformed into the Commission for Bioethics at the Cabinet of Ministers of Ukraine, then into the Commission on Bioethics Issues at the NASU. Now it is a central body for coordination of bioethical activity in Ukraine. Its activity contributed to establishing contacts between Ukrainian scientists, Ukrainian government, nongovernmental organizations (NGOs) and UNESCO, WHO, Council of Europe, European Parliament and European Union, NGO in CIS and other countries. The Commission takes an active part in different bioethics activities: bioethics symposia and congresses organizing, implementation of bioethics principles into legislation and social practice, public bioethics discussions, education in bioethics, etc. Now it is a central coordinative and organizing center on bioethics in Ukraine. Its responsibilities include the following: bioethics education; drafting recommendations for bioethical expertise, development of proposals concerning legislation in the field of bioethics; support of Ukraine in international cooperation regarding bioethics; coordination and monitoring of departmental bioethics commissions' and committees' activities; and informing the public about current concerns in bioethics. The Commission is an organizer of regular International Congresses on Bioethics (2002–2013) in Kyiv.

In 2000, the Ukrainian Association on Bioethics (UAB) became the first officially registered all-Ukrainian nongovernmental organization committed to propagation of bioethics ideas, which consolidated under the aegis of philosophers, biologists, health professionals, scientists, and public representatives. Organization

of the First Ukrainian-British Bioethics Symposium in 2000 and translation, publication, and free dissemination of the book "Bioethics: bridge to the future" by the founder of bioethics V. R. Potter by UAB in 2002 became important steps in the development of bioethics in Ukraine. The first monograph on bioethics in Ukraine "Bioethics: beginnings and foundations. Philosophical and methodological analysis" (Authors: S.V. Vekovshynina, and V.L. Kulinichenko) – was published by UAB in 2002. The first Ukrainian Standard Operation Procedures for Ethics expertise of biomedical research was developed and published by UAB in cooperation with the National Scientific Centre for Medical and Biotechnical Research of the NASU. UAB is an organizer of regular International Symposia on Bioethics (2000–2012) in Kyiv.

Various public organizations, such as the Psychiatric Association of Ukraine, the National Scientific Centre for Medical and Biotechnical Research of the NASU, the Information Centre for Bioethics, Kyiv Ecological and Cultural Centre, Kharkiv Humane Society, the Bazylevych Institute of Bioethics, the Ukrainian Medical and Legal Association, Institute of Medical Law, Pharmaceutical Law and Bioethics at the Academy of Advocacy of Ukraine, the All-Ukrainian Council for Patients' Rights and Safety, the All-Ukrainian Physicians' Society, have become the major actors of bioethics developments. With their efforts, a number of foreign books, journals, and other materials have been translated into Ukrainian and Russian; course books and teaching manuals on bioethics have been written and published to be used in Ukrainian universities and institutes; many seminars and symposia on bioethics have been held; and bioethics training programs have been elaborated.

What Have the Major Concerns Been Over Time?

A range of topical issues pertaining to bioethics in Ukraine have arisen over time: (1) the clarification of theoretical and methodological fundamentals of bioethics important for bioethics as a special branch of science; (2) the acquisition of status of an academic discipline taught at higher educational institutions; (3) the implementation of bioethical principles and requirements into Ukrainian legislation and social practice; (4) building relations with European international organizations (UN and UNESCO, WHO, etc.) in the area of bioethics; and (5) the standardization of ethics expertise and accreditation of ethics committees.

What Resources Have Been Developed (e.g., Books, Programs, Media, Networks, Societies)?

Over the last 12 years, about 20 large symposia and congresses as well as a great number of smaller seminars and workshops on bioethics, medical law, and ethics committees (Kyiv, Khakiv, Lviv) have been held in Ukraine. Lots of articles, brochures, and books on medical ethics and law issues, bioethics, and ethical

expertise have been published. Several fundamental studies in theoretical and practical issues of bioethics, which resulted in defense of candidate and doctoral theses in philosophy of science and ethics, have been conducted.

It is necessary to mention the great role of WHO, United Nations and UNESCO, other international organizations, and funds in the development of bioethics in Ukraine, constant collaboration of Ukrainian NGOs with Russian, Belarusian, and Moldavian bioethicists and other countries of the Commonwealth of Independent States (CIS).

Ukraine takes an active part in the development of bioethics at the international level represented by its experts; it participates in work of the European Council, United Nations and UNESCO, WHO, and other organizations. In particular, Ukraine participated in discussion and adoption of the United Nation International Convention against the Reproductive Cloning of Human Beings (International Convention against the Reproductive Cloning of Human Beings, 2005) and UNESCO's Universal Declaration on Bioethics and Human Rights (Second Session of the Inter-governmental Meeting of Experts aimed at Finalizing a Draft Declaration on Universal Norms on Bioethics, 2005). In 2010, the Ukrainian Unit of the UNESCO Chair in Bioethics (based in Haifa, Israel) on the basis of the Academy of Advocacy of Ukraine was established.

In 2001, an important bioethical resource – the Forum for Ethics Committees in the CIS (FECCIS) – was established in the CIS region within the framework of the WHO project "The Strategic Initiative for Developing Capacity in Ethical Review" (SIDCER). During the period of its existence (2001–2007), Ukraine was involved into FECCIS activities: development of regulatory and methodical basis of research ethics and ethical expertise, development and implementation of educational programs for members of ethical committees, creation of information space and extensive dialogue of different parties involved in the ethical review of biomedical research, and process of harmonization of regional and international ethical standards in biomedical research (Kubar, Yudin, Nikitina, & Vladimirova, 2007).

What Steps/Measures Have Been Taken (Policies, Legislation, Infrastructures, Teaching Programs, Committees, etc.)?

Transformation of Ukrainian legislation toward meeting international requirements to conducting biomedical investigations, obtaining informed consent to medical intervention from patients, ethical work, has been initiated in the second half of the 1990s.

The first step in bioethics development was establishment of the Ethics Committee at the state Pharmacological Centre of the Ministry of Health (1995), transformed into the Central Commission on Ethics Issues (exist from 1996 till 2012), and local ethics committees at higher educational institutions, research institutes and medical and prophylactic establishments in order to provide ethics expertise in clinical trials and other biomedical research.

The Commission on Bioethics headed by the vise-president of the National Medical Academy of Science of Ukraine (NMASU) Yurii Kundiev (at the Ukrainian Cabinet of Ministers; 2001–2005) transformed into the Commission on Bioethics Issues at the Presidium of the NASU (exist from 2005 till now); the Commission was created for coordination of all bioethics actors in Ukraine. Many other public organizations and centers promoting bioethics have been created in Ukraine during 2000–2012.

Of huge importance is the Law "On Pharmaceutical Products" in line with requirements of the Directive 2001/20/EC of the European Parliament, the Council of Europe, ICH-GCP, and the Declaration of Helsinki; the law was approved by the Ministry of Health of Ukraine in 2006. The law specifies regulation of development, manufacturing, operation, exploitation, control over security of pharmaceutical products, and determines the rights and obligations of persons, responsible for their putting into operation or exploitation in Ukraine.

In 2004, an elective course in bioethics for students of the 5th year at medical universities was approved by the Ministry of Health. The course consists of lectures (10 h), practical seminars (17 h), and students' individual work (54 h). Today, bioethics is approved as a compulsory course only in medical specialties (dentistry, pharmacy).

Current Bioethics Infrastructure

Teaching of Bioethics at University and Other Levels

Since 2000, some bioethics courses and training modules have begun to appear in the undergraduate and postgraduate university programs for medical professionals, biologists, social workers, and veterinaries.

Today, bioethics in Ukraine is mostly taught as a part of philosophy training program or as a fragment of routine courses for medical students, biologists, or veterinarians.

The Philosophy Department of the Shupyk National Medical Academy for Postgraduate education (Kyiv) was one of the first in Ukraine to introduce the course "Bioethics as modern medical ethics" (12 h) for postgraduate students in 2000. Today, it has a great experience in bioethics teaching for medical postgraduates. A considerable experience in teaching bioethics and organizing of methodical seminars for students has been accumulated at the Bohomolets National Medical University and at Ukrainian Medical College (Kyiv).

In the western region of Ukraine, bioethics is taught in the context of fundamental principles of Christian morals. The Galytsky Lviv Medical University offers an elective course in bioethics for the third year students. The Valeology Department at the Karazin Kharkiv National University has become a methodological and theoretical center for teaching bioethics in Eastern Ukraine. It offers a special course "Bioethics as the ethics of health" (90 h). Bioethics is also taught at institutes of higher education in Dnipropetrovsk, Zaporozhzhia, Luhansk, Odesa, Poltava, and Sumy.

Development of bioethics courses in Ukraine is still complicated by the fact that many professors during the Soviet period taught Marxist philosophy and had no opportunity to study special foreign literature and discuss bioethics problems with foreign colleagues freely.

In Ukraine as in other European countries, there is a tendency to teach bioethics not as global bioethics but as applied biomedical ethics. The reason is that the majority of bioethics teachers for medical students are physicians with a pure humanitarian background which influences the general tendency of bioethics education and academic discussion of main bioethics problems.

Bioethics Committees

In the beginning of the 1990s, bioethics committees began to be established.

The Ethics Committee at the State Pharmacological Centre of the Ministry of Health (then - Central Commission on Ethics Issues at Ministry of Health of Ukraine) was the first central body aimed to systematize ethical expertise of all biomedical research in Ukraine in 1995.

Over the past 10 years, the Central Commission on Ethics Issues at the Ministry of Health of Ukraine has reviewed over 2,000 drug trials, more than 500 of them being multicenter ones. In 2010, local ethics committees and commissions monitored biomedical investigations at 412 health-care facilities and medical establishments within Ukraine. The number of large-scale clinical trials amounted to 384 and 30,000 individuals (11,000 in 2005) participated in them (Kornatskii, Talaieva, & Silantieva, 2011).

However, there are still a lot of unresolved issues: (1) institutionalization of ethics committees, (2) securing their independence, (3) establishing hierarchy and relations between ethics committees at different levels, and (4) training and certifying of members of ethics committees. The creation of an association of ethics committees is essential for the coordination of their work, the protection of those involved in investigations as well as the professional development of the researchers.

Unfortunately, it should be noted that the degree of formalization and bureaucracy of ethical expertise in Ukraine is rather high. This defect can be avoided only by comparing “ideals” (projects that are declared) with “reality” (the practice of biomedical research). The fact is that the existing “paradigm" of ethical expertise has a “preventive and idealistic” character: It aims to prevent adverse and side effects of studies and minimize potential risks to subjects not during research but at a design stage. That is why the idea of the real “monitoring” of studies is rather slow to move and put into practice. Thus, the principle of prevention is simultaneously both the main advantage and weakness of the ethical expertise paradigm.

Lack of financial resources and weak material base of ethics committees are related to the functions and status of local ECs as independent and not-private organizations. Institutions are usually not interested in the development and financial support of the ECs functioning in their premises. The problem is that the list of

financial activities authorized for institutions includes only scientific expertise; ethical expertise is not included in this list.

A great resonance got a question of a division of powers and responsibilities between the Central Ethics Commission of the Ministry of Health and local committees. In 2007, the Ministry of Health of Ukraine developed "Typical Regulation on the Ethics Committee," which has several provisions that conflict with each other. Thus, it said that all "ethics committees are equal in their powers to approve the clinical trial," but during a multicenter clinical trial, the applicant must apply for approval of clinical trials exclusively to the Central Ethics Commission of the Ministry of Health. In practice, this provision actually deprives local ECs of the right to "approve" and monitor not only multicenter, but single-center clinical studies at the institutions where they work.

In 2010, the draft Law of Ukraine "On pharmaceutical products" was posted on the official Web site of the Ministry of Health for public hearings; in 2012, new rules restoring the authority of local ethical committees in ethical expertise of clinical and other biomedical research were approved.

As the first country in CIS, Ukraine introduced the "Ethical code of Scientists"; it was approved by the National Academy of Science of Ukraine in 2009.

Expert Bodies/Centers

The Ministry of Health, the Ministry of Environment Safety, National and Medical Academies of Sciences of Ukraine, philosophical and medical chairs at universities, many NGOs, and ethics committees are involved in the process of implementation of bioethics principles into biomedical research, medical practice and environment protection.

The Commission on Bioethics (2012) at Ministry of Health of Ukraine, the Commission on Bioethics issues at the Presidium of the National Academy of Sciences of Ukraine, and numerous local committees have been playing a great role as expert bodies.

The Commission on Bioethics issues at the Presidium of NASU prepared recommendations on the ratification of the Convention on Human Rights and Biomedicine for the Ukrainian Parliament. In cooperation with the Ministry of Justice, much work has been done on comparing Ukrainian legislation with the main statements of every article of the Convention. Ukrainian bioethicists are also UNESCO bioethics experts.

Relevant Legislation

The Constitution of Ukraine is the main law proclaiming the priority of the individual, his/her life and health, dignity, honor, personal inviolability and safety, protection of human rights and freedoms (art. 3). The Constitution states the principle

of freedom and equality with regard to human rights and dignity (art. 21); nonadmission of discrimination (art. 24); the inalienable right to life (art. 27); and everyone's right to have their dignity respected (art. 28). The Constitution declares that everyone has the right to health protection, medical care, and medical insurance (art. 49), and that everyone has the right to an environment that is safe for life and health is guaranteed by the right of free access to information about the environment situation, the quality of food, and consumer goods (art. 50). Thus, the Constitution secures the fundamental human rights to life and health.

Another important document is the Basic Legislation on Health Care in Ukraine. This law was adopted in 1992. It has continuously been revised and amended. It sets general health-care principles. There are some other important laws concerning bioethics issues: On Pharmaceutical Products, On Prevention of AIDS and Social Protection of Population, On Providing Psychiatric Care, On Prohibition of Reproductive Human Cloning, On Transplantation of Organs and Other Anatomic Human Materials, On Rules of Conducting Clinical Trials of Pharmaceutical Products and Reviewing Materials of Clinical Trials.

In 2004, the representative of Ukraine, professor Z.A. Shkiriak-Nyzhnyk, was elected to the Board of the Steering Committee on Bioethics of Council of Europe as a Committee Reporter on the activity of Ethics Committees at medical research institutions. In the framework of the Steering Committee on Bioethics of the Council of Europe, Ukraine participates in the development of guidelines for the protection of fetus and embryo, and in the design of a protocol related to genetic testing (Kundiev, Chaschin, Chaschin, Pustovit, & Vitte, 2007, p. 320).

Public Debate Activities

The end of the twentieth century was marked by the collapse of totalitarian regimes, renewal of private ownership, and drastic changes in the professional and practical ethos in post-Soviet countries, all of which promoted extensive discussion of bioethics problems in the society, first of all in the field of medicine and health care. Issues of corruption in medicine and ethical principles of health-care delivery, doctors' errors, informed consent, problems of organ donation, and others got prominent coverage in leading newspapers and journals.

A number of TV programs and sites on the Internet are devoted to problems of high-quality medical aid. Of great public resonance was a fatal case in Cramatorsk (Donetsk oblast). A schoolboy died after vaccination against measles and rubella due to untimely medical aid (The schoolboy died from toxic shock, 2008). The criminal case of activity of "black" (illegal) transplant business was also widely discussed. The group of four Ukrainian surgeons, who worked at one of the well-known Kyiv's clinics, used their official positions to take part in a criminal group that recruited and transported citizens of Ukraine abroad for illegal transplantation of kidneys (2007–2011) (Crime of transplantologists, 2012).

Public discussion concerning rights of dying people as well as ethical principles of biomedical studies with involvement of people is virtually absent. Problems of widespread corruption at medical establishments as well as overpricing medical products and medicines are hushed up.

Other

Use of laboratory animals in scientific research is regulated by the Law of Ukraine № 3447-IY of 21.02.2006 "Against the Cruel Treatment of Animals" and "General Ethical Principles of Experiments on Animals" adopted by the First Ukrainian National Congress on bioethics in 2001. According to these regulations, laboratory animals are to be provided with humane care and healthful conditions during their stay and use in research.

Major Bioethical Issues and Discussions

Beginning of Life

Legalization of abortion is an important embodiment of the bioethical principle of respect for autonomy and women's choice. Abortion is available on request during the first 12 weeks of gestation. Thereafter, induced abortion is available within 13–22 weeks from conception, on judicial, genetic, vital, broad medical, and social grounds, as well as for personal reasons with the special authorization of a commission of local physicians.

Since 2006, according to the Ministry of Health Order N508 Statement on Abortion Procedures and Obligatory Requirements Regarding Statistics Recording (2006) and Resolution N144 of Cabinet of Ministry Realization of Civil Code Chapter N281 (2006), the social grounds and personal reasons discontinued to be indications for abortion performance in the second trimester. According to the law, only assault or incest, life-threatening conditions, or fetal impairment can be indications for legal abortion.

From January 2007 Ukraine follows WHO standards – a baby born after 22 weeks of gestation with weight $\geq$ 500 g is considered not as a foetus but as a new-born. However, the practice when medical staff strongly advise to have an abortion in any health disorders in pregnant woman or the fetus, in Ukraine, as in other post-Soviet countries, can be acknowledged to be rather common (Hrevtsova, 2011).

The current birth rate in Ukraine can be assessed as low (10.8 births/1,000 population as of 2010). Total fertility rate amounted to 1.45 children born/woman in 2008–2009 (Bogatyreva, 2011). As specified in the annual report of the Ukrainian Institute for Strategic Studies, the Ministry of Health, the birth rate compensates only about half of the death rate (Annual report about health condition, sanitary and epidemiological situation in Ukraine, 2008). It is associated

with transition to a modern European model of childbearing: increased mean age of mother at childbirth, postponement of the initiation of childbearing, decreased number of children, decreased birth rate at younger fertile age, concerns about medical complications and infertility at a later age, and other social and economic circumstances.

Iodine deficiency disorders (IDDs) are recognized as a national health problem in Ukraine. According to some studies, about 38 million Ukrainians suffer from iodine deficiency to varying degrees. Of the 417,000 children born each year, 341,000 have congenital iodine deficiency (Iodine deficiency in Ukraine becomes threatening, 2008). Unluckily, various business interests related to promotion of iodine-containing preparations in the pharmaceutical market in the county are the only reasons why health-care specialists have not yet supported adoption of the law on universal salt iodization.

End of Life

Average life expectancy is one of the lowest in Europe (67.9): Maximum male life span equal 64.2 years was registered in 1992–1992; in women, it was 74.9 in 2008–2009 (Bogatyreva, 2011, p. 123–124).

The problem is that Ukrainians do not get high-quality medical care at the final stage of their life. Palliative and hospice care have not been developed in Ukraine. This worsens the suffering of dying people and is indicative of a lack of a humane attitude toward them on the part of the state and society.

As for the terminal stage, according to Ukrainian legislation, it is a physician's responsibility to give medical aid to any patient for improving his or her condition. At present, euthanasia is forbidden and being treated as premeditated murder. As provided in Clause 115 (intentional homicide) of the Criminal Code of Ukraine, it carries punishment of up to 7–15 years imprisonment. Current legislation is not promoting the liberalization of this issue.

Health and Disease

According to the WHO prognosis, Ukraine's population could fall from 45,778 million (2010) to 30 million (by 2030), if medical care in the country remained as low standard as it is at present. In many ways, today's dramatic situation in health care and environment protection can be explained by the loss of moral values and priorities of the society that existed during the Soviet period as well as political and economic instabilities.

Outstanding physicians who lived and worked in Ukraine during the twentieth century (M. Maksimovich-Ambodic, D. Samolovich, M. Pirogov, N. Strazhesko, A. Bohomolets, M. Amosov, and others) not only followed high ethical standards and rules in their medical practice but also developed and extended them (Kundiev et al., 2007). They used new methods of diagnostics, treatment, and prevention only

after having studied those in research on animals and often in "auto-experiments." They developed the best tradition of Zemstvo medicine (a special form of medical and sanitary care of the rural population in 1864–1917) and were against an abnormal system of private medical practice that made physicians to live on money they received from their patients. They tried to develop a new system of public health care based on democratic principles, equity, creative approach, and with the emphasis on preventive medicine.

In the Soviet period, medical ethics used the best of what had been accumulated by preceding generations. All medical graduates took the Oath of the Soviet Physicians based on Hippocrates Oath and collectivistic ethics. However, in practice, the totalitarian state often used physicians, their knowledge, and power for non-humanistic and moreover repressive aims, for example, psychiatrists for punishment of dissenters.

Health-Care System, Access to Health Care

One of the cardinal bioethics principles is respect for autonomy and informed consent. According to Ukrainian Law "Basic Legislation on Health Care," a physician is obliged to explain the patient the state of their health, the goal of suggested research and treatment measures, and a prognosis for a possible disease evolution including potential risk for person's health and life. The patient's consent should be sought before applying methods for diagnostics, treatment, and prevention of a disease (art. 43.1).

In spite of the fact that the right to free medical care provided by state and municipal medical establishments is guaranteed by the Constitution (art. 49), in the majority of cases, people have to pay the full cost of medicines and services out of their own pockets. Due to chronically underfunded health care, legislation of Ukraine in terms of free medical care is violated almost in all regions of the country as patients are illegally charged for medical services. Considerable contingents of people with low social and economic status have problems with access to health care. Untimely delivery of medical care, territorial remoteness of medical establishments, waiting in long queues to see the doctor, high cost of medicines, and corruption are among the main causes.

Unfortunately, systematic recording and analysis of cases of medical harm is not done in Ukraine. Huge public and personal financial resources have been spent to relieve the consequences of medical harm and for social payments to the disabled (Legal nuances of medical errors, 2012). According to the State Court Administration, in 2009, only 10 persons were convicted for improper performance of their health-care professional duties, including those resulting in death or other grave consequences (Legal nuances of medical errors, 2012).

Presently (2011–2014), a pilot project on reforming medicine is being implemented in Kyiv, Vinnytsa, Dnipropetrovsk, and Donetsk oblasts (regional authority areas). According to the new conception of medical service the following are envisioned: (1) medical care will be provided at three levels: primary,

secondary, and tertiary health care; (2) the main care will be delivered by family doctors who must supersede internists and specialized doctors; (3) first aid will be reformed; and (4) budget funding for free care delivery will be preserved, and medical care insurance, hospital funds, and other ways of cash security will be implemented (Health care reform in Ukraine will start in 2014, 2012).

Traditional Medicine

In the Soviet tradition, traditional medicine is considered to be the official scientific medicine. All other areas of medicine (folk, homeopathic, Oriental) are referred to as nontraditional or alternative medicine. There are several governmental and nongovernmental institutions of alternative medicine which train the relevant specialists.

A new discipline, valeology, which has flourished in recent years, appears to be interesting as an area of alternative medicine (Kulinichenko, 2001). Valeology is the science of how to keep healthy. It includes knowledge and skills to be healthy, which can be scientifically proven but have not officially been recognized yet. Several valeologic centers have been created, for example, in Kyiv, Kharkiv, and Sevastopol. Valeology as a discipline is officially taught for teachers at the Karazin Kharkiv State University.

Genetics

According to the Law on Prohibition of Reproductive Human Cloning (2004), it is unlawful to perform human cloning as well as to import or export cloned human embryos. Ukraine has acceded to the European Agreement on the Exchange of Therapeutic Substances of Human Origin (1958), the International UN Declaration on the Human Genome and Human Rights (1997), and the Additional Protocol to the Convention on Human Rights and Biomedicine Concerning Prohibition of People Cloning (1998), that provide the general principles of manipulation of genetic material, which would not conflict with human dignity.

The Law on State Biosafety System of Creation, Trials, Transportation, and Use of GMOs was adopted in 2007. However, this law has several deficiencies. The main gap of the law is that it does not involve establishing an institution responsible for providing safety of creation, trials, registration, transport, use, and utilization of GMOs. As a result, it can lead to the situation of fragmented responsibility and holes in biosafety systems. In addition, this law does not provide any registration procedure for GMOs either. No GMO threshold for food products is set; no labeling requirements are outlined (although mandatory labeling of GM food is provided by the Consumer Law). Finally, protected natural areas and zones of genetic safety for GMOs are not mentioned either (New Biosafety Law in Ukraine: Effort to Regulate or to Legalize GMOs, 2007).

Reproductive Medicine

Surrogacy programs including commercial surrogacy and surrogacy in combination with egg/sperm donation are legal. Ukrainian surrogacy laws are the most favorable in the world and fully support the individual's reproductive rights.

Surrogacy is officially regulated by Clause 123 of the Family Code of Ukraine and Order 24 of the Health Ministry (Reg. 04.02.97). Ukrainians can choose between gestational surrogacy, egg/sperm donation, special embryo adoption programs, and their combinations. No specific permission from any regulatory body is required. The prospective surrogate should be 20–40 years old. She must be mentally and somatically healthy and have at least one healthy child of her own. Surrogates must not have any relation to commissioning parents. A written informed consent of all parties (prospective parents and surrogate) participating in the surrogacy program is mandatory. The marital status of the surrogate is irrelevant. Ukrainian legislation allows prospective parents to carry on a surrogacy program and their names will be on the birth certificate of the child born as a result of the surrogacy program from the very beginning. The child is considered to be legally "belonging" to the prospective parents from the very moment of conception. The surrogate cannot keep the child after the birth. Even if a donation program took place and there is no biological relation between the child and intended parents, the prospective parents' names will be on birth certificate. Embryo research is allowed; gamete and embryo donation is permitted on a commercial level.

Medical Research

According to the Basic Legislation on Health Care (art. 44), the Law on Pharmaceutical Products and other legislative documents, new methods of prophylaxis, diagnosis, treatment, rehabilitation, and medicines, which have not been approved for use yet or are under trial, can be applied merely for the benefit of healing a person and only after obtaining their informed written consent. For 14–18-year-old patients, it is necessary to obtain their personal informed written consent as well as their parents' or other representatives' informed written consent (Lukianova & Shkiriak-Nyzhnyk, 2003).

However, in fact, doctors-researchers frequently make the following mistakes: (1) do not receive the informed consent from the patient leaving the latter uninformed about the fact that they are involved in a study; (2) obtain consent from patients not in writing but only orally, thereby violating the requirements regarding the scope and content of informing; and (3) design a consent form incorrectly, thus misleading participants. Unfortunately, clinical studies in many cases turn out not to provide any direct benefit to patients' health or be of little scientific value.

In many countries, the lion's share of medical research falls on clinical trials. Today, the list of problems in this area includes the following: (1) the accreditation

and licensing of clinical facilities for conducting clinical trials (CT), (2) the validity of placebo-controlled studies, and (3) state regulation of insurance of clinical trial subjects (Kornatskii et al., 2011; Zhupanets, Moroz, Bezuglaia, & Grintsov, 2011). Over the past 5 years, the number of studies on the bioequivalence of drugs as well as phase I clinical trials increased greatly. The first circumstance is of particular importance for Ukraine because the domestic market contains 86–92 % of generics. Conducting phase I clinical trials is complicated by the limited number of specialized clinics and the poor facilities as according to existing legal norms healthy volunteers can be hospitalized only in specially equipped hospitals.

Public Health

Ukraine currently faces a number of major public health issues. Besides a demographic crisis due to the high death rate and low birth rate, a high mortality rate among working-age males from preventable causes such as alcohol poisoning is a factor contributing to depopulation (http://www.worldbank.org/html/prddr/trans/julaug99/pgs3-4.htm). The high unemployment rate especially in rural areas might be considered among the main reasons. The nation also suffers a high mortality rate from environmental pollution, poor diets, widespread smoking, and deteriorating medical care (Starostenko,1998). Of current concern are consequences of the Chornobyl disaster which affected agricultural areas of 18,000 square miles, and estimates say that 40 % of the country's forested areas were also contaminated. As of January 1, 2010, 2,354,471 residents were registered by labor and social protection services as affected by the disaster. Analysis of the health condition of the affected cohort is indicative of an increase in the incidence of thyroid and breast cancers by 5.6 and 1.5 times, respectively (Bogatyreva, 2011, pp. 244–245). Insufficient provision of the affected population with non-polluted food has contributed to increased internal irradiation of the population. To mitigate the negative impact, the government subsidizes programs aimed at improvement of the affected population's health.

In addition to the UN Framework Convention on Climate Change, Ukraine signed and ratified the Kyoto Protocol (1997) which outlines the procedures and principles for sharing of the country's commitments to reduce greenhouse emissions. The country received over three billion hryvnias (375,000,000,000 dollars) for the sold quotas to reduce emissions of carbon dioxide into the atmosphere specified by the Protocol. In general, emissions of pollutants into the atmosphere from stationary sources are gradually reducing; on the contrary, emissions from vehicles are increasing.

Ukraine is one of the first countries in Europe to sign and ratify the Aarhus Convention (1998–1999). However, involvement of the public in decision making regarding the environmental situation is still difficult because of the lack of influential civilian institutions and corruption. Urban green zones and nearby forest areas are being destroyed to be built up with new blocks of flats and offices

in violation of the sanitary and other legislative norms; private and state enterprises often ignore safety rules; and advertising and sale of alcoholic beverages and cigarettes is widespread.

In recent years, there has been some decrease in rates of occupational traumatism, morbidity, accidents, and fires.

Infectious Diseases

Over 4.5 million Ukrainians, mostly children, are vaccinated for a wide variety of diseases each year. The Law on the Protection of the Population Against Infectious Diseases (2000) determines the legal basis for activities of bodies of executive power, bodies of local self-government, enterprises, institutions, and organizations, directed at prevention of human infectious diseases. Unfortunately, a widespread scare about vaccine side effects has led to a sharp drop in immunizations that could result in disease outbreaks spreading beyond the former Soviet republics.

In Ukraine, babies are to be vaccinated against tuberculosis (TB) at birth within the first 3–7 days and then revaccinated twice when 7 and 14 years old. In spite of this, Ukraine is among the countries with a high TB morbidity rate. The major challenges in TB morbidity are as follows: (1) increasing number of cases of multidrug-resistance TB, (2) lack of conditions for treatment of TB patients at temporary detention facilities, (3) TB coinfection in 50 % of HIV infected, and (4) underfunding of relevant state program for TB (Bogatyreva, 2011, p. 174).

Ukraine has one of the fastest growing HIV/AIDS epidemics in the world. Experts estimated at the beginning of 2010 that 360,000 people (0.78 % of the adult population) of Ukraine were HIV positive (Bogatyreva, 2011). As a result of large-scale antiretroviral therapy introduction in 2007, a decrease in the number of registered patients and mortality rates as well as a stabilization of these parameters in 2008–2010 were recorded, for the first time since 1994. However, access to antiretroviral therapy does not meet the patients' needs yet.

The epidemiological situation regarding hepatitis B and C is deteriorating because of the high risk of nosocomial and community-acquired infection in public and private dentistry surgeries, beauty and hairdressers' salons, due to inadequate quality of disinfection and sterilization in medical institutions in collecting and processing blood and its components.

Transplantation Medicine and Organ Donation

The first renal transplant in the world was performed by Prof. Yurii Voronoi in Ukraine (Kharkiv) in 1933. Today, however, Ukraine lags behind the USA and other developed countries in terms of the number of transplants. Ukraine has a mere 1.5 transplants per million (compared to 20–40 donors per one million residents in other developed countries) (Poliachenko, 2007).

The Law on Transplantation of Organs and Other Anatomic Human Materials (1999) established a presumption of the dead person's disagreement on taking their organs, and thus put an end to the practice of unauthorized organ harvesting that had existed back in the USSR. Each capable adult person during their life may give their consent or refusal to become a donor of anatomical material after death. In the absence of such a notarized declaration, anatomical materials from a deceased person may still be harvested with the spouse's, relatives', or legal representatives' consent.

Lack of effective legal mechanisms of donation promotion led to curtailment of transplantology and reduction in the number of legal transplantations. The existence of "black" market organ donation in Ukraine means that some poor people may sell their organs and some unmoral physicians are ready to make money on human health (Crime of the transplantologists, 2012).

Out of the scope of regulation of the law are such important medical interventions such as transplantation of gonads, reproductive cells and alive embryos, donation of blood and blood products, bioimplantates made from anatomical structures, and tissues harvested from cadavers for the further use in the reconstruction of bone or other tissue defects in the patient.

Emerging Technologies (Nanotechnology, Information Technology etc.)

In Ukraine, research institutes of the NASU and NAMSU, universities conduct research on nanotechnologies, nanobiology, nanomedicine, nanopharmacology, nanopharmacy.

Important studies on carbon nanostructures were held in the Shevchenko Kyiv State University in 1985, 6 years earlier than in Japan. A possibility of existence of tubular carbon (carbon nanotubes) was speculated. Manufacturing nanotubes by electrolysis in molten salts, which is considered to be the latest technique in the West, was developed by academician Yu. Delymarsky and coworkers in Kyiv as early as in 1964. These studies were ahead of time and remained non-demanded (http://nano.com.ua/content/blogcategory/23/40/).

The Paton Electric Welding Institute and the Bohomoletz National Medical University have developed methods for synthesis of nanomaterials of metals (silver, copper, iron) and organic compounds (carbon). The Chuiko Institute of Surface Chemistry of the NASU has been conducting research on nanodispersed silica suspension properties for the past 10 years.

In connection with development and introduction of nanoproducts in the Ukrainian society, the concept of ethics corresponding to the complexity of arisen ethical challenges generated by nanotechnologies has been discussed. Of current concern is the appropriate ethical education of scientists and engineers involved in nanotechnology. Ethical challenges associated with nanotechnology were widely discussed during the IV National Congress on Bioethics in 2010.

Intensive Care

In accordance with the Law on Transplantation of Organs and Other Anatomic Human Materials, a human is considered to be dead from the moment of brain death. The moment of death of a potential donor is established by consultation of physicians of the corresponding health establishment or research institution. These physicians cannot participate in harvesting the donor's anatomical materials, in their transplantation or manufacturing bioimplants.

IC ethical problems are as follows: (1) impossibility to perform high-quality intensive care at home or in an ambulance, (2) depersonalization of patients in hospitals, (3) failure of life-support equipment as a result of depreciation and lack of operating skills in medical staff and patients themselves, (4) iatrogenic harm of invasive methods of intensive therapy, and (5) limited doctors' personal responsibility for the patient due to the administrative governing in the state sector of health care (Zilber, 2009). IC units still lack beds as well as equipment of appropriate quality.

Palliative Care

In Ukraine, the first hospice facilities were established in 1997–1999 in Lviv, Ivano-Frankivsk, and Kharkiv. Today, there are ten in-patient hospice and palliative care departments at oncology and multidisciplinary hospitals in different regions. In some cities, there are several charitable palliative care structures at church and various public organizations. Unfortunately, the majority of them do not receive sufficient funding and are kept only by the enthusiasm of medical staff, volunteers, and support of local authorities.

In July 2008, the Institute for Palliative and Hospice Medicine under the Ministry of Health was created. The Institute is aimed at coordination of the development of the governmental palliative care program, improvement of relevant legislation, staff training, and development of relevant protocols and guidelines. Thanks to these activities, the number of palliative care facilities is increasing. In 2002, there were 400 in-patient beds in 12 palliative care facilities; in 2007, 550 beds in 18 facilities; and in 2008, 600 beds in 19 facilities (Gubs'kii, 2012).

But the number of palliative care facilities, their material and technical level, the legal basis for the accreditation and functioning, funding and delivering of health services, especially in terms of narcotic (opioid) analgesics use, in general, do not meet international standards, including the WHO protocols. The problem of availability of modern opioid analgesics, including tablet forms of morphine for palliative patients, remains unresolved in Ukraine, which causes sharp resentment not only on the part of patients and their families, but among doctors, general public, and domestic and international human rights organizations as well.

Christian churches have been established at many hospitals, with clergymen carrying out pastoral care for the dying.

Care of Elderly

The age structure of the Ukrainian population is indicative of a regressive type of generations' revival. According to the UN scale, the population is considered to be old when the percentage of people aged over 65 is more than 7 %. As a whole, in Ukraine, it has reached 15.9 % and among the rural population 19.8 %. Therefore, its population is estimated as very, very old. Along with high aging rate of people, Ukraine is distinguished by very high aging rate of the female population.

There is also an increasing population of the elderly supported by a decreasing number of taxpayers. Immigration and population decrease have increased this trend, which would doubtless be accelerated if Ukraine joined the EU. Secondly, some relatively inexpensive medical and social interventions could markedly decrease the numbers dying prematurely but leave them to consume more expensive health care.

Until recently, there have been frequent cases and relevant facts of nonpublic directives from administrations of medical institutions not to provide surgical and intensive care to people over 70–80, which is indicative of widely spread event of stigmatization and discrimination against elderly patients. Rural areas are particularly affected by the lack of necessary medical and social services. The lonely elderly in care homes, entirely dependent on the state, are in severe conditions.

The problems of obesity, which impact hugely on the health of the elderly, and of diabetes, which is increasingly prevalent and brings major problems especially to the elderly, need urgent attention and a multi-sectoral approach from government, health, schools, and the food industry itself.

Chronic Diseases

The health and demographic crisis is determined by constant decreasing and aging population over the past 10 years as well as an unprecedented high level of mortality, particularly from such chronic diseases as cardiovascular and cerebrovascular pathologies, malignancies, respiratory diseases, diabetes, and increase in number of people suffering from neurodegenerative diseases of the brain.

For a variety of economic and moral reasons, ideals of a healthy lifestyle, which were influential in the Soviet Union, gave way to the ideals of consumerism, the freedom of private business, and corruption. Moreover, due to the relatively high cost of diagnosing and lack of regular medical checkup, many chronic diseases are detected when being in advanced stages.

Chronic disease prevalence is high – nearly half of the adult population (i.e., those between 18 and 65 years of age) suffers from one or more chronic diseases or conditions. Angina, which is detected in 7.3 % of cases, is the most common disease. Elevated cholesterol (3.8 %) takes the second position, diabetes mellitus (3.6 %) and osteoporosis (2.4 %) the third and the fourth position, respectively. The prevalence of cancer among Ukrainians is 0.8 %. Most Ukrainians simply do not live up to the age group which represents the average age for cancer rise (data of the World Bank).

Smoking poses important medical and social problems. It's a grave danger to public health, which contributes to a range of chronic non-communicable diseases: cardiovascular, malignancies, chronic obstructive pulmonary diseases, etc. At least 45 % of men and 30 % of women, and over 70 % of students and older pupils smoke regularly. The fight against smoking is not systematic. Of the latest important laws, the Law on Measures to Prevent and Reduce the Consumption of Tobacco Products and Their Harmful Influence on the Population's Health (2005) is the primary law governing smoke-free places, packaging, and labeling.

Currently, in Ukraine, there are a number of programs to combat the development of chronic diseases: the Program on Prevention and Treatment of Hypertension in Ukraine aimed at early detection of risk of cardiovascular system; the program on "Diabetes Mellitus" providing patients with insulin therapy and oral antidiabetic drugs; National Tuberculosis Program, National Program on HIV-AIDS.

Psychiatric Care

Ukraine has inherited a psychiatric system overshadowed by particularly disturbing legacies from the Soviet Union, where psychiatric diagnoses and confinement were used as forms of political repression. However, in post-communist Ukraine, the state security systems have been reformed and there is no evidence of political abuse of psychiatry.

Compared with the other countries, Ukraine had the highest prevalence of mood disorders (9.1 %) and the second highest prevalence of substance misuse disorders (6.4 %). In 2004, only a small proportion (4.9 %) of those with any mental disorder had received any treatment during the preceding 12 months, including 19.7 % of those who had a serious mental disorder (Yur'yev, 2004).

Mental health care remains essentially state funded and hospital based. However, Ukraine is accessing the European Committee for the Prevention of Torture and Inhumane and Degrading Treatment or Punishment (CPT), which enables monitoring all facilities where prisoners or patients are in custody or detained. The Ukrainian Psychiatric Association proposed the new Law on Psychiatric Assistance (2000). The Law is broadly in line with similar legislation elsewhere in Europe, but there are significant difficulties in translating its principles into everyday psychiatric practice.

The ICD-10 classification of mental disorders (WHO, 1992) has officially replaced Snezhnevsky's nosography, although it has not yet been universally adopted. The transition from centralized control to a social health insurance system, adopting principles of managed care, is under scrutiny. Ukrainian psychiatrists are developing new models of delivering services and devising new strategies for mental health care.

Pediatric Care

Given the demographic prospects of Ukraine marked by negative trends, the state of child welfare and maternity is of particular concern. According to the data of the

Ministry of Health, among children who died under 1, almost one third passed away in central district and maternity hospitals due to the lack of necessary equipment and qualified professionals. Children under 3 and disabled children are not provided with free medicines at all (Bogatyriova, 2011, p. 55). The decision of the state to solve the problem of child care by single payment at birth, which was nearly 9 % of the average salary rate (in the first year of the child), has led to some increase in the number of children being born in recent years, but the rise in birth rate is being depreciated by exorbitant prices for baby food and necessities.

In the USSR, one of the best systems of children's vaccination and safety against epidemics in the world was created, but in connection with Ukrainian society liberalization and giving patients the right to withdraw from the medical intervention in recent years, parents began to refuse to vaccinate children.

Infectious diseases remain one of the five leading causes of infant mortality under 1 year. In addition, every ninth child, and in total more than a million children less than 14 years old suffered from an infectious disease (from 2004 to 2008). Death and serious complications have also been reported. However, only 32 % of parents believe that vaccination is necessary and safe. But other parents due to the fear of complications refuse to vaccinate their children, putting them at risk of infectious diseases such as diphtheria, measles, mumps, tetanus, and hepatitis B.

Emergency Care

Emergency care is supposed to be free for everyone including those without state health insurance. However, once the patient's condition is stabilized, the doctors will probably ask for a fee for their services due to the low salary that the state provides. Emergency departments are open nonstop all year. Every year, one in three residents of Ukraine seeks emergency care. Unfortunately, the latter has many unsolved problems. Late delivery and poor quality are among the main challenges. Three most common types of violations of patients' rights deserve a special mention: (1) the patient's opinion and consent regarding the extent and quality of intervention is not taken into account; (2) the aid is limited to the simplest measures that cannot restore health, leading to irreversible consequences: chronic diseases or disability; and (3) if the physician does not receive a immediate effect, the routine and standardized practice is replaced by hyper-therapy without obtaining approval of patients or their relatives.

Of course, in critical conditions, the patient does not always have the practical possibility to choose doctors, medical facilities, strategy, volume of medical intervention, specific methods of diagnosis or treatment, which leads to the violation of their rights.

General Practice

Since the Soviet time, Ukraine has had the system of training internists and pediatricians, who were specialists in their fields.

In accordance with the new project of reform initiated by the Ministry of Health in 2000, health care is planned to be clearly divided into primary health care, which will be delivered by *family doctors*, as well as secondary (specialized) and tertiary (highly specialized) health care. The legal framework for family medicine has been developed and the Scientific and Methodological Center for Family Medicine of the Ministry of Health has been established. According to the plans, internists and pediatricians in outpatient care would be replaced by family doctors by 2020. Family doctors are able to provide qualified, including emergency, medical care to the vast majority of patients. However, the institution of family medicine is still in the making and cannot solve all health-care challenges.

Health Promotion and Education

Due to the low-income rates and high cost of diagnostic and therapeutic procedures, Ukrainians often turn to the representatives of alternative medicine and use folk methods of treatment and self-treatment. In pharmacies, the majority of products are represented by generic medicines and copies of drugs with unknown efficiency, which often poses a hazard to patient's health, and causes financial loss; 88.2 % of adverse reactions to drugs in Ukraine are known to be caused by generic drugs. Besides, unfortunately, the system of establishing original generic drugs equivalence is only being created.

Active governmental and nongovernmental programs aimed at health promotion are as follows: Reproductive Health of the Nation for 2006–2015, National Program Against Tuberculosis for 2007–2011, Ukraine against AIDS, All-Ukrainian Youth Project (since 2010), Tuberculosis and HIV/AIDS Control in Ukraine Progect, etc.

Through these programs, patients with cancer, tuberculosis, AIDS, and diabetes can get free medicine, medical care, medical devices (e.g., metal stents). However, the low level of patients' awareness, limited funding, and patients' distant location from health-care centers may limit access to these services.

There is no unified program for the development of mass physical education and sport. Also, the number of sports facilities for children is limited. In addition, there is practically no promotion of a healthy lifestyle.

Scientific and Professional Integrity, Conflict of Interest, Corruption

In Ukraine, during the last 20 years of independence, five physicians' codes of ethics have been developed and adopted. In 2009, the All-Ukrainian Congress of Physicians Societies adopted the Ukrainian Physician's Ethical Code, which included the basic principles of bioethics: respect for autonomy and dignity, do no harm, beneficence, privacy, and confidentiality.

There are a lot of medical organizations uniting physicians of various medical specialties: the Dental Association of Ukraine, the Ukrainian Association of

Ophthalmologists, the Association of Cardiologists of Ukraine, etc. Generally, these organizations are poorly integrated and cannot significantly influence policy in health care, largely due to strong tradition of command-and-governance institute of health. Traditionally, only the Ministry of Health and its establishments can provide physicians the right to pursue professional activities, conduct their certification, grant licenses, and determine the scope and list of medical disciplines at universities. In 2008, the draft of the Law on Physicians' Self-government, which proposed to entrust many regulation functions of physicians' professional activities to the All-Ukrainian Physicians Society, the national organization of independent professional government that could have united all the doctors of Ukraine, was submitted to the Supreme Council of Ukraine. However, this law was not adopted.

The most frequent violation of medical ethics is related to the infringement of the Constitutional provision to deliver free medical services in public institutions. It involves several reasons: (1) depreciation of basic funds resulting from inadequate funding from the state, (2) low salary for doctors, (3) lack of health insurance, (4) imbalance of public and private sectors, (5) total corruption in the society, (6) lack of citizenship, and (7) a violation of bioethical principles by doctors. Lack of personal doctors' liability for committed medical errors is another ethical problem. The responsibility for errors of doctors working in the public health-care system is allocated to the administration of medical institutions.

Many people note the conflict between two strategies of patients' management arising in medical practitioners: the strategy of advisability and benefit for the patient who expects that long-term preservation of natural functions and capabilities of the body is possible and the strategy of the latest expensive technology and business benefits. Due to the lack of information, the patient is often prevented from making the right choice between therapeutic, surgical treatment strategies and the strategy of alternative medicine.

Relation with Industry and Donors/Sponsors

At this stage of bioethics development, the relation between bioethics and the industry is still weak. Financial support for the development of bioethics by the State is largely aimed at administrative and legal work to improve the health-care system activity at the Ministry of Health level.

Projects for development of medical and environmental bioethics are funded by private foundations, such as the Soros Foundation "Vidrodzhennia," MATRA (the Netherlands), McArthur Foundation, USAID (USA), etc., as well as by the international organizations, such as the International Bank for Reconstruction and Development, European Commission, WMA, and UNESCO. A number of initiatives for congresses and workshops, centers and programs on bioethics are organizationally and financially supported by certain research institutes and universities, for example, by the Shupyk National Medical Academy of Post-graduate Education, the Institute of Occupational Medicine, the NAMSU, and NASU.

Future Challenges

In the Field of Bioethics Infrastructures (Need for Legislation, Ethics Committees, Ethics Education, etc.)

The imperfect legislation, frequent discrepancy between resolutions, lack of continuity in lawmaking, and poor efficiency of the institute of the human and citizen rights should be attributed to disadvantages of the legal regulation of bioethics. Unfortunately, the model bills on bioethics (e.g., On the Legal Foundations of Bioethics and the Guarantee of its Security), which were developed by the CIS Interparliamentary Assembly and have passed the public consultation phase, have not been adopted as the laws of Ukraine.

Opportunities for education in the field of bioethics and good clinical practice on the international level for specialists from Ukraine are still limited. In the majority of cases, the training is limited to congresses, symposia, seminars, conducted in Ukraine, but the participation of leading specialists from other countries is often limited by financial capacity of the inviting party. Ukraine does not have a state system of bioethics and GCP education for medical pre- and postgraduates yet.

The main directions of a future international cooperation in the field of bioethics are the extension and intensification of contacts with the CE Commission for Ethics in Science and Commission for Ethics at the European Parliament, UNESCO, and WHO.

In the Field of New and Emerging Issues

In recent years, topical issues of consumer rights, various social services, starting with housing and public utility services and shops, and ending with hairdresser's or beautician's services, have been discussed in the Ukrainian society. Bioethical problems of human ecology, food quality, and occupational hygiene are also considered to be urgent. Of great concern are misappropriation of public finances and property by high-ranking officials, problems of injustice, inequality in distribution of social benefits, which affect disadvantaged and vulnerable social groups, especially children, pensioners, and people with disabilities. Along with the Physician's Ethical Code, Ukrainian society has been discussing ethical principles of valeologists, teachers, social workers, and politicians.

Any Other Problems and Opportunities for the Further Development of Bioethics in the Country

Among the positive aspects and original achievements of bioethics as a theory and practice, science and academic discipline in Ukraine, one should note the following: (1) the desire to consider bioethics as global ethics that combines medical and

environmental ethics; (2) the formation of multiple bonds of bioethics with valeology, sanology, social work, practice of ethical expertise, pedagogy, Christian ethics; and (3) the desire to write "the discipline" in the cultural and historical context and relate the achievements of Western bioethics to the tradition of soviet biophilosophy.

Guidelines for the ethical expertise of the studies carried out in natural and biosphere reserves, national nature, and landscape parks were developed in 2003 (Nikolskii et al., 2003). However, the practice of routine ethical expertise of scientific studies on objects of nature and wildlife in reserves and national parks has not become widespread, or supported in the community yet.

Ukraine needs radical transformation of the health-care system, an improvement of the way it operates, structural adjustment, and an improvement of patient care.

In bioethics education, there is an urgent need to teach bioethics not only as applied biomedical ethics but as a special form of worldview, a really interdisciplinary science, and practice uniting different fields of natural sciences and humanities.

Summary Conclusion

To conclude, the process of reception and assimilation of bioethical principles and values in Ukraine cannot be called simple. The difficulties are connected with the following: (1) the transitional nature of the Ukrainian economy, (2) a spiritual crisis caused by the assertion of private property as a social value, (3) the legacy of the administrative and command system of governance in medicine and collectivist ethics, (4) traditional medical paternalism and doctors' abuse of power over human lives, and (5) technocracy – the predominance of diagnosis over therapy and an attitude toward the patient as an object of medical intervention.

At the current stage, Ukraine, like the majority of post-Soviet countries, is in the process of civil society formation. Under these circumstances, the role of bioethics, as a social institution, science and discipline that promotes formation of genuinely democratic relationships based on respect for human rights and freedoms as well as other living creatures and nature objects, is important. Problems of bioethics are becoming markedly interdisciplinary in nature. Therefore, all new social institutions, governmental agencies, and community organizations are being involved in the solution of these problems.

In the systems of Ukrainian health care and higher education, ecology, and conservation of natural resources, bioethics can and must become the main alternative to phenomena such as moral nihilism, consumerism, biologization, technocracy, and anthropocentrism. At the same time, there must be creative rethinking of its forms and methods based on the current political, economic, and social situation in Ukraine. The future of bioethics will be certainly determined by the nature, quality, and pace of democratic reforms in all spheres of Ukrainian society.

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USA

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Gerard Magill

Introduction

Bioethics in the United States has developed into a highly sophisticated enterprise, including both secular and religious perspectives, since World War II. The pace of its development continues robustly as the established and the emerging aspects of bioethics increasingly involve diverse global populations with vast environmental implications. The continued breakthroughs in medicine and biotechnology contribute significantly to the continuing challenges that the field encounters from scientific, cultural, and ecological perspectives. With the impressive number of academic and professional institutions that engage the field in a scholarly and critical manner

G. Magill
Center for Healthcare Ethics, Duquesne University, Pittsburgh, PA, USA
e-mail: magillg@duq.edu

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and the striking growth in degree granting Universities for the field of bioethics, there is a fast flowing stream of newly trained experts to provide strenuous leadership for the future.

Bioethics Development

The development of bioethics in the United States as a distinct discipline reflects the extraordinary growth in biotechnology, medical science, and health care. The historical roots of US bioethics can be traced to crisis moments after World War II that helped not only to initiate academic centers and professional associations but also to instigate government intervention on pivotal issues that shaped the new field.

Moments of Crisis

Albert R. Johnson has provided perhaps the most comprehensive account of the history of medical ethics and the birth of bioethics in the United States (Jonsen, 1998, 2000) from which this essay has developed several points. The 1803 code of medical ethics written by the English physician Thomas Percival (1740–1804) provided a basis for the 1847 *Code of Ethics* for the *American Medical Association*, a new organization at that time. The code has undergone several revisions since then including receiving a new name, the *Principles of Medical Ethics*, in 1903 and 1912. The fast pace of breakthroughs in science and medicine after World War II, such as tuberculosis treatment, synthetic penicillin (first discovered in 1928), polio vaccines, antihypertensive drugs, discovery of DNA, early cancer chemotherapy, effective oral contraceptives, heart transplantation, definition of brain death, etc., created a fascinating new landscape for ethical discourse in medicine. Also, moments of crisis challenged the new discipline of bioethics to mature quickly. In particular, there were two crises that absorbed the public: the Willowbrook experiment ending in 1958 and the Tuskegee experiments ending in 1972.

At Willowbrook State Hospital for retarded persons in New York, an experiment began in 1956 to study the natural history of hepatitis. The experiment infected retarded children with hepatitis, recognizing that insofar as most children would contract the disease eventually during their stay at the hospital, the intentional infection would provide subsequent immunity. The purpose was to study the disease in order to create a vaccine, and the outcome was successful insofar as an effective vaccine was created to prevent viral hepatitis type B. Nonetheless, parents of the children and the public were outraged that helpless children had been intentionally infected in the experiment and that consent had not been obtained.

In 1972, the media broke another shocking story about human experimentation in Tuskegee, Alabama. The U.S. Public Health Service had continued an experiment for 40 years, starting in 1932, with 600 African American poor and uneducated patients, 400 of whom had been diagnosed with syphilis, the other 200 without syphilis constituting the control arm of the study. But those with

syphilis were not informed about the diagnosis, not told that they were part of a research study, and not advised that penicillin treatment was available. The purpose of the study was to understand what damage the disease causes the body, discoverable only after the infected patients died. After the public became aware of the study (already known in professional circles), a panel including the bioethicist Jay Katz was appointed to investigate the study. In 1972, the panel deemed the study to be unethical from the beginning, and the study ended immediately with 74 patients still living. The media story had astounded the public and forced the government to develop better regulations for federal funding of research with human subjects, leading to the National Commission discussed below.

Just recently, another long-term study shocked the public when revealed by the media. In the fall of 2010, the media reported that the U.S. Public Health Service supported research on sexually transmitted diseases in Guatemala from 1946 to 1948. The US President's Bioethics Commission undertook a thorough fact-finding investigation reviewing approximately 125,000 pages of documents and approximately 550 secondary sources collected from public and private archives around the country, plus a fact-finding trip to Guatemala to meet with Guatemala's own internal investigation committee. The research study intentionally exposed and infected vulnerable populations to sexually transmitted diseases without the subjects' consent. The President's Commission report was titled, "*Ethically Impossible: STD Research in Guatemala from 1946 to 1948*" (September, 2011). The Commission Chair Amy Gutman reported that the Guatemala experiments involved unconscionable basic violations of ethics, even as judged against the researchers' own recognition of the requirements of the medical ethics of the day (bioethics.gov).

Early Centers and Associations

The nascent field of bioethics led to the establishment of centers to foster discussions across disciplines. For example, in 1969, the *Hastings Center* on the river Hudson in upstate New York was established as an Institute of Society, Ethics, and the Life Sciences under the leadership of the philosopher Dan Callahan. The center specializes in the contributions of interdisciplinary working groups. In June 1971, the first issue of the *Hastings Center Report* appeared. The center and its journal continue to shape and lead the discipline today, four decades later.

Also, in July 1971, André E. Hellegers, born in the Netherlands and teaching at Georgetown University's School of Medicine, provided the leadership (until his death in 1979) for the new *Kennedy Institute of Ethics* at Georgetown University in the nation's capital city, Washington, D.C. Its original title was the *Joseph and Rose Kennedy Center for the Study of Human Reproduction and Bioethics*. The *Kennedy Institute* was founded to be an academic research and teaching center to address moral perspectives related to prominent policy issues, publishing quarterly the prestigious *Kennedy Institute of Ethics Journal* (since 1990). LeRoy Walters was appointed as director of the Center for Bioethics within the *Kennedy Institute*.

He and his faculty colleague Warren Reich developed much needed resources for bioethics. They initiated a research library with funding from the National Library of Medicine that would become a leading resource over subsequent decades, publishing the landmark *Bibliography of Bioethics* (Walters, 1975), and eventually being known as the *Reference Center for Bioethics Literature*. A few years later, Warren Reich edited a four-volume collection, *The Encyclopedia of Bioethics*, with subsequent updating, to provide a comprehensive scholarly resource (Reich, 1978). The *Kennedy Institute* nurtured an early generation of scholars as faculty chairs or Kennedy professors who would lead the field of bioethics over subsequent decades. Many of these scholars became leaders in the field, including Tom Beauchamp, John Connery, James F. Childress, H. Tristram Engelhardt, Jr., William May, Richard McCormick, and Gene A. Outka. Also, it was at this time that Robert Veatch moved from the *Hastings Center* to the *Kennedy Institute*, succeeding Edmund D. Pellegrino as director of the institute in 1989. One of the best-recognized accomplishments was the first systematic analysis in the fast-growing field, *Principles of Biomedical Ethics*, now in its 6th edition (2009), coauthored by Tom L. Beauchamp and James F. Childress (Beauchamp and Childress, 1979, 2009).

Around the same time as these centers were formed, in 1969, a new professional association was established for the discipline, the *Society for Health and Human Values* (SHHV). The society hosted its first annual meeting in October 1971. The society sought to foster medical humanities (including art, history, philosophy, and literature) in medical education, especially focusing upon understanding health, disease, and healing, thereby going beyond ethical issues in health care to include broader issues of human values. Other associations and organizations followed as the discipline of bioethics developed. In 1986, the *Society for Bioethics Consultation* (SBC) was initiated with the mission to study and support ethics consultation services in health care. In the fall of 1994, the *American Association of Bioethics* (AAB) was established to foster dialogue among scholars in the discipline, to enhance their clinical activities, to encourage teaching, to promote research, and to create a new stream of bioethicists.

Then, in January 1998, the *Society for Health and Human Values* (SHHV) combined with the *Society for Bioethics Consultation* (SBC) and the *American Association of Bioethics* (AAB) to form an integrated organization called the *American Society for Bioethics and Humanities* (ASBH). The consolidation was organized by representatives of the different associations and was voted on by mail ballot of the full memberships with overwhelming approval. The ASBH holds an annual conference in different cities within the United States. In addition to this large national organization, there is a smaller and more focused annual conference that involves a significant participation of bioethicists from the United States called the *International Conference on Clinical Ethics and Consultation* (ICCEC). The ICCEC initially hosted biannual conferences in 2003, 2005, and 2007. In 2008, the conference focused on emerging ethics committees as a preconference participant in the World Congress of the *International Association of Bioethics*. Thereafter, the conference has met annually in different cities across the world.

Government Interventions

The development of the new discipline of bioethics also was influenced by government oversight reflecting sensitivity to both the *Nuremberg Code* in 1947 and the World Medical Association's *Declaration of Helsinki* in 1962, *Ethical Principles for Medical Research Involving Human Subjects*. In particular, two government commissions, the National Commission and the President's Commission, had unusually significant influence on the nascent field. In addition to these government commissions, between 1978 and 1980, there was an important but short-lived *National Ethics Advisory Board* that was established at that time in the US Department of Health, Education, and Welfare. This board's focus was upon research on children and the human fetus. In 1980, the board was discontinued in part because of a controversial fetal research protocol that it had been developing. A closer look at the accomplishments of the two government commissions helps to enlighten the context for the emerging discipline of US bioethics.

The *National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research* was established in1974. In the wake of discussions over the Tuskegee scandal and debates over fetal research, President Nixon signed the National Research Act in 1974 to establish ethical parameters to sanction behavior in federally funded research. The work of the National Commission led to a clearer understanding of the meaning of research on human subjects and the importance of consent, including its 1977 report on *Research Involving Children* that had arisen from the Willowbrook crisis in 1958. The Commission recognized proxy consent by parents for nontherapeutic research upon children with a crucial caveat that there was only minimal risk to the child. The commission culminated with a report arising from a retreat in 1976 at Belmont House, the *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*. The report, initially approved in 1978 and published a year later (Belmont Report, 1979), promotes three ethical principles as foundational for medical research, respect for persons, beneficence, and justice. After completing the report the National Commission ended in 1978.

Another government body for ethics oversight was the *President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research*. Building on the prominence of the National Commission, the President's Commission adopted a broader purview dealing with a range of bioethical issues. The commission brought even further prestige to the nascent discipline of bioethics insofar as its members required presidential appointments. This first President's Commission published several crucial reports that helped to delineate the terrain of bioethics, including, *Defining Death: Medical, Legal and Ethical Issues in the Determination of Death* (1981), *Splicing Life: The Social and Ethical Issues of Genetic Engineering with Human Beings* (1982), *Screening and Counseling for Genetic Conditions: The Ethical, Social, and Legal Implications of Genetic Screening, Counseling, and Education Programs* (1983), and *Deciding to Forego Life-Sustaining Treatment* (1983). Since the original President's Commission in

1980, there has been many others with a variety of progressive or conservative bioethicists being appointed, reflecting the politics of presidents. Reports by the *National Bioethics Advisory Commission* (NBAC), now called the *Presidential Commission for the Study of Bioethical Issues*, are available through the US Department of Health and Human Services (HHS). Also, a remarkably useful index to reports from NBAC has been prepared under the directorship of Eric M. Meslin (bioethics.gov).

A further crucial contribution from the branch of government, this time from the United States Supreme Court (410 U.S. 113), was the legalization of abortion until viability around 7 months in its 1973 *Roe v Wade* decision. The decision was based upon a woman's right to privacy implied in the due process clause of the Fourteenth Amendment. Since then, the nation has been split more or less equally on the abortion debate into so-called pro-life and pro-choice camps, and the bioethics debate on the issue continues unabated, not least from the substantive body of scholarly literature on feminist bioethics which extends across the entire discipline (e.g., Mahowald, 2006).

Bioethics as a Discipline

Over these decades, the new discipline adopted a word to identify its interdisciplinary field – the word "bioethics" was used to combine biology and ethics. The creation of the name for this new field can be attributed not only to André Hellegers at the *Kennedy Institute* but also to Van Rensselaer Potter who was a research oncologist at the University of Wisconsin who published work profiling the word bioethics (Potter, 1971). Albert Jonsen suggests that the definition of bioethics by Warren Reich in *The Encyclopedia of Bioethics* (Reich, 1978) appears to have settled the purpose of bioethics as the study of the ethical dimensions of medicine and the biological sciences (Jonsen, 1998).

Whether bioethics is technically a discipline continues to be disputed insofar as there is ambivalence about its methodological approaches (to provide and use a normative framework) and its theoretical approaches (to ascertain which normative framework is adequate for the moral life). Rather than settle on any given ethical theory or method, bioethics has tended to focus more on principles to solve problems and guide actions (Beauchamp and Childress, 1979), in contrast to theories representing different ways of systemically organizing principles and rules. There have been efforts to create a foundational theory or a persuasive method for the disciple, but none have elicited consensus. Examples include the following: locating medical ethics within the philosophical tradition of contract theory (Veatch, 1981), presenting bioethics as dealing with controversy resolution via agreed procedures that uphold autonomy and beneficence as content poor yet nonetheless also as foundational principles providing boundaries for dispute resolution (Engelhardt, 1986), promoting beneficence around which medical ethics should develop (Pellegrino and Thomasma, 1981), adopting casuistry and the focus on decision-making in clinical ethics (Jonsen, Siegler and Winslade, 2006),

and relating applied ethics to a systematic account of common morality as a public system to guide decisions and actions while allowing some irresolvable moral disagreement without conceding to relativism (Gert, Culver and Clouser, 2006).

There appears to be a general agreement that a variety of methods are needed for bioethics, including methods adopted in fields like law, philosophy, theology, history, literature, and sociology as well as quantitative and qualitative research methods, including ethnographical and experimental methods (Sugarman and Sulmasy, 2010). In part due to the lack of an agreed approach to bioethics and because of the significant contribution that varied approaches make to theoretical and applied issues in the field, it is no surprise that anthologies in bioethics continue to be popular (e.g., Steinbock, Arras and London, 2003). As a result, it appears that bioethics in the United States can be construed at least as a discipline in a secondary manner insofar as it relies upon other clearly defined disciplines like theology, philosophy, law, medicine, and the social sciences to engage practical issues as a matter of applied ethics. In this secondary manner, bioethics will likely develop the type of disciplinary standards for excellence and assessment that other disciplines have developed over their longer histories. Perhaps one of the greatest ironies of US bioethics is that it has not yet reached consensus on an acceptable code of ethics, though the ASBH has been trying to accomplish this difficult task for several years.

Current Bioethics Infrastructure

In the United States, a sophisticated bioethics infrastructure has emerged that engages religious and secular discourse, relating patient rights in clinical ethics with systemic issues in organizational ethics.

Religious Bioethics

In addition to the centers and professional associations mentioned above, many large nonprofit and religiously affiliated health systems have professional ethicists at senior positions in the organization as director or vice president of ethics. These professional bioethicists typically focus on matters related to clinical ethics or organizational ethics within their health system, collaborating with colleagues in the field. Religiously affiliated health care constitutes a significant portion of US health care. By far, the largest of these is Catholic health care. Because of the extensive outreach of Catholic health care across the nation, providing approximately one sixth of the nation's health care, there is a professional association to support its needs including bioethics, the *Catholic Health Association* (founded in 1915) serving approximately 600 hospitals and 1,400 care facilities (long-term care, etc.). Also, in religious bioethics, there are prominent journals that adopt a religious perspective, such as *Christian Bioethics* and *The National Catholic Bioethics Quarterly*.

Secular Bioethics: Degree Programs and Journals

An abundance of academic hubs for bioethics are now well established across the nation. Many of these academic centers offer degree programs to train an ongoing stream of bioethicists. In addition to Ph.D. programs that offer traditional doctoral degrees, for example, in philosophy, there is a variety of doctoral degree programs that are dedicated specifically to the field of bioethics as a distinctive discipline. For example, there are research doctorate degrees (Ph.D.) as well as professional doctorate degrees focusing upon normative ethics. Also, there are doctorate degree programs (Ph.D.) that provide extensive training in empirical research. Moreover, there are many master's degree programs in different universities across the United States. A list of academic centers and degree programs in bioethics can be found on the website of the American Society for Bioethics and Humanities (asbh.org/meetings/resources/academics.html).

In addition to these academic hubs for bioethics, there is an abundance of scholarly publications, books and journals, on bioethics in the United States. Examples of books in the field are discussed below in relation to major topics. The major journals on bioethics in the United States include: *The American Journal of Bioethics*, *The Journal of Medicine and Philosophy*, *Theoretical Medicine and Bioethics*, and *HEC Forum* (Healthcare Ethics Committee Forum: An Interprofessional Journal on Healthcare Institutions' Ethical and Legal Issues). Also, there are journals that focus especially on the relation between bioethics and law, such as *The Journal of Law, Medicine, & Ethics* and the *American Journal of Law & Medicine*. From the perspective of public debate, public policy, and legislation in the United States, major developments are identified in the next section that discusses specific bioethical issues.

Rights of Individuals

The autonomy of the patient, with concomitant rights such as regarding consent, has become a central reference point in US health care and is crucial for issues related to clinical ethics and organizational ethics. In the scholarly literature, there continues to be significant debate about different meanings of personal autonomy and processes of consent (Miller and Wertheimer, 2010) reflecting the indispensable rights of patients. One of the clearest practical approaches to the rights of individuals, especially from the perspective of upholding patient autonomy and requiring informed consent, is the *Comprehensive Accreditation Manual* of the *Joint Commission* that reviews and accredits health care facilities on a voluntary basis every 3 years (laboratories, every 2 years) in the United States. The independent, not-for-profit organization was founded in 1951 and is the nation's oldest and largest standards setting and accrediting body in health care. Currently, the *Joint Commission* evaluates and accredits more than 19,000 health care organizations and programs in the United States (jointcommission.org). In the organization's *Comprehensive Accreditation Manual* (Joint Commission, 2011), section

RI delineates the "Rights and Responsibilities of the Individual," as dealing with these issues: identification of fundamental, overarching patient rights; the right to effective communication; the right to participate in care decisions; the right to informed consent; the right to know the care providers; the right to participate in end-of-life decisions; and services provided by organizations to respect patient rights.

Clinical, Organizational, and Professional Ethics in Health Care

Because of the significance of patient rights in US health care, with the robust focus upon patient autonomy and informed consent, it is understandable that the dominant interest in bioethics tends to focus upon clinical issues. However, clinical ethics relates in an integrative manner with organizational ethics and professional ethics in health care.

In addition to general discussions across a range of relevant issues about organizational ethics in health care, there are pivotal issues that need close scrutiny in bioethics: the pervasive compromise of trust, the neuralgic question of legitimate complicity and accountability, and the egregious problem of conflicts of interest such as occurred in the death of the first gene-therapy trial patient, Jesse Gelsinger in 1999. A foundational aspect of organizational ethics deals with the issue of compromised trust that has occurred because of market forces in medicine detracting from or compromising patient care. Issues related to this trust crisis, such as research ethics, disputes over decision-making, or medical errors are discussed below. To help organizations better manage the dilemmas they encounter when market or business forces press against patient needs, bioethics needs to investigate more thoroughly how to navigate the awkward issue of legitimate complicity, whereby individual accountability and collective or corporate interests can be squared in a manner that holds health care accountable. Moreover, conflicts of interest can be egregious in health care, and a clear sense of how to manage or resolve them is needed to maintain confidence in the general system (Rodwin, 2011). Although many of these organizational issues overlap with discussions about professional ethics, the latter requires a much more constructive approach that fosters the development of virtue and character among clinicians as they integrate their clinical and organizational responsibilities (Pellegrino and Thomasma, 1993).

Major Bioethics Issues and Discussions

In addition to the general development of bioethics as a discipline, in which a variety of topics were very influential as discussed above, there are several major issues in bioethics that have reached a level of stability, being well developed though continuing scrutiny is required, as follows.

Research Ethics and Institutional Review Boards (IRBs)

Given the outrage over the scandals at Willowbrook and Tuskegee and in light of the government commissions that followed in their wake, US bioethics was highly attuned early in its formation to the controversial issues around research and experimentation on human subjects. The *National Commission* vigorously embraced the policy of the *National Institutes of Health* to have institutional review boards (IRBs) that would review and oversee research protocols implementing federal regulations. The President's Commission also was involved in the early development of IRBs with its 1981 report, *Protecting Human Subjects*, and its 1983 report, *Implementing Human Research Regulations*. Also, in 1974, a new federal office (under the leadership of the renowned bioethicist John C. Fletcher from 1975) was created at the *National Institutes of Health* to provide compliance oversight of research institutions engaging in human research subjects, the *Office for Protection from Research Risks* (OPRR). The US Department of Health and Human Services (HHS) now houses OPRR as the *Office for Human Research Protections* (OHRP) to protect the rights, welfare, and well-being of subjects involved in research conducted or supported by the HHS. Also, OHRP provides clarification and guidance, develops educational programs and materials, maintains regulatory oversight, and provides advice on ethical and regulatory issues in biomedical and social-behavioral research (hhs.gov/ohrp). Moreover, the *Joint Commission* that accredits health care facilities in the United States has a specific standard (in section RI on patient rights) to protect patients who are also enrolled as research subjects. Standard RI.01.03.05 reads, "The hospital protects the patient and respects his or her rights during research, investigation, and clinical trials" (Joint Commission, 2011).

A highly influential organization was established in 1974, continuing today, to support and educate IRBs – *Public Responsibility in Medicine and Research* (PRIM&R). The organization, based in Boston, offers training and professional development for animal care and use as well as human research subjects, such as in Human Research Protection Programs (HRPPs). Also the organization is involved strenuously in policy advocacy and provides a resource center with many reports (white papers, etc.) and networking opportunities for members, such as at its many conferences, including its annual *Advancing Ethical Research* (AER) Conference and its annual *Institutional Animal Care Use Committee* (IACUC) Conference. Over the decades since it was established, the organization has become a leading body to support and train IRB members, such as via its certification programs, including the *Certified Institutional Review Board* (IRB) Professional and the *Certified Professional Institutional Animal Care and Use Committee* (IACUC) Administrator (primr.org). Although this organization and its programs emphasize compliance, bioethics weaves through everything so that ethical practices arise from advanced knowledge of relevant regulations.

Another very helpful resource for the continuing discourse in bioethics about research ethics and IRBs is the Hastings Center's professional publication (six times annually), *IRB Ethics & Human Research*. Moreover, there were several influential reports just before and after the start of the new millennium from the

President's *National Bioethics Advisory Commission* (NBAC), such as *Research Involving Patients with Mental Disorders That May Affect Decisionmaking Capacity* (1998), *Ethical and Policy Issues in Research Involving Human Subjects* (2001), and *Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries* (2001).

Also, there is an abundance of excellent scholarly studies on IRBs and research ethics, covering many topics such as the following: the history of and relevant codes and regulations governing research involving human subjects, such as the *Common Rule* (explained further below), regulations from the Department of Health and Human Services (HHS) and requirements from the US Food and Drug Administration (FDA); the social value and sound design of scientific research, including equipoise, randomization, and placebo-controlled trials; fair selection of research subjects, including special or vulnerable populations (ethnic or minority groups, children, prisoners, subjects with impaired decision-making capacity); appropriate ratio or balance between risks and benefits; independent oversight and review; informed consent, waivers of consent, and respect for human participants; and behavior of the research investigators to maintain ethical standards in the research, such as relating to conflict of interest, falsification of data, and accurate authorship (Emanuel et al., 2008).

The *Common Rule* mentioned above is the federal policy for the protection of human subjects, published in 1991 and codified in separate regulations by 15 federal departments and agencies. The HHS regulations, *45 CFR part 46*, include four subparts: subpart A, also known as the federal policy or the *Common Rule*; subpart B, additional protections for pregnant women, human fetuses, and neonates; subpart C, additional protections for prisoners; and subpart D, additional protections for children (hhs.gov/ohrp/humansubjects/commonrule).

There is continuing public interest in the bioethical debate over developed countries like the United States undertaking research in developing nations, including being responsive to the *Council for International Organizations of Medical Sciences* (CIOMS) and being respectful of regulations from other governing bodies globally, such as the Council of Europe's regulations governing human rights and clinical research ethics. In addition to the topics mentioned above regarding research ethics and IRBs, other issues need to be discussed from the international perspective of research involving human subject, including collaborative partnerships between researchers and host nations, especially striving for justice and avoiding exploitation; fair and proper selection of participating communities that host the research; and making the drugs that are developed from the research affordable for the populations who participated and other developing populations (Macklin, 2004). This discourse on international research ethics, especially when US government funding is involved, recently led the *Presidential Commission for the Study of Bioethical Issues* under the Commission Chair Amy Gutman to assemble an *international research panel*. The panel represents ten countries as a commission subcommittee to conduct an independent review of the effectiveness of US rules and international standards for protecting human subjects in the US government–supported scientific studies.

Institutional Ethics Committees

The institutional review board is typically distinct from the institutional ethics committee, the former dealing with compliance over research with human subjects, the latter focusing upon issues related to patient care, such as deciding to withdraw treatment in end-of-life care. A brief account of the development and work of ethics committees reveals an extensive aspect of the work of bioethicists in clinical ethics. In 1976, the New Jersey court that adjudicated the Quinlan case (discussed below) supported a role for developing ethics committees to resolve the sort of disputes over end-of-life care rather than bringing them to courts for resolution. However, progress was slow, and in 1983, the report by the President's Commission, *Deciding to Forego Life-Sustaining Treatment* gave further support to the concept of developing ethics committees to address end-of-life decision-making. The report included as an appendix (item F), a statute that had been prepared by the *American Society for Law and Medicine* for the design of hospital ethics committees. Dramatic progress was made over subsequent decades, and now ethics committees are widespread across US health care, including hospitals, long-term care facilities, etc.

Over several decades, the role of an ethics committee has developed around several tasks: to educate the committee and colleagues in health care about relevant bioethics issues related to patient care; to review policy in the organization to enhance patient care consistent with relevant regulations; to engage in ethics consultation in situations where significant dispute arises about treatment decisions for patients; and to undertake research on all of the above to foster quality improvement of patient care across the organization. Different organizations focus upon these tasks in varying ways.

A fairly dominant model has emerged based on the work undertaken by the *National Center for Ethics in Health Care* (NCEHC), founded in 1991, at the Veterans Health Administration in the Department of Veteran Affairs. The NCEHC, under the leadership of Ellen Fox, chief ethics in health care officer, developed in 1999 a program called IntegratedEthics (one word). The program has three integrated functions: the ethics consultation function provides assistance to patients, families, and staff; the preventive ethics function develops policies and fosters a quality improvement system; the ethical leadership function creates a culture that inspires employees to act in an ethical manner (ethics.va.gov/integrated ethics).

Because a great deal of the time of ethics committees deals with ethics consultation, an explanation of what is involved sheds light on the work of the bioethicist in the clinical ethics environment of a hospital, or long-term care facility, etc. The role of the ethics consultant is typically to act as a facilitator (individually or working in a team) at times of dispute between patient, clinicians, and family over treatment decisions. Hence, sophisticated mediation skills are usually crucial for successful ethics consultations (Dubler and Liebman, 2004). The goals are to bring the relevant stakeholders together, to ascertain the facts, to clarify the problem, to consider appropriate options, and ideally, to build consensus, if feasible, around a decision, such as to withdraw end-of-life treatment like a ventilator or medically assisted feeding.

The *American Society for Bioethics and Humanities* (ASBH) published a set of core competencies to assist in the process of ethics consultation. In 1998, the first edition was published, *Core Competencies for Health Care Ethics Consultation*, with a revised and updated second edition published in 2011 (American Society for Bioethics and Humanities, 2011). The monograph has four main sections: the nature and goals of ethics consultation; the core competencies for health care ethics consultation (HCEC) that describes the necessary skills and knowledge for ethics consultation; evaluating health care ethics consultation services; the ethical dimension of HCEC as an emerging professional practice. The ASBH also has an education guide that was designed around the 1st edition of its core competencies but also remains relevant for the revised edition (American Society for Bioethics and Humanities, 2009). Related to but distinct from the ASBH *Core Competencies*, the field continues to await the development by ASBH of a code of ethics for bioethicists in general and ethics consultants in particular. Moreover, there remains significant discordance among ASBH members about the best way to train ethics consultants, a process that currently requires urgent attention. Finally, just as there are excellent studies on research ethics and IRBs as discussed above, there are excellent studies that are widely adopted by ethics committees, especially regarding ethics consultation and decision-making in clinical ethics (Jonsen, Siegler and Winslade, 2006; Aulisio, Arnold and Youngner, 2003).

End-of-Life Decision-Making

A large proportion of the work of ethics committees deals with end-of-life decision-making. The ethical dilemma over withholding or withdrawing end-of-life treatment from patients has revolved around two issues: the treatment being futile and/or the patient or surrogate deciding to forego or discontinue available treatment. In this debate, the underlying bioethical factors have been resolved, even if specific decisions continue to elicit dispute and controversy for a given patient, family, or care provider.

In the United States, the legal and ethical debate over withdrawing treatment in end-of-life care became national in 1975 when Karen Ann Quinlan was brought by ambulance to the emergency department of Newton Memorial Hospital in New Jersey. Being comatose from a barbiturate overdose, she was placed on a ventilator to breath and provided a nasogastric tube for medically assisted feeding, with her condition deteriorating over subsequent months, involving transfer to other facilities. She was diagnosed to be in a persistent vegetative state (PVS), though such a diagnosis is difficult to provide with accuracy until after death, with effectively no possibility of recovery. Her parents asked the physicians to remove the ventilator to let her die. The physician and hospital declined out of fear of criminal charges that might result, so the parents petitioned the court to end the treatment. The New Jersey Supreme Court eventually adjudicated the case, overruling a lower court decision. In 1976, the court concluded that under the right to privacy in the US constitution, the patient, if lucid, could decide to withdraw treatment; the Court added that the parents of the patient, given her legal incompetency, were

appropriate surrogates to exercise that right for the patient, adopting a substituted judgment standard that has become widely adopted in such cases. Moreover, the court ruled that the state had no compelling interest in forcing the patient to continue in the circumstances she found herself with no prospect of recovery. Interestingly, after the ventilator was withdrawn, the patient began to breath spontaneously, was transferred to a nursing home, and lived another 10 years via artificial feeding as a PVS patient, dying in 1985 at the age of 31. An important part of the court's ruling was to encourage ethics committees to be developed in hospitals as an appropriate body to resolve such cases. This case led to the *California Natural Death Act* in 1976 that provided the nation's first living-will statute whereby patients could document their wishes about end-of-life care.

Several other major cases followed the Quinlan case. Each ruling created further precedent, cumulatively clarifying the legal and ethical landscape for end-of-life decisions in the United States. The courts recognized the substituted judgment standard whereby surrogates can decide for an incompetent patient and the best interest standard whereby a decision is made based on the patient's best interests. The case of Nancy Cruzan in 1990 was especially significant insofar as the Missouri Supreme Court ruled against the request of the patient's parents to withdraw a feeding tube from their PVS daughter. The US Supreme Court backed the Missouri Supreme Court, arguing for a requirement of clear and convincing evidence that the patient would have wanted treatment withdrawn. Subsequently a Missouri Circuit Court accepted new testimony that Nancy had previously provided clear and convincing evidence, artificial feeding was withdrawn, and the patient died 12 days later. Another crucial legal precedent had been established. As a result, end-of-life care decisions are now legally and ethically acceptable across the United States via living wills, advanced directives, and health care power of attorney designation. On this matter over multiple cases and court ruling, the law is effectively settled (Menikoff, 2001).

However, permitting these end-of-life decisions about withholding or withdrawing treatment is different from assisted suicide measures. In two decisions in 1997, courts rejected a right in the US constitution for assisted suicide. In the case of *Washington v. Glucksberg*, the US Supreme Court ruled that the Due Process Clause in the Fourteenth Amendment of the US Constitution (prohibiting the government from interfering with an individual's rights and liberties) does not include the right to assisted suicide. Also, in the case of *Vacco v. Quill*, the US Supreme Court ruled that the Equal Protection Clause in the Fourteenth Amendment of the US Constitution (prohibiting States from denying an individual equal protection under the law when faced with comparable circumstances) did not permit assisted suicide being understood as substantially similar to withdrawing end-of-life care. However, these rulings did not prevent individual States from passing legislation to permit assisted suicide, and several States in the United States have since passed such legislation.

In the face of an increasing demand to legalize assisted suicide, there is a robust movement among many bioethicists to resist the legislative trend by supporting the role of hospice care and palliative care to provide appropriate relief from pain at the

end of life. In particular, there is widespread agreement about the legitimacy of using palliative or terminal sedation to induce a coma for patients whose pain is so intractable that no other effective relief is available. Typically, such patients die within a few days of the coma being induced. The palliative care movement has become increasing significantly in the United States (Emanuel and Librach, 2011).

Future Challenges

In addition to the above topics that are well developed and fairly stable in US bioethics, there are several other large arenas that need to be much better engaged and therefore present significant challenges for US bioethics: patient safety, organ and tissue procurement, and genetics and biotechnology.

Patient Safety

The debate over patient safety emerged as a substantive concern after a shocking report on avoidable medical error at the turn of the millennium (Institute of Medicine, 2000). The astoundingly high number of patients being killed as a result of avoidable medical error gripped the nation – and there is no current data that the original estimates of up to 100,000 deaths per annum in the IOM report have diminished noticeably. However, since the IOM study, improvements have been made to report medical errors and near misses called sentinel events in a concerted effort to enhance patient safety, as evidence by the inclusion of a category on "National Patient Safety Goals" in the Joint Commission's *Accreditation Manual* (section, NPSG) that assesses health care facilities (Joint Commission, 2011). Nonetheless, it remains extraordinarily difficult to obtain reliable, comprehensive statistics on medical error and sentinel events because there is no centralized mandatory database. A gargantuan task for bioethics is to help create an independent organization, perhaps located in the *National Institutes of Health*, to accurately track and radically diminish the outrageous numbers of patients whose health and lives are being compromised by the current fragmented system of reporting.

Organ and Tissue Procurement

There has been remarkable progress in the procurement and transplantation of tissue and organs over recent decades, and future progress appears immensely promising, bringing many accompanying dilemmas for bioethics. The definition of brain death (by an Ad Hoc Committee at Harvard University's Medical School in 1968) opened the doors to more extensive procurement – the patient could be declared to be dead, while tissue and organs remained viable for transplantation.

Recently, there has been a return to cardiopulmonary criteria for death to facilitate donation after cardiac death (DCD) from non-heart-beating cadavers (NHBCs) via controlled death (whereby life support is removed in a controlled environment) and uncontrolled death (whereby catheters are inserted to preserve organs of patients who arrive dead). There is general agreement that death is a process, but if it is required to wait until the end of the process, viable procurement would not be feasible. Hence, the crucial step for DCD interventions is to recognize that the patient is legally dead even though technically artificial resuscitation could but will not occur. The so-called Pittsburgh Protocol that was developed at the University of Pittsburgh's Medical Center specifies that death occurs at a specific period of time after life support is removed, with procurement occurring immediately thereafter. The *National Network for Organ Sharing* (UNOS) adopts all of these criteria for defining death. An extensive debate has developed and will continue over the definition of death and transplantation ethics (Veatch, 2000). A fundamental problem is the dramatic shortfall of procurement in the face of massively increasing demand, requiring both policy and technology solutions. From the policy perspective, the debate revolves around opt-in (such as on a driving license) or opt-out approaches (where the assumption is that citizens are donors unless they indicate otherwise). From the technology perspective, significant breakthroughs are being researched to develop ways for organ and tissue growth in laboratories.

Human Genetics, Biotechnology, and Population Health

The health and safety not only of individuals but also of large populations and even the species and planet environment are now an important part of bioethics discourse in the wake of sequencing the human genome, creating human embryonic stem cells, and the manipulation of pluripotent stem cells. The pace of progress in science and medicine, from molecular science and synthetic biology to regenerative medicine and tissue engineering, is astounding, and bioethics must keep apace with transcultural and global attentiveness. Several NBAC reports have been issued by the President's Commission to guide the bioethics debate in the public arena, including: *Human Research Involving Human Biological Materials: Ethical Issues and Policy Guidance* (1999); *Ethical Issues in Human Stem Cell Research* (1999); *Cloning Human Beings* (1997); and another ongoing study, *New Directions: The Ethics of Synthetic Biology* (2010). However, bioethics continues to struggle with keeping apace with scientific progress, not least in the foundational debate about transhumanism and posthumanity (Buchanan, 2011). Furthermore, new technologies bring new world-wide threats, and bioethics now has to engage with disaster related issues of global health. Such threats can be terror or crime related as well as caused by virulent pandemics (Annas, 2010). Now that the global population has passed seven billion, especially in an environment where climate change can cause flooding across vast coastal areas, a basic problem for global bioethics will be justice related especially regarding the provision of clean water, nourishing food, and basic housing for enormous populations.

Summary Conclusions

The development of bioethics in the United States has spawned a comprehensive discipline that combines clinical, organizational, professional, and global ethics. Its sophisticated infrastructure fosters robust interdisciplinary discourse with multiple academic degree programs and professional resources to maintain a continuing stream of future experts. There are plenty of issues that require their expertise.

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