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# **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

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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 Oiu 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, genetrans 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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