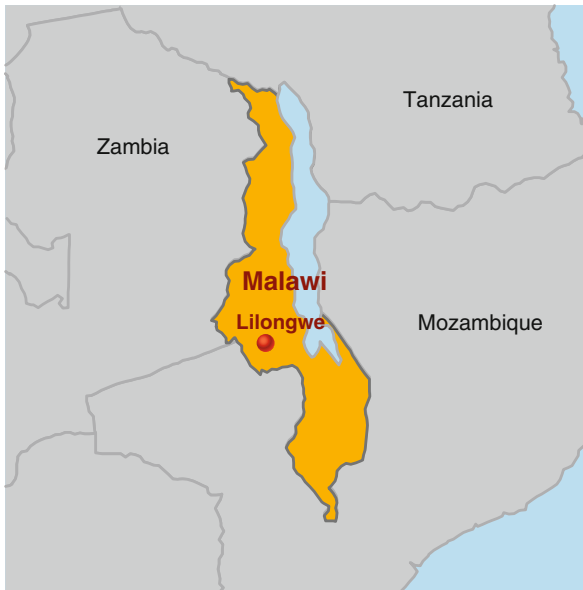


J. M. Mfutso-Bengo, Lucinda Manda-Taylor, Vincent Chipiliro
Jumbe, Isabel Kazanga, and Francis Masiye



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

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.

CEBEAS 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 Ubuntu.

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).
- Accredite, 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 non-smokers, 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 than 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.

References

- Bagheri, A. (2008). News and views. Regulating medical futility: Neither excessive patient's autonomy nor physicians paternalism. *European Journal of Health Law*, 15(2008), 45–53.
- Braveman, P. & Gruskin, S. (2002). Defining equity in health. *Journal of Epidemiology and Community Health (JECH)* 2003: 57, 254–458. University of California, USA.
- Chitando, E. (2008). Religious ethics, HIV and AIDS and Masculinities in Southern Africa. In R. Nicolson (Ed.), *Persons in Community. African Ethics in a Global Culture*. Pietermaritzburg: University of KwaZulu-Natal Press.

- Chunda, R., & Lavy, V. (2005). Palliative care in children with advanced HIV/Aids. *Malawi Medical Journal*, 17(2), 51–52.
- Emmanuel, E. J. (2004). Ending concerns about undue inducements. *Journal of Law, Medicines & Ethics*, 32 (1).
- Government of Malawi. (2010). *Malawi millennium development goals report*. Lilongwe, Malawi: Ministry of Development Planning and Cooperation.
- Government of Malawi, (Undated), Malawi vision 2020: National long-term development perspective for Malawi. Accessed at <http://www.sdn.org.mw/malawi/vision-2020/index.htm>
- Kasenene, P. (2000). African ethical theory and the four principles. In R. M. Veatch (Ed.), *Cross-cultural perspectives in medical ethics* (Vol. 141, pp. 347–357). Sudbury, MA: Jones and Bartlett Publishers.
- Leino- Kilpi, H., Valimaki, M., Arndt, M., Dassen, T., Gasull, M., Lemonidou, C., Scott, P. A., Bansemir, G., Cabrera, E., Papaevangelou, H., & McParland, J. (2000). *Patient's autonomy, privacy and. Informed consent* (Vol. 39). JM Graf von der Schulenburg 2009: 2(2)50–54.
- Malawi Health, in <http://www.mapsofworld.com/malawi/health.html>. Accessed, July 8, 2011.
- Mangham, L. (2006). Who benefits from public spending of health care in Malawi? An application of benefit incidence analysis to the health sector. *Malawi Medical Journal*, 18(2), 60.
- Mbiti, J. (1970). *African religions and Philosophies* (p. 141). New York: Anchor Books.
- Mfutso-Bengo, J., & Masiye, F. (2011). Toward an African Ubuntuology/uMunthology bioethics in Malawi in the context of globalization. In C. Myser (Ed.), *Bioethics around the globe* (p. 155). Oxford: Oxford University Press.
- Ministry of Health. (2005). *Malawi community home based care policy and guidelines*. Lilongwe, Malawi: Ministry of Health.
- Ministry of Health. (2011). *Malawi health sector strategic plan 2011–2016*. Lilongwe, Malawi: Author.
- Mueller, D. H., Lungu, D., Acharya, A., & Palmer, N. (2011). Constraints to implementing the essential health package in Malawi. *PLoS One*, 6(6), e20741. doi:10.1371/journal.pone.0020741.
- Mzoneli, Z. C. (Ed.) (1998). *Perspectives on Ubuntu. A tribute to FEDSEM*. Alice: Lovedale Press, p. 66.
- National Statistical Office (NSO) [Malawi] and ICF Macro. (2011). *Malawi demographic and health survey 2010: Preliminary report*. Calverton, Maryland: NSO and ORC Macro.
- Pera, S. A., & Van Tonder, S. *Ethics in nursing practice*. Cape town, South Africa: Inta.
- PlusNews. (2012). MALAWI: Government proposes mandatory HIV test for pregnant women. Retrieved August 16 2012 <http://www.plusnews.org/Report/75984/MALAWI-Government-proposes-mandatory-HIV-test-for-pregnant-women>
- Ponje, A. A. (2012). Nyasa times, the morality of medical workers' strikes. Retrieved August 16, 2012 <http://www.nyasatimes.com/malawi/2012/06/05/the-morality-of-medical-workers-strikes/>
- Sebidi, L. J. (1998). Toward a definition of Ubuntu as African humanism. In M. G. Khabela & Z. C. Mzoneli (Eds.), *Perspectives on Ubuntu. A tribute to Fedsem*. (pp. 62–67). Alice: Lovedale Press.
- Selinger, C. P. (2009). The right to consent: Is it absolute? *British Journal of Medical Practitioners*, 2(2), 50–54.
- The Government of Malawi. (1994). *The constitution of the Republic of Malawi*. Lilongwe: Government Printers.
- The Malawi Project, in <http://www.malawiproject.org/about-malawi/thenation/hospitals-healthcare/>. Accessed July 8, 2011.
- UNAIDS. (1999). Comfort and hope: Six case studies on mobilizing family and community care for the people with HIV/AIDS. June 1999. UNAIDS/99.10E USAID.
- UNESCO Chair in Bioethics. (2003). *Informed consent*. Israel National Commission for UNESCO. Israel: University of Haifa.

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- UNGASS Country Progress Report. (2010). Malawi HIV and AIDS monitoring and evaluation report: 2008–2009. <http://www.unaids.org/en/Regionscountries/Countries/Malawi/>. Accessed October 27, 2011.
- Ungvarski, P. J., & Flaskerud, J. H. (1999). *HIV/AIDS: A primary guide to primary care management* (4th ed.) (Vol. 676, 544 pp). Philadelphia, PA: Sanders.
- United Nations, The Universal Declaration of Human Rights
- World Health Organization. (2008). World Health Statistics: Country profile sheet. Retrieved July 20, 2012 <http://www.who.int/countries/mwi/en/>