



United Nations
Educational, Scientific and
Cultural Organization



CONFERENCE PROCEEDINGS

**International Conference on Bioethics
Organized by the UNESCO Regional Centre for
Documentation and Research on Bioethics
at Egerton University, 12-14 August 2008**

Egerton, March 2009

The ideas and opinions expressed in this publication are those of the authors and do not necessarily represent the views of UNESCO.

The designations employed and the presentation of material throughout the publication do not imply the expression of any opinion whatsoever on the part of UNESCO concerning the legal status of any country, territory, city or area or of its authorities, or concerning its frontiers or boundaries.

SHS/2009/PI/H/2

Table of Contents

Introductory Speech during the Opening of the Conference on Bioethics at Egerton University on Tuesday, 12 August 2008	iv
Opening Speech for the Conference on Bioethics	vi
Overriding patient autonomy in medical practice: Best interests, necessity, therapeutic privilege and public policy.....	1
HIV/AIDS in Africa: A Bioethical Hard Blow to Human Dignity and Human Rights	6
Rethinking state participation in HIV vaccine trials.....	21
Developing Challenges and Ethical Considerations of Genetically Modified Organisms (GMOs) in Biomedical Research	28
Genetically Modified Food Products: Ethical Dilemma and Implications for Food Security.....	35
Biopiracy: Threat to Biodiversity Conservation	45
Use of indigenous plants in sustaining health and livelihoods in Africa ..	53
Plants as source of Traditional Medicine: Ethical implications on unregulated and uncontrolled use	58
Is there an African Bioethics?.....	68
Bioethical Issues in African Culture and Religions.....	76
African Traditional Medicine: Ethical-Deontological and Medico-legal constraints in Italy	82
African Traditional Medicine: Ethical-Deontological and Medico-legal constraints in Italy	87
Towards a more effective regulation of Human Biomedical Research in African communities	92
Ethical dilemma in using Placebos for drug research	99
Bioethics Teaching in African Institutions of Higher Learning.....	104
Legal approaches in Bioethics in Italy	111
Closing speech	114
Annexes.....	117
<i>Programme</i>	117
<i>List of Participants</i>	122
<i>Members of the organizing committee</i>	129

Introductory Speech during the Opening of the Conference on Bioethics at Egerton University on Tuesday, 12 August 2008

By Prof. JM Mathooko, Chair, UNESCO Bioethics at Egerton University

UNESCO Regional Adviser in Africa, Dr. John Nkinyangi, Deputy Vice-Chancellors & Principals, Representatives of various Government Ministries & Institutes, Participants, Ladies and Gentlemen. Let me start by warmly welcoming you to Egerton University, the home of the UNESCO Regional Bioethics Documentation & Research Centre and also thank you for finding time from your busy schedule to be here today. Today marks the first major activity in the brief existence of the UNESCO Regional Bioethics Documentation & Research Centre; a moment we are interacting, sharing experiences and reflecting on issues related to bioethics. Such gatherings are rare not only in Kenya but also in Africa as a whole. It is my considered belief that you will interact, discuss and opine to demystify bioethics amongst our scholars and other person(s) engaged in matters involving ethical considerations. This Conference comes at an opportune time when Kenyans are gearing for debate on abortion – is it ethical or unethical? That is the big question. As you are already aware from the Invitation Letters sent to you for this Conference, the theme is *“Bioethical Perspectives and Practices in Research, Medicine, Life Sciences and Related Technologies in Sub-Saharan Africa”*. This conference will endeavour to foster bioethical reflections and information sharing amongst stakeholders involved in medicine, life sciences and related technologies. The sub-thematic areas include ethical implications in human research; ethical issues in animal experimentation in science; genetically modified organisms and products: an African Dilemma; biodiversity and environment; biopiracy; traditional medicine; bioethical issues in African cultures and religions; ethical dilemmas in medicine; bioethics teaching in African institutions of higher learning; legal approaches in bioethics; and Is there a need for a Code of Ethics for researchers? We hope, through the diverse papers to be presented in this Conference, you will be enriched and even know what bioethics is in the first place. In addition to the activities in the conference hall, participants are welcomed to a trees’ planting session at the Bioethics

Square in the Egerton Botanic Garden after the closure of the Conference. This is ethical and affirms our commitment to the Mother Earth.

Ladies and gentlemen, the UNESCO Regional Bioethics Documentation & Research Centre wishes to thank UNESCO Regional office, Gigiri-Nairobi, Ministry of Education through KNATCOM, and Egerton University, and especially the Vice-Chancellor Prof. James Tuitoek, for supporting this Conference. We wish them well.

The Organizers of the Conference wish you a blessed stay at Egerton University. God Bless you.

Opening Speech for the Conference on Bioethics

By Prof. Karega Mutahi, the Permanent Secretary, Ministry of Education, Republic of Kenya

The Vice Chancellor, Egerton University, The UNESCO Regional Advisor for Social and Human Sciences in Africa, Dr. John Nkinyangi, The UNESCO Chair in Bioethics, Prof. Jude Mathooko, Distinguished Guests, Ladies and Gentlemen. I am most delighted to be with you today, to open this very important conference on Bioethics. Today marks an important occasion for Kenya and our region as a whole. The holding of this conference on Bioethics at Egerton University, (the home of the UNESCO Regional Bioethics Documentation & Research Centre), offers us a unique opportunity to reflect on the importance of Bioethics in Science and Technology and its applicability in various disciplines in the development process.

Africa faces bioethical challenges in research and technology especially as they relate to medicine and life sciences. Questions on human cloning, stem cell research, genetic testing, genetically modified organisms, and human organ donation continue to dominate public debate. All these issues directly touch on the well-being of human beings, with or without consideration of their social, legal and environmental dimensions.

East African states and Africa as a whole have to take urgent independent decisions on the application and utilization of these novel advances in Science and Technology. In depth understanding of the impact of these scientific activities on human beings, biodiversity and the environment is critical, if we are to avoid disastrous consequences.

Ladies and Gentlemen, awareness of Bioethics and its challenges in Kenya has grown steadily in the last five years. Kenya now leads in the field of bioethics, with representation in UNESCO Committees such as the Inter-governmental Bioethics Committee (IGBC) whose chairman is a Kenyan, and being the only country in Africa with a UNESCO Regional Bioethics Centre.

You no doubt recall that the Director General, in Addis Ababa in February, 2007, emphasized the importance of Bioethics in the development of Science and Technology in Africa, that it ignores bioethics at her own peril.

Ladies and Gentlemen, UNESCO has continued to support the effort Kenya is making in the development of Bioethics. For instance, Kenya was privileged to host the 14th International Bioethics Committee (IBC) meeting in May, 2007, and in July, 2007 held the 2nd Ethics Teacher Education Training. UNESCO has also provided grants for the holding of workshops for the Domestication of the Universal Declaration on Bioethics and Human Rights in the region. In addition, one of the activities in the 2008-2009 biennium is to

provide assistance in the establishment of a National Bioethics Committee.

Through these activities, the role of Bioethics in Science and Technology is now more appreciated. As a Government, we thank UNESCO for this support and especially the Regional Office in Gigiri for its support to this conference on Bioethics.

Kenya is strategically placed as a focal point to boost efforts in networking, fostering and integrating UNESCO declarations in the field of Bioethics at national and regional levels through capacity building, establishment of national committees, and enhancement of the implementation of the ethics Teacher training Programme. The Ministry of Education supports the efforts of UNESCO in developing core courses in Bioethics to be taught at the University level. In this regard, Kenya wishes to be the first country to be considered for mounting this Core course in our public universities.

Ladies and Gentlemen, we appreciate and thank UNESCO for providing books and their facilities to the Regional Bioethics Documentation & Research Centre. You will recall that this centre was established through Draft Resolutions adopted during the 33rd General Conference held in 2005.

Since inception, it has become key to the development of Bioethics in the region. It has increased the platform for collaboration, networking and information sharing on bioethical issues among institutions of higher learning. The centre also has the mandate to create a regional database on bioethics research and policy, and to initiate, guide and contribute to public debate on bioethical issues.

Our desire in the Ministry of education is to see this Centre grow from strength to strength and become a centre of reference in Bioethics in this region and in its collaboration with UNESCO and other organizations.

We appreciate that topics to be presented in this Conference are relevant to our development agenda and for the well being of our society, especially now that we are focusing on the realization of vision 2030. I have noted that areas in medicine, law, genetically-modified organisms and herbal medicine have been given emphasis in this conference. These are areas which have aroused much public debate and which are of interest to you to discuss and recommend bioethical issues that require further consideration.

I want to challenge our universities to take the lead in research in these areas for the betterment of the welfare of our people. I have no doubt that, bioethical issues will now be better understood, especially when the Science, Technology & Innovation Agenda is being emphasised by the government through the Ministry of Higher Education, Science & Technology. I urge our scientists to take advantage of the existing good will for our common good.

Ladies and Gentlemen, the Government takes Research and Development (R & D) seriously since it is the means of creating wealth and enhancing and sustaining human development. The Government's implementation of the sessional paper No. 1 of 2005,

on policy framework for Education, Training and Research, attests to its commitment in this field. I encourage you to deliberate and make recommendations on how Bioethics can be part of curricula at all levels of our education. Also, consider how “Wanjiku” could benefit from the advancement of bioethics.

Ladies and Gentlemen, in conclusion, let me thank the organizers of this conference, and Egerton University for taking the lead in this area of Bioethics. I also wish to thank you for attending this conference. For those of you, who have not visited Kenya before; please find time to see our beautiful scenery and wildlife in our National Parks.

Ladies and Gentlemen, I now have the pleasure to declare this Conference on Bioethics officially opened.

Thank you and God bless you.

Prof. Karega Mutahi
Permanent Secretary, Ministry of Education

Overriding patient autonomy in medical practice: Best interests, necessity, therapeutic privilege and public policy

Sylvester C. Chima

*Programme of Bio & Research Ethics and Medical Law,
College of Health Sciences, University of KwaZulu-Natal,
Durban, Republic of South Africa
E-mail: chima@ukzn.ac.za or chimasc@hotmail.com*

Abstract *Prima facie, every competent adult has the right to decide whether to consent or refuse any medical treatment, even if such refusal could lead to death. However, this right to respect for autonomy is a rebuttable right, which could be overridden where there is temporary or permanent mental incapacity, such as due to unconsciousness, in infancy, or mental retardation. In these cases, an individual's right to informed consent can be overridden on the basis of necessity, best interests, or as a matter of public policy. In view of ongoing ethical and medico-legal dilemmas regarding the management of patients, including withdrawal of life sustaining nutrition and hydration from patients in a persistent vegetative state (PVS), compulsory quarantine for emerging infectious diseases or treatment of unconscious patients. It is important that physicians and patients are aware of instances where an individual's autonomy rights may be legally overridden, without recourse to medical paternalism.*

Key words: *Dilemmas, Ethics, Rights, Paternalism, Self-determination*

The Concept of Autonomy

Autonomy in medical law and ethics refers to self-determination or freedom of choice. This ethical principle that each person has a right to decide what can be done to his or her own body during medical treatment has found expression in some health statutes and ethical codes through the doctrine of informed consent. Autonomy by itself has never been fully recognized as a legally enforceable right. Instead two other rights, derived from the principle of respect for autonomy, have been almost universally accorded legal protection. The first is the right to bodily integrity, protected by legal rules against assault or battery. The second is the right to bodily well being, protected by professional negligence laws. A patient's right to autonomy during medical treatment was outlined by Cardozo J in the case of

Schloendorff v Society of New York Hospital, 1914, which opinion was reaffirmed by the US Supreme Court in *Cruzan v Missouri Department of Health*, 1990. Here the court noted that:

“No right is held more sacred or is more carefully guarded by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of another”.

Therefore a physician who exceeds the consent given by a patient will be guilty of infringing the patients’ right to bodily integrity and well being (Beard, 2005), as stated in Box 1 below.

Respect for Autonomy

“The first point to make is that it is unlawful so as to constitute both the tort and crime of battery, to administer medical treatment to an adult, who is conscious and of sound mind, without his consent...such a patient is completely at liberty to decline to undergo treatment, even if the result of his doing so will be that he will die”

(Airedale NHS Trust v Bland 2003)

Box 1

Patient Autonomy as a Moral Dilemma

Despite numerous legal cases which illustrate the importance of the principle of respect for autonomy in the common law there may arise in medical practice, major ethical dilemmas, where physicians and legal authorities encounter problems in upholding the principle of respect for autonomy. Instead there may be need to abandon rights-based autonomy, in favor of utilitarian principles, either on the basis of necessity, best interests or public policy. This article analyzes relevant case law and ethical principles, to find instances where respect for autonomy could be considered to have only a *prima facie* standing and may instead be overridden when there is a conflict between equally compelling moral considerations.

The Doctrine of Necessity

Necessity is an established doctrine in common law, where it is routinely applied during the emergency treatment of patients. It is usually considered lawful to treat emergency patients, within the limits of what is medically necessary, until such a patient is in a position to consent to further treatment. As explained in *F v Berkshire Health Authority*, 1989: “That there exists in the common law a principle of necessity which may justify action, which would otherwise be unlawful, is not in doubt” (Goff LJ, 1989). Brooke LJ

summarized three requirements for the application of the doctrine of necessity in *Re A 2000*:

- (a) The act is needed to avoid inevitable or irreparable evil
- (b) No more should be done than is reasonably necessary for the purpose to be achieved
- (c) The evil inflicted must be disproportionate to the evil avoided

The Roman Catholic doctrine of double-effect also justifies such action where it argues that if the intent of the action is to affect overriding good, then such action is defensible, even if unintended harm occurs. Some legal authorities have suggested that harm should be weighed against the potential benefit before deciding on the best course of action via a risk/benefit analysis (Kennedy and Grubb, 2003).

The Doctrine of Best Interests

It has been stated that best interests is centered primarily on respecting and promoting autonomy and is aligned with the desire-fulfillment theory which subscribes to the position that well-being consists in having one's desire fulfilled. In other words, to maximize a person's well-being, one ought to give them whatever they want. Opponents of this theory argue that there could be a conflict between what an individual wants and what is actually good for them (Hope, 2008). Based on this conflict between 'wants' and 'needs', one can divide the best interests' argument into 'subjective' and 'objective' categories. The 'objective' view of best interests is the idea that judgments on what is best can be determined independently of the view or wishes of the individual concerned. Based on this view, the action or omission that brings about maximization of the relevant consideration in a particular situation is that which is in the individual's best interests (Dawson, 2005). Those who oppose an objective view have argued against it on the basis of what parameters or competing factors would be taken into consideration in determining what would be in the best interests of the individual concerned. The defining argument for the objective view is that it should be based on independent parameters, which are combined to maximize the good, even if we do not know what those parameters are, or how to determine them.

Advocates of the 'subjective' view of best interests tend to argue that the concept of best interests should be determined by what a particular individual would choose if they were competent. In its moderate form, it could be argued that where knowledge is available of the individual's wishes, best interests should be based on these. The central idea in the subjective argument would be that if I value certain types of beliefs, for example, religious beliefs. Actions that tend to take account of these views would be in my best interests and

In many cases, it will not only be lawful for doctors on the ground of necessity, to operate on or give other medical treatment to adult patients disabled from giving their consent; it will be their common law duty to do so. In the case of adult patients made unconscious by an accident or otherwise, they will normally be received into the casualty department of a hospital, which thereby undertakes the care of them. It will then be the duty of the doctors at that hospital to use their best endeavors to do, by way of an operation or other treatment, that, which is in the best interests of such patients....Emergency is however not the criterion or even a pre-requisite: it is simply a frequent origin of the necessity, which impels intervention. The principle is one of necessity, not of emergency. The doctrine should strictly be confined to action taken to preserve the life, health or well being of another, who is unable to consent to it.'

(Re F 1990)

Box 2

enhance my autonomy, while actions that tend to ignore these beliefs would tend to compromise my autonomy (Dawson, 2005).

Autonomy and Public Policy

The Universal Declaration of Human Rights 1948 and all similar documents generally guarantee a right to life. The UK Human Rights Act 1989 states:

“Everyone’s right to life shall be protected by law. No one shall be deprived of his life intentionally save in the execution of a sentence of a court following his conviction of a crime for which this penalty is provided by law”.

However, this fundamental right to life is frequently overridden where courts have authorized the withholding or withdrawing of life sustaining nutrition and hydration, from patients in a persistent vegetative state (PVS). This was shown in the English case of *Airedale Trust v Bland* 1993, the American cases of Karen Quinlan and Terry Schaivo (Stewart, 2007), and the South African case of *Clarke v Hurst* 1992. Here, the Courts held that these acts of omission were compatible, with the fundamental rights outlined in international conventions on human rights and were therefore not unlawful. Further, the European Convention on Human Rights (ECHR) guarantees the right to liberty and security, but gives exceptions, where such liberty could be curtailed, including:

‘The lawful detention of persons for the prevention of the spreading of infectious diseases, of persons of unsound mind, alcoholics or drug addicts or vagrancy.’

These exceptions were tested in *Association X v UK* 1979. The ECtHR¹ held that where a small number of children had died as a result of a vaccination scheme, whose purpose was to protect the health of

¹ European Court of Human Rights

society by eliminating infectious diseases. It could not be said that there had been an intentional deprivation of life within the meaning of article 5 of the ECHR². Further justifications for the detention of patients for the treatment of infectious diseases in the best interests of society have recently been applied in the detention and treatment of individuals with extremely drug resistant tuberculosis (X-DR TB), based on the legitimate principle of limiting one individual's autonomy to prevent harm to another (Efferen, 1997).

Mental Capacity and Patient Autonomy

In the legal and ethical analysis of treating people against their will, a great deal depends on whether the patient is competent or has legal capacity. There is a presumption in common law that any adult has capacity unless proven otherwise by acceptable evidence. The common law test for the establishment of a patient's capacity to exercise autonomy rights was outlined as shown in box 3 below:

Determining Mental Capacity

'Capacity is ultimately a legal not a medical decision...it is for the court to decide the question of capacity, although the court must pay attention to the evidence of experts in the medical profession who can indicate the meaning of symptoms and give some idea of the mental deterioration which takes place in cases of this kind.' (Richmond v Richmond 1914)

"A person lacks capacity if some impairment or disturbance of mental functioning renders the person unable to make a decision whether to consent to or to refuse treatment. That inability to make a decision will occur when: (a) the person is unable to comprehend and retain the information which is material to the decision, especially as to the likely consequences of having or not having the treatment in question.(b) The patient is unable to use the information and weigh it in the balance as part of the process of arriving at a decision." (Re MB 1997)

Box 3

² European Convention on Human Rights and Biomedicine

A lack of capacity cannot be established merely by reference to a person's age, appearance, intelligence, level of education or a condition of his, or an aspect of his behavior, which might lead others to make unjustified assumptions about his capacity. Deciding upon the best interests of a patient who lacks capacity is not always straightforward. Therefore, judgments about mental capacity are pivotal in health care, since they determine the ability of patients to make choices about their own care.

Therapeutic Privilege

Therapeutic privilege represents a more controversial basis for the overriding of patient autonomy when compared to other criteria. This doctrine contends that a physician may legitimately withhold information to any patient, based on judgments that divulging such information could be potentially harmful to the affected patient. This occurs especially in cases of depression or emotional lability. The precise use of therapeutic privilege varies across legal jurisdictions. While some jurisdictions permit a physician to withhold information where it would be contrary to the therapeutic intent and lead to deterioration in the patient's condition. Others permit the withholding of information only if the patient's knowledge of the information would have health-related consequences. The American Medical Association, 2007 suggests that physicians may withhold information about a patient's diagnosis or treatment when disclosure would pose such a serious psychological threat, as to be medically contraindicated. However, it warns that therapeutic privilege should not be used to prevent patients from exercising their right of self-determination.

Concluding Comments

In recent times medical practice is gradually moving away from the era of paternalism based on a 'reasonable doctor standard' towards respect for autonomy and 'prudent patient standards'. Societal pressures in the areas of civil liberties and consumerism have influenced these shifts towards libertarian rights based autonomy. This change in approach means that physicians must recognize that what is 'best' varies from patient to patient, partly because of different cultural values held by each patient. It has been suggested that the easiest way of learning about patient values is by asking the patients themselves, thereby involving patients in the decision-making process. Numerous decisions by the courts and newer legal statutes have emphasized the need to value patient's rights. However, it must be noted that the recognition of patient's rights in every situation is difficult because of the conflict that may arise between the need to treat patients in their best interests, and the need to provide effective therapy. Patients must learn to recognize that

'rights' are only justifiable claims that individuals can make upon other individuals or upon society. As such, rights are not absolute, but only assert *prima facie* claims (Beauchamp and Childress 2003). To paraphrase Donaldson LJ as shown in box 4 below:

Patient Autonomy as a Rebuttable Right

'Prima facie every adult has a right and capacity to decide whether or not he will accept medical treatment, even if refusal may risk permanent injury to his health or even lead to premature death...However, the presumption of capacity to decide, which stems from the fact that he person is adult is rebuttable...An adult may deprived of his capacity to decide either by long-term incapacity, or retarded development, or temporary factors such as unconsciousness or confusion, or the effects of fatigue, pain or drugs...' (Re T 1992)

Box 4

From the foregoing analysis one can conclude that patient autonomy is an important legal and ethical right that needs to be enhanced in medical practice. However, this ethical principle when in competition with other equally important moral considerations could be ethically and legally overridden in the best interests of the patient or on the basis of necessity or public policy.

References

- Airedale NHS Trust v Bland, 1993. 2 WLR 316.
- Association X v UK, 1979. App No 7154/75; 14 DR 31.
- Beard M, Midgley J.R., 2005. Therapeutic privilege and informed consent: Justified erosion of patient autonomy. Journal of Contemporary Roman-Dutch Law (THRHR) 68: 51-69.
- Beauchamp T.L., Childress, J.F., 2001. Principles of Biomedical Ethics, Oxford: Oxford University Press.
- Buchanan, A. Brock, D., 1989. Deciding for others: The ethics of surrogate decision making, Cambridge: Cambridge University Press.
- Clarke v Hurst, 1992. NO (4) SA 636 (D).

- Council of Judicial Affairs, 2007. Code of Medical Ethics: Current Opinions with Annotations. Chicago, IL: American Medical Association.
- Cruzan, by her parents and co-guardians v Director, Missouri Department of Health, 1990. Supreme Court of the United States 497 U.S. 261 Decided.
- Dawson, A., 2005. The determination of the best interests in relation to childhood immunization. *Bioethics* **19**: 1467-8519.
- Efferen, L.S., 1997. In pursuit of tuberculosis control: civil liberty v public health, *Chest* **112**: 5-6.
- European Convention on Human Rights and Biomedicine, 1997. Oviedo: Spain.
- F v Berkshire Health Authority (Mental Health Act Commission intervening), 1989. 2 All ER 545.
- Hocton, A., 2002. The Law of Consent to Medical Treatment. London: Sweet and Maxwell.
- Hope, T., Savulescu, J., Hendrick, J., 2008. Medical Ethics and Law: The Core Curriculum. Edinburgh: Churchill Livingstone.
- Human Rights Act, 1998. London: United Kingdom: Department of Health.
- Kennedy, I., Grubb, A., 2003. Principles of Medical Law. London: Butterworths.
- Re A, Children: Conjoint twins: surgical separation, 2000. 4 All ER 961.
- Re F, 1990. 2 A C55 .
- Richmond v Richmond, 1914. 111 LT 273 27, 148.
- Re M.B, 1998, An adult: Medical treatment 2 FLR 426.
- Re T, 1992. Adult: Consent to Medical Treatment. 2 FLR 458.
- Re T, 1992. 3 WLR 782.
- Schloerndorf v Society of New York Hospital., 1914. 211 NY, 105 NE 92.
- Singh, J.A., Upshur, R., Padayatchi, N. 2007. XDR-TB in South Africa: No Time for Denial or Complacency. *PLoS Med* **4**: e50 doi:10.1371/journal.pmed.0040050.
- Stewart R.S., 2007. Withholding and withdrawing life support: Moral Dilemmas, Moral Distress, and Moral Residue. *Online Journal of Health Ethics* **2** :1-14.
- Universal Declaration of Human Rights., 1948. Adopted by General Assembly resolution 217 A (III) of 10 December, 1948. New York, NY: United Nations.

HIV/AIDS in Africa: A Bioethical Hard Blow to Human Dignity and Human Rights

Paul Chummar

The Catholic University of Eastern Africa

P. O. Box 62157 City Square

00200 Nairobi, Kenya

Email ID: pchummar@gmail.com / paulc@cuea.edu

Abstract *The gravity of HIV/AIDS is still relevant in the Sub-Saharan countries and it is a bioethical issue. It is a severe blow to the human dignity and human rights. The pandemic causes the disintegration of the person and is mainly the result of human, social, and political actions. In this situation the need for an African Bioethical Solution seems to be inevitable. The presentation paper tries to outline possible specific steps towards such a solution.*

Key words: *Bioethics, Human Dignity, Human Rights, Person, Social ethics, Sexual ethics, Medical ethics, Povert, Government, Gender inequality, Initiation, Public health, Education for healthy life, Marriage customs, Influence of western sexual behaviour, Healing process,, Care for the sick, Inculturated bioethical solutions.*

Introduction

It is a paradox that although none of the African nations have the potential power for a nuclear or atomic weapon of mass destruction. that AIDS has proved itself to be the “virus of mass destruction”, very specially, in the African continent. Since the segmented approach has proved less successful in the fight against the pandemic, UNAIDS has, in the last few years, been proposing a “comprehensive approach”. This paper attempts to treat the problem of HIV/AIDS from the bioethical perspective, with an emphasis on the innate nature of human beings, Human Dignity and Human Rights, and to highlight some possible ethical and bioethical areas which deserve our special attention. To undertake this in the African context I would like to do this in two main steps: I. HIV/AIDS: a Bioethical Issue and HIV/AIDS: a severe blow to human dignity and human rights and II. African Bioethical Contributions in the eradication of HIV/AIDS and for the care of those who are infected.

Part I.

HIV/AIDS: a bioethical issue

HIV/AIDS is a bioethical issue since, on the one hand, it annihilates the *bios* (Greek), the life of humans, and, on the other hand, the definition “Acquired Immune Deficiency Syndrome” for this (so far) incurable, fatal disease of AIDS intrinsically related it to human actions. As the slogan says, “You don’t get AIDS; you acquire AIDS”. In 95% of the cases AIDS is a fatal disease “acquired” either through one’s own action or by the actions of another person.

Ethics is the rational discipline that deals with the different aspects of human life and human actions and activity, in order to orient such activity toward what is good for the person and, ultimately, for his self-actualisation. And HIV/AIDS is the result of *un-bio-ethical way* of acting that obstructs the fullness of life. Further, ethics is a practical and normative discipline: i.e. it deals with actions and the norms of the right way of living, which bring natural morality to the level of science. Through critical thinking, analysis and scrutiny, it is the urgent task of ethics to identify the sources and roots of this fatal infection. Scrutinizing them from this perspective we find the sources and roots of AIDS related to *three* main applied ethical areas – *social, sexual* and *medical* – offer fertile ground for HIV/AIDS in African context.

HIV/AIDS: a severe blow to the human dignity and human rights

There is “no more vibrant, hope-filled or complex idea alive in the world of today than human rights and dignity for all” (Mann, 1999, p. 21). Since the onset of AIDS the gap between this rhetoric and reality is experienced as very great. The spread of the pandemic has increased not only violence against the body of a person, but also exercises violence against the societal existence of the person, but caused also marginalisation and discrimination of the person and of his health condition. What a contradiction! A society which lavishly invests in human health discriminates against its own objective even in the main arena of the disease! It is, therefore, more than appropriate to reflect on the two very basic notions – human dignity and human rights – with regard to the pandemic and its causes.

Human dignity

The dignity of a human being is inseparable from their being. According to classical scholastic understanding human dignity is understood as twofold although both types are intrinsic in the nature of a person: one is understood as an *endowment* or *gift* and the other as an *achievement* or *acquisition*. The first type – *dignity as an endowment to the person* – is received by the person at birth. All the world religions and natural religions recognise this specific understanding. Because every human being is by nature a valuable being, a being to be revered and respected from the very beginning of his/her existence. The *second type of dignity* – *achievement or acquisition* – is the

dignity to which human beings are called *as intelligent and free persons capable of determining their own lives by their own free choices*. The formation of this dignity depends upon the individual person as well as other persons and it is directly connected with the choices and actions of the persons (cf. May, 1991. p. 23).

Human rights

The notion of human rights has very long and remote roots in Stoic philosophy. It is based on the understanding that all persons are equal because of their capacity of participation in *world reason* (*Weltvernunft* and *Brüderlichkeit* have their root in the capacity of reasoning of a person [Stocis]). Substantial contributions to the idea of human rights were made by philosophers and theologians of the Middle ages. Decisive impetus towards the modern understanding of the notion of human rights was given by the *Intellectual World of Humanism, Rationalist Natural Law* and the *Enlightenment*. After a revolutionary breakthrough in the understanding and embodiment of the notion in the Declaration of Independence of the United States and in the French revolution and the French Constitution, the notion of Human Rights gained its decisive development in the Universal Declaration of Human Rights by the United Nations Organization (UNO) in 1948. The understanding of human rights today is very close to *Natural Law* thought: i.e. the basic rights are derived from the fact that in contradistinction to all other beings, human nature is endowed by reason and free will and therefore of a common, equal dignity of all human beings (cf. Peschke, 2004, p. 243-249).

Disintegration of the Person due to HIV/AIDS

Both the notions – human dignity and human rights – emerge from a holistic understanding of the notion of the human person. But with HIV/AIDS the wholeness of the person disintegrates not only in the understanding of its own wholeness, but also in the segmental procedures used to combat the pandemic. HIV/AIDS is a fatal and direct attack on the existence of the person and the *Person* whose dignity and right suffer from AIDS must be the starting point of the discussion on HIV/AIDS. The direct assault on the dignity of the person due to the pandemic are manifested in the person's right to life and health, sexuality, physical expression of love, intimacy, transforming and fulfilling human relationships, the transmission of life, child bearing, and the continuity of human societies.

Stigmatisation

Stigmatisation of the person – infected or affected by AIDS is irrational, harmful and powerful in supporting the degradation of the person's dignity. It is the denial of truth, unjustifiable by any means. To radically overcome the assaults against human dignity and human rights, the root causes must be tackled. I dare to say that most of this process of disintegration of the notion of the person in African society has deep roots in the colonial era and in the unstoppable stream of

western cultural currents and their influences on Africans. It is to be remembered that the African continent, the cradle of humanity, was rich in its culture and economy before the colonial burglars landed on the continent. The emergence of the virus has taken place in different sources and contexts.

1. Some social ethical and political sources and contexts

Poverty: The core reason for the spread of pandemic in Africa is certainly poverty. The current political and economic situation in Africa deepens the inequality between rich and poor, and the people are more and more divided into super rich and miserably poor. In their utter poverty in order to survive and to feed their children, some women and men exchange their bodies for sexual activities. It makes no difference whether they die of AIDS or of hunger.

Many employees and casual workers in the towns, hailing from far away areas are not financially capable of going home every weekend. Their sexual gratification is then achieved with casual sex workers. And on their home visits they infect their partners too.

Governments: As African governments get more and more weighed down by huge international debts they are not financially capable of doing enough to prevent the spread of infection through effective ethical educational methods and to care for the infected and affected. Nor, to a certain extent, is it a government priority. Often the faith communities and NGOs are resorted to in this AIDS no mans land.

Public health and education for healthy life is still only available for some privileged groups in many African countries and it is not understood as a 'common good' for all from the perspective of human rights. The right for bodily privacy, decent wages and safe housing, clean water and adequate nutrition are reserved for those who can pay them and not for the poor. But Universal Declaration on Human Rights, which affirms that the right to health of a person is to be guaranteed by the laws of the states (cf. Universal Declaration of Human Rights art. no. 25, and Treaty on Economic, Social and Cultural Rights art. no. 12) and which is guaranteed in the constitution of almost all the nations, remains a purely rhetoric statement and confined to books and the statements of higher authorities. It states: "... everyone has the right to a standard of living adequate for ... health and well-being of himself and his family, including food, clothing, housing, medical care and the right to security in the event of ... sickness and disability ... Motherhood and childhood are entitled to special care and assistance" (<http://www.pdhre.org/rights/health.html>). It is a shocking fact that worldwide more than 121 million children do not have school education and that 65 million of them are girls. The highest concentration of unschooled girls is in Sub-Saharan Africa. Who teaches these girls about healthy living and ethically good sexual life?

2. Some social and sexual contexts

Gender inequality: In the traditional African society women and girls have less status than the men and boys. The subjugation to sexual violence at home and outside home is generally tolerated and fuels the infection rate. Gender inequality and subordinate roles marginalize them and hinder self-sustenance and self-empowerment (economic powerlessness, feminized poverty, feminized illiteracy) and subordinate them to their male partners and guardians and often limit their freedom to make free and independent decisions, even in matters of sexuality. Their dependency is of such a high degree that the ability to say no to sexual activities with an infected husband, or other persons in the case of widow inheritance in some cultures, is curtailed. Domestic violence and multiple forms of discriminatory practices in a household in a male dominated society is accepted and taken for granted! The superstition that sexual intercourse with virgins and young girls, cures infection is not yet condemned everywhere as a barbarous and heinous act by men. In refugee camps women and girls are victims of the sexual exploitation of armed forces and camp officials on whom they are very often dependent. The culturally accepted practice of polygamy is another serious cause of infection of AIDS.

Initiation: Without understanding the real anthropological, social, and cultural meanings of the customs, zealous European Missionaries tried to abolish traditional moral African customs which were protecting Africans in the ethical matrix. For example: the abolition of the initiation rite of passage as one of the most important junctures from childhood to adulthood. Initiation is preceded by a number of social and sexual ethical instructions, where a young person is prepared ethically for adulthood and where the person has to learn from elders of the family how to live responsibly as an adult and as a partner in married life, how to behave in matters of sexuality and procreation, in parenthood, family and community. This transmission of ethical principles from one generation to the next in the context of initiation is now mostly broken, leaving a *moral vacuum*. The growing curiosity about sexual knowledge and its functioning are then satisfied mainly through the media and peers in immoral ways.

Marriage customs: Another important means of destruction to the sound ethical system crept in through the prohibition of traditional marriage customs and by their replacement by foreign Christian marriage customs. The African traditional understanding of marriage and its rites envisage the character and certainty of a life-long binding union and its successes, and are intrinsically supported by both families of bride and groom and their communities. Unlikely the western marriage custom, African marriage is a *progressive reality* which does not come into existence at the moment of the marriage ceremony. It is a gradual, progressive maturing process of the man

and woman into an intimate relationship, developed through a process of negotiations, visiting, and gift-giving first through both families, and later ratified by the communities. In this long process of growing together into partnership, into an inseparable unity of the bride and groom, procreation plays most important role. An African marriage celebration between the extended families and the communities causes a huge expense. Due to the financial burden of the African marriage custom, more and more people are now prone not to marry, but to live as partners or as friends without family and community support. This new pattern causes unstable relationships and changing partners. Or, delayed official marriages lead to unethical sexual contacts which in turn offer fertile grounds for the transmission of HIV/AIDS.

Influence of western sexual behaviour: Having been the objects of a very long colonial era, slavery, illiteracy, and exploitation, there is great pressure in *Africa as else where in the world* for a life without many ethical ought's. Through globalization in the African continent western contraceptives capable of controlling the biological consequences of pregnancy and sex stimulants ensuring increased pleasure of pre- and extra-marital sexual activities have arrived via pornographic materials, television programs and chemicals for rocketing sexual vitality. The innate nature of sexual activities as expressions of love, intimacy and partnership between two legitimate partners is then degraded to consumerism.

3. Some medical ethical contexts

Healing process: African anthropology understands that humans are *homo patients* and one's health or illness is closely related to the relationship of a person to their community and to the creator of life. Illnesses are understood as both natural and unnatural. In many African minds, an epidemic is brought by supernatural forces since humans are breaking the taboos of sexuality and moral values. Then, in the process of holistic healing, the person must be reintegrated into the community - with the living, with the ancestors and the forthcoming generations - and with the Creator. Many believe that HIV/AIDS is an ethical issue, since the illness are the consequences of breaking the ethical values.

Care of the sick: Traditional African care of the sick is basically communitarian and specifically it starts with family members, extending to friends and then to the community at large. Even the expense of the care of the sick is met by family, social and communitarian sources. The ambiance of family, extended family and community gives the most effective support to the patient and avoids isolation. But the stigmatization of HIV/AIDS means that there is an increasing unethical tendency of removing HIV/AIDS patients from the home and community and abandoning them to anonymity in

hospitals or elsewhere. Since there is no comprehensive health care insurance system for all and the political resources of Africa are incapable of adequately providing ARVs to the infected, the ethical responsibility of caring for the sick according to the UN's Universal Declaration of Human Rights (1948) is still a dream.

The outcry of the poor over access to ARVs is serious evidence of the negligence of the health care system and a serious offence against human dignity and human rights. This obvious negligence reinforces the common belief that AIDS is a "disease of bad people"! The world of AIDS and its complexity is, therefore, an urgent challenge for ethicists for an inculturated African bioethics capable of eradicating the pandemic from the continent.

Part. II: African Bioethical Contributions in the Eradication of HIV/AIDS and Care for the Infected

"A stick in your neighbour's house can never kill a snake in your house", states an African proverb! Some African thinkers and scientists conclude that AIDS is a western creation to destroy Africans and that in the meantime the promotion of condoms is good business. African problems must be solved by African means. *An African ethical problem can never be figured out by a material solution or by imported solutions.* An African ethical problem needs an ethical solution that comes out of the continent, out of its own innate culture and anthropological understanding and moral values. There is no need to start with various imported ethical theories, but rather with the ethical theories of this continent, which have emerged and have been known and practised for thousands of years. Africa is the cradle of human life! If ethicists are now confronted with a fatal pandemic, we must first refresh our faded memories with the moral principles of this continent.

Very often the HIV/AIDS is acquired because of the lack of proper knowledge and moral discernment. Therefore the ethical education for the ordinary people must contain a differentiation in the understanding of their actions. Ethics has the solemn duty to state norms and give clear directions for a fulfilled and holistic life for the people of a certain culture and anthropological setting.

Some African hopeful resources

There are so many hopeful resources here in Africa in the fight against the pandemic. Amongst them: 1. The profound anthropological and fundamental moral understanding of the Africans does not differ much from universal anthropological and fundamental moral principles, such as, the principle of life as the greatest gift to humans, respect for life, love for life and procreation, and an understanding of the existence of the person in the strong living chain of ancestors and the lives which are to come in the future. 2. The deep religious sense and rich expressions of interiority which are essential for fostering moral values and principles. 3. The great human resource of young and energetic people who are capable

of education, knowledge, development and contextualisation of African values in a modern world. 4. A strong sense of solidarity, family and community life and care for the sick and dying. 5. An ever growing political awareness and political sense that is capable of changing the social and economic reasons for the spread of HIV/AIDS. 6. A greater thrust for the recognition and promotion of human rights, freedom and equality.

The traditional African ethical understanding can thus provide basic norms for an *inculturated bioethics*. These should be different conditioning principles in their drafting and derivation: for example: “the principle of life” as the greatest gift from God; “the principle of liberation” which serves to free people from every kind of suffering and bondage; “the principle of inclusion” which seeks liberation for both the oppressed and the oppressor so that an holistic life can take boom.

Conclusion

Such an ‘African fundamental ethics’ based on anthropological, cultural, philosophical, and moral principles and values, provides the foundation for further ethical considerations. Africa needs programmatic ethicists to develop a sound bioethical pattern for Africa. It will be a long and vast undertaking. And the goal of an inculturated version of bioethics is to help Africans form an *African consciousness* and to have an African *ars vivendi* derived out of their own culture and sound traditions and practices for the *prevention* and *care* of HIV/AIDS. In facing the reality of death due to AIDS, bioethics has to develop a new version of *ars moriendi* which affirms the dignity of the person even at death.

An African proverb states that “the best time to plant a tree was twenty years ago; the next best time is today!” That “today” means taking steps now towards an *inculturated bioethics*. It is an urgent and crucial challenge still ahead of us all.

References

- Ammicht-Quinn, R./Hacker, H.: 2007, AIDS. SCM Press, London
- Dube, M.W./Kanyoro, M.R.A.: 2004, Grant Me Justice! HIV/AIDS & Gender. Orbis Books, New York
- Magesa, L.: “AIDS and Survival in Africa: A Tentative Reflection”, in: *Moral and Ethical Issues in African Christianity*. J. N. K. Mugabi and A.Nasimiyu-Wasike (eds.): 2003, Acton, Nairobi:, p. 197-216.
- Mann, J. M. (ed.): 1999, Human Rights: An Introduction. Routledge, New York
- May, W.E. 1991, An Introduction to Moral Theology. Out Sunday Visitor, Huntington
- Peschke, K. H.: 2004, Christian Ethics. TPI, Bangalore
<http://www.pdhre.org/rights/health.html>: Human rights

HIV/AIDS – A major medical ethics dilemma

Douglas K Ngotho

Egerton University,
Faculty of Health Sciences, P.O Box 536, Njoro, Kenya.
E-mail: dkngotho@wananchi.com:

Abstract: *The HIV/AIDS pandemic has profoundly affected most aspects of people's lives in terms of social, economic and cultural rights that relate to human rights, ethics and law. The problem posed by the pandemic differs from those of past epidemics by virtue of unique properties of the causative agent, dramatic societal changes and the transition of medical practice from a professional ethic to a technology – independent business ethic. The pandemic threatens both individual and societal human rights and public health. Moral values have been brought in sharp focus in terms of conflict and there-in lies a major ethical dilemma. Medical ethics has as its pillars values of beneficence, non-maleficence, autonomy, justice, dignity and truthfulness and honesty. Such values provide a useful framework for understanding conflicts but the approach to particular situations will inevitably be unique. How to balance between individual rights of those infected and affected by the disease and the rights of the larger society is a major ethical issue. Considerations should be framed around obligation, conviction and constrained rights. Ultimately it is a discourse of moral conviction about individual rights and duty to others.*

Key Words: *HIV, Infectious disease, rights, morals, obligation, challenges.*

Introduction

Historically, the [Western](#) medical ethics may be traced to guidelines on the [duty](#) of physicians in antiquity, such as the [Hippocratic Oath](#), and early [rabbinic](#) and [Christian](#) teachings. In the medieval and early modern period, the field is indebted to [Muslim physicians](#) such as Ishaq bin Ali Rahawi (who wrote the *Conduct of a Physician*, the first book dedicated to medical ethics), [Jewish thinkers](#) and [Roman Catholic scholastic](#) thinkers such as [Thomas Aquinas](#). Sahin and Ali (2002) noted that the four principles of respect to autonomy, justice, beneficence and non- maleficence existed in the writings and philosophy of Mawlana, a 13th Century Muslim Scholar. These intellectual traditions continue in [Catholic](#), [Islamic](#) and [Jewish medical ethics](#). To a lesser extent the protestant traditions have evolved too (Pauls and Hutchison, 2002). The evolution of ethics has been dynamic and although it has always been meant for common

good, it has been used to justify injustices. Donal (2006), notes that the Nazis used the five tenets of social Darwinism to justify their reign of terror. The tenets stated that morality was relativistic, humans do not have a unique status, human dignity is relative, some lives are not worth living and survival of the fittest is an ethical principle.

While the secularized field was largely borrowed from Catholic medical ethics, in the 20th century a distinctively [liberal Protestant](#) approach was articulated. In the 1960s and 1970's, building upon [liberal theory](#) and [procedural justice](#), much of the discourse of medical ethics went through a dramatic shift and largely reconfigured itself into [bioethics](#). Medical ethics is primarily a field of [applied ethics](#), the study of [moral values](#) and judgments as they apply to [medicine](#). As a scholarly discipline, medical ethics encompasses its practical application in clinical settings as well as work on its history, philosophy, theology, and sociology.

HIV/AIDS pandemic has profoundly affected most aspect of people's lives in terms of social, economic and cultural rights that relate to human right, ethics and law. The problem posed by the pandemic has been made worse by the lack of human and financial resources available in many health care systems especially among the less developed societies. Whereas HIV/AIDS is fundamentally a human rights issue, its ramifications on the larger society are so staggering as a public health crisis that what affects an individual sends ripples much further a field than any hitherto known epidemic. The pandemic has created unprecedented challenges for both the health workers and the health infrastructures. A large proportion of health facility beds are occupied by patients associated with this affliction.

Values in medical ethics

Six of the values that commonly apply to medical ethics discussions are:

- [Beneficence](#) - a practitioner should act in the best interest of the patient. (*Salus aegroti suprema lex.*)
- [Non-maleficence](#) - "first, do no harm" (*primum non nocere*).
- [Autonomy](#) - the patient has the right to refuse or choose their treatment. (*Voluntas aegroti suprema lex.*)
- [Justice](#) - concerns the distribution of scarce health resources, and the decision of who gets what treatment (fairness and equality).
- [Dignity](#) - the patient (and the person treating the patient) have the right to dignity.
- [Truthfulness](#) and [honesty](#) - this forms the basis of the concept of [informed consent](#).

It is within the backdrop of these values that the effects of the HIV/AIDS pandemic need to be weighed.

The dilemmas start with the oaths that health practitioners take in that they have been skewed more towards the patient at the expense of the larger society.

The Hippocratic Oath stated thus:

"I swear...that.... all that may come to my knowledge in the exercise of my profession or outside of my profession or in daily commerce with men, which ought not to be spread abroad, I will keep secret and will never reveal. If I keep this oath faithfully, may I enjoy my life and practice my art, respected by all men and in all times; but if I swerve from it or violate it, may the reverse be my lot." (Smith and Berlin, 2001)

The updated version of this oath "Declaration of Geneva" and the International Code of Medical Ethics, undertaken by medical practitioners states: "the health of my patient will be my first consideration", "I will respect the secrets which are confided in me", "I will maintain utmost respect for human life from time of conception, and even under threat, I will not use my medical knowledge contrary to the law of humanity".

Furthermore, there are many more different ethical issues related to HIV/AIDS testing, treatment, and research. Key issues include confidentiality, informed consent, end of life, research design, conflict of interest, vulnerable populations, and vaccine research (Leslie., Wolf and Bernard, 2001).

Beneficence may have both a positive or negative effect in the HIV/AIDS pandemic. One of the key challenges is confidentiality. Without promises of confidentiality patients are far less likely to share private and sensitive information required for their care. Should this confidentiality be absolute, though, without taking cognizance of the wider society? When does the protection of others through breach of patient confidentiality become worth the risk to that individual who may be HIV - positive but will avoid testing in order to avoid being reported?

What about the issues such of lack of disclosure among discordant couples or deliberate spread of infection by an individual?

Can one warn the sexual partner or spouse of an HIV positive patient if the patient is not willing to do so? Can the sanctity of doctor patient relationship be maintained within a managed care setting which requires the doctor to be sensitive not only the patient but the employer or insurer who is trying to reduce costs in order to maintain the profit margins? Should one record it in the notes that one is HIV positive? Should one document in a discharge note the HIV status if one is HIV positive? Should one document in a referral letter the serostatus?

The American Medical Association *Code of Medical Ethics* Opinion 5.05 states that information disclosed to a physician by a patient is confidential but subject to certain exceptions that are

ethically and legally justified because of overriding societal considerations (AMA, Opinion 5.05).

Being an infectious disease, HIV/AIDS is disease is supposed to be reported as a public health concern. Some balance, therefore, requires to be made between the individual and the common good of the public. As a policy matter, the AMA strongly recommends that all states adopt requirements for confidential HIV reporting to appropriate public health authorities for the purpose of contact tracing and partner notification (AMA, 2005).

HIV status and reporting requirements raise legal issues related to patient confidentiality. Legal protection of patient privacy and confidentiality depend on whether or not public concern outweighs the interest in preserving the doctor-patient privilege. The balancing of this interest is a particular challenge when it comes to privacy concerns associated with HIV status.

[Non-maleficence](#) may be misunderstood too depending on the context in which it is applied. Will the exposure of an individual who is infecting others irresponsibly make one feel that not only has the individual right been trampled on let alone that harm has been done on the individual? When does the common good override the rights of the individual?

Autonomy is also not without dilemmas. This especially comes to the fore in two major areas namely solemnizing marriages and the rights of the unborn vis-avis the rights of the mother. Virtually all religious institutions in Kenya, for example, require certification of the serostatus of individuals who want to get married. To what extent is this at variance with the individual rights? An even more subtle debate still rages on the rights of the unborn child and the opponents and proponents of abortion remain horn-locked. The issue gets even more compounded in the presence of HIV/AIDS. Can a pregnant mother, for example, be forced to take highly active antiretroviral therapy (HAART) for the sake of the foetus if she declines?

Fairness and equality in the distribution of resources is also a key ethical dilemma. Whereas the disease is rampant among the poor and less endowed than the rich in the society, the meagre resources tend to reach the latter group notwithstanding the fact that all persons infected or affected by HIV/AIDS are entitled to adequate prevention, support, treatment and care with compassion and respect for human dignity.

Access to health care, especially in developing countries has been skewed towards the well endowed in the society and yet the burden of disease is with the less endowed. This is unequivocally not only justice denied but also a major ethical dilemma especially because the poor have very little voice in the distribution of the said resources. Conversely, whether by acts of commission or omission, the latter group holds the key in addressing the issue of HIV/AIDS within society.

Dignity, truthfulness and honesty are virtues to extol. The latter two issues call on the health workers to ensure that the clients have an informed consent before any procedure is carried out. This too may generate a dilemma in this pandemic in that a client may decline testing or even treatment even if other parameters indicate otherwise but it may be a necessary evil. Accordingly, dignity to HIV/AIDS patients has been a far cry as stigmatization has been and is still the major hurdle to overcome. As much as the society would want to blame the ills of the pandemic on the infected and the affected, the scourge will not be dealt with unless the society comes to terms with reality and accepts the existence of these people, empathizes with them and takes a helping stance. This is also a key dilemma that demands for a paradigm shift in judgmental platform on attitudes and practices towards these individuals within the society.

These dilemmas cannot and will not be solved by declarations and legal registrations in the absence of the incorporation of knowledge, attitudes and practices of all the stake holders, key of who are the infected and affected. The law may set out to protect public health but it is also bound to take measures to protect the individual to allow him or her to come forward for testing and any available treatment.

This demands contextualization of HIV policy from talk about ethics and law in the same breath which is done for obvious reasons, because the ethical dilemmas that arise are invariably played out in legal terms. Nonetheless, the blurring of the distinction between law and ethics can sometimes obscure the fact that tensions may exist between ethical imperatives and legal obligations. It is therefore worth considering the interaction between law, ethics and HIV.

Ethics and law cannot go hand in hand in this pandemic. With some of the very complex dilemmas that arise with HIV, the existing law is not a sufficiently subtle mechanism to deal with the all the different interests involved and may lead to inappropriate and anomalous results.

The potential inadequacy of existing law does, however, provide an opportunity. Because so many of the legal issues thrown up by the HIV epidemic are new, the development of new legal principles and solutions will be required. There is therefore an opportunity to direct the law in the way the society wants it to go, that is, to have ethics drive law reform and not the other way around.

A real possibility is that careful and informed ethical debate can guide the direction on how to solve the dilemmas and the directions to take (Joanne, 2000). In the final analysis this is likely to influence the evolution of the law. The eventuality will help balance between individual rights of those infected and affected by the disease and the rights of the larger society. The success of the different policies will depend entirely on the mutual respect for the

confidentiality of the patients' care that flows from the patient to the medical practitioner.

Conclusion and recommendations

Human rights per se are not a trump card. Discussion must be framed around obligation, conviction and constrained rights within the framework of a pandemic whose solution to issues will evolve as difference scenarios are played out. Ultimately, it is a discourse of moral conviction but individuals must keep in mind their duty to others.

That apart, this write up recommends the following:

- Although formal legal and ethical standards should not be violated as much as possible on the basis of patient welfare or other deeper values the community good should hold pre-eminence in such scenario.
- Antiretroviral therapy and health care provision would improve the lives of those with HIV/AIDS, thus giving them hope and assisting them to lessen their apprehension on HIV/AIDS as a reportable disease.
- Addressing the issue of stigmatization would make HIV/AIDS confidentiality become less traumatizing.
- Individualizing approach and identifying important aspects of each situation will help in considering positive and negative consequences of the ways in which we might respond and in discovering better approaches.
- Identifying checks and balances so as to fine-tune ethical principles and share responsibilities in provision of care and decision making.
- Encouraging debates on ethical issues on HIV/AIDS to engulf expression of unique knowledge from across board. This will facilitate consensus-building on critical issues by evaluating all relevant facts and view-points and in so doing encourage the formation of laws that will embrace the ethical considerations that will be all inclusive. Because so many of the legal issues thrown up by the HIV epidemic are new, ethical principles should drive the development of new legal principles and solutions in these complex dilemmas that arise with HIV/AIDS.
- Developing urgent teaching modules for medical and paramedical students that will help them understand approaches to ethical problems related not only to HIV/AIDS but also to other infections diseases that they might be confronted with in the future.

Acknowledgement

I want to acknowledge the role played by Egerton University as a Regional Bioethics Centre. This has endeared my thoughts about the HIV/AIDS pandemic and the ensuing issues like no other forum has ever done.

References:

- American Medical Association. Health Policy: H-20.915 *HIV/AIDS Reporting, Confidentiality, and Notification*. http://www.ama-assn.org/apps/pf_new/pf_online?f_n=browse&doc=policyfiles/HnE/H-20.915.HTM. Accessed September 4, 2005.
- American Medical Association. Opinion E-5.05. Confidentiality. *Code of Medical Ethics*. http://www.ama-assn.org/apps/pf_new/pf_online?f_n=browse&doc=policyfiles/HnE/E-
- Donal, P.O., 2006. Human dignity in the Nazi era. Implications for contemporary bioethics. <http://www.biomedcentral.com/1472-6939/7/2>
- Joanne, E., 2000. Medical Ethics: Debates, dilemmas and decision. *Can J Infect Dis*. Mar- April, 11(2): 72- 73.
- Leslie, E., Wolf, I.D., Bernard, L.O. Ethical dimensions of HIV/AIDS. <http://invisite.ucsf.edu/inside?Page=kb-08-01-05>
- Pauls, N. and Hutchinson: Protestant bioethics for clinicians. [http://www.cma.ca/cmaj/ethics_Protestant_ethics_166\(3\)339/bioethics.htm](http://www.cma.ca/cmaj/ethics_Protestant_ethics_166(3)339/bioethics.htm)
- Sahin, A. and Ali, T. The “four principles of bioethics” as found in 13th century Muslim scholar mawlanas teachings. <http://www.biomedicetral.com/1472-6939/3/4>
- Smith, J.J. and Berlin, L., 2001. The HIV- Positive Patient and Confidentiality. *American Journal of Roentgenology* 2001; 176:599-602.

Rethinking state participation in HIV vaccine trials

Elizabeth Akoth Oduwo

*Faculty of Law, McGill University & Research Assistant,
Biomedical Ethics Unit, McGill University*

Abstract *In this paper, we rethink state participation in HIV Vaccine research in Kenya in an approach that is contextually intuitive. Our goal is to gain an essential grasp of the context in which HIV vaccine trials are conducted and the ethical susceptibilities facing Kenya in vaccine research. Our common understanding of biomedical research with participants is that the researcher, physician, participant, guardian-regulator and sponsor-facilitator are the key parties involved, as is evidenced in research ethics regulations, instruments, discussions and policies. In Kenya, the state is heavily involved in HIV vaccine research. In our approach, we build a framework through which we study state involvement by mapping for the state roles based on the aforementioned traditional parties in biomedical research involving participants. We explicitly define each role, by outlining their interests, legal basis and boundaries, and the extensive institutional structure behind each role. Through our close study, we became aware of the coherency of the interests vested in each role, the resulting multiplicity in these roles and the ethical challenges brought about by this multiplicity. This study is beneficial to Kenya as we gain awareness of, and thus can prevent ethical susceptibilities in the environment of HIV Vaccine trials.*

Key words: *Guardian-regulator, Physician, Research-subject, Researcher, and Sponsor-Facilitator*

Introduction

Kenya has a multi pronged strategy to address the devastating HIV/AIDS pandemic. A preventative HIV/AIDS vaccine can be useful and in the long term may eradicate HIV/AIDS (Grady et al., 2006) and HIV vaccine research is an integral part of the Kenyan strategy (MoH, 2005). Vaccine research is challenging on many fronts and has become the subject of many debates (Guenter et. al., 2000). The case of Kenya Aids Society Vs Arthur Obel, the incident at Nyumbani children's home (Siringi, 2004), the HIV Net 012 trials in Uganda (Ahn et al., 2003) and the debate surrounding the use of placebos in international clinical trials (CIOMS, 2002) illustrate the complexity of and the ethical challenges of conducting HIV vaccine research.

A large variety of tools are available to discuss ethical standards for vaccine research. Beauchamp and Childress (2001) have elucidated 4 ethical principles, which have been the foundation for numerous discussions about research with participants. Numerous international guidelines deal with ethics in research, including the Declaration of Helsinki, Nuremberg code and the Ethical considerations in HIV preventative vaccine research (UNAIDS, 2000). The HIV vaccine research framework in Kenya is set up by the HIV/AIDS prevention and Control Act (HIV Act), the Science and Technology Act (S & T Act), the Guidelines for Ethical Conduct of Biomedical Research Involving Human Subjects in Kenya (biomedical research guidelines) (NCST, 2004) and the Kenya National Guidelines for Research and Development of HIV/AIDS Vaccines (vaccine guidelines) (MoH, 2005).

This paper focuses on state involvement in HIV vaccine trials and analyses the context in which HIV vaccine research is conducted. The state participates in vaccine research in the capacity of researcher, guardian-regulator, participant and sponsor -facilitator. As we analyze state engagement in vaccine research through these roles, we define and show that there is pluralism in state involvement in HIV vaccine research and outline the vulnerabilities that arise in the discussed pluralism. This knowledge is essential to understand the framework for vaccine research in Kenya and to build a sound ethical basis for HIV vaccine trials that addresses the challenges wholesome.

State participation in HIV vaccine trials

There have been five clinical trials conducted in Kenya, including four phase I trials and one phase IIa trial (MoH, 2005). The Kenya Aids Vaccine Initiative (KAVI)³ has through sponsorship of International Aids Vaccine Initiative (IAVI) conducted vaccine research in collaboration with Kenyatta National Hospital and the University of Nairobi (UoN) (UoN, 2009). The US Army Medical Research Unit-Kenya: The Walter Reed project⁴ has an ongoing vaccine trial. The Center for Disease Control and Welcome Trust have conducted trials with the Kenya Medical Research Institute (KEMRI). KAVI, KEMRI and UoN are public institutions. Other state institutions involved in vaccine research are the National Aids Control Council (NACC), National Council for Science and Technology (NCST), and the National Aids Vaccine subcommittee

³ Kenya AIDS Vaccine Initiative lists 5 HIV vaccine research sites in Kenya where vaccine research has been carried out by KAVI in partnerships with other researchers mainly the Kenya National Hospital. (KAVI, 2008).

⁴ The US Army Medical Research Unit of Kenya through the Walter Reed US Army project is sponsored and is conducting an HIV vaccine trial which begun in 2006 at Kericho, Kenya in partnership with KEMRI.

(NAVS) who respectively facilitate, regulate and sponsor vaccine research.

This discussion on ethics in HIV Vaccine research in Kenya focuses on the state because there is a significant and plural state involvement in HIV vaccine research. By organizing state involvement into capacities based on the traditional themes of participation in biomedical research involving human beings, we can outline roles for the state.

State roles

Our approach maps state participation onto the roles of guardian-regulator, physician, researcher, participant and sponsor-facilitator based on a traditional understanding of the parties in biomedical research involving human subjects. This analysis builds a theoretical model of state participation that unravels the pluralism in state participation in HIV/AIDS vaccine research. We discuss the legal basis of each role, outline the state institutions involved and locate multiplicities that make each role vulnerable.

The role of the state as a Guardian- regulator

The state as guardian-regulator protects the well being of Kenyan participants and other parties involved in vaccine research. Chapter 74 of the Constitution of Kenya recognizes the individual right to protection from inhuman treatment. Section 39 of the HIV/AIDS Act gives the S & T Act and the NCST the power to regulate HIV research. The S & T Act in Section 3 and 4 establishes the NCST and outlines its functions. The NCST, in turn, sets guidelines for Biomedical Research using ethical principles and standards similar to those found in international instruments. NCST regulatory activities include setting research priorities areas, scrutinizing research protocols, inspecting research sites and annual reporting. The NCST may refuse to issue a permit or withdraw a permit if its' requirements are not met. However, there is no record of criminal cases related to research with participants⁵. Material transfer agreements (MoH, 2005) are part of the vaccine guidelines and promote the sharing of intellectual property between researchers involved in vaccine research.

The role of guardian-regulator has some susceptibility for exploitation; (1) there is little mechanism for policing research regulations and no set processes to initiate a criminal investigation or proceedings, (2) the S & T Act delegation of functions to the NCST links these two roles, blurring their responsibilities and creating a

⁵ A search of cases in the online national database of Kenya Law Reports did not reveal any listed criminal cases filed in the area of research with participants though there has been a civil suit proceedings filed that relate to a HIV cure.

vacuum, and (3) the lack of acknowledgement of interests other than participants may push the onus of their protections on other roles.

The role of the state as a Physician.

Chapter 71 of the Constitution of Kenya provides for the fundamental right to life, thus securing the individual right to health for every Kenyan. Through the Ministry of Health, the state employs doctors, nurses, laboratory technicians, pharmacists and other staff to run the public healthcare system.

The roles of the state as physician and as researcher converge in the vaccine framework providing rich ground for analysis as is illustrated by the Nyumbani incident. The late father D'agostino started Nyumbani children's home as a charity orphanage for HIV/AIDS orphans. He was the registered guardian and doctor for the home. Moses Otsyula, a scientist, accused Father D'agostino of, and sued him for illegally taking samples from children who had shown resistance to the HIV and sending these samples to foreign investigators. The minister for health ordered an investigation into the matter, and the NCST scheduled inspection visits (Siringi, 2004). This case illustrates a tension in the physician role and a threadbare understanding by the government of the physicians' role in the vaccine research framework whereby physicians who enter into research are thought of primarily as physicians and thus avoid the responsibilities of researchers.

In summary, the role of the state as physician is proximate to the researcher role which creates susceptibilities in the framework as; (1) the Ministry of Health pools the responsibilities of the two roles, which allows lexical ranking of the pooled duties of both roles and (2) as physician, the state bears a quantifiable HIV/AIDS burden which may unduly influence the state as researcher.

The role of the state as a participant

Participants are individuals who volunteer themselves to be experimented upon, in a vaccine trial (NCST, 2004) (MoH, 2004). A theoretical study of Kenyans as participants in the collective allows us to conceptualize a role for the state as a participant. HIV/AIDS research is globalised; research sites are chosen after comparison of countries. NCST and the HIV vaccine subcommittee must approve a research proposal to conduct HIV/AIDS vaccine research in Kenya before individual subjects are recruited (MoH, 2005). This conceptual role presents real challenges. The state must consider her duty to protect herself from harm or the risk of harm, is not obliged to further research interests and would be justified in declining to participate in a study where the benefits are considered insufficient.

The vaccine guidelines provide for the Community Advisory Board (CAB). This provision reflects a growing trend to more inclusive approaches towards local communities (Langlois, 2007). The role of the CAB is to facilitate community support for Vaccine research (MoH, 2005) and to disseminate information to the

community hosting the research. However, these dual purposes create ambiguity for the CAB whose members have to serve the conflicting interests of the participant and the facilitator. Moreover, there are no provisions to protect the input of the CAB.

State as Researcher

The S & T Act establishes KEMRI (section 12, fourth schedule) as a public research institution that carries out biomedical research involving human subjects. The University of Nairobi Act (Section 7) authorizes UoN to carry out vaccine research, which it carries out through its' college of health sciences in collaboration with the public health care system. UoN has an ongoing vaccine research program in collaboration with KAVI that is sponsored by IAVI.

According to the biomedical research guidelines, researchers must seek affiliations with KEMRI, UoN, Moi University, the MoH or local hospitals. International researchers must include domestic experienced researchers as senior scientists in their project (NCST, 2004), (MoH, 2005). This definition of the researcher in the research framework is narrow as it precludes the exclusion of the state and may inhibit the growth of independent researcher and tightly links the researcher role to the sponsor role.

The role of the state as a sponsor -facilitator

The HIV/AIDS research guidelines and the CIOMS guidelines recognize the role of the sponsor in research. International sponsors in vaccine research in Kenya have been IAVI, KAVI, Centre for Disease Control, National Institute of Health and the Medical Research Council (MRC). Domestic sponsors include KEMRI and UoN who host research sites, NACC, NAVSCOP, and MoH have committed resources to vaccine research⁶. International sponsorship agreements on vaccine research are challenging because the state acts in multiple role of sponsor and researcher.

The HIV/AIDS Vaccine subcommittee carries out the role of facilitator. This subcommittee has representatives from the NCST, Pharmacy and Poisons Board and the MoH. Its' primary activity is to advise on concepts notes sent in by investigators who wish to carry out vaccine research on the relevance and the preclinical safety and immunogenicity data of the preclinical studies. There is a dualism in the preview system as institutions in the vaccine subcommittee that asses concept notes for facilitation purposes later have to assess the same research as research proposal for research authorization and clearance in the capacity of regulator. Furthermore, some of the institutions that preview the concept note may have collaborations in,

⁶ University of Nairobi receives IAVI sponsorship for an ongoing Vaccine research programme at the University of Nairobi through its' Kenyan counterpart KAVI that is worth about 7 million US dollars (UoN, 2009).

sponsorship agreements with or have committed resources to the vaccine research proposed.

Conclusion

This discussion of the role of the state in HIV vaccine research has unraveled the pluralism in state participation in HIV vaccine research and showed that there are converges among the outlined roles where conflicts of interests arise. As long multiplicity in state participation in HIV Vaccine research is not resolved, vaccine research will remain ethically challenging and issues, incidents and conflicts will continue to occur.

Recommendations

The discussion above indicates that the HIV vaccine research framework deserves further indepth analysis that questions using an overarching approach the effect of state participation in vaccine research. Specifically;

1. A detailed analysis of the duties in each role should be done to resolve duplicities and conflicts among the roles.
2. The legal framework for HIV Vaccine research trials and the legal basis for each should be clarified.
3. Discussions on HIV vaccine trials ought to be encouraged, particularly domestic perspectives as they may provide a nuanced appreciation of the challenges of research environment.
4. The role of state to facilitate and sponsor HIV Vaccine research, which is expressed in the HIV vaccine subcommittee and its interaction in the research framework may benefit from further analysis and discussion.

References

- Ahn, M. J. (2003). Ethics and the AIDS pandemic in the developing world. *Journal International Association Physicians AIDS Care* 2(2), 81-87.
- Beauchamp, T. L., & Childress, J. F. (2001). *Principles of Biomedical Ethics*. New York: Oxford University Press.
- CIOMS. (2002). *International Ethical Guidelines for Biomedical Research Involving Human Subjects*. Geneva.
- Guenter et. al., (2000). Ethical implications in international HIV Vaccine trials: summary of a consultative process conducted by the joint United Nations Programme for HIV/ AIDS UNAIDS. *British Journal of Medical Ethics* 25: 37-43.
- HIV and AIDS Prevention and Control Act (2006).
- Kenya AIDS Society vs. Arthur Obel H.C.C.C 1079 of 1997 & C.A 188 of 1997.
- KAVI. (2008). Clinical trials and studies conducted at KAVI. Retrieved February 22, 2009
- Langlois, A. (2008). The UNESCO Universal Declaration on bioethics and Human Rights: Perspectives from Kenya and South

- Africa. *Healthcare Care Anal.*, 16(1), 39-51.
- Kenya National Guidelines for Research and Development of HIV/AIDS Vaccines, (2005).
- Girard, M. P., et. al., (2006). A review of vaccine research and development: The human immunodeficiency virus (HIV). *Vaccine*, 24.
- Guidelines for Ethical conduct of Biomedical Research Involving Human Subjects in Kenya, (2004).
- Siringi, S. (2004). British scientists face lawsuit. *The Lancet Infectious Diseases*, 4(7).
- The Science and Technology Act, (2000).
- University of Nairobi. (2009). Ongoing research activities at the University of Nairobi. Retrieved February 22, 2009
- US Army Medical Research Unit-Kenya: The Walter Reed Project. HIV RESEARCH. Retrieved February 22, 2009

Notes

- Kenya AIDS Vaccine Initiative lists 5 HIV vaccine research sites in Kenya where vaccine research has been carried out by KAVI in partnerships with other researchers mainly the Kenya National Hospital. (KAVI, 2008).
- ¹ The US Army Medical Research Unit of Kenya through the Walter Reed US Army project is sponsored and is conducting an HIV vaccine trial which began in 2006 at Kericho, Kenya in partnership with KEMRI.
- ¹ A search of cases in the online national database of Kenya Law Reports did not reveal any listed criminal cases filed in the area of research with participants though there has been a civil suit proceedings filed that relate to a HIV cure.
- ¹ University of Nairobi receives IAVI sponsorship for an ongoing Vaccine research programme at the University of Nairobi through its' Kenyan counterpart KAVI that is worth about 7 million US dollars (UoN, 2009).

Developing Challenges and Ethical Considerations of Genetically Modified Organisms (GMOs) in Biomedical Research

Fiona N. Mbai^{1,2*}, Raphael M. Ngure¹ and Bonnie.S. Dunbar.^{2, †}

¹Department of Biochemistry and Molecular Biology, Egerton University, P. O. Box 536 Egerton, Kenya. ²Africa Biomedical Center and [†]University of Nairobi (Center for Biotechnology and Bioinformatics), Nairobi, Kenya.

*Corresponding author: F.N. Mbai
E-mail: fionambai@gmail.com

Abstract *The ethical considerations in animal experiments which dating back to the first use of animals as research models have not always kept in tandem with the developments and advances in research and technology. New challenges have emerged largely as a result of recent advances including cloning and the advent of genetically modified organisms (GMOs). In Africa where legislation and ethical boundaries are yet to be clearly established, these developments raise serious concerns. Issues that feature prominently in regard to ethics of animal use in biomedicine include: environmental impact, food safety, gene manipulation as well as animal treatment in research settings. Many of these manipulations are relatively new and long-term implications for animal welfare have not yet been established for the majority of existing GMOs. Establishment of bioethical frameworks that addresses new developments, emerging technology and the implications resulting from adopting and advancing the use of these developments in Africa is long overdue. Scientists and societal opinions are often varied creating a need for shared responsibility to find a middle ground or consensus. Engagement of stakeholders ranging from society representatives, scientists, policy makers and the legal fraternity would therefore ensure that a relevant comprehensive ethical framework is established.*

Key words: Genetic, Biotechnology, Biosafety, Stakeholders, Policy, Frameworks.

Introduction

Compelling differences exist on the positions held by animal welfare proponents and the scientific community concerning animal experimentation. There are some questions as to whether developments in animal and human health which have been attributed to science-based technology are inherently progressive (Festing, 2008). Others suggest that preventative medicine and introduction of public health measures outweigh biopharmaceutical developments (e.g. vaccines, and drug design) achieved with the use of animals as research models (Russow, 1999). Most scientists are of the opinion that biomedical experiments using animals are indispensable. Regardless of the relative positions on this argument, issues concerning the transferability of data from animals to humans requires clear justification. Sideris et. al., 1999 state that “anyone involved in research with laboratory animals should have some appreciation of the history of such research and the ethical attitudes that accompanied that history”. The disparate opinions will continue to be defended intensely from all positions. Nevertheless, based on current research trends, animal research models are unlikely to be abandoned altogether. Therefore, there is a need to establish policies and bioethics frameworks that consider all views so as to develop multifaceted and inclusive representation required to achieve consensus on divisive issues.

Genetic engineering and transgenics.

Genetic engineering involves the selection of a specific DNA sequence (e.g. gene) which is isolated, modified and re-inserted into a new species thereby generating a “transgenic” organism or what is now referred to as a genetically modified organism (GMO; Melo at al., 2007). The resulting organisms can subsequently be used in studies that enhance our knowledge in such areas as food production or facilitate the development of new medical therapies (Yu and Oberto, 2000; Pretty, 2001; Cartagena Protocol on Biosafety). These processes could, in some instances, have unintended consequences on the environment, or animal and human health (Donnelley, 1999). Combinations of non-human and animal DNA may result in the genetic crossing of species boundaries. In addition, combining genes from different species could potentially introduce genetic diseases for which there is no cure, or result in environmental risks that have not been previously encountered or anticipated (UNEP, 1997; Reinhardt, et. al. 1998). The risks and benefits should also be weighed relative to the potential pain and suffering of genetically modified animals.

It is not always possible to predict outcomes of genetic manipulations in GMOs, therefore, they are likely to present novel challenges in their veterinary care due to lack of clinical knowledge that ensures appropriate care for such animals (Fox and Obernier, 2005; Park, et. al. 2008). While some animals may have obvious physiological defects or disease susceptibility, others may have no

such obvious flaws. Often, these animals are engineered for specific purposes of introducing susceptibility to specific diseases e.g. immuno-compromised animals which are now contributing to the study of HIV/AIDS (Mosier et. al. 1991). From an ethical perspective, the design of such studies requires special considerations and measures to care for genetically engineered animals throughout the entire study period.

An ethical framework that monitors such proposed studies and more importantly regulates the use of the outcomes of such research is critical in order to face the challenges that transgenic organisms are likely to present. Based on the current trends, biomedical and agricultural research studies which involve genetic changes in animals is likely to increase in the future.

Role of the Veterinarian in Animal Care in Research Environments.

Care of laboratory animal comprises husbandry, veterinary clinical care, and regulatory oversight of vertebrate species maintained in captivity (Moore and Mephram, 1995; Smith, et. al., 2001). This includes experimentation, testing, and educational situations that involve live vertebrates maintained in confinement for those purposes. Research training is critical for all laboratory animal veterinarians to prepare for unintended consequences of genetic manipulations (Fox and Obernier, 2005). The clinical pathology and the well being in most transgenic animals are altered, and, in many cases, the resulting pathology is unknown. The possibility of unpredictable outcomes and the lack of clinical information for many GMOs compounds the problems faced by veterinarians and animal care staff.

Veterinarians are invaluable in evaluating research projects, ensuring that all aspects of the animal's welfare are fully considered while evaluating the ethical acceptability and scientific indispensability of projects. Because of special challenges that are likely to be experienced by GMOs, the specially trained veterinarian would be in a position to propose special measures in research projects involving use of transgenic animals.

Scientific responsibility

Three R's.

There have been arguments made that animals suffer needlessly during experimentation as there are viable alternatives. Other arguments claim that the available alternatives can not replace the value of animals as biological research models (Schuppli and Fraser, 2005). While cases could be made for these contrasting views, it should be possible to strike a balance between the two arguments. Alternatives are now routinely considered in biomedical research and education making it possible to conduct much research without the use of animals, or, dramatically reduced the number of animals required for experimentation. These include the advances in cell culture and microorganism models as well as biotechnological

developments that alleviate the suffering of animals through the use of non - invasive procedures. The Three Rs (first introduced by the British biologists William Russell and Rex Burch in the 1950s) capture the salient aspects of these developments - Replacement, Reduction, and Refinement. With the advent of cloning and generation of transgenic animals both for research and food production, it seems prudent given the prevailing challenges, to modify this axiom to the "Four R's"-the fourth including "responsibility".

Importance of Institutional Animal Care and Use Committees.

Institutions that use laboratory animals for research or instructional purposes are required to establish an Institutional Animal Care and Use Committee (IACUC; Anderson 2007) which oversees and evaluates all aspects of the institution's animal care and use program (Schuppli and Fraser, 2007). Generally, IACUCs are composed of veterinarians, scientists and representatives from society, usually a person(s) who are not affiliated with the institution and at least one member of the general public who is not affiliated with the institution in any way (Fox and Oberneier, 2005). To meet the required legal responsibility to ensure that research staff are trained and qualified to use animals most countries have instituted an animal care and use committee (ACUC; Medina, et. al. 2007) and animal welfare acts (Reinhardt, et. al. 1998). The IACUC is also responsible for review of research activities and together with the institution, the IACUC ensures that personnel are trained and qualified. International research collaborations, as well as technology transfer position IACUCs as invaluable advisory resources on country and region specific standards for research involving the use of animals.

Stakeholders,Partners and Legal Frameworks.

The majority of institutions carrying out biomedical research have developed institutional ethics guidelines relevant to routinely used animal models (Dresser 1999). National ethics committees could review facilities; provide support to different institutional ethics committees; optimize both animal welfare and scientific validity, and set up mechanism for accreditation. This would greatly enhance responsible animal use between institutions in an age where local collaborative research and training is common practice. A national ethics committee has a key role in developing guidelines and standard operating procedures that harmonize the ethics of animal use. Incorporation of periodic updates in the bioethics of animal use in biomedical courses as well as development of training materials for students, researchers, veterinarians and stakeholders would ensure that new developments in science and technology are taken into consideration. Strategically linking institutional, regional and national ACUCs can help build momentum in which, local solutions to local problems can inform effective national and bioethics policies.

The debate between those for and against the use of animals in research and bioengineering of GMOs underlies the need for

approved recommendations, and, guidelines for policy oversight with provisions for long range impact. In many countries, laws and regulations that govern animal experimentation have been passed, others are still pending and many, previously passed, do not adequately address evolving challenges of new technologies (Jones 1986). Ethical codes alone may not be sufficient to serve as principles for researchers and institutions and may have to be supported by training and legal frameworks. Since it is inherently difficult to separate public morals, ethics and the law (Russow, 1999; Sideris et. al. 1999), then related ethical views are likely to be incorporated in the law.

In Africa for example, creation of national and regional policies could ideally refer to established international policies relating to humane and ethical use of research animals. Most of the established frameworks in other regions have undergone the rigours of deliberation and policy formulation. Therefore the implementation of established international policies would serve as a potentially useful resource for national stakeholders formulating specific recommendations. In so doing, regional policy makers could take into consideration other national policies and cultural sensitivity and regional development requirements.

Conclusions and Recommendations.

The diversity of research areas in institutions presents a unique challenge for development of ethics guidelines for research animal models. This article focuses on the unique ethical challenges of animal research involving genetic manipulations and the need for uniform guidelines which anticipate potentially long lasting environmental and genetic impact. GMOs may affect existing genetic diversity, particularly if released into the environment without appropriate breeding control measures. In Africa a coordinated framework that regulates the possible impact of unintended outcomes of genetic manipulations is required. To achieve the desired goals, institutions need effective government policies that make it possible to secure animal welfare standards, and, share information as widely as possible. This would prepare for biological, social, and cultural consequences as a result of both local and imported biological technologies.

References.

Anderson L.C. 2007, Institutional and IACUC Responsibilities for Animal Care and Use Education and Training Programs *ILAR Journal*. **48**: 90-95.

- Cartagena Protocol on Biosafety
<http://www.iisd.org/pdf/biosafety.pdf>. Accessed June 28th 2008.
- Donnelley, S. (1999). How and why animals matter. *ILAR Journal* **40**: 22-28.
- Dresser, R.: 1999, Community representatives and nonscientists on the IACUC: What difference should it make? *Institute of Laboratory Animal Resources Journal* **40**:29-33.
- Fox, J.G and J. Obernier.: 2005. Veterinarians in biomedical research: A perilous future? *Journal Veterinary Medical Education*. **32**:301-305.
- Jennings, M and J. Smith.: 2004, Developing ethics training for laboratory animal users. [*Alternatives to Laboratory Animals*](#).**32**:545-548.
- Jones, D.D.: 1986, Legal and regulatory aspects of genetically engineered animals. *Basic Life Sciences* **37**:273-283
- Medina, L.V, K. Hrapkiewicz, M. Tear and L.C. Anderson.: 2007, Fundamental training for individuals involved in the care and use of laboratory animals: A review and update of the 1991 NRC Core Training Module. *Institute of Laboratory Animal Resources Journal*. **48**:96-108.
- Melo, E.O, A.M. Canavessi, M.M. Franco and R. Rumpf.: 2008, Animal transgenesis: state of the art and applications. *Journal of Applied Genetics*. **48**: 47-61.
- Moore, C.J. and T.B. Mepham.: 1995, Transgenesis and animal welfare. [*Alternatives to Laboratory Animals*](#). **23**: 380-397.
- Mosier, D.E, R.J. Gulizia, S.M. Baird, D.B. Wilson, S.H. Spector, et. al.: 1991, Human immunodeficiency virus infection of human-PBL-SCID mice. *Science*. **251**: 791-794
- Park, J.H, D.A. Stoffers, R.D. Nicholls, and R.A. Simmons.: 2008, Development of type 2 diabetes following intrauterine growth retardation in rats is associated with progressive epigenetic silencing of *Pdx1*. *Journal of Clinical Investigation*. **118**: 2316-2324.
- Pretty, J.: 2001, The rapid emergence of genetic modification in world agriculture: contested risks and benefits. *Environment Conservation* **28**:248-262.
- Reinhardt C.A, E.Wolf and A-M. Van Zeller.: 1998, The use of transgenic animals in the European Union. *Report and Recommendations of the 28th ECVAM Workshop*. [*Alternatives to Laboratory Animals*](#). **26**: 21-43.
- Russell, W.M.S and R.L Burch R.L.: 1959, *The Principles of Humane Experimental Technique*. London: Methuen & Co. LTD. [Reissued: 1992, Universities Federation for Animal Welfare, Herts, England.] Available online

(http://altweb.jhsph.edu/publications/humane_exp/het-toc.htm).

Russow L-M.: 1999, Bioethics, animal research, and ethical theory. *Institute of Laboratory Animal Resources Journal*. **40**:15-21.

[Schuppli, C.A](#) and D. [Fraser.](#): 2005, The interpretation and application of the three R's by animal ethics committee members. *Alternatives to Laboratory Animals*. **33**: 487-500.

Sideris, L, C.R. McCarthy and D.H. Smith.: 1999, Roots of concern with non-human animals in biomedical ethics. *Institute of Laboratory Animal Resources Journal*. **40**: 3-14.

Smith, AL.: 2001, Laboratory animal medicine in a time of crisis. *Comparative Medicine*. **51**: 290- 205.

UNEP/CBD/SBSTTA/3/2 30 June 1997, Convention on biological diversity. *Subsidiary body on scientific technical and technological advice*. Third Meeting Montreal, Canada 1 to 5 September 1997

Yu, P. and G. Oberto.: 2000, Alzheimer's disease: transgenic mouse models and drug assessment. *Pharmaceutical Research* **42**: 107-114

Website References:

<http://www.ccac.ca/> - Canadian Council on Animal Care (CCAC)

<http://www.felasa.eu>. -Federation of European Laboratory Animal Sciences Associations (FELASA).

Genetically Modified Food Products: Ethical Dilemma and Implications for Food Security

Asenath J. Sigot
Masinde Muliro University of Science and Technology,
P.O. Box 190 Kakamega 50100, Kenya
(dvc-aa@mmust.ac.ke)

Abstract Genetic modification of food is a complex, explosively controversial and rapidly growing science and technology. This new industry is a modern prodigy, effectively placing evolution in the hands of those who possess the right knowledge and resources. It is indeed one of those captivating phenomenon which exists where science, social values and commerce collide. Hence, genetic modification is a serious issue in food security; it affects the food supply of the entire population, it has strong impact on agriculture and environment, it is a new technology with unpredictable consequences, and therefore, requires reliable policies and methods for assessment, monitoring and regulation. The truth about genetically modified(GM) foods is very much a subjective entity. However, some key questions beg for answers; what are the main issues of concern for human health? Are the products of biotechnology safe for human consumption? Do moral ethics hold a legitimate place in what is ostensibly a scientific debate? What are the implications of genetic engineering for food security? Scientists must help provide answers to these questions by ensuring that the debate on genetically modified food addresses the science of it as well as the ethics and the facts, not opinions, so as to respond to society's concern. Both scientists and consumers must know the possible ramifications of genetic engineering especially as it relates to agricultural products, food security and sustainable livelihoods. This paper focuses exclusively on concerns surrounding the increasing controversial debate over the use of GM products for food production and examines some ethical and food security implications.

Key words: biotechnology; concerns; crops; genetic engineering; nutrition; sustainable livelihoods;

Introduction

There is an increasingly contentious debate about the potential value of modern biotechnology and in particular of transgenics in helping to achieve food security and sustainable development. The challenge facing consumers and policy makers is not only to understand what

the technology can do, or has done elsewhere but also to establish what opportunities it presents, the conflicting views, and the ethical questions involved. Biotechnology is simply using living systems to give society more or better foods and other products. In the understanding of science and especially in advances in genetics, specific genes and traits are optimized to provide even greater benefits while reducing or eliminating undesirable features. (McHughen, 2000) This technology, which is based on recombinant DNA (rDNA), is also called Gene Splicing, Genetic Engineering (GE) or Genetic Modifications (GM), which in turn gives rise to Genetically Modified (GM) foods (McHughen, 2000; Whitman, 2000).

Food crops can be genetically modified to improve appearance, taste, nutritional quality, drought tolerance, and insect and disease resistance. However, achieving food security is about more than just fulfilling yield deficits. Food security is having sufficient physical, social and economic access to safe, nutritious and culturally acceptable food at the household level, without having to resort to emergency supplies (Makoru *et al.*, 2003). This demands either adequate food production or food imports. Furthermore, agricultural choices are as much about food quality as they are about nutritious needs, livelihoods, culture, poverty, trade and sustainable development. Genetic modification technology may be useful in addressing some of these aspects. However, the potential of such technologies is controversial.

There is considerable uncertainty about the impact of GM foods on human health and environmental health, and also whether these products will provide sustainable solution to food insecurity (Desjardins *et al.*, 2001). The risks and benefits associated with GM technologies are difficult to quantify. Hence, public concerns over the safety of GM foods remain an issue of debate. Stakeholders have four issues on GM foods that need attention: first; the implications of transgenic technologies for biosafety as well as for human health and well-being, secondly; how the modern techniques resulting from genetic modification technology differ from selective breeding in traditional biotechnology; thirdly, the ethical and ideological perspectives over GM foods; and fourthly, whether or not genetically modified food offer a sustainable food security option. This paper attempts to address these four important questions. It focuses exclusively on the debates around concerns and risks of GM foods, ethical dilemma, and implications for food security; its other possible uses and implications are not, however, discussed.

Some Potential Risks and Concerns about GM Foods

Just as with all new technologies, GM foods pose some potential risks both known and unknown. The introduction of transgenic foods into the existing food production system has generated a number of questions about possible negative consequences focusing on health effects, environmental safety and conservation, consumer choice, intellectual property rights, ethical issues, and labeling. Critics of

genetic engineering of foods say that the new patent laws are giving investors of GM foods a dangerous degree of control over food sources. They believe that GM foods are inherently hazardous and could produce new toxins in food or even generate new allergies among consumers (Choike: org, 2008)???

GM crops, for instance pose a risk of them escaping into other fields. If this happens then they cannot be called back. It may finally interfere with the food chain. Genetic pollution is another risk, where pollen travels by wind and fertilizes neighbouring crops, thus contaminating other crops and their seed supply. There is no legislation relating to economic liability to protect farmers whose crops are contaminated by GM (Gene Watch, 2003). Another potential risk of GM foods is that it might put control of the food chain in the hands of corporations or multinational agricultural companies. Some of these companies use Intellectual Property Rights to gain control over staple crops. This raises important questions over the control of GM science and for food security. The concern is whether allowing patents on genes is in the public interest because innovation may be stifled, not encouraged (Nuffield, 2002). Hence, adoption of GM crops can lead to domination of world food production by a few biotechnology companies. The main risk here is “Terminator” gene, which could pollute natural varieties. This means the seeds cannot germinate and be recycled. The seeds are sterile, so that farmers are forced to buy new seeds every planting season instead of being able to save, store, and replant them Hence, this technology is not being used to help the poor households especially in developing countries who cannot afford to purchase seed every planting season.

There is another concern that GM foods pose allergy risks because most of the foreign proteins being gene-spliced into food have not been eaten by humans before or tested for their safety. Almost all food allergens are protein (Anderson, 2004). The following are some crucial safety questions: Does the food contain genes from known allergenic sources? Does it contain genes from toxic sources? Are the concentrations of natural toxic substances increased? Is the fat, cholesterol or other nutrient content changed? Does the food contain a substance that is new to the food supply?

It has been recommended that, like all foods, GM foods should bear labels if they carry allergens or toxins, or if they are substantially altered in nutritional composition, so consumers will be able to identify such foods (Whitman, 2000). But, one major concern here is whether the consumers will be literate enough to identify such foods.

Advocates of the use of genetic engineering techniques in agriculture contend that this new biotechnology promises increased productivity, better use of natural resources and more nutritious foods. Opponents are concerned about potentially adverse implications for the environment and food safety. The United Nations Food and Agriculture Organization (FAO) estimates that in 1999, 39.9 million hectares of land were planted with transgenic crops. Of this, 71% were crops “modified for tolerance to a specific

herbicide" (FAO, 2000). This means that for the genetic modification within these crops to be of any practical use, whatsoever, the crops must be sprayed with the herbicide to which it is resistant. As a result, these plants are actually a likely promoter of increased chemical usage and pollution. Those who support genetic modification of food attempt to sway opponents that from a strictly environmental viewpoint, GM crops provide the distinct advantage, that they will reduce the use of chemical pesticides by millions of kilograms (Paarlberg, 2006; Tribe, 2004). Hence, to suggest that GM food crops will significantly reduce the use of chemical pesticides is to conveniently ignore the fact that more than 70% of GM crops currently in production are designed specifically to encourage chemical pesticide use (Madell, 2000).

Traditional Biotechnology versus Modern Biotechnology

Traditional biotechnology improves the quality and yields and have given to us almost all of our foods, from maize, beef, bread and even wine through traditional fermentation technologies. The new modern techniques resulting from genetic modification technology differ from selective breeding in traditional biotechnology practices in at least two significant ways: First, and perhaps most obviously or alarmingly, DNA technology has enabled 'wide transfer' of genes between unrelated species. Secondly, the emphasis is on commercially important strains (Anderson *et al*, 2004).

The era of modern biotechnology started in the early 1970s when American Scientists Herb Boyer and Stan Cohen developed recombinant DNA (rDNA) or "gene splicing" methods, in which fragments of DNA are joined together to create a new genetic combination. DNA technology allows the transfer of genes from one organism to another, even across the usual species barriers faced by conventional breeders (McHughen, 2000)

The first GM plants were produced in 1983, when food scientists applied GM technology to improve food crops, especially in pest and disease management, animal and crop yield, and food quality (McHughen, 2000). The traditional and modern methods differ primarily in precision, speed and certainty. While the goals of traditional breeding and modern genetic engineering are similar, the new techniques greatly expand the realm of possible strategies by eliminating the species barriers presented by sexual reproduction.

Uncontroversial techniques of modern biotechnology include tissue culture, gene mapping, and molecular markers, which are used to improve the efficiency of plant breeding. A successful cross of a traditional African rice with a high yielding Asian variety by West Africa Rice Development Association, has resulted in a high-yielding Asian variety. The best characteristics of both rice types have been combined, including drought tolerance, disease and pest resistance and high yields (McCalla *et al.*, 2000). The main concern in modern biotechnology has largely focused in the transfer of genes between species as opposed to genetically improved organism within the same

genotype. The fear in most stakeholders is that genetically modified or engineered crops and foods will displace food crops grown naturally through traditional biotechnology. Furthermore, there is a growing anxiety about whether non-GM and organic farming systems could co-exist alongside GM farming.

Ethical Dilemma over GM Foods

Clearly, quite apart from the issue of whether humans can genetically modify foods which are safe for consumption is the explosive issue of whether we should. For a variety of reasons, many people at this point in time seem to think we should not due to their ethical and ideological perspectives. Ethical issues associated with creating GM foods are focused on tampering or interfering with nature by mixing genes of different species. It does what nature would never do. Other ethical concerns include disruptions of the original genetic intelligence of the host since the introduced gene may act differently when working within its new host. The natural organism's intrinsic values are thus violated. Transferring animal genes into plants raises important ethical issues for vegetarians and religious groups. It may also involve experimenting the GM foods with animals which are unacceptable to many people (Ho Mae-Wan *et al.*, 2003).

Groups who oppose GM technologies on ethical grounds argue that biotechnology is tampering with nature, offending the fundamental rights of living organisms, particularly when it involves transfers of genetic material across different species. Advocates of this view consider both producing and consuming GM products to be immoral because consumption condones production. Consumers who wish to avoid animal products for religious or other reasons criticize the mixing of plant and animal genes. If for example, genes from a pig were transferred to a vegetable, Jewish, Muslim and vegetarian consumers may not wish to eat that product and would want to be aware of the source of those inserted genes. These ethical concerns are critical and cannot continue to be subdued.

Many countries around the world are facing a difficult ethical dilemma as a result of the widespread use of genetically modified foods especially as food aid. "Should people die of hunger now or eat GM foods and die later?" (Salmon, 2002). Francis Nthuku of Biotechnology Trust Africa goes on to say "A hungry country will eat GM organisms". Should opinions and perceptions about GM food stand in the way of technologies that can potentially improve the survival and quality of life of millions of people in developing countries? Scientists must help provide an answer to this question by ensuring that the debate on GM foods addresses facts not opinions, so as to respond to society's concerns.

Millions of people are at risk of starvation. Poor countries are exposing themselves to high risks when they accept GM food aid. Furthermore, in African traditional farming, households don't buy new seeds every season. They mainly recycle seeds. If food aid comes

in as grain, farmers will actually plant these grains. And, once it is planted, it is introduced automatically into the food chain without all the necessary studies. It has been suggested that in addition to offering little to Africa's small-scale farmers, GM foods threaten to further undermine the fragile agricultural systems that these farmers depend upon (Kuyek, 2002). The ethical issue of the need to address the hunger that exists today cannot be avoided. However, there are currently knowledge gaps related to GM foods and biosafety, making uncertainties pervasive.

GM Foods Implications' for Food Security

The potential to provide the world with better food at lower prices via genetic modification is enormous and expanding daily. Optimists see in GM technology potential solutions to food security and the alleviation of hunger among the world's poor, including 'hidden hunger', that results from inadequate levels of micronutrients in children's diets. Regardless of all the potential benefits, numerous consumer groups are concerned about the safety of GM food. Those who are concerned express that rather than having desirable attributes, GM-derived food may be more toxic or carcinogenic, result in more allergies, or be nutritionally less adequate than GM-free food (Ho Mae-Wan *et al.*, 2003). Furthermore, the feared effects like many scientific experiments may not show up for decades. They also invoke several types of ethical arguments to justify the rejection of GM foods.

Science played a major role in meeting the challenge of producing enough food to feed the additional billions of people added in the past 50 years or more (McCalla, *et al* 2000). However, despite good global agricultural performance, most sub-Saharan Africa have many undernourished and micronutrient deficient groups. This implies a lack of access to food on the part of the poor. If the rate of growth of food production relative to population and income growth falls, then price increases will likely follow, further compromising the ability of the poor to obtain food. In order to reduce poverty and food insecurity, agricultural productivity must improve. Biotechnology has the potential to improve agricultural production, but it is controversial. The risks and the benefits of new technology however, must be carefully evaluated by all potential beneficiaries. As with many new technologies, there are both opportunities and risks associated with producers adopting, and consumers accepting, GM foods.

It has been recommended that developing countries do not allow patents on genes, plants and animals in order to protect their food security (Gene Watch, 2003). Some positive potential benefits of GM foods include: adaptation of crops and other foods to grow in harsh climates; pest resistance and herbicide tolerance, drought tolerance; possible reduced damage to and loss of crops, disease resistance; enhanced competitiveness on the global market; and high yields. For example, tissue culture bananas and sweet potatoes have

proven a great success with Kenyan farmers because of high yields (Salmon, 2002)

Negative impact of GM foods include; cost of mandatory labeling, if implemented, will lead to higher food costs; concentration of the agronomic industry in the hands of a few multinational companies has a potential for tighter cooperate control over price of GM seeds and subsequent affordability of food and payment of royalties to patent holders; shift in consumer demand for non GM foods could result in a higher price for non-GM foods; the development of new GM niche products with high value- added returns would cost more because of their specialized nature; gene transfer to non-target species; reduced effectiveness of pesticides.

While large biotechnology corporations, and some governments, try to promise genetically modified crops as a solution to food shortage and malnutrition, Consumer International (CI) insists there is no evidence that GM crops will solve these problems. Genetic modification will not solve world hunger (Bianchi, 2008). The supposed benefits of GM have not been proven to outweigh potential risks to the environment, human and animal health. The claims by biotechnology companies are detracting attention from real causes of hunger in Africa, such as the lack of access to and distribution of food, as well as internal conflict and poor infrastructure. CI further reiterated that GM food is also poorly suited to African farmers in part because it is expensive.

The United Nations World Food Programme (WFP), in a paper entitled "Tackling hunger in a world full of food" states that there is already "sufficient food produced at a global level to meet the needs of every individual alive" (WFP, 1998). Apparently then, agricultural productivity is not the only problem creating starvation. Despite adequate global food production, many still go hungry because increased food supply does not automatically mean increased food security. What is important is who produces it, and who has the purchasing power to acquire it (Ho Mae-Wan *et al.*, 2003). Poor households cannot afford expensive - modern technologies that theoretically raise yields.

Most households are concerned about biosafety, and the consequences of introducing GM food without proper, independent, human safety evaluations and environmental assessments. Most countries especially in Africa do not have the proper regulatory framework in place to cope with GM foods, yet they are being pushed very hard by the biotech corporations to introduce GM foods. Most farmers are not ready to destroy their traditional food production systems. They don't want to put control of the food chain in the hands of a small number of unscrupulous biotech corporations. A large part of food shortages has to do with food distribution and access. Despite what others believe, GM food is not the only food available. If other food is available, shouldn't the consumer be able to choose? The main emphasis should be to look at ways to develop sustainable farming as a potential solution to the hunger crisis, not

experimental foods. This is about making the most of resources that farmers have in order to end poverty in rural areas.

Biotechnology is one tool with the potential for feeding the world in the future. However, it is a solution not without problems, but it is one we cannot afford to ignore. We have fallen behind in educating consumers about the potential of biotechnology and in reassuring them about safety concerns. There is no such a thing as 100 percent safe food in today's world. There is need to fully assess the risks and benefits of all "new" foods, and when the benefits far outweigh the risk we need to move ahead. Incentives are needed for research attention to developing food crops for improved food security. Without them, poor farmers and consumers in developing countries will not have access to, and benefits from, these new technologies that would allow them to increase food production.

6. Recommendations and Way Forward

- Safety approval of genetically modified crops is expensive, since the control procedures are extremely comprehensive. Each genetically modified food must be assessed individually. They cannot be dealt with en masse.
- Good agricultural results should not be threatened by the uncontrolled introduction and utilization of genetically modified crops already available in the market.
- Each country must possess the capacity to assess the implications of introducing genetically modified foods from the standpoint of their impact on the environment, health and safety, and they must also be able to evaluate alternatives. It is important that each country tests GM foods itself because some effects are locale specific.
- Design a comprehensive policy on GM foods including: Food production and distribution, and Food Aid; Testing, labeling and traceability; Regulations; Control and monitoring and; Population Health Surveillance Study.
- Support for research into genetically modified foods to a far larger extent than is currently the case, for example using action-oriental framework that will provide a basis for the assessment of benefits and drawbacks of the possible uses of genetically modified foods in specific contexts and relative to the interests of the target population.
- Ensure that genetically modified foods are in line with overall social problems relative to the reduction of and nutrition problems, and to ensure the underpinning of civil society, and openness through access to relevant information and broad-based and open dialogue with members of civil society.
- Impart on consumers the knowledge of molecular genetics, to improve food production and farming in beneficial ways with promise of more nutritious, diverse, less expensive and more abundant food.

7. Conclusion

GM foods have the potential to solve many of the world's hunger and malnutrition problems, and to help protect and preserve the environment by increasing yield and reducing reliance upon chemical pesticides and herbicides. Yet there are many challenges ahead for governments, especially in the areas of safety testing, regulating, international policy and food labeling. It can be concluded that the concerns surrounding the genetic modification of food pivot on various possibilities: It is possible that transferring genes between natural kingdoms, will have unforeseen - and as yet unimaginable impacts on human health and/or the environment. The potential challenges lies in deciding which of two possibilities is more likely; the possibility the GM food products will cause harm, or the possibility that GM foods will bring significant benefits to sustain livelihood.

Like most new technologies, people all over the world will always be uncertain about the possible changes. There is no technology that is absolutely risk free. Biotechnology of GM foods could have risks, but, the way we address it will be to talk and see the science of it and the ethics. The potential for unintended effects and unforeseen impacts should not be downplayed. To sum up, in the words of entomologist Chris Geiger (Madell, 2000) *"True, transgenic crops hold a great deal of promise. But let's remember that we are tinkering with one very complex system (the genome). I believe that the precautionary principle should be followed with all transgenic introductions, that is, err on the side of caution ... I have not yet seen a transgenic crop product for which there is a truly compelling need that outweighs the unknown risks"*. There are some potential benefits, however, we must proceed with caution to avoid causing unintended harm to human health and the environment. Despite the persistent boasting of GM companies that their products offer solutions to food security and environmental pollution, it is apparent that any such solutions remain mere possibilities.

References

- Anderson, K. **et al.**: 2004. Implications of Genetically Modified Food Technology Policies for Sub-Saharan Africa. Forum Paper. African Development and Poverty Reduction: The Micro-Micro Linkage.
- Bianchi S.: 2008. G8 Summit: Africa Needs Food Security, Not Experimental Crops: [http://c:/G8/SUMMIT/Africa Food Seminar](http://c:/G8/SUMMIT/Africa%20Food%20Seminar).
- Choike.org.: 2006. Food Safety: rigging the game Choike: org. A Portal on Southern Civil Societies, <http://c:/choike/GM/food.htm>
- Desjardins, E. **et al.**: 2001. Protecting Our Food Supply: Public Health Implications of Food Biotechnology. A position Paper for the Ontario Public Health Association (OPHA) .
- FAO :2000. How appropriate are currently available biotechnologies in the crop sector for food production and agriculture in

- developing countries. (Internet
<http://www.fao.org/biotech/c1doc.htm>)
- Gene Watch: 2003. Genetic Technologies: a Review of Developments in 2002. Briefing Number 22.
- Ho Mae-Wan **et al** : 2003. A case for GM-Free Sustainable World. Independent Science Panel. London.
- Kuyek D. :2002. Genetically Modified Crops in Africa: Implications for small farmers. Grain. Briefing. Spain
- Madell, S. : 2000. "The Social Implications of Genetically Modified Food".
- Makoru N. **et al** : 2003. Africa Environment Outlook 2. CBO and UNEP
- McCalla **et al.**: 2000. Feeding the Developing World in the next Millennium: A Question Science?
- McHughen A.: 2000. Biotechnology and Food 2nd Ed. American Council of Science and Health (P2-3) New York, N.Y.
- Nuffield, : 2002. Council on Bioethics. The Ethics of patenting DNA.
- Paarlberg, R.: 2006. Are Genetically modified (GM) crops a commercial risk for Africa?, Int. J. Technology and Globalisation, Vol.2, Nos 1/2 pp 81-92
- Salmon K.: 2002. Ethical Dilemma over GM crops. A Hungry Country Will Eat GM Organisms. Inter Press Service.
- Tribe, D.: 2000. "The need to dish out facts on GM foods" Sydney Morning Herald 06 Apr. p. 15
- Whitman D.B.: 2000. Genetically Modified Foods: Harmful or Helpful? Discovery Guides.
<http://www.CSA.com/discoveryguides/discoveryguides-main.php>
- World Food Programme , :1998. Tackling hunger in a world full of food: [<http://www.wfp.org/info/policy/hunger/p1.html>]

Bio piracy: Threat to Biodiversity Conservation

Priscah J. Rongoei
Egerton University, Department of Environmental Science,
P.O.Box 536, Egerton
Email address: rongoeipj@hotmail.com

Abstract Biodiversity is Africa's richest asset. The knowledge its people have developed over centuries on the properties of plants, seeds, algae and other biological resources is now coveted by scientists for medicinal, agricultural and other purposes. Biodiversity is the means of livelihoods for the poor people and their source of basic needs for nutritional and health care. This study has been compiled from literature review and internet. Biodiversity in Sub-Saharan Africa today is being threatened by attempts to pirate and control it through patenting and by the biotechnology of genetic manipulation. This patenting has resulted in the disincentive in the conservation efforts of the remaining biological resources. Bio piracy operates through the application of Intellectual Property Rights (IPRs) to genetic resources and traditional knowledge. Patents on life forms threaten community access to three of the most critical elements of human survival: food, water and health care. Most Sub-Saharan countries are signatories to the International Convention on Biological Diversity (CBD). This agreement provide a degree of protection to indigenous peoples with respect to the sustainable use of biodiversity, equitable sharing of benefits arising from their commercial use and the preservation of traditional knowledge and practices. Biodiversity has become a "free-for-all out there" and until the CBD solves the problems of access and benefit sharing, the robbery will still continue.

Key words: Biological resources, Bio-prospecting, Intellectual Property Rights, 21st Century, Sub-Saharan Africa

Introduction

Africa is being impoverished by the loss and degradation of its most fundamental capital stock- its genes, species, habitats and ecosystems (Winpenney, 1990). Some scientists predict that if present trends continue, some 25% of the world's species will be lost in the next 20 to 50 years (Winpenney, 1990). Biodiversity today is threatened by attempts to pirate and control it through patenting and by the biotechnology of genetic manipulation.

Biodiversity in simple terms refers to all life forms, including plants, animals, and micro-organisms, whether naturally occurring or

modified, wild, cultivated or domesticated (O’Riordan and Stoll-Kleemann, 2002). More resources from Sub-Saharan Africa such as bacteria, timber, barks of trees, and others have been exploited yet they are facing a new attack- bio piracy.

Africa is a continent of exceptionally high ethnic and biodiversity. A key resource for food, pharmaceutical and agricultural products, it is this diversity which now endangers it. Sub-Saharan Africa is losing huge benefits from biodiversity for lack of legal protection against biopiracy yet biodiversity is the fifth thematic area of World Summit on Sustainable Development (WSSD) (Winpenny, 1990). The knowledge its people have developed over centuries on the properties of plants, seeds, algae and other biological resources is now coveted by scientists for medicinal, agricultural and other purposes. The multinational companies have benefited much from Africa’s biodiversity without sharing the benefits with the communities who discovered, kept and transmitted the knowledge.

Methodology

The data has been collected by use of literature review from library books, newsletters, peer reviewed journals, television documentaries and internet browsing.

Results and Discussion

What is biopiracy?

Biopiracy is the illegal appropriation of life- micro-organisms, plants, and animals (including humans) - and the traditional cultural knowledge that go with it. Macmillan English dictionary defines biopiracy as the practice of using plant or animal genes for scientific research without having the legal right to do so. Biopiracy is illegal because it is the violation of International Conventions which does not recognize, respect or adequately compensate the rightful owners of the life forms appropriated or the traditional knowledge related to their propagation, use and commercial benefit. This biopiracy operates through the application of Intellectual Property Rights (IPR) to genetic resources and traditional knowledge.

Bio-prospecting and biopiracy

Bio-prospecting is the search for biological resources and accompanying indigenous knowledge for the purpose of commercial exploitation.

Bio-prospecting is not inherently contrary to the interests of indigenous peoples or a threat to biodiversity, it facilitates biopiracy. In other words, bio-prospecting identifies biological resources and traditional knowledge with commercial potential, while biopiracy appropriates these resources and knowledge (or privatizes them for commercial gain) without obtaining Prior Informed Consent (PIC) or awarding just compensation (GRAIN article, 1995).

Bio-prospecting is currently being seen by many as an important tool to bring about sustainable development and the

conservation of biological resources through their sustainable use and the fair and equitable sharing of benefits. Others see this as a legalised biopiracy, the 21st century's "politically correct" version of the age-old practice of appropriating the genetic heritage and knowledge of local communities around the world (GRAIN article, 1995).

The convention on Biological Diversity: Bilateralism and Biopiracy

The Convention on Biological Diversity (CBD) recognition of genetic resources as the sovereign rights of nation states, its call for the equitable sharing of benefits derived from genetic resources, and its encouragement of private sector involvement set the stage for the first bilateral deals to be drawn up. United Nations Conference on Trade and Development (UNCTAD) suggests that the Convention enjoys a clear advantage compared to other multilateral environmental agreements, since it has the potential to draw upon private sector investments and market forces as a means for achieving its objectives (UNCTAD, 1996).

The Convention recognizes that states have sovereign rights over their natural resources, and that terms and conditions for access to these materials are within the domain of national legislation. The Convention also recognizes the "knowledge, innovations and practices of indigenous and local communities" and especially "encourage the equitable sharing of benefits arising from the utilization of such knowledge, innovations and practices" (Article 8(j)). The Convention sanctions bilateral agreements by making repeated reference to "mutually agreed terms" for access to genetic materials (Article 15.4), subject to "prior informed consent" of the state (Article 15.5) (CRSRC, 1993).

The Biodiversity Convention offers passive endorsement of bilateral contractual agreements that will pit indigenous communities and countries against one another. While multinational corporations are free to patent bio-materials, there are no effective guidelines and conditions defined for recognizing and rewarding the contributions of indigenous peoples and other informal innovators who are responsible for nurturing, using and developing biodiversity worldwide. (RAFI Occasional Paper, 1994).

Biodiversity as a Strategic Resource and its Threats

Biodiversity which is referred to the broad range of life forms found within a given ecosystem is the backbone of food security and basic health needs (O'Riordan and Stoll-Kleemann, 2002). As the source of primary material and active ingredients for many commercial products- foods, pharmaceuticals, cosmetics, biotechnology, veterinary science, seeds and agro-chemicals- it is recognized as a highly strategic resource with commercial potential comparable to that of petroleum or uranium (Global Exchange, 2007).

The following market figures (annual net sales) illustrate the importance of biodiversity as a strategic resource of the 21st century (Table 1).

Table 1: Biodiversity as a strategic resource

Food	\$2- 3 trillion
Agroforestry	\$300- 400 billion
Pharmaceutical	\$300 billion
Agrochemical	\$35 billion
Commercial seed	\$23 billion
Biotechnology	\$23 billion
Veterinary medicine	\$19 billion
Cosmetic	\$15 billion

Source; RAFI, Wall Street Journal, Agriculture News-2000)

Approximately 90% of the world's remaining biodiversity is concentrated in tropical and sub-tropical regions within developing countries (Winpenny, 1990) located in the southern hemisphere. These areas have been identified by the World Watch Institute as regions with exceptionally high levels of cultural and biodiversity and high concentration of endemic plant species.

Biodiversity is under siege, threatened by the compounded effects of carbon-dioxide emissions, unregulated industrial logging, desertification, natural resource extraction (through activities such as hydroelectric power generation and mining), genetic contamination (through the use of Genetically Modified Organisms), commercial exploitation of endangered species and the disappearance of traditional cultures (O'Riordan and Stoll- Kleemann, 2002; Cunningham et al., 2005).

While affecting the world as a whole, the impact of biodiversity depletion is most dramatically felt by indigenous and rural communities whose livelihood and local economies depend upon it. However, the disappearance of indigenous cultures also represents loss of the cultural wealth of humanity as well as that of traditional knowledge relating to the sustainable uses of biodiversity and conservation (RAFI Occasional Paper, 1994).

The privatization of life

Privatization of life refers to the ownership of life forms and traditional knowledge. Life forms and knowledge are privatized via IPRs (patent) so that individuals or corporations can claim ownership of biological resources and applicable processes. Patents on life forms threaten community access to three of the most critical elements of human survival: food, water, and health care (Global Exchange, 2007).

Privatization of life threatens food security by jeopardizing farmers' access to essential agricultural resources. Patents on life forms deny farmers access to their traditional medicines and force them to pay royalties for seed and livestock derived from patented stock (RAFI Occasional Paper, 1994).

The costs associated with the acquisition, maintenance and protection of patents prevent IPRs from benefiting the developing countries where the vast majority of biological resources are located. Because of these costs, 95% of patents on life or life processes are held in industrial countries, despite the fact that 90% of the world's biological resources are found in developing countries (Global Exchange, 2007; GRAIN seedling, May 2000). These costs render patent ownership financially untenable for the majority of the world's population.

Patents on life are not only a gross abuse of the patent system, they are ethically and morally wrong as they treat life as nothing more than a commodity, people and animals no more than machines (Mae-Wan, 1998).

Methods of Bio-pirating

Corporate bio-prospecting and biopiracy ventures are increasingly undertaken in collaboration with intermediate bodies- including Universities, Governments, Non-Governmental Organizations (NGOs)- which are able to contribute expert yet relatively low-cost field research and input and are generally better placed to gain access to biodiversity "hot spots". In exchange for their involvement, intermediary partners often receive project funding, scholarships or technological hardware; however, corporate partners inevitably retain the vast share of royalties relating to the sale of any marketable products (Global Exchange, 2007).

In recent years, certain environmental organizations have also become involved in bio-prospecting activities, lending a degree of credibility to the ventures but also casting doubt upon the integrity of these organizations' commitment to social justice and environmental preservation.

The Impacts of Biopiracy and Bio-prospecting

The following examples demonstrate the threat posed to indigenous cultures and livelihood by bio-prospecting and biopiracy ventures in Africa.

- **South Africa** - The recent patent involved Hoodia cactus from the Kalahari Desert. For many years, the San people of Southern Africa ate pieces of the cactus to stave off hunger and thirst. The parastatal Council for Scientific and Industrial Research (CSIR) in South Africa found the molecule that curbs appetite and sold the rights to develop an anti-obesity drug to pharmaceutical company Pfizer (Merck, 2002).
- Pirates are adding to their benefits not only through plant genetic resources but also through the removal of livestock germplasm from the South. In 1987, a joint venture between the Commonwealth Scientific and Industrial Research Organization (CSIRO) - an Australian Government agency- and a consortium of Australian producers (known as the Boran and Tuli Producers Consortium), collected Tuli

embryos from Zimbabwe (and Boran from Zambia). In 1990, live calves landed in Australia and has created a controversy over African Cattle becoming important additions to cattle market in Australia and led to valuable new breeds of cattle without any benefit being returned to the countries that developed the breeds (Singh, 2000).

- In 2005, Syngenta launched the Spellbound Busy Lizzie (*Impatiens walleriana*) which is the most popular plant in the west, providing instant colour and usually used by florists. *Impatiens walleriana* is too upright to achieve this goal and many botanists had been hunting for a way to make this plant trail downwards. Syngenta Company claimed that “after many years of research” it had produced *Impatiens walleriana* that “can achieve, at maturity, trails of 70cm masses of large flowers throughout the summer until the first frost”. It was later found out that Spellbound’s magical secret came from a rare African plant, the *Impatiens usambarensis*. This grows in the unique ecological habitat of the Usambara mountain range in Tanzania, south of Mount Kilimanjaro (<http://www.edmonds-institute.org>). The company is making a fortune selling it to the mass market but the Tanzania communities that live in this region do not receive any benefit. This is the silent plunder of natural resources from developing countries
- It is not just in the world of medicine and horticulture but also in fashion that the debate over biopiracy rages. In 2004, the Observer newspaper revealed how British scientists from Leicester University worked with US firm Genencor to patent a microbe that lives in the caustic lakes of Kenya’s Rift Valley. It was discovered that when jeans are washed with this, the microbe produces an enzyme that “eats” the indigo dye, giving them a naturally faded look. The company has since made more than \$1million in sales to detergent makers and textile firms yet the communities living in these regions do not receive any penny.

Conclusion

Biopiracy is a “silent disease” which is hardly detectable and it frequently does not leave traces hence, is an elusive activity perpetrated and often abetted by many well-known multinational companies. Unfortunately it does not attract the same media coverage or public outcry as other environmental problems, such as deforestation and pollutant emissions. But this silent pillage is robbing Sub-Sahara Africa, of the means to finance important sustainable development projects, and is powerful disincentive for their biodiversity conservation efforts.

Recommendations

- The Convention on Biological Diversity must become the multilateral framework for South-South collaboration and South-North negotiation over access to- and development of-germplasm. The solution for governments of the South and indigenous/farming communities is not to adopt industrial intellectual property regimes but to strengthen the community innovation capacity- the collective integrity- of indigenous communities.
- The state should ensure that at least half of benefits derived from commercial use of biological resources are channelled back to local communities.
- **Intellectual integrity:** This means the right of indigenous communities to say “no” to biopirates, or to legitimate bio-prospectors. While it is proper and necessary to upgrade international accords related to “prior informed consent” (PIC) for the collection of biomaterials and indigenous knowledge, it is urgent that the Convention also acknowledge the right of nations and communities not to consent. The assumption is that communities have “no intention of consenting” (NIC).
- **PIC and NIC:** In the absence of a convincing global ethic or clear intention on the part of the international community, indigenous communities and national governments have every right and reason to declare a moratorium on further collecting and new agreements. Once equitable institutional and financial mechanisms are operational and supported by a strong multilateral umbrella, the measured flow of germplasm could resume (within the context of PIC and NIC).
- **Moratorium:** There is no reason, at any time, to permit the patenting of living products or processes. There is even less reason for the South to allow intellectual property over biomaterials when their own medicinal plants and indigenous knowledge lies unprotected and pirated by corporations.
- **No Patenting:** The institutional mechanisms established by the Convention must recognize the minority. Life forms be respected and not privatized.
- **Participation:** The institutional mechanisms established by the Convention must recognize the minority contribution of the donors of funds, and the majority contributions of the donors of germplasm. It would be unacceptable for the North to argue, or for the South to accept, that financial support for conservation and sustainable use of biodiversity and its attendant decision-making are a foreign aid activity.
- **Indigenous Peoples:** International and regional indigenous peoples' organizations must receive financial support to ensure their full and effective participation in all decision-making fora that affect the conservation and use of biomaterials and indigenous knowledge.

- Awareness to the researchers and to the public on conservation of their heritage
- Legal framework required to protect our bio-resources (Bio-safety Bill).

References

- Congressional Research Service Report for Congress, (CRSRC): 1993. "Biotechnology, Indigenous Peoples and Intellectual Property Rights". Pp.11
- Cunningham, W.P., Cunningham, A.M., and Saigo, B, : 2005. (8th Edition). Environmental Science: A Global Concern. McGraw-Hill, New York. Pp. 216-230.
- Global Exchange,: 2007. Focus on Biopiracy in Africa. In, <http://www.biopiracyreport.html> Accessed 26th May 2008.
- Genetic Resource Action International (GRAIN) article in Seedling, : 1995. Towards a biodiversity Community Rights Regime. In: http://www.GRAIN_seedling-1995.htm Accessed 26th May 2008.
- Genetic Resource Action International (GRAIN) article in Seedling, :2000. Towards a biodiversity Community Rights Regime. In: http://www.GRAIN_seedling-2000.htm Accessed 26th May 2008.
- Mae-Wan Ho, : 1998. Genetic Engineering: Dream or Nightmare? The Brave new World of Bad Science and Big Business, Gateway Books.
- Merck, H, : 2002. Focus on Biopiracy in Africa. In: Science in Africa. <http://www.biopiracyinaf.htm> Accessed 26th May 2008
- O'Riordan, T., and Stoll-Kleemann, S. (Eds),: 2002. Biodiversity, Sustainability and Human Communities: protecting beyond the protected, Cambridge University Press. London. Pp. 33-46.
- Rural Advancement Foundation International (RAFI), :1994. RAFI Occasional Paper prepared by RAFI and the Indigenous People's Biodiversity Network. Transfer sourcing and indigenous knowledge and pirating medicinal plants, November, 1994.
- Singh, S, : 2000: Rampant Biopiracy of South's Biodiversity. In: Third World Network. <http://www.rampant.htm> Accessed 26th May 2008.
- United Nations Conference on Trade and Development (UNCTAD), : 1996. The Biotrade Initiative: A New Approach to Biodiversity Conservation and Sustainable Development, UNCTAD, Geneva.
- Winpenny, T.J. (Ed),: 1990. Development Research: The Environmental Challenge. Overseas Development Institute, London. Pp. 145-156.

Use of indigenous plants in sustaining health and livelihoods in Africa

Samuel T. Kariuki
Egerton University, Department of Biological Sciences, P.O.
Box 536 Egerton, Kenya
E-mail: stkabuitu@gmail.com

Abstract *The use of indigenous plants in primary healthcare in Africa has evolved with time. In many African states the practice can be divided into pre-colonial, colonial and post-colonial periods. It was the main source of medicine in pre-colonial era but was suppressed and sidelined during colonial era by the colonialists. However, it has emerged as the most popular practice after independence. The western world has made the practice popular after people realized that food supplements in food stores and pharmacies are natural products. The increased use of plant based drugs such as artemisin for malaria treatment instead of sulphur-based fansidar has also boosted this practice. Patients have noticed that there are no serious side effects associated with herbal medicine as in conventional medicine. The screening of plants has shown them to consist of numerous different substances including vitamins, trace elements, macronutrients, curative and toxic substances.*

Since these plants are applied in admixture form some healing cases appear miraculous as nobody exactly understands the interactions. When some substances are carcinogenic others are anti tumour; when some are toxic others are detoxifies, immune boosters and others nutritive. This synergy makes crude extracts more curative than pure compounds. Some patients after being discontinued from conventional medical treatment due to their terminal conditions have resulted in using herbal treatment that has given them a lot of hope.

Key words: *Herbalists, extract, admixture, synergy, conventional and chronic.*

Introduction

The use of indigenous plants in primary healthcare is an old practice. It has been nearly parallel to the conventional medicine, but is now recognized as an important part of the economy and healthcare services. People have realized that there are excellent livelihood and health opportunities associated with the future development of this practice. However, there are also many challenges to be overcome before these opportunities can be realized. It is estimated that 80% of

Africa depend on indigenous plants based medicine, while about 25% of the prescribed medicine in the world contain some plants derivatives (WHO, 2003). These natural products can now be purchased from health food shops, supermarkets and chemists. The doctors using indigenous plants are commonly referred to as 'herbalists'. These herbalists who were previously a lowly educated folk now constitute of some educated people including some professionals. This diverse composition of practitioners has resulted in more patients seeking this treatment.

Collection of plant materials

Most of the plants used in this practice are collected predominantly from Government forests. This has often resulted in conflicts between government officials and herbalists. All plant forms; trees, shrubs, herbs and vines are collected depending on plant organs to be used. However herbalists have regarded these resources as 'common property' and often use destructive harvesting methods of the roots and stems sometimes uprooting the entire plant (Wyk, 2002). This has resulted in some plant species being threatened with extinction such as *Warburgia ugandensis*, *Osyris lanceolata*, *Mondia whytei*, *Prunus africana* and some *Aloe ssp.* (Akere, 1991).

There are some experienced practitioners who know the most potent plant, organ per plant species, habitats for particular species and the time of the year when to collect such plants. In order to sustain the supply of these plants government has boosted forest protection, many herbalists trained on sustainable harvesting methods and encouraged to cultivate their own medicinal plants (Lambert et al, 1997)

Processing and packaging of herbal medicine

Herbal products are used in either raw or semi-processed form(Lezhneya,et al). These products are in powder, concoctions, infusions, pastes or tablets and capsules(Martneza,1980).

Often herbal products are used in admixture and in different concentrations of the plants used.! The practitioners know this through experience. Some plants are known to work synergistically while some species detoxify the toxic ones (Stuart, 1971). For instance, *Erythrina abyssinica* is used to detoxify *Warburgia ugandanensis* (Lelei, 2008).

Mode of preparation either boiling in water, soaking in cold water, time required for extraction and the dose is also learned through experience and informal training mainly oral (Rono, 2008). Consequently this practice is not standard amongst different practitioners and within different countries.

The common methods used in drug administration

There are different avenues used in drug administration usually depending on the type of drug and the expected body's reaction to

the drug. Most of drugs orally administered are usually those believed not destroyed in alimentary canal. These are given in large quantities due to the low active ingredients in the concoctions (Anderson, 1998). The sublingual ones are rapidly absorbed and avoid acidic action in stomach and liver metabolism. This acidic action in stomach and liver metabolism is also avoided by applying some medicine through rectal route. Poultice is applied directly on skin and to sprains while some herbalists make some cuts on skins and apply ash or infusion believed to act as intravenously administered drugs. For patients with headache and chest problems some herbalists apply some preparations in form of snuff or cigar believing that when snuff or smoke is inhaled it will induce sneezing or cough respectively thus expelling the disease (Wyk, 2002). These methods have been found to introduce drug in cerebral circulation and dilation of respiratory systems the latter being effective in relieving asthma. Steaming and bathing in herbal preparations are also used in treating common cold and skin diseases. *Ocimum spp.* and *Lippia spp.* are commonly used in former cases while *Warbugia* and *Aloe spp.* are used in latter conditions (Stuart, 1971).

The herbalists use bottles to store concoctions while powders are packaged in papers and bottles. However most of them do not indicate the drug composition, expiry date and dosage. Since most of drugs are in raw or semi-processed form they have a short shelf-life (Stuart 1971).

Diagnosis and treatment of diseases

Most of herbalists depend on their experience in disease diagnosis and treatment (Chrubasic, et al). This risks giving wrong treatment unless for an obvious problem such as skin disease, snake bites or boils. They depend on trial and error method that often may result in prescribing over dose or under dose. However, there are some herbalists who insist on patients' first getting proper diagnosis from conventional doctors and technicians before prescribing medicine. This is now improving and accrediting the practice that was previously regarded as primitive and synonymous to witchcraft (Njiru, 2008).

Trade in herbal medicine

There is both local and export market for herbal products in Africa. There are herbalists who now make an income in selling medicinal plants seedlings, raw materials such as roots, bark or semi-processed products to other practicing herbalists. This business also occurs across the African countries and out of Africa mainly for plant extracts. However, most of this trade is informal and thus not easily quantified. The rich plant species diversity in Africa (for instance; Cameroon 9,000 *spp.*, Democratic Republic of Congo 11,000 *spp.*, Kenya 7,500 *spp.* and Madagascar 11000 *spp.*) (WWF, 1993) has resulted in the increasing investments in new drug discovery programmes by some multinational pharmaceutical companies. This

commercialization of indigenous plants has increased over-harvesting of some plant species. The herbal products have become available in both rural and urban centres and since they are cheaper than conventional drugs more people have improved in health and productivity. Hong Kong is the largest importer of plant pharmaceutical products with annual figures of USD 133.7 million, while Europe imports approximately 25% (132,000 tonnes) of which 20% is estimated to originate from Africa. In 1996 approximately 26,500 tonnes of medicinal plants were exported from Africa to Europe (Wyk, 2002). The screening of Kenyan plants for their phytochemical properties showed presence of many species with potential for exploitation in drug industry (Mwangi et al, 1999). This shows that if some plants are domesticated and well processed Africa can diversify its exports and improve its foreign exchange. This would improve Africans' health and livelihood.

Case study

A case study at Egerton University Herbal Medicine Research Centre, in Kenya showed that most of the patients in urban areas seek herbal treatment after failing to recover from conventional medicine at hospitals. Most of these patients were also suffering from chronic diseases such as diabetes, asthma, arthritis, ulcers and cardiac problems. One lady had a breast cancer treated and operated but the tumor recurred. When treated at the centre, the tumor disappeared. One man had one leg amputated after severe diabetes infection. The other leg had already developed wounds but after treatment at the centre, the wounds healed and the man now walks with clutches from a wheelchair. It has also been found that although through scientific analysis pure compounds can be isolated from plant extracts, herbals have proved to work best in crude forms.

Conclusions and recommendations

Herbal and conventional medicines need to be integrated. This will give patients options of using any form of medicine as the goal in any practice is to improve healthcare and livelihood of the people. Herbalists need to be trained on proper plant identification, diagnosis, dosage and safe packaging. Conventional doctors need to be introduced to natural products and plant analysis and testing should be part of training. This will add value on our indigenous plants and improve in resource conservation and protection. The two forms of medicine and practitioners should be available in most of hospitals so that patients have a choice of treatments.

Acknowledgements

I wish to give my appreciation to the UNESCO Regional Bioethics Centre at Egerton University, in Kenya for giving chance to the preparation of this paper. I am also indebted to different herbalist groups in Kenya for furnishing me with a lot of information about

their profession. This goes particularly to groups at Ngorika, Nyeri, Embu, Eldoret and Kakamega.

References

- Akere, J.: 1991. Conservation of medicinal plant. Cambridge univ. Press, London
- Anderson, J.E.: 1998. The use of Biological assays to Evaluate Botanicals. *Drugs inform. J.* 2:514-518
- Wyk, B.E.: 2003. People's plants. A guide to useful plants of S. Africa. Briza Publications, Pretoria.
- Chrubasic, S., Enderlein, W., Bauer, R. and Grabner, W.: 1997 Evidence for antirheumatic effectiveness of *Herba urticae dioicae* in acute arthritis, *J. Phytomed.* 2:105-108
- Lambart, S.J. Srivastava, J. and Vieyer, N.: 1970 Medicinal Plants. Rescuing a global heritage. World Bank technical Paper no. 355, World Bank, Washington, D.C.
- Lelei, J. (2008) Pers. Comm.
- Lezhneva, L.P., Maravev, I.A. and Cherevatyi, V.S.: 1986. Antibacterial activity of *Urtica dioica* Leaves *Resursy* 2:255-257
- Martinez, M.C.: 1980. The nettle as food. Alcala de Henares Univ. Spain
- Mwangi, J.W., Masengo, W, Thoithi, G.N and Kibwage 1,0.: 1999. Screening of some Kenyan medicinal Plants using Brine Shrimp Lethality Test. *J.Parm. Sc.* 2:63-69.
- Rono, P.: 2008. Pers comm.
- Njiru, J, 2008. Pers. comm..
- Stuat, M.: 1971. herbs and Herbalism. Crescent Books. New York.
- World Wide fund (WWF) : 1993. African bio-diversity. Foundations for the Future Bio-diversity Programme support manykal
- WHO,: 2003. World Health Organization Report on traditional medicine. Fact sheet, No.134, World Health Organization, Geneva.

Plants as source of Traditional Medicine: Ethical implications on unregulated and uncontrolled use

Wairimu A. Muia

Biological Sciences Department, Egerton University, P.O. Box 536, Njoro Kenya.

Email: wairimumuia@yahoo.com

Abstract *Plants constitute a major component of traditional and complimentary medicines. In Africa 80% of the population depend on plant and animal based medicines to meet their primary health needs. Documented scientific evidence shows that certain herbal medicines and plant products are effective in treatment of diseases. However un-regulated and in-appropriate use of plant medicines may have negative or deleterious effects. Investigations of the potential toxicity of naturally occurring substances commonly used as ingredients of plant medicinal preparations have shown previously unsuspected potential for toxicity, mutagenicity, carcinogenicity and teratogenicity. In many cases traditional medicines are not subjected to regulatory controls and regimes applicable to modern drug development. Local herbalists are unwilling to reveal information regarding their preparations. As such there is no assurance on the safety, efficacy and quality of these preparations and continued un-regulated use of such drugs can have serious ethical implications. This opinion paper gives an overview on some of the useful plant products and explores evidence on plant products known to cause potential genotoxic effects.*

Key words: *carcinogenicity, crude drugs, genotoxic, herbal medicine, mutagenicity, quality assurance*

Introduction

Herbal medicine (plant medicine, botanical medicine or phytotherapy) is a broad term covering all Traditional medicine (TM) and “Complementary” or “Alternative medicine” (CAM) systems utilizing plants (Singh, 2008). In Africa, 80% of people depend on plant and animal based medicines to meet their primary health needs (WHO, 2003). In Asia there is substantial consumption of traditional medicine. In developed countries many pharmaceutical products are based on/or consists of biological materials sourced through reference to TM (WHO, 2003).

Increased awareness about herbal medicine in recent times among the general population the world over can probably be attributed to increased drug resistance observed in modern drugs, cost effectiveness of herbal medicines and efficacy of some herbal

products such as artemisin (from *Artemisia annua*) for malaria treatment (Singh, 2008).

However un-regulated and uncontrolled use of plant medicines untested for efficacy and safety may have negative effects making their administration unethical because TM are not subjected to regulatory controls and regimes applicable to modern drug development (ICH guidelines, 1996). Data on side effects of TM is accumulating discrediting the popular belief that TM has no side effects. (<http://www.herbs-hands-healing.co.uk>, 2008).

Some naturally occurring substances used as ingredients of herbal medicines are now known to possess mutagenic and / or carcinogenic (genotoxic) and teratogenic potential questioning the ethics and moral values in the continued use of such plant products.

Regulatory authorities all over the world require data on the genotoxic potential of new drugs, as part of the safety evaluation process before commencement of clinical trials and marketing (Jena *et al.*, 2002). The aim of this opinion paper is to explore some of the plants with medicinal value and highlight plants with known genotoxic potential as a way of bringing awareness on effects of uncontrolled use of un-tested herbal medicines and their ethical implications to human health.

Plants as sources of medicines

A century ago most of the few effective drugs were plant based (Humphreys, 1982; Vickers and Zollman, 1999). For example, foxglove (*Digitalis purpurea*), a common ornamental plant for curing heart diseases; Madagascan periwinkle (*Catharanthus roseus*), for leukaemia chemotherapy and cinchona bark for treating malaria.

Today many more plants some of which are described below have been shown to possess potential pharmacological activity in various test systems. Extracts from *Maytenus ilicifolia* and *M. aquifolium* for treatment of gastric ulcers in Brazil folk medicine were demonstrated to have anti-ulcerogenic effects (Souza-Formigoni *et al.*, 1991). The methanol extracts of plumule and radicle of Lotus (*Nelumbo nucifera* Gertn.), a plant used as a cardiogenic, transquillizer and antihypertensive agent in Taiwan was found to contain reducing powers and free radical activities (Wang *et al.*, 2003).

Aqueous extracts of *Vernonia amygdalina*, *Garcinia kola* and *Gongronema latifolium* used as medicinal plants in Nigeria were shown to possess antimicrobial (Oshodi *et al.*, 2004). *Sansevieria* species and *Cannabis sativa* species used as folk remedies in South Africa have been shown to exhibit antibacterial and immune modulatory effects (Case, 2005). Ethanol extracts of edible plants, *Entanda africana* (bark), *Terminalia avicennoides* (bark), *Mitragyna stipulosa* (bark) *Lannae acida* (stem bark) caused inhibitory and cidal effects to bacteria (Aboaba *et al.*, 2006). Some Chinese medicinal plants have been found to have potential natural antifungal agents against food borne pathogens (Lee *et al.*, 2007).

Plant carcinogens and mutagens

Plants are also a source of mutagens and carcinogens and can cause cancer or even teratogenic effects when suspect plants are consumed (Nagao *et al.*, 1978). Mutations in the somatic cells of a complex organism may lead to cancer and those occurring in germ cells may be heritable resulting in genetic abnormalities in subsequent progeny (IPCS report, 1985, IPCS, 1990). Some important products with toxic, carcinogenic and/or mutagenic activity are discussed below.

Pyrrolizidine alkaloids

The pyrrolizidine alkaloids (PAs) occur in fifty species of Compositae, Bignoniaceae and Leguminosae which include species used as medicinal herbs in East Africa (Kokwaro, 1976). PAs are highly toxic and cause cancer in humans and liver disease in grazing animals (Tazima, 1984). Carcinogenic PAs are described in IARC monograph (1976). A PA isolated from the stalks of *Petasites japonicus*, a herbal remedy in Japan and PAs occurring in the Russian comfrey, *Symphytum officinale*, a herbal tea and a constituent of salads are carcinogenic and mutagenic, respectively (Hirono *et al.*, 1977; Hirono *et al.*, 1978),

Flavonoids

Flavonoids occur widely in plants used as human foods and in drug preparations (Brown, 1980). The flavonoids quercetin and kaempferol are mutagenic in the *Salmonella* tester strains (Hardigee and Epler, 1978; Uyeta *et al.*, 1981). Quercetin caused single-strand DNA breaks in the mouse Lymphoma system (Meltz and MacGregor, 1981).

Quinones

Quinones also occur naturally in plants used as human food (Brown, 1980; Ames, 1983). Mutagenicity of quinones in *Salmonella* strains have been demonstrated (Ashwood *et al.*, 1982; Tikkanen *et al.*, 1983; Chesis *et al.*, 1984). Clark (1982) was able to show mutagenic activity of juglone 5-hydroxyl-1, 4-naphthoquinone in the first brood of adult male *Drosophila*.

Cycasin

Cycasins occur in cycad plants found in tropical and subtropical regions of the world. Cycad starch from nuts of *Cycas circinalis* and *Cycas revoluta* is used in Mariana and Ryuku islands (Japan), Indo-China, India and Africa (IARC monograph, 1976). In these areas the nuts are also prepared for use as external and internal medicine (Whiting, 1963). Mugeru and Nderito (1968) observed induction of tumours in liver, kidney and lungs of rats after chronic ingestion of starchy kernels of a cycad, *Encephalatos hilderbrandtii*.

Bracken fern toxin

Bracken ferns, *Pteridium aquilinum* and *P. esculentum* which are eaten by man as greens or salads in certain parts of the world are

poisonous to livestock, particularly cattle. The toxin causes avitaminosis and chronic neurological problems in addition to being radiomimetic. Fresh bracken fern extracts are highly mutagenic in *D. melanogaster* (Clark, 1982). A chemical extract from bracken fronds has been shown to be mutagenic in *Salmonella* tester strains (van der Hoeven, 1984).

Plant mutagens in crude drugs

Mutagens in crude drugs have also been reported. Shehab (1980) showed that water extract of *Teucrium pilosum*, a plant used against constipation in Qatar, had anti-mitotic effects in roots of *Allium cepa*. Nakamura and Yomoto (1982) showed that juice from ginger, *Zingiber officinale*, a Chinese medicinal herb, increased mutagenicity of N-methyl-N-nitroguanidine (NTG) and 2-aminofluorene (2-AF) in *E. coli*. Morimoto *et al* (1982) showed mutagenicity of 45 samples of crude drugs using *Bacillus subtilis* rec assay and *Salmonella* microsome assay.

Uwaifo *et al* (1979) reported mutagenic activity of a chemical compound isolated from *Uvaria chamnae*, a medicinal herb used as a purgative in Nigeria in *Salmonella* strains. Marimoto *et al.*, (1983) reported mutagenicity of methanol extract of *Gentiana radix*, a plant widely used as a component of bitter drugs in Chinese medicines. Mutagenicity of extracts from *Dictamnii radice* a component of Chinese medicine was reported by Mizuta and Kanamoni (1985).

Aqueous extracts of three plants used in Brazilian popular medicine including *Achyrocline satureoides*, *B. anomala*, *L. divaricata* *Myrciaria tenella*, *Smilax campestris*, *Tripodanthus acutifolius* and *Cassia corymbossa* were found to be mutagenic in Ames *Salmonella* test (Vargas *et al.*, 1991; De Sa Ferrira and Vargas, 1999). The methanol extracts of the plumule and radicle of Lotus were non mutagenic in *Salmonella* tester strain (Wang *et al.*, 2003). Ethanolic gross extracts of *Jacaranda decurrens* used in treatment of syphilis, diaphoresis, inflammation *etc.* in Brazil were found to be mutagenic in *Drosophila melanogaster* (dos Passos *et al.*, 2007).

Plant antimutagens and anticarcinogens

Anti-mutagens and anti-carcinogens in plants have also been reported. These compounds possess chemo protective activity against mutagenesis and carcinogenesis. Some plants with such properties are presented. Vegetable juice of ginger and cabbage were found to inhibit mutagenic activity of protein and amino acid tryptophan pyrolysates that are mutagenic in bacteria (Morimoto *et al.*, 1978; Nakamura and Yamamoto 1982).

Some plant flavonoids were shown to inhibit genotoxic effects of cooked food pyrolysates. Many plant extracts have been shown to ameliorate a number of diverse genotoxins (Ishii *et al.*, 1984). Wood *et al.*, (1982) reported antimutagenic activity of polyphenolic acid and its metabolites in bacterial assays.

Water, alcoholic and oil extracts of dry nuts of *Semecarpus anacardium* a plant used in Ayurvedic medicine for treatment of amoebiasis and arthritis were found to possess antimutagenic activity (Kothali *et al.*, 1997). Chemical components in green tea suppress activity of many chemical mutagens (Hour *et al.*, 1999). Ethanol extract from roselle (*Hibiscus sabdariffa*) flowers and whole fresh plant of *Murdannia loriformis* used in Thai traditional medicine was antimutagenic and chemoprotective in colon carcinogenesis model and antimutagenic in *Salmonella* assay besides showing inhibitory effects on crypt focus formation in rats respectively (Chewonarin *et al.*, 1999; Intiyoti *et al.*, 2002). Ethanol extract of *Momordica charantia* (bitter melon) a plant used for treatment of *Diabetes mellitus* was found to possess antimutagenic and chemoprotective activity against colon carcinogenesis (Chiampanichayakul *et al.*, 2001).

Pyrogallol present in un-fractionated and methanol extract of *Embllica officinalis* extracts, a plant with anti inflammatory, antifungal, antimicrobial and hepaprotective medicinal activities has been found to be anti-proliferative in human tumour cell lines *in vitro* (Khan *et al.*, 2002) Several plants used in traditional medicine and as local animal feed in rural areas in Thailand indicated significant antimutagenicity *in vitro*, suggesting a potential pharmacological importance for health maintenance and the prevention of cancer and other chronic diseases (Thepouyporn *et al.*, 2006).

Biodiversity conservation an ethical issue

Most medicinal plants used as sources of medicines are gathered from uncultivated biodiversity sources in the wild (Correa, 2002). Continued use of plant biodiversity as source of herbal medicine without prompt and appropriate measures to conserve it has ethical implications.

Ethical issues in validation and quality assurance of herbal medicines

The quality, efficacy and safety of herbal medicines prescribed by local herbalists cannot be assured raising ethical concerns. Investigation on potential contamination of herbal medicines is important since their natural origin, practices used in harvesting; handling, storage, production and distribution subject them to contamination (Bugno *et al.*, 2006). A national policy on TM is essential to harmonize, validate and establish internationally recognized guidelines for assessing quality of herbal medicines. An excellent report worth emulating from Andhra Pradesh Forest Department presents value addition techniques for commercially important medicinal plants of Andhra Pradesh including pharmacoepial standards (FRLHT Report, 2002).

Conclusions and recommendations

The literature explored has shown plants used as human medicine and food contain mutagens and carcinogens and anti-

mutagens. To evaluate the safety of administering crude drugs to patients over long periods and their ethical implications, it is important to investigate plants for their potential mutagenic/carcinogenic and anti mutagenic activity in addition to toxicity tests. Such tests would add value to herbal products and instil confidence in administering and consumption of such preparations. Avoiding contamination of material will go along way in improving the quality of the production and manufacturing process. There is need for a government policy describing quality assurance guidelines of herbal medicines administered herbalists. To augment this, a code of ethics and professional conduct should be introduced to remove fraudulent and quackery behaviour in self claimed healers that spoil professional ethics that would otherwise help to promote and conserve traditional knowledge in herbal medicine.

References

- Aboaba, O. O, Smith S I and Olude F O.: 2006., Antibacterial effect of edible plant extract on *Escherichia coli* 0157:H7, Pakistan Journal of Nutrition **5** (4) 325-327, 2006.
- Ames B.N. :1983. Dietary carcinogens and anti-carcinogens, Science, **221**, 1250-1263.
- Ashwood, M.J. Smith, G.H.N. Towers, Z, Abrahamowski, Poulton G.A and Liu M.: 1982., Photobiological studies with dictamine, a furoquinoline alkaloid, Mutation Research **102**, 401-412.
- Brown J.P.: 1980, A review of the genetic effects of naturally occurring flavanoids, anthroquinones and related compounds, Mutation Research, **75**, 243-277.
- Bugno A, Aparecida A, Almodovar1 B, Tatiana C P, Pinto, T J A and Sabino M.: 2006., Occurrence of toxigenic fungi in herbal drugs. Brazilian Journal of Microbiology **37**, 47-51.
- Chesis, P. I., Levin D. E., Smith M. T., Ernster L. and Ames B. N. 1984., Mutagenicity of quinones; pathways of metabolic activation and deactivation, Proceedings of National Academy of Sciences. (U. S. A.), **81**, 1696-1700.
- Chewonarin T, Kinouchi T, Kataoka K, Arimochi H, Kuwahara T, Vinitketkumnuen U and Ohnishi Y.: 1999, Effects of Roselle (*Hibiscus sabdariffa* Linn.), a Thai Medicinal Plant, on mutagenicity of various known mutagens in *Salmonella typhimurium* and on formation of Aberrant crypt foci induced by colon carcinogens azoxymethane and 2-amino-1-methyl-6-phenylimidazol[4,5-*b*] pyridine in F344 rats, Food and Chemical Toxicology **37**, 591-601
- Case, O.: 2005, An assessment of medicinal hemp plant extracts as natural antibiotic and immune modulation phytotherapies, MSC Thesis, South African Herbal Science and Medicine, Faculty of Natural Sciences, University of Western Cape.
- Chiampanichayakul ,S., Kataoka K, Arimochi H, Thumvijit S, Nakayama TH, Vinitketkumnuen U and Ohnishi Y.: 2001, Inhibitory effects of bitter lemon (*Mormodica charantia* Linn.) on

- bacterial mutagenesis and aberrant crypt foci formation in rat colon, *Journal of Medical Investigations*. **48**, 88-96.
- Clark, A.M.: 1982, The use of larval stages of *Drosophila* in screening for some naturally occurring mutagens, *Mutations Research*. **2**, 89-97.
- Correa, C.M.: 2002, Protection and promotion of traditional medicine : implications for public health in developing countries. Sadag, Geneva.
- De Sa Ferreira F and Vargas F.: 1999, Mutagenicity of medicinal plant extracts in Salmonella microsome assay, *Phytotherapy Research*. **13 (5)**, 397-400.
- Dos Passos D B S, Menezes P M, Nunes W B, de Oleveilla A G and de Carvalho S,: 2007. Evaluation of the mutagenic and/antimutagenic activity of the medicinal plant Jacaranda decurrens (Carobinha- do-campo) by the SMART/eye test in somatic cells of *Drosophila melanogaster*. *Cytologia* **72(3)**, 351-355.
- Foundation for Revitalization of Local Health Traditions (FRLHT): 2002, Value addition techniques for commercially important medicinal plants of Andhra Pradesh including pharmacoepeial standards for 61 species, AP_CF/LAB Report/Final
- Hardigee, A. A. and Epler J. L.: 1971, Mutagenicity of plant flavonoids in microbial systems, *Mutation Research*, **53**, 89.
- Hirono, I, Mori H and Haga M.: 1978, Carcinogenic activity of *Symphytum officinale*, *Journal of National. Cancer Institute.*, **61**, 865-868.
- Hirono, I. , Mori H. J, Yamada K, Haga M , Tateshatsu M H. and Kansey Y.: 1977, Carcinogenic activity of petastenine, a new pyrrolizidine alkaloid from petasites japonicus maxim, *Journal of National Cancer Institute*, **58**, 1155-1157.
- Hour, T C, Liang YC Chu, I and Lin JK.: 1999, Inhibition of eleven mutagens by various tea extracts, (-) Epigallocatechin-3-gallate, gallic acid and caffeine. *Food and Chemical Toxicology* **37**, 569-579.
- <http://www.herbs-hands-healing.co.uk>, 2008, Herbs hands and Healing, 26th may 2008
- Humphreys, J.: 1982, Plants that bring health or death. *New Scientist* **93**, 513-517.
- I. A. R. C.: 1976, Some anti-thyroid and related substances, nitrofurans and industrial chemicals, I. A. R. C. Monographs for the Evaluation of Carconogenic Risk of Chemicals to Humans, Vol. 7, WHO, Lyon.
- International Conference on Harmonisation (ICH) of technical requirements for registration of pharmaceuticals for human use (1996) Guideline for industry: specific aspects of regulatory genotoxicity tests for pharmaceuticals (61 FR 18199) Drug Information Branch, HFD-210, CDER, FDA, 5600 Fishers Lane, Rockville, MD 20857
- Intiyoti Y, Kinouchi T, Kataoka, K, Tomomi H, Vinitketkumnuen U and Ohnishi .: 2002, Antimutagenicity of *Murdannia loriformis* in

- Salmonella* mutation assay and its inhibitory effects on azoxymethane-induced DNA methylation and aberrant crypt focus formation in male F344 rats. *Journal of Medical Investigations*. **49**, 25-34.
- Ishii R., Yoshikawa K, Minakata H, Nomura H and Kada T.: 1984, Specificities of bio-mutagens in plant kingdom. *Agricultural and Biological Chemistry*, **48**, 2587-2591.
- IPCS: 1985, Guide to short-term tests for detecting mutagenic and carcinogenic chemicals, environmental health criteria **51**, World Health Organization, Geneva.
- IPCS: 1990, summary report on the evaluation of short-term tests for carcinogens. (collaborative study on in vivo tests), Environmental Health, Criteria 109, World Health Organization, Geneva.
- Jena G.B, Kaul C.L, Ramarao P.: 2002, Genotoxicity testing, a regulatory requirement for drug discovery and development: impact of ICH guidelines. *Indian Journal of Pharmacology* **34**, 86-99.
- Khan M. T. H., Lampronti I, Martello D., Bianchi N., Jabbar S, Choudhuri MSK, Datta BK and Gambari R.: 2002, Identification of pyrogallol as an antiproliferative compound present in extracts from medicinal plant *Emblica officinalis*: Effects on in vitro cell growth of human tumor cell lines. *Intern. Journal of Oncology*. **20**, 187- 192
- Kokwaro, J. O.: 1976, Medicinal plants of East Africa. East Africa Literature Bureau, Nairobi.
- Kothari, A. B, Lahiri M, Ghaisas S. D and Bhide S. V.: 1997. *In vitro* Studies on antimutagenicity of water, alcoholic and oil extracts of *Semecarpus anacardium*, *Indian Journal of Pharmacology* **29**, 301 - 305.
- Lee S. H, Chang K. S, Su M. S, Huang Y. S and Jang H. D.: 2007, Effects of some Chinese medicinal plant extracts on five different fungi. *Food Control* **16 (12)**, 1547-1554.
- Meltz M L and Macgregor J T.: 1989, Activity of the plant flavonoid quercetin in the mouse lymphoma L5178TK./TK-mutation, DNA single strand breaks and balb/c 3TZ chemical transformation test. *Mutation Research*. **88**, 317-324.
- Mizuta M and Kanamori H.:1989, Mutagenic activities of dictamine and Y-fagarine from *Dictamine radics* cortex (Rutaceae), *Mutation Research*. **114**, 221-225.
- Morimoto K, Ohara M. Kada T.: 1978, Studies of natural desmutagens: Screening vegetable and fruit factors active in inactivation of mutagenic pyrolysate products from amino acids, *Agricultural and Biological Chemistry* **42**, 1235-1238.
- Morimoto I, Watanebe F, Osawa T. Okitsu T and Kada T.: 1982, Mutagenicity screening of crude drugs with *Bacillus Subtilis* REC: assay and *Salmonella*/microsome reversion assay. *Mutation Research*. **97**, 81-1102.

- Mugera G M and Nderito P.: 1968, Tumors of the liver, kidney and lungs in rats fed *Encephalatos hilderbrandtii*. *British Journal of Cancer* **22**, 563-568.
- Nagao M, Sugimura T and Matsushima T.: 1978, Environmental mutagens and carcinogens, *Snn. Review of Genetics* **12**, 117-159.
- Nakamura, H. and Yamamoto T.: 1982. Mutagen and antimutagen in ginger, *Zingiber officinale*, *Mutation Research* **103**, 119-126.
- Oshodi A. A, Amolo I A and Eleyinmi A F.: 2004, The antimicrobial activity of Nigerian medicinal plants potentially usable as hop substitutes. *Master Brewers Association of Americas Technical Quarterly*, **41(5)**, 398-402.
- Shehab, A. S.: 1979, Cytological effects of medicinal plants in Qatar I. Mitotic effects of water extracts of *Pulcaria crispa* on *Allium cepa*. *Cytologia* **44**, 607-613.
- Singh A. P.: 2008, Ethics in herbal medicine. <http://www.siu.edu/~ebl/leaflets/ethics.htm> 26th May 2008.
- Souza-Formigoni, M. L, Oliveira M. G, Monteiro M. G, da Silveira-Filho N. G, Braz S and Carlini E A.: 1991, Antiulcerogenic effects of two *Maytenus* species in laboratory animals. *Journal of Ethnopharmacology*. **34(1)**, 21-27.
- Tazima Y.: 1984. Naturally occurring mutagens, in: E. H. Y. Chu and W. M. Genoroso (eds.) *Mutation Cancer and Malformations*, Environmental Science Research, Vol. **31**, Plenum, New York.
- Thepouyporn, A, Karunee K. Pooudong S and Changbumrung S.: 2006, Mutagenicity study of weeds and common plants used in traditional medicine and for animal feed. *Southeast Asian Journal of Tropical Medicine and Public Health* **37 (3)**, 195 - 202.
- Tikkanen, L, Matsushima T, Nato S and Yoshimura K.: 1983, Naturally occurring quinones have mutagenic activity in TA2637 +S9. *Mutation Research*. **124**, 25-34.
- Uyeta, M., Tane S and Mazaki M.: 1981, Mutagenicity of hydrolysates of infusion of green and black tea in the Ames test, *Mutation Research*. **88**, 233-240.
- Uwaifo, A. O, Okone D. A and Bababunmi E A.: 1979, Mutagenicity of Chamvaritin: A benzyl dihydrochalcone isolated from a medicinal plant. *Cancer Letters* **8**, 87- 92.
- Van der Hoeven J, Brugemann I. M and Debetts F. M. H.: 1984, Genotoxicity of quercetin In mammalian cells. *Mutation Research* **136**, 9-21.
- Vargas V M, Guidobono R R, Henriques J A.: 1991. Genotoxicity of plant extracts, *Mem Inst Oswaldo Cruz*, **86 (12)** 67 -70.
- Vickers A and Zollman C.: 1999. ABC of complimentary medicine, *British Medical Journal* **319**, 1050- 1053.
- Wang L, Yen, J. H , Liang H I and Wu M. J.: 2003, Antioxidant effects of Methanol extracts from Plumule and Blossom (*Nelumbo nucifera* Gertn.), *Journal of Food and drug analysis*, **11(1)**, 60-66.
- Whiting, M. G.: 1963, Toxicity of cycads, *Economic Botany* **17**, 271-302.

WHO. : 2003, World Health Organization Report on Traditional medicine, Fact sheet, No 134, World Health Organization, Geneva.

Wood, A. W, Huang M .T, Chung R. L, Newmark H .L, Lehr R. E, Yagi H .J, Sayer M D, Jerina M and Conney A. H. : 1982, Inhibition of mutagenicity of bay dio-epoxides of polycyclic aromatic hydrocarbons by naturally occurring plant phenols, Exception activity of ellagic acid. Proceedings of the National. Academy of Sciences (U. S. A.) **79**, 5313-5517.

Is there an African Bioethics?

Karori Mbũgwa

Department of Philosophy, University of Nairobi, P. O. Box
30197 Nairobi, Kenya. Email: Karori.mbugua@uonbi.ac.ke

Abstract *Is there an African bioethics? This paper addresses this question by first exploring the ongoing debate on the nature and status of African philosophy. It is argued that if African philosophy exists, then by extension, an African bioethics which is a sub-branch of philosophy, must thus exist. Further, a distinction is made between bioethics as a set of moral principles rooted in a people's culture which should guide clinical care and scientific research and bioethics as a discipline in the university, with a set of codes, standards, recognized practitioners and customs. It is argued that bioethics in the former sense has always existed in Africa but bioethics in the latter sense is a relatively new development in the continent.*

Key words: *Bioethics, Bioethical colonialism, African Philosophy, Ethno-Philosophy, Professional Philosophy.*

Introduction

This paper is an attempt to answer the question of whether there is such thing as an African bioethics. In answering this question, it is important to focus on a different, though related question, namely, is there such thing as African philosophy? A positive answer to this question would mean that African bioethics exists if it is taken to be a sub-field of philosophy. If African bioethics exists, then what distinguishes it from, say, Asian bioethics or Western bioethics and why is this distinction important? These are some of the questions that this paper will attempt to answer with a hope of giving a contribution from an African perspective of Bioethics.

Bioethical Colonialism

In recent years, a debate has been ranging concerning whether the principles and methods of Anglo-American bioethics, are the same as those of other cultures. Various people have argued that the Western bioethical principles of respect for autonomy, beneficence, non-maleficence, and justice are non-existent or unacceptable in other cultures. Bioethicists, especially from the developing world, have been concerned about what they perceive as the negative consequences of the globalization of bioethics. They perceive this approach as a form of moral imperialism, and an attempt by developed world agencies to advance their biomedical research agenda at the expense of the developing countries. Many have

argued that, a truly global bioethics must highlight ethical pluralism, that is the coexistence of alternative and competing ethical frameworks.

Tamidayo Ogundiran laments that bioethics in its present form is rooted in and largely dominated by Western culture, and it is still foreign to most African countries. He therefore calls for the inclusion of bioethics in the medical education in Africa. In his own words 'It is now time for Africa to join the rest of the world by introducing ethics education into the curricula in all medical schools where it is not presently taught (Ogundiran 1994: 4). Similar sentiments have been echoed by Munyaradzi Murove when he says that, the current discourse on bioethics in Africa is trapped in Western categories of thought and relies heavily on Western analytical philosophy. He maintains that an authentic discourse on bioethics in Africa must take cognizance of the fact that most Africans rely on traditional medicine for their health care needs (Murove 2005).

It is interesting to note that just as with African bioethics, the question of what constitutes the essence of Asian bioethics has been a topic of scholarly interest. In a paper entitled, 'The Bogus Debates on Bioethics', Suman Sahai argues that, bioethics is a wasteful intellectual luxury which India cannot afford. She maintains that, developing countries should not just follow the ethical dilemmas of the North, but balance ethics of biotechnology against ethics of poverty. As she graphically puts it: 'If there is an outcry in the West against the recombinant bovine growth hormone rBBST, which increases milk production in cows, it is understandable for a society that is afloat in an ocean of milk. But is it logical in India, a country with severe milk shortages and many children who do not get minimal nutrition? Should India with its acute fodder shortage and an average milk production of two litres per cow per day, spurn on ethical grounds a technology that has the potential to improve this production using the same amount of fodder? (Sahai 1997: 24). Thus for Sahai, only wealthy countries have the luxury of debating the ethical dilemmas arising from the use of latest advances in both medicine and biotechnology.

Two other Asian scholars, Hyakudai Sakamoto and Leonardo de Castro, have also addressed the issue of the globalization of bioethics. Sakamoto calls for a new global bioethics which he insists must be holistic in contrast to the Western individualistic bioethics. He argues that among the Asian people, the happiness of the community supersedes that of the individual (Sakamoto 2002: 32). But Castro is more cautious in his call for an authentic Asian bioethics as he warns that, in an attempt to assert Asian identity in bioethics, one must be careful not to lump all Asians together. The point is that, even within Asia, different bioethical perspectives exist. In addition, one must realize that there are certain ethical principles that transcend both culture and geographical boundaries (Castro 1999: 227).

It is however important to note that, it is not only Africans and Asians who have voiced concern over the importation of bioethical concepts into their cultures. Diego Gracia in a paper entitled, 'The Intellectual Basis of Bioethics in Southern European Countries' argues that bioethics is perceived by Southern Europeans as something foreign. He asserts that because bioethics made its first appearance in the Anglo-American culture, Europeans are trying to 'remake' or to 'recreate' the discipline according to their cultural and ethical traditions' (Gracia 1993: 98).

In the light of the foregoing observations, it is important that scholars reflect on the question of whether there can be African philosophy and its approach to ethics and bioethical issues.

Conceptions of African Philosophy

As already indicated, the question whether or not African bioethics exists cannot be addressed without due cognizance of the answer to the question whether or not, an African philosophy exists. A negative answer to this question would imply a negative answer to the former. Similarly, since bioethics is one branch of ethics, to assert the existence of an African philosophy, is to assert the existence of an African bioethics, which in turn, is one of the traditional branches of philosophy.

The question of the existence and nature of African philosophy remains the subject of vigorous debate. A great deal of the literature on African philosophy, is nothing but a metaphilosophical debate as to whether or not such a philosophy exists. The question of the existence of African philosophy was first raised by early European missionaries and anthropologists who claimed that, the African mind was pre-logical, pre-rational and antiscientific and therefore incapable of philosophical discourse. It is useful to note that while this question is asked of African philosophy, it is not asked about Western or Oriental philosophy. It is taken for granted that these philosophies exist without question.

But some people think that, to speak of African philosophy is to make a huge generalization because as it stands Africa is not a homogeneous continent. It is a vast region made of over fifty countries and numerous ethnic groups each with a unique identity. Yet, others feel that the debate over the nature and existence of African philosophy is no longer interesting. According to these critics, Africans must start doing African philosophy instead of endlessly talking about African philosophy.

In attempting to answer the question whether or not African bioethics exists, one must first examine the answers that have been given to this fundamental question. Four main orientations in African philosophy can be distinguished: professional philosophy, ethnophilosophy, philosophic sagacity and nationalist-ideological philosophy. For the purpose of this paper, the first two trends, namely, ethno-philosophy and professional philosophy will be described.

a. Ethnophilosophy conceives of African philosophy as the attitude of mind, logic and perception behind the manner in which African peoples think or act. The key proponents of this trend include Placide Tempels, Alexis Kagame and John Mbiti. An ethnophilosopher is committed to the task of describing a world outlook or a thought system of a particular community. Ethnophilosophy advocates that an African philosophy should be concerned with articulating and reconstructing the implicit philosophy behind the habits, customs and beliefs of a society. It treats African philosophy as consisting in a set of shared beliefs, values, categories, and assumptions that are implicit in the languages, practices and beliefs of African cultures; in short the uniquely African worldview. For this reason, African philosophy is seen as an item of communal property rather than an activity for an individual.

Some critics of this orientation such as Odera Oruka have argued that this approach is too culturally specific and descriptive to be described as philosophy (Oruka 1975). Others think the ethno approach to philosophy represents a form of acceptance of the inferiority of the Africans since it claims that African thinking is intrinsically emotional, and occurs in the collective instead of the individual. But Gbenga Fasiku thinks that submitting ethnophilosophy to systematic and critical analysis would make it worthy of the name philosophy (2008: 103).

b. Professional philosophy: This consists in analysis and interpretation of reality in general. The main advocates of this orientation in philosophy include Odera Oruka, Kwasi Wiredu and Paulin Hountondji. It consists of criticism and argument, which to its proponents are the essential characteristics and conditions for any form of knowledge to be judged as philosophy. Professional philosophers explicitly reject ethno-philosophy which, is largely descriptive arguing that analyzing and clarifying conceptual issues is, the essential methodology of philosophy. However, some have objected that philosophy as practiced in African Universities today is strictly speaking not African as it is based on the Western model; almost all African philosophers are Western-trained. Besides, philosophical teaching in African universities is still limited to teaching ideas and arguments of past or contemporary Western philosophers. Another criticism leveled against the professional approach to African philosophy is that it assumes that Western philosophy is the benchmark by which all other cultures' philosophies are to be understood and measured.

Approaches to Bioethics

Following from the two orientations in African philosophy described above, African bioethics can be thought of in two distinct ways, namely, bioethics as a set of moral principles rooted in culture (ethnophilosophy approach) and bioethics as an academic discipline (professional philosophy approach). The discussion of each is important.

a) The Ethnophilosophy Approach

An ethnophilosopher will look for African bioethics in African people's culture or world view. This is what might be referred to as ethnoethics. Patricia Marshall and Barbara Koenig have noted '...denying the importance of cultural background and beliefs, and their significant power to shape and transform the meanings attached to the experience of health and illness, sustains a rendering of bioethics deprived of richness of cultural context' (Marshall and Koenig 2004). The sources of such bioethical principles, especially in Africa where the introduction of writing is relatively recent, will include popular sayings, proverbs, songs, mythology, folklore and other cultural practices such as male circumcision, marriage and leadership.

One important characteristic that should distinguish African bioethics from Western bioethics is that, African culture places considerable value on conformity of the individual to the social group. This helps to preserve the unity of social groups. John Mbiti, paraphrasing Rene Descartes, aptly puts it, in African culture 'I am because we are, and since we are therefore I am (Mbiti 1969: 108-109). In other words, African ethics is communalistic in nature and is to be contrasted with the Western ethical tradition with its emphasis on an individual's sense of self and autonomy of being. In this regard, African bioethics has more in common with Asian bioethics than with Western bioethics.

With these cultural differences, it is obvious that while the application of principle of informed, for example, might be readily accepted in a Western set-up, it will be difficult to apply it in the African context (without modification) where the influence of the community on individual decision-making is very high. As a number of commentators have pointed out, this does not mean that there is no independent thinking and action in African societies but it always has to be within the norms of the community.

Failure to recognize cultural differences and variations in the understanding of human dignity, health and disease can lead to ethical conflicts. Quoting Rony Brauman, past President of Médecins Sans Frontières, Sikku Hellsten has reported on the ethical dilemmas that foreign medical doctors face while working in Africa. In war ravaged Somalia, for example, many Somali youths refused life saving amputations preferring to die with their gangrenous limbs intact. In Uganda the moral value that the Western medical professionals and aid agencies give to children and pregnant women was challenged by the local customs and values. Food aid allocated to malnourished children and pregnant women was given to the elders instead. The explanation given by the locals was that 'children are a renewable natural resource, while the elderly cannot be replaced' (Hellsten 2008: 72). These two examples demonstrate the need for a culturally sensitive bioethics.

b. The Professional Philosophy Approach:

As an approach to bioethical discourse in Africa, the professional approach to African bioethics is not likely to be *methodologically* different from Western bioethics. It will be a collection of logically argued ideas of individuals about bioethical issues rather than a body of communal thought. This is because, professional philosophers adopt a universalistic definition of philosophy. According to this view philosophy (and in this case bioethics) must have the same meaning in all cultures although the questions prioritized in these cultures will be different.

Unfortunately academic bioethics, like professional philosophy, is still largely foreign in most African countries. Indeed, despite the rapid growth of bioethics research centers especially in Europe and North America, there are still relatively few places in Africa where one can obtain formal bioethics education even at the certificate level. This is hardly surprising considering that even in the West bioethics as an academic discipline did not become established until a few decades ago.

The strengthening of bioethics education and research and the raising of public awareness of bioethical issues in Africa must be given priority. Appropriate structures for deliberation and action on bioethical issues must also be put in place. In this regard, the establishment of UNESCO Bioethics Documentation Center at Egerton University in Kenya and the hosting of an international bioethics conference at the same institution in August 2008 are steps in the right direction but more needs to be done. African bioethicists must consider the possibility of starting a professional society and a bioethics journal which will serve as platforms for the exchange of ideas and research findings.

But it is not enough to adopt a definition of bioethics that stresses the speculative and personal dimensions of the discipline. For bioethics to be practically relevant, the individual reflections of African bioethicists must primarily be geared towards resolving bioethical dilemmas confronting Africa today. Indeed this is what will distinguish African bioethics from other regional bioethics.

Traditionally, bioethics has always been associated with cutting edge biotechnologies such as *in vitro* fertilization, organ transplant, and gene therapy. These technologies are virtually non-existent in most parts of Africa. The principles of Western bioethics which were formulated to address ethical issues arising from these advances in medicine cannot, therefore, be expected to adequately equip African researchers and medical students with the necessary ethical skills to face the bioethical dilemmas that they encounter daily.

Africa is also the poorest continent and arguably the origin of some of the world's deadliest diseases such as AIDS and tropical diseases such as malaria and sleeping sickness-diseases. These diseases pose serious moral challenges which African bioethicists must pay attention to. Controversies over HIV/AIDS research and

access to affordable treatment in particular must be given top priority. It is also useful to point out that majority of research participants in clinical trials in Africa are likely to be highly vulnerable due to low levels of education and poverty. African bioethicists must pay special attention to bioethical issues and dilemmas arising from such trials. They must also bear in mind that traditional medicine remains the most accessible and affordable system of health for the majority of Africans especially in the rural areas. For this reason, African bioethics will need to expand its purview beyond Western biomedical systems. There are numerous legal and ethical issues surrounding the practice of traditional medicine that need to be addressed. The most prominent ones pertain to patient safety, the quality of health care, confidentiality and the question of biopiracy. As Aceme Nyika recently proposed, traditional medicine, like orthodox medicine, should become a regulated profession (Nyika 2007). There is an urgent need to develop an ethical code of practice, conduct and confidentiality for traditional medical practitioners in Africa.

Conclusion

This paper has noted that there are two different conceptions of bioethics; bioethics in the sense of set of moral principles rooted in culture, and bioethics as an academic discipline. What is not in dispute is the fact that Africa is lagging behind in academic bioethics. As already noted Africa has very few trained bioethicists and there is no vibrant culture of bioethical discourse among philosophers, scientists and medical practitioners. But if Bioethics is a cultural issue, then such a bioethics exists in Africa because no society can survive for long without some grounding in morality. Whatever definition of African bioethics one prefers, for it to be authentically African, Africans must endeavor to fashion it according to their cultural norms as well as practical realities. In any case, there is bound to be an overlap between the two approaches to bioethics.

As argued in this paper, the mainstream concerns, approaches and values of Western bioethics may not be directly relevant to medical practitioners and researchers in Africa. African bioethicists must pay special attention to those bioethical problems that are peculiar to the continent of Africa and third world in general while at the same time not ignoring bioethical problems in the developed world emanating from cutting edge biotechnologies. In any case, as a number of scholars have argued, there exist certain fundamental ethical principles that ought to be applied across national and cultural boundaries.

References

De Castro, L.: 1999, Is there an Asian Bioethics? *Bioethics*, 13 July: 227-235.

- Fasiku, G.: 2008, African Philosophy and the Method of Ordinary Language Philosophy, *The Journal of Pan African Studies* 2(3): 100-116.
- Gracia, D.: 1993, 'The Intellectual Basis of Bioethics in Southern European Countries', *Bioethics*, 7(2/3): 97-107.
- Hellsten, S K.: 2008, Global Bioethics: Utopia or Reality? *Developing World Bioethics*, 8(2): 70-81.
- Marshall, P and Koenig, B.: 2004, Accounting for Culture in a Globalized Bioethics, *Journal of Law, Medicine and Ethics* 32, 252-266.
- Mbiti, J.: 1969, *African Religions and Philosophy*. Nairobi: Henemann, 1969.
- Murove, F. M.: 2005, African Bioethics: An Exploratory Discourse, *Journal for the Study of Religion*, 18(1): 16-36
- Nyika, A.: 2007, Ethical and Regulatory Issues Surrounding African Traditional Medicine in the Context of HIV-AIDS, *Developing World Bioethics* (1): 25-34.
- Oruka, H. O.: 1975, Fundamental Principles in African Philosophy, *Second Order: An African Journal of Philosophy*, 4(1): 44-45.
- Potter, V. R. :1971, *Bioethics: Bridge to the Future*. Englewood Cliffs, N. J.: Prentice-Hall, 1971.
- Ogundiran, T. O. :2004, 'Enhancing the African Bioethics Initiative', *BMC Medical Education*, 4:21.
- Sakamoto, H.: 200, 'Towards a New Global Bioethics', *The Abstracts of Seventh Tsukuba International Bioethics Roundtable*, 15-18 February, 2002.

Bioethical Issues in African Culture and Religions

Stephen Mbugua Ngari

Egerton University, P.O. Box 536 Egerton, Kenya

Email: ngaristephen@yahoo.com

Abstract *There are many issues arising from the practice of medicine, surgery, research on human tissue, euthanasia, cloning, and trials of drugs on humans, hence ethics must be the prevailing principle in the medical practice. Bioethics is an important element in the research and practice of medicine in the world today. The Greek medic Hippocrates focused on the physician's duty to the individual patient whose life and welfare are sacred. This continues to influence the professional ethics of biomedical practices today. Both the secular and religious outlooks on bioethics have raised sharp differences on the limits of bioethics on the human person. The definition of life, rights, and the good of practice raise many controversies and divided opinions among various interest groups. With the current health risks to humanity like HIV/AIDS, cancer and other terminal diseases, there is an urgency to come forth with a common platform that is both unifying and beneficence to the human condition. This paper surveys the various approaches to bioethics from the secular, religious-with reference to Catholic church's Bioethics, and the African culture and situation. Disparity of expertise, resources and outlook into the world of biomedical practices continue to pose a risk and an opportunity to the African situation. Unified bioethical practices are recommended in order to unite the various disciplines and their views on the ethics and morals of human life. The paper proposes three principle guidelines in ethical practices in bioethics; autonomy, justice, and beneficence.*

Key words: *Bioethics, Sacredness, Ethics, Justice, Beneficence, Autonomy, Natural law.*

Introduction

Bioethics has its written origins about 2400 years ago with Hippocrates in the ancient Greek. He focused his ethics on the physician's duty to the patient whose life and welfare are sacred. The religious bioethics, in special reference to the Catholic church's teachings on medical ethics, has the same outlook and is grounded on the moral law which is, a combination of the scriptural teaching, theology, and natural law. As in Hippocrates Catholic, Bioethics is based on the principle of the sacredness of life; it emphasizes that, all

medical procedures, research and opinions should be guided by the act of protecting human life from conception to death.

Bioethics in Secular practices

Bioethics in a secular spectrum, views itself from a pragmatic principle of achieving the largest possible amount of pleasure over pain thus maximizing the fundamental right of human beings to choose their destiny. In 1978, the United States of America Congress appointed a commission known as the Belmont Commission to look into the issues of bioethics and the current practices in America (Shea, 2002). This Commission came forth with three principles as follows:

- a) **Beneficence:** Proposes that “help yourself and other people”. Always address the promotions of the good of others. This is essential because medical practice contributes to the good and development of the client (respect the dignity of your client and promote his/her welfare) always act for the best interest of the client, and maximize the ratio of benefits in relation to harm in your practice.
- b) **Autonomy:** The principle states simply “allow rational individual to make free informed choices”. Always ensure freedom and self-determination to enable the client to choose his/her own direction in life, namely, create a conducive environment, encourage growth and development and always avoid dependent medical practice relationships.
- c) **Justice:** “Treat people fairly, treat equals equally and, unequal unequally”. In other words, provide equal treatment to all regardless of age, sex, ethnicity, socio-economic status, disability, cultural background, religion, and sexual orientation et cetera, “all to be done for the good of others”.

These principles were later developed to include those persons who did not have the rational capacity to make choices, like the unborn, the comatose patients, and the mentally challenged among others. The earlier perceptions in ethics dealt with such individuals as ‘non-persons’ and therefore had no moral rights. Some opinions went to the extreme with Peter Singer of Princeton, one of the key proponents of secular bioethics holding that some animals have more moral value than infants and disabled human adults (Shea, 2002).

The main issues that come across in bioethics is therefore two folds: the religious, and the secular based. The secular based opinions are based on the biological and social as well as democratic principles. For example, some secular bioethics has various names for

the human life at different stages. For some, the early stages of fertilization have been referred to, as 'beginning' or implantation, or pre-embryo. At such times, the concept of human life or person were not introduced. This helped to justify certain scientific procedures and researches on the embryo without referring it to human life. When an embryo becomes human is determined by some physiological and anatomical criteria rather than, the belief in formation of the individual or person at conception. Some say that human life begins 5-7 days after fertilization, some 14 days (formation of the primitive streak), some at brain formation (formation of neuro-cortex of the brain later in pregnancy).

Other issues that have been raised on the secular bioethics are on euthanasia popularly called. mercy killing or salvage from pain and inhuman condition at certain levels of illnesses and age. Cloning has also been taken with various meanings which in real sense, should be viewed as interfering with the individuality as well as natural law by manipulating the natural genetic selection and arrangement.

Bioethics in the Catholic Perspective

Fundamental to Catholic, bioethics is a belief in the sanctity of life: the value of a human life, as a creation of God and a gift in trust, is beyond human evaluation and authority. God maintains dominion over it and human beings or other agents have no right to terminate it at any stage. In this view, human beings are stewards, not owners, of their own bodies and are accountable to God for the life that has been given to them. Life is an absolute value and is also transcendental. The Catholic understanding of its meaning and purpose is founded in a belief in the resurrection of Christ and the hope of an afterlife (Markwell & Brown, 2001).

The doctrine of natural law, as articulated by Thomas Aquinas in the 13th century, views human life as a basic good that cannot be made subject to utilitarian estimation. Life is the basis and necessary condition of other goods, and human beings have an innate desire to seek these goods, such as sexual reproduction, social life and knowledge. Human inborn tendencies provide the basis for their moral obligations and for fundamental human rights. The Catholic tradition also holds that human life and personhood begin at conception.

Contemporary Catholic bioethics is concerned with a broad range of issues, including sexuality, marriage, reproduction, birth control, sterilization and abortion. In recent years, Catholic bioethicists have registered opposition to some emerging reproductive technologies, including artificial donor insemination, in-vitro fertilization, surrogacy and cloning. Also of concern are end-of-life issues, including advance directives, palliative care and pain control, suicide, euthanasia and the refusal or cessation of futile treatments, organ donation and the definition of death. Catholic bioethicists have contributed to the debate on the right to health care,

conceived as a community and governmental responsibility. In general, they have applied principles of social justice to this debate.

On one hand, the Catholic Bioethics defines the means through which life should be preserved and protected. If the government has a duty to health care provision, then the person has a right to receive care at a reasonable and within the means that the government can afford. On the other hand, the family has a moral obligation to preserve life. The principle of relativity, however, applies here because of the family's means to meet the cost of certain medical procedures. For some, it is reasonable, for others, it is impossible. The answer is that each family has a duty to do what is best for the person in question without sacrificing its integrity and means of survival. A good example is where there is an illness of a spouse, for example, the husband: should the family sell its house, land and take all possible loans to sustain the life of the husband who has terminal cancer. The answer is as controversial as it stands. The social good regardless, should be maintained because the family cannot sacrifice itself beyond reasonable level for such treatment.

Other major issues in bioethics are in terms of medical research. Should scholars research and make trials on healthy persons while researching on HIV/AIDS, if the risks are high? What of the new medicines, should they be tried with humans long before they are ascertained to be fairly safe? Bioethics maintains the principles of 'beneficence and justice'. Therefore, the good of the person on whom research is done should be a fundamental determinant of the research. High ethical standards should be maintained in such practices and the sacredness of the human life taken into account. At this stage, the principle of *Veracity*: "Do not lie, defraud, deceive or mislead. Always cultivate truthfulness, an asset in good working relationship. Physicians should explain the rights of the client and its limitations, and ensure that the client obtains clear information for informed consent in becoming subject of research. The subjects should be informed of the possible consequences of the procedures as well as the liabilities of the researcher in the same processes.

African Perspective in Bioethics

Generally, African cultures hold on the paramount importance of human life and health. A healthy person is beneficial to the family and community at large. However, most of the biomedical research in Africa is not as developed as in the developed countries. The procedures of research, resources, and capacity is limited (Coleman and Bousseau, 2006). It is envisioned that, lack of adequate capital for research, dependency on donor subsidy for research, may compound the problem of independence and ethics in the African situation.

While the African culture does protect the life, its medical research may not be as advanced as the western developed capacities. Mostly, the current researches are based on herbal medicine, testing and admission to human beings, is very liberal and may pose many dangers to the people in areas of safety of the medicine or procedure

as well as dosage levels. The situation continues to be handicapped by lack of legitimate governmental bodies that regulate such practices. There is also an increasing acceptance of herbal medicine due to its cost benefit and perception that it works better and is safer. This could be justified by the high cost of laboratory procedures and specialized medical procedures against a financially constrained people whose income is very low. The commercialization of the herbal medicine raises ethical questions on the preservation of biodiversity as well as the abuse of such drugs in the areas of misdiagnosis and treatment. There is an ethical dilemma now about how well these herbalists are trained, their measurements and standardization of herbal medicine as well as knowledge of the effects of such medicine on the patients.

African Perspective on Organ Donation

For many African cultures (like the Luo, Kamba, Kisii and Gikuyu) organ donation could be translated as witchcraft. Usually organs from other persons were used in sorcery. Therefore, bearing an organ of a dead person meant possessing his or her spirits to some extent which can be manipulated. There is need to explain the modern scientific procedures on organ donation so that the African "world view" on the same and its ethics can be transformed

The disposal of the human body after death was to be done in such a way that it was kept off the visibility of the people and could not be manipulated or maintained for other purposes rather than disposal. Any other use constitutes to taboo. Lack of proper disposal could lead to problems with the spirits of the deceased (Luo community among others). Donation of the body for medical research raises serious issues from an African perspective. There is need to create an awareness of the usefulness of biomedical research for the good of the human life and health. There is need to also demythologize the different African outlooks that may inhibit such practices in the advancement of knowledge on human organs and medicine.

Conclusion

Bioethics in African culture and religions has the common front in carrying out biomedical practices in the best interest of the human person and good. However, some of the secular biomedical practices can tend to go beyond such parameters are not controlled by proper use of ethical standards to guide their best practices. It is therefore necessary that proper use of bioethics be put in place in order to harmonize the cultural, religious and secular approaches to bioethics. A dialogue is important in facilitating a common platform where all the stakeholders' interests and values are upheld without compromising the good of the biomedical research. It is only proper that ethics upholds the sacredness, the beneficence, and the autonomy of the human life and person. This will give the world of

bioethics a strong background in their respective research on humanity.

References

- Boatright, J. R.: 1995, *Cases in Ethics and the Conduct of Business*. Englewood N. Jersey. Prentice Hall.
- Brad, A.: 1994, *Ethics and the Good Life. A Text with Readings*: Belmont. Wadsworth Publishing Co.
- Coleman C. H. and Marie-Charlotte Bouesseau: 2008, *Strengthening Local Review of Research in Africa: Is the IRB Model Relevant?* (www.catholicdoctors.org.uk, 2008).
- Flannery A, ed.: 1988, *Vatican Council II: The conciliar and post conciliar documents*. rev ed. Northport (NY): Costello Publishing.
<http://www.aquinasonline.com/Topics/natlaw.html>
- Ganz, F. D., B., Hersch, M., Fischer, A., Gurman, G., and Sprung, C., L.: 2006, *The Impact of Regional Culture on Intensive Care End of Life Decision Making: An Israeli Perspective From the Ethicus Study*. *Journal of Medical Ethics* 32(4): 196-199. April 1, 2006
- Markwell J. and Brown S.: 2001. *Catholic Bioethics*:
www.usc.edu/hsc/info/newman/resources/ethics.html
- Percesepe G.: 199, *Introduction to Ethics. Personal and Social Responsibility in a Diverse World*. Englewood Cliffs N. Jersey: Prentice Hall
- Shaw, W.. J., and Barry, V.: 1998, *Moral Issues in Business* (7th Ed). Belmont: Wadsworth Publishing Co.
- Shea, J. B.: 2002. *Catholic Bioethics*. *Canadian Journal of Medical Association* 166(10) 1252-1262
- Wildes KM, Mitchell AC, eds.: 1997, *Choosing life: a dialogue on Evangelium Vitae*. Washington: Georgetown University Press; 1997.

African Traditional Medicine: Ethical-Deontological and Medico-legal constraints in Italy

Nunzia Cannovo^o, Giovanna Ricci*, Paola Buccelli^o and Pierpaolo Di Lorenzo^o

^oDepartment of Public Medicine and Social Welfare - University of Studies of Naples Federico II - drncannovo@libero.it, via Pansini 5, 80131, Naples, drncannovo@libero.it, via Pansini 5, 80131, Napoli; tel/fax: 00390817463468

*RTD Department of Substantial and Procedural Law Disciplines - Forensic Medicine Section - Faculty of Law - University of Studies of Camerino; giovanna.ricci@unicam.it; tel: 00390737402435.

Abstract *The cultural and social features typical for immigrant populations in Italy can represent a big hurdle for their access to the services provided by the national health system. As an answer to the users' demand to apply specific practices of African Traditional Medicine (ATM), the Authors endeavour to examine some ethical-deontological and medico-legal issues accompanying this request, bearing in mind that in Italy ATM is not recognised among the alternative medicines.*

Key words: *African traditional medicine - malpractice - informed consent*

Introduction

The steady increase of migration flows towards Italy, both legal and illegal, has brought about for the Italian Health Service (SSN) the necessity to deal with a new category of users showing specific biological risks as well as peculiar social and cultural behavioural models conditioning their access to health services.

The number of immigrant citizens can be drawn from the figures about the presence of foreigners in Italy released by the Ministry of the Interior, to be integrated with the estimate of "irregular" migrants by Caritas.

As regards the extra-European geographical area of origin of the strangers hospitalized in public facilities in Italy in the year 2000, according to the figures released by the Ministry of Health, 30,1% is represented by citizens coming from Africa, 12,7% from Asia and 10,2% from Central and Southern America (Ministry of Health, Italy, 2000).

Taking into account the high percentage of services provided to citizens of African origin, a comparison was carried out between

the concept of health within African Traditional Medicine (ATM) and the ethical-deontological precepts underlying Italian medical culture; some medico-legal reflections on the topic are here presented.

The right to health

Italian law formally grants all people, including strangers, legally or illegally present on the territory (Ministry of Health, Italy 2000) the right to make use of the services of the National Health System; this is translated into practice with the inclusion of the legal immigrant into the register of welfare patients and entails the choice of the family practitioner, as well as the access to urgent or otherwise essential, even if continuing, hospital and outpatient treatments.

It must be furthermore reminded that, if the health service turns out to be urgent and/or essential, it can be used even by strangers without legal status (S.T.P.: Strangers Temporarily Present on the territory).

Everyone is granted access to preventive medicine programmes, with particular regard to the safeguarding of pregnancy and maternity, to the health of minors, to vaccinations, to interventions within the scope of international prophylaxis and to the treatment of infective diseases.

The concrete availability of the right for the stranger to recur to medical services implies the necessity to cancel or at least reduce the high degree of risk in the cases where immigrants lack access to the health services due to factors referable to their lifestyle, religious faith and mode of interrelationship.

The issue of informed consent and the differences within the approach to health

The Italian Law 145/01, in compliance with the Constitution, provides for any medical action to be preceded by an adequate and thorough information, which is the fundamental prerequisite for obtaining the consent of those entitled.

In the case of health services provided to strangers, there comes about the important issue of communication difficulties between the main actors of a clinical case, not only and not entirely due to the frequent verbal obstacles to communication, but also for the different ideological approach they have on themes related to the concept of health, disease and healing (Dama *et al.*, 1992).

The main part of the African population residing in Italy, is rooted in its own cultural, religious, economic, political and social traditions. In Africa, the concept of disease does not coincide with the dysfunction of the body. The state of good health is obtained in the presence of a satisfying integration of the mental, spiritual and emotional conditions of the individual, the family and the community he/she belongs to.

In other words, in African culture the well-being of the individual must coincide with the well-being of the family he/she belongs to as well as of the community into which he/she is

integrated, thus leading to the prevalence of common interest over the individual's interests.

In this view, the individual's consent becomes the expression of the will of the whole collectivity. Moreover, this concept of state of health is not limited to the living and is also extended to the forefathers, as the ancestors have the task to watch over the state of health of the community (Dime, 1995).

When a person falls ill, the cause of the disease is searched for in the infringement of an inviolable law by the tribal family as a whole and the task of the traditional African "medicine man" is to research and identify which law was broken, so as to be able to prescribe the adequate treatment (Delle, 1994).

Within ATM, therefore, the diagnostic process is based on a double-sided: on one side it is necessary to interpret the etiopathogenesis of the disease on both physical and mental level, on the other side to identify the spiritual and mystical elements which irritated the deity (Dime, 1995).

The differences appear also in the treatment process, which may entail the use of medical plants as well as the recourse to divinations, sacrifices and spells (Okpako, 1999).

Medico-legal aspects related to the use of ATM

According to ATM, medicine is considered like a supernatural power which - even if it could generally be exercised by anyone - must be opportunistically managed by individuals who are specialized (in order to avoid the risks associated with this practice (Little, 1954) and upright (in order to guarantee the compliance with moral precepts) (Omonzejele, 2008).

Unlike this, in Italy the exercise of the medical profession is subject to the obtainment of the specialized University degree, the passing of the State examination and, finally, the registration in the medical register of the relevant professional category (art. 348 of the Italian Criminal Code.).

Thus, against those who practice ATM in Italy, and who in most of the cases do not satisfy the necessary formal requisites for exercising medicine, a report can be filed for the unlawful practice of the sanitary profession.

Moreover, the same individuals can be charged with "abuse of popular credulity" (Art. 661 of the Italian Criminal Code, Book 3) because ATM is not officially included in the group of alternative medicines and thus the recourse to healing rituals as a possible therapeutic tool is not foreseen.

Another important medico-legal issue is represented by the potential charges of malpractice due to the damage caused to patients following the interaction between substances commonly used in African traditional medicine and drugs included in the pharmaceutical formulary.

In many cases, the medical staff of public facilities in Italy ignore the effects of the medical herbs taken in by the in-patients.

There are several plants which, in ethnobotanics, are believed to have curative powers (Okpako, 1999): the University of Pisa for example, presented a classification thereof amounting to about 200 specimens regarding the ones used on the island of Madagascar alone (Norsia and Borgognoni, 2006).

It must also be considered that, in striking contrast with the ethical-scientific principles set for international experimental studies, very often the results of researches carried out by herbalists do not find large circulation and remain confined among those who are engaged in the same experience.

Conclusions and recommendations

The sanitary operator in charge of managing the diagnostic and therapeutic treatment of an African patient has to frame this individual within the metaphysical, ethical and cosmological framework of his/her country or, even better, community of origin. In the light of its guiding principles, ATM cannot be subdued to the scientific paradigms of the Western world, though this contrasts with the Italian health system structure and may lead to a ghettoization of the individuals linked to their own culture.

The World Health Organization drew up a report about politics and strategies related to traditional medicine (WHO, 2002), promoting a comeback to the holistic approach of this kind of medicine.

An aspect not to be neglected is represented by the economic condition of African communities. In the countries of origin, where poverty is a plague, ATM is the only possible form of medical support. For African immigrants in Western countries, this medicine, apart from representing the umbilical cord which links them to the country of origin, remains the type of medical assistance a person has to recur to when he/she is still illegal and does not know yet the laws of the new country of residence.

Today, the challenge is thus represented by planning an efficient and organized health system equipped to welcome the immigrants. Within this system the communicative abilities between the persons involved in the clinical story and their cultural compatibility must be developed and fostered, also supporting a specific training of the technical staff, in order to promote ATM's holistic approach and encourage the cooperation between physicians and patients from abroad.

References

- Dama, A., Esposito, T., Arcella, T.: 1992, *Cultura malattia migrazioni. La salute degli immigrati extracomunitari in Italia ed in Campania: aspetti sociali, medici e psicologici*. Regione Campania USL 27 Dipartimento di Salute Mentale, Pomigliano D'Arco.
- Delle E.: 1994, *Il paziente africano: bianco-nero, nero-bianco, nero*, in AA.VV., pp. 33-36.

- Dime, C.A.: 1995, African Traditional Medicine: Peculiarities. Ekpoma, Nigeria: Edo State University Press.
- Iwu, M.: 1982, African Ethnomedicine. Enugu, Nigeria. Snaap Press.
- Little, K.: 1954. The Mende in Sierra Leone. In African World. London, England. Oxford University Press; 127-128
- Norscia, I., Borgognoni-Tarli, S.M.: 2006, Ethnobotanical reputation of plants species from two forests of Madagascar: a preliminary investigation. South Journal of Botany (72) 656-660.
- Okpako, D.T.: 1999, Traditional African medicine: theory and pharmacology explored. ItPS (20) pg. 482-485.
- Omonzejele, P.F.: 2008, African Concepts of Health, Disease, and Treatment: An Ethical Inquiry. Explore 4 (2), 120-126.
- Ozekhome, F.: 190, The Theory and Practice of Traditional Medicine in Nigeria. Lagos, Nigeria. Okey Chime and Co.
- World Health Organization (WHO): 2002, Legal status of traditional medicine and complementary/alternative medicine. Geneva: WHO Unit on Traditional Medicine.
- Italian Ministry of Health: 2000, D.G. Sistema Informativo e Statistico e degli Investimenti Strutturali e Tecnologico, Ufficio di Statistica, *Il ricovero ospedaliero degli stranieri in Italia nell'anno 2000*, Rome

African Traditional Medicine: Ethical-Deontological and Medico-legal constraints in Italy

Nunzia Cannovo^o, Giovanna Ricci, Paola Buccelli^o and Pierpaolo Di Lorenzo^o*

^oDepartment of Public Medicine and Social Welfare - University of Studies of Naples Federico II - drncannovo@libero.it, via Pansini 5, 80131, Naples, drncannovo@libero.it, via Pansini 5, 80131, Napoli; tel/fax: 00390817463468

**RTD Department of Substantial and Procedural Law Disciplines - Forensic Medicine Section - Faculty of Law - University of Studies of Camerino; giovanna.ricci@unicam.it; tel: 00390737402435.*

Abstract *The cultural and social features typical for immigrant populations in Italy can represent a big hurdle for their access to the services provided by the national health system. As an answer to the users' demand to apply specific practices of African Traditional Medicine (ATM), the Authors endeavour to examine some ethical-deontological and medico-legal issues accompanying this request, bearing in mind that in Italy ATM is not recognised among the alternative medicines.*

Key words: *African traditional medicine - malpractice - informed consent*

Introduction

The steady increase of migration flows towards Italy, both legal and illegal, has brought about for the Italian Health Service (SSN) the necessity to deal with a new category of users showing specific biological risks as well as peculiar social and cultural behavioural models conditioning their access to health services.

The number of immigrant citizens can be drawn from the figures about the presence of foreigners in Italy released by the Ministry of the Interior, to be integrated with the estimate of "irregular" migrants by Caritas.

As regards the extra-European geographical area of origin of the strangers hospitalized in public facilities in Italy in the year 2000, according to the figures released by the Ministry of Health, 30,1% is represented by citizens coming from Africa, 12,7% from Asia and 10,2% from Central and Southern America (Ministry of Health, Italy, 2000).

Taking into account the high percentage of services provided to citizens of African origin, a comparison was carried out between

the concept of health within African Traditional Medicine (ATM) and the ethical-deontological precepts underlying Italian medical culture; some medico-legal reflections on the topic are here presented.

The right to health

Italian law formally grants all people, including strangers, legally or illegally present on the territory (Ministry of Health, Italy 2000) the right to make use of the services of the National Health System; this is translated into practice with the inclusion of the legal immigrant into the register of welfare patients and entails the choice of the family practitioner, as well as the access to urgent or otherwise essential, even if continuing, hospital and outpatient treatments.

It must be furthermore reminded that, if the health service turns out to be urgent and/or essential, it can be used even by strangers without legal status (S.T.P.: Strangers Temporarily Present on the territory).

Everyone is granted access to preventive medicine programmes, with particular regard to the safeguarding of pregnancy and maternity, to the health of minors, to vaccinations, to interventions within the scope of international prophylaxis and to the treatment of infective diseases.

The concrete availability of the right for the stranger to recur to medical services implies the necessity to cancel or at least reduce the high degree of risk in the cases where immigrants lack access to the health services due to factors referable to their lifestyle, religious faith and mode of interrelationship.

The issue of informed consent and the differences within the approach to health

The Italian Law 145/01, in compliance with the Constitution, provides for any medical action to be preceded by an adequate and thorough information, which is the fundamental prerequisite for obtaining the consent of those entitled.

In the case of health services provided to strangers, there comes about the important issue of communication difficulties between the main actors of a clinical case, not only and not entirely due to the frequent verbal obstacles to communication, but also for the different ideological approach they have on themes related to the concept of health, disease and healing (Dama *et al.*, 1992).

The main part of the African population residing in Italy, is rooted in its own cultural, religious, economic, political and social traditions. In Africa, the concept of disease does not coincide with the dysfunction of the body. The state of good health is obtained in the presence of a satisfying integration of the mental, spiritual and emotional conditions of the individual, the family and the community he/she belongs to.

In other words, in African culture the well-being of the individual must coincide with the well-being of the family he/she belongs to as well as of the community into which he/she is

integrated, thus leading to the prevalence of common interest over the individual's interests.

In this view, the individual's consent becomes the expression of the will of the whole collectivity. Moreover, this concept of state of health is not limited to the living and is also extended to the forefathers, as the ancestors have the task to watch over the state of health of the community (Dime, 1995).

When a person falls ill, the cause of the disease is searched for in the infringement of an inviolable law by the tribal family as a whole and the task of the traditional African "medicine man" is to research and identify which law was broken, so as to be able to prescribe the adequate treatment (Delle, 1994).

Within ATM, therefore, the diagnostic process is based on a double-sided: on one side it is necessary to interpret the etiopathogenesis of the disease on both physical and mental level, on the other side to identify the spiritual and mystical elements which irritated the deity (Dime, 1995).

The differences appear also in the treatment process, which may entail the use of medical plants as well as the recourse to divinations, sacrifices and spells (Okpako, 1999).

Medico-legal aspects related to the use of ATM

According to ATM, medicine is considered like a supernatural power which - even if it could generally be exercised by anyone - must be opportunistically managed by individuals who are specialized (in order to avoid the risks associated with this practice (Little, 1954) and upright (in order to guarantee the compliance with moral precepts) (Omonzejele, 2008).

Unlike this, in Italy the exercise of the medical profession is subject to the obtainment of the specialized University degree, the passing of the State examination and, finally, the registration in the medical register of the relevant professional category (art. 348 of the Italian Criminal Code.).

Thus, against those who practice ATM in Italy, and who in most of the cases do not satisfy the necessary formal requisites for exercising medicine, a report can be filed for the unlawful practice of the sanitary profession.

Moreover, the same individuals can be charged with "abuse of popular credulity" (Art. 661 of the Italian Criminal Code, Book 3) because ATM is not officially included in the group of alternative medicines and thus the recourse to healing rituals as a possible therapeutic tool is not foreseen.

Another important medico-legal issue is represented by the potential charges of malpractice due to the damage caused to patients following the interaction between substances commonly used in African traditional medicine and drugs included in the pharmaceutical formulary.

In many cases, the medical staff of public facilities in Italy ignore the effects of the medical herbs taken in by the in-patients.

There are several plants which, in ethnobotanics, are believed to have curative powers (Okpako, 1999): the University of Pisa for example, presented a classification thereof amounting to about 200 specimens regarding the ones used on the island of Madagascar alone (Norsia and Borgognoni, 2006).

It must also be considered that, in striking contrast with the ethical-scientific principles set for international experimental studies, very often the results of researches carried out by herbalists do not find large circulation and remain confined among those who are engaged in the same experience.

Conclusions and recommendations

The sanitary operator in charge of managing the diagnostic and therapeutic treatment of an African patient has to frame this individual within the metaphysical, ethical and cosmological framework of his/her country or, even better, community of origin. In the light of its guiding principles, ATM cannot be subdued to the scientific paradigms of the Western world, though this contrasts with the Italian health system structure and may lead to a ghettoization of the individuals linked to their own culture.

The World Health Organization drew up a report about politics and strategies related to traditional medicine (WHO, 2002), promoting a comeback to the holistic approach of this kind of medicine.

An aspect not to be neglected is represented by the economic condition of African communities. In the countries of origin, where poverty is a plague, ATM is the only possible form of medical support. For African immigrants in Western countries, this medicine, apart from representing the umbilical cord which links them to the country of origin, remains the type of medical assistance a person has to recur to when he/she is still illegal and does not know yet the laws of the new country of residence.

Today, the challenge is thus represented by planning an efficient and organized health system equipped to welcome the immigrants. Within this system the communicative abilities between the persons involved in the clinical story and their cultural compatibility must be developed and fostered, also supporting a specific training of the technical staff, in order to promote ATM's holistic approach and encourage the cooperation between physicians and patients from abroad.

References

- Dama, A., Esposito, T., Arcella, T.: 1992, *Cultura malattia migrazioni. La salute degli immigrati extracomunitari in Italia ed in Campania: aspetti sociali, medici e psicologici*. Regione Campania USL 27 Dipartimento di Salute Mentale, Pomigliano D'Arco.
- Delle E.: 1994, *Il paziente africano: bianco-nero, nero-bianco, nero*, in AA.VV., pp. 33-36.

- Dime, C.A.: 1995, African Traditional Medicine: Peculiarities. Ekpoma, Nigeria: Edo State University Press.
- Iwu, M.: 1982, African Ethnomedicine. Enugu, Nigeria. Snaap Press.
- Little, K.: 1954. The Mende in Sierra Leone. In African World. London, England. Oxford University Press; 127-128
- Norscia, I., Borgognoni-Tarli, S.M.: 2006, Ethnobotanical reputation of plants species from two forests of Madagascar: a preliminary investigation. South Journal of Botany (72) 656-660.
- Okpako, D.T.: 1999, Traditional African medicine: theory and pharmacology explored. ItPS (20) pg. 482-485.
- Omonzejele, P.F.: 2008, African Concepts of Health, Disease, and Treatment: An Ethical Inquiry. Explore 4 (2), 120-126.
- Ozekhome, F.: 190, The Theory and Practice of Traditional Medicine in Nigeria. Lagos, Nigeria. Okey Chime and Co.
- World Health Organization (WHO): 2002, Legal status of traditional medicine and complementary/alternative medicine. Geneva: WHO Unit on Traditional Medicine.
- Italian Ministry of Health: 2000, D.G. Sistema Informativo e Statistico e degli Investimenti Strutturali e Tecnologico, Ufficio di Statistica, *Il ricovero ospedaliero degli stranieri in Italia nell'anno 2000*, Rome

Towards a more effective regulation of Human Biomedical Research in African communities

Sylvester C. Chima

Programme of Bio & Research Ethics and Medical Law, College of Health Sciences, University of KwaZulu-Natal, Durban, Republic of South Africa.

E-mail: chima@ukzn.ac.za or chimasc@hotmail.com

Abstract *In view of ongoing violations of international ethical codes, and the exploitation of vulnerable participants during biomedical research in developing countries, it would be advisable for African countries through the mechanism of the African Union (AU), to develop and implement directives designed to guide the conduct of human biomedical research within Africa, similar to recent directives implemented by the European Union (EU). These directives could focus on procedures for obtaining culturally appropriate informed consent, formation of local research ethics committees, standards of care, such as the use of placebos, and issues of distributive justice, including compulsory no-fault compensation for injuries arising from biomedical research, and other post-trial benefits. These directives should be mandatory but adaptable to the laws and constitutions of each AU member state.*

Key words: *Bioethics, Developing Countries, Governance, Research, Rights*

Introduction

Africa is a complex multicultural society challenged by problems of underdevelopment, poverty, preventable communicable diseases, poor healthcare infrastructure, and differences in belief systems. Therefore African communities represent a classic 'vulnerable' population group, which is deserving of the highest standards of ethical practice, when contemplated as a source of human subjects for the conduct of biomedical research. Recent reports have suggested that there is ongoing migration of the commercial research enterprise to developing countries to avoid the tougher regulatory framework currently operating in developed countries (Shah, 2006). This is because developing countries represent a captive population of less sophisticated individuals, in terms of their understanding of informed consent, protected by lax laws and inadequate regulations. Therefore African communities appear ripe for exploitation by

unethical researchers and unscrupulous sponsors. Concerned authorities have reported that participants in developing countries are not adequately informed of their rights during biomedical research, including the right to full disclosure and compensation in case of injury (National Bioethics Advisory Commission (NBAC), 2001). Ethicists and legal experts have argued that because of the hazardous nature of the research enterprise, a conflict of interest does arise between the need to test hypotheses and the requirement to respect and protect the rights of research subjects. This conflict of interest requires regulatory oversight in the form of appropriate laws, to protect participants. (*Grimes v Kennedy Krieger Institute (KKI)*, 2001). In this paper I argue that in light of these abuses, biomedical research in Africa would benefit from a regional regulatory framework, that provides guidance on issues such as the role of research ethics committees (RECS), informed consent procedures, standards of care, and aspects of distributive justice, such as compensation for injuries arising from biomedical research (Chima, 2006).

Limitations of current ethical regulations and international ethical codes

Ethical regulation is based on the application of ethical principles, which have been universally adjudged to have *prima facie* standing in human biomedical research. These four principles are *respect for autonomy*, which requires acknowledgement of the individual's freedom of choice and right to informed consent. *Beneficence and Non-maleficence*, which require researchers to do good and avoid harm. *Justice*, which requires that burdens and benefits of research, should be equally shared by all (Belmont Report, 1974). The modern impetus for a review of ethical practices arose out of the atrocities perpetrated during the Second World War by Nazi researchers. The pace of review has increased following recent advances in biotechnology, such as DNA analysis, human genome project, and emergence of new diseases like HIV-AIDS. As new technologies and diseases have emerged, new ethical dilemmas have arisen. The Nuremberg trials led to the formulation of the *Nuremberg Code* 1947, which were described as universally applicable to most areas of biomedical research. Since US jurists developed this code however, the question has been asked why it has not been adopted as part of international law. Though often referred to, it has never been applied in criminal prosecutions and is only cited in civil cases such as *Abdullahi v Pfizer* 2003, where researchers were accused of conducting therapeutic research in contravention of the code, and *Grimes v KKI* 2001, where researchers were accused of informed consent violations by conducting non-therapeutic research without full disclosure. Because of this limited application in Court decisions, it has been difficult for an international 'common law' on biomedical research to develop. The Nuremberg code was never universally accepted by the medical community since promulgation (Beecher, 1959). The Nazi experiments were considered too extreme, and despite evidence of

similar experiments in the USA such as the Syphilis study in Tuskegee (Jones, 1981). Medical paternalism, which was common globally during this period, absolved these ethical violations and physician groups described the Nuremberg code as too 'legalistic'. Therefore the medical profession proceeded to develop an alternative code, the *WMA Declaration of Helsinki* 1964, intended as a statement of ethical principles providing guidance for conducting research on humans.

The WMA declaration has undergone several revisions since inception, while controversies surrounding its interpretation and application persist. This has led to continued search for more appropriate ethical codes such as the WHO-CIOMS guidelines, described as the 'implementation in practice' of the Helsinki Declaration (Levine, 1993). However, the limitations on enforceability of international ethical codes still remain. While dismissing the *Abdullahi v Pfizer* case, brought by the claimants under the US Alien Tort Claim Act (Ford and Tomossy, 2005), and referring it for trial by Nigerian Courts, the trial judge noted that international codes such as the Nuremberg code and the Declaration of Helsinki represented 'aspirational goals' not enforceable by a court of law. "While this Court may disapprove of Pfizer's actions, it must apply established law -- not some normative or moral idea" (Lin, 2005). The above evidence highlights the need for creation of enforceable local laws and regional regulations which protect vulnerable research participants in developing countries as previously suggested (Chima, 2007).

Research ethics committees: Roles and limitations

RECs have a very important role to play in modern biomedical research. This involves ensuring compliance with current statutory regulations and ethical obligations. A REC is expected to function as an independent oversight committee by acting as guardian and ombudsmen, advocating for the rights of human subjects and making sure these rights are protected. However, RECs in developed countries have been criticized for being too idiosyncratic (Ashcroft and Benn, 2005), and producing variable responses depending on panel composition and other factors. Consensus opinion suggests that RECs rarely exercise their statutory powers to protect the rights of human subjects, including monitoring of recruitment methods and information disclosure (Applebaum, *et al* 1987). A recent study on RECs in the WHO Africa Region found that 36% of countries did not have a standing national REC, although 80% had ad-hoc review systems for approval of research projects. 64% reported the presence of standing RECs, although only 44% actually functioned as envisaged (Kirigia, *et al* 2005). Therefore, RECS alone cannot fully protect the rights of research participants and it would be important to have additional oversight in the form of statutory regulations. Therefore rules for REC reform in Africa should form part of the proposed AU directive.

Learning from EU directives on biomedical research

While the desirability and importance of ethical review of all biomedical research conducted amongst African communities cannot be overstated, the mechanism for establishing effective governance remains a matter of debate. The current approach in European countries based on directives for the approximation of laws, regulations and administrative provisions relating to good clinical practice in the conduct of clinical trials, provides a good reference point for the harmonization of regulations for the ethical conduct of biomedical research in African countries. EU directives are binding but adaptable to the laws of member states, and provide detailed guidance on issues such as the definition and formation of RECS (Directive 2001/20/EC). Another directive provides guidelines on good clinical practice (GCP) during clinical trials, and the role of research sponsors (EU Directive 2005/28/EC). These directives require that member states introduce laws enforcing these regulations within their territories. Based on this mandate the UK Department of Health (DOH) introduced regulations known as the *Clinical Trials Regulations 2004*. Similar regulations would be equally effective and necessary for African countries.

Distributive justice and biomedical research in Africa

The principle of distributive justice may be defined as fair, equitable and appropriate treatment in light of what is due or owed a person. The critical issue in research is how to equally share the burdens and benefits of research between participants, sponsors, and society-at-large. In Africa and other developing countries, post-trial benefits and compensation for injuries arising during biomedical research are major concerns. Differences in the distribution of burdens and benefits of research are justifiable only if they are based on morally relevant distinctions between persons, especially the vulnerable, where vulnerability refers to a substantial incapacity to protect one's own interest owing to such impediments such as poverty, underdevelopment and lack of alternative means of obtaining healthcare. While researchers may not be responsible for unjust conditions where research is being conducted, they should refrain from promoting injustice. Under conditions of scarcity or competitiveness, the understanding and application of justice could conflict with other ethical obligations. Therefore researchers working in African communities must guard against derogation of these moral obligations. Justice seeks to reduce inequity, so that no class of people, as defined by poverty, age, race, nationality, mental competence or conditions of health, are to be exploited as research subjects, by assuming a disproportionate share of research burdens and risks. Therefore in light of recent evidence on the difficulties of obtaining compensation for injuries by claimants from developing countries as shown by the *Abdullahi v Pfizer* case, and non-compensation for injuries arising from recent microbicide trials in

Africa (Roddy, 1999, Moodley 2007), and also because of socio-cultural issues prevalent in Africa. It is recommended that a no-fault compensation scheme would be most ideal for redressing injured research participants in Africa. This should form part of the proposed AU directives on biomedical research, regardless of any envisaged administrative challenges.

Standard of care applicable to research conducted in Africa

The interpretation of the 'standard of care' to be applied during therapeutic research in Africa has been the subject of intense debate since the controversies arising from studies on prevention of mother-to-child transmission of HIV-AIDS (Ijsselmuiden, 1998). While some authorities have advocated a universal standard based on the best available current therapy, others have argued for a locally determined standard of care, which reduces global inequalities, rather than a best available standard typically available only in developed countries. A pragmatic approach would be a 'standard of care' which is universally available and applicable. An example of this would be the use of oral rehydration therapy (ORT) for diarrheal diseases in developing countries, which has been found a successful cost-effective alternative, when compared with the 'gold standard' intervention of intravenous rehydration in developed countries (Bhutta, 2004). Re-interpretation of the 'standard of care' to suit the needs of African populations would be another subject for inclusion in any proposed AU directive.

Conclusions and Recommendations

In view of ongoing violations of international ethical codes by some researchers and sponsors, especially in the realm of commercialized research, and considering the vulnerability of African communities. It is imperative that African countries through the mechanism of the African Union (AU) develop local, regional and culturally appropriate methods for regulating the conduct of biomedical research in Africa. The provision of such regulations for the conduct of biomedical research in more developed countries is a valuable lesson for African countries on the need to regulate the conduct of biomedical research in Africa in a systematic manner, especially in the current climate of tackling underdevelopment through the millennium development goals (MDG). A unified approach will provide assurance to the international scientific community, that research conducted amongst African communities is based on the same ethical and legal principles available to research subjects in developed countries. Such regulations would promote more ethical research practices in Africa, and enhance human rights. The AU should consider formulating directives, similar to those implemented by the EU. These would go a long way in unifying and simplifying regulatory provisions aimed at enhancing ethical conduct of biomedical research in Africa.

References

- Abdullahi v Pfizer Inc., 2003.. No 02-9223 US CA NY. 2d Cir.
- Applebaum P.S., Lidz, C.W., Meisel, A., 1987. Consent to research In: Informed consent: legal theory and clinical practice. Oxford: Oxford University Press.
- Ashcroft, R.E., Benn, P.M., 2005. Reforming research ethics committees: latest proposals are a missed opportunity for a radical review. *BMJ* **331**: 587-588.
- Beecher, H.K., 1959. Experimentation with Man. Springfield, IL: Charles C Thomas.
- Benatar S.R., Singer, P.A., 2000. A new look at international research ethics. *BMJ* **321**: 824-826
- Bhutta, Z., 2004. Standard of care should reflect local conditions and not the best Western standards. *BMJ* **329**: 1114-15
- Chima, S.C., 2006. Regulation of biomedical research in Africa. *BMJ* **332**: 848-851
- Chima, S.C., 2007. Contemporary ethical issues and the regulation of biomedical research in African communities In: A Gateway to Biomedical Research in Africa. New York, NY: Nova Science Publishers, 19-38.
- European Commission Directive 2005/28/EC of the European Parliament and of the Council, 2005. Official Journal of the European Union L91/13.
- Directive/2001/20/EC of the European Parliament and of the Council, 2001, Official Journal of the European Communities L121/34.
- Ford, J., Tomossy, G., 2005. Clinical trials in developing counties: The plaintiff's challenge. *Law, Social Justice & Global Development Journal* <http://elj.warwick.ac.uk/global/issue2004-1/fordtomossy.html>. Accessed 06 September 2005.
- Jones, J.H. 1993. Bad Blood: The Tuskegee syphilis experiment. New York, NY: The Free Press.
- Lin, A., 2005. Class action against Pfizer is dismissed. *New York Law Journal*. <http://www.law.com/jsp/article.jsp>. Accessed August 8 2008.
- Moodley, K., 2007. Microbicide research in developing countries: have we given the ethical concerns due consideration. *BMC Medical Ethics* **8**: 1-7
- National Bioethics Advisory Commission, 2001. Presidential bioethics commission issues report on clinical trials research in developing countries. Bethesda, MD: www.bioethics.gov. Accessed February 1 2009.
- Ijsselmuiden, C.B., 1998. Ethics of placebo-controlled trials of zidovudine to prevent the perinatal transmission of HIV in the third world. *N Engl J Med* **338**: 838-841
- Kiriga, J.M., Wambebe, C., Baba-Mousa, A., 2005. Status of national research bioethics committees in the WHO Africa region. *BMC Medical Ethics* **6**: 10 doi:10.1186/1472-6939-6-10.

- Levine, R.J., 1993. New international ethical guidelines for research involving human subjects. *Ann Intern Med* **119**: 339-341.
- Roddy R.E., Zekeng, L., Ryan, K.A., Tamoure, U., Weir, S.S., Wong, E., 1998. A controlled trial of Nonoxynol-9 film to reduce male to female transmission of sexual transmitted diseases. *New Engl J Med* **339**: 504-510
- Shah S.: 2006, *The Body Hunters: Testing new drugs on the worlds poorest people*. New York, NY: The New Press.
- National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1974. *The Belmont Report: Ethical principles and guidelines for the protection of human subjects of research*. Washington, DC: Department of Health Education and Welfare.
- The Medicines for Human Use (Clinical Trials) Regulations, 2004. Statutory Instrument No. 1031, London: Her Majesty's Stationery Office.
- United Nations Millennium Development Goals 2000-2015. www.un.org/millenniumgoals/ United Nations.
- US Adjutant Generals Department, 1949. *Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10*, Vol. 2, pp. 181-182. Washington, DC: U.S. Government Printing Office.
- World Medical Association, 2000. *Ethical principles for medical research involving human subjects*. Ferney-Voltaire, France: www.wma.net/e/policy/b3.htm. Accessed February 1 2009.

Ethical dilemma in using Placebos for drug research

Solomon Monyenye
University of Nairobi
Box 30197 – 00100
NAIROBI
Tel. 0722 702072 (cellphone)
Email: solomonmonyenye@yahoo.com

Abstract Article 6(2) of the Universal Declaration of Bioethics and Human Rights clearly states that scientific research on human subjects should only be carried out with the prior, free and informed consent of the person concerned. This Declaration inevitably creates ethical dilemma in medical research. During tests on new drugs, researchers usually divide patients into two groups. The experimental group receives the “test” drug to be tested. The control group is given a placebo, a resemblance of the “test” drug but with no medicinal value in it. This group is never told the truth about the placebo, so they believe they are receiving proper treatment just like other patients. Hence, the ethical dilemma! The researcher is caught between the obligation to tell the truth, as required by Article 6(2), and the need to conceal truth, as required by scientific methodology. This paper examines this dilemma through the lens of two divergent ethical theories of Utilitarianism and Categorical Imperative, expounded by John Stuart Mill and Immanuel Kant respectively. To resolve this dilemma, the paper suggests that the researcher be guided by either or both of these theories to help decide whether or not the use of placebo is an ethically justifiable lie.

Key words: Consent, experimental group, “test” drug, control group, Utilitarianism, Categorical Imperative

Introduction

During clinical trials of new drugs, medical researchers often use *placebos*, in which a “test group” of patients receives the therapy using the drug being tested, while a “control group” receives the *placebo* (a resemblance of the drug being tested but with no medicinal value) without their knowledge. The purpose is to determine if results from the “test group” prove better than those of the “control group”, thereby proving the desired effectiveness of the test drug.

Although the use of *placebo* in clinical trials of new medications has for a long time been considered a crucial part of research methodology, the continued use of this methodology raises questions on its moral justification since it violates international

guidelines of UNESCO's *Universal Declaration on Bioethics and Human Rights*. (UNESCO, 2006). The Declaration clearly states that "scientific research should only be carried out with the prior, free, express and informed consent of the person concerned and that this information should be adequate, provided in a comprehensible form and should include modalities for withdrawal of consent". (Article 6(2)).

Prior to the UNESCO adoption of Article 6(2), *The Nuremberg Code of Ethics in Medical Research* had been developed by the Allies after the Second World War (Mappes and DeGrazia, 1996). The Code places voluntary consent at centre stage before experiments using human subjects can be judged as morally acceptable. It recommends that the person involved should have legal capacity to give consent; be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. The Code also requires that before the experimental subject makes an affirmative decision, he should be told clearly the nature, duration, and purpose of the experiment, the methodology to be used, all inconveniences and hazards reasonably to be expected, and the effects upon his health or person which may possibly come from his participation in the experiments. (*ibid.*)

In 1964 the Eighteenth World Medical Assembly, meeting in Helsinki, Finland, adopted an ethical code to be used as a guide by medical doctors involved in biomedical research involving human subjects (*ibid.*, p. 199-201). This code, popularly referred to as *The Helsinki Declaration*, has been amended several times, but echoes the Nuremberg Code concerning informed-consent requirement and the requirement that animal experimentation must precede human experimentation. However, the Helsinki Code goes beyond the Nuremberg Code in certain important respects. Two differences are especially noteworthy. (1) The Helsinki Code distinguishes between clinical (therapeutic) and non-clinical (non-therapeutic) biomedical research and sets forth *specific criteria of ethical acceptability* for each, as well as other basic principles common to both. (2) The Nuremberg Code is silent regarding the informed-consent requirement in the case of the legally incompetent. The Helsinki Code addresses such cases, asserting the ethical acceptability of what is sometimes called "proxy consent."

The relevant part of the Helsinki Code that seems to have guided UNESCO's *Universal Declaration of Bioethics and Human Rights* states that "in any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. The research protocol should always contain a statement of the ethical considerations involved and should indicate that the

principles enunciated in the present Declaration are complied with.”
(*ibid.* p. 201)

Ethical dilemma in using *Placebo* for Research on new medicine

An example of ethical dilemma facing researchers in medicine is that of experimentation on the effectiveness of a new drug where tests involve two **groups of patients**. One group (the experimental group) receives the actual drug while the other (the control group) is given the *placebo*, a resemblance of the drug but with no medicinal value. The ethical concern is that this group is ***never told the truth*** about the *placebo*! As can be seen, this is a direct contravention of UNESCO’s Article 6(2), the Nuremberg Code of Ethics in Medical Research and the Helsinki Code cited above.

Yet, the researcher needs to conceal this truth in order to be able to carry out his research successively. Otherwise the control group would not accept to participate as subjects in the experiment if they knew the truth. Hence, the ethical dilemma! The researcher is caught between the demands of the Nuremberg and Helsinki Codes and that of UNESCO’s Article 6(2) obliging him to **tell the truth** and await ***their consent***, and his desire to **conceal the truth** in order to retain the subjects in the *placebo* group to enable him produce the scientific results needed to prove the effectiveness of the new drug. To resolve this ethical dilemma this paper proposes that the researcher be guided by the following two divergent philosophical theories: the Utilitarian theory advanced by John Stuart Mill and the Categorical Imperative advanced by Immanuel Kant.

Mill’s Theory of Utilitarianism

In his book, *Utilitarianism*, the British philosopher John Stuart Mill (**Mill, 1897**) attempts to lay down an objective principle for determining when a given action is right or wrong. He calls this maxim the principle of utility. It states: an action is right in so far as it tends to produce the greatest happiness for the greatest number. The essence of utilitarianism as a philosophy is that it lays stress upon the effects which an action has. If an action produces an excess of beneficial effects over harmful ones, then it is right; otherwise it is not. The fundamental point in utilitarianism is this: the ***consequences*** of a given action determines its rightness or wrongness, not the *motive* from which it is done.

That notwithstanding, Mappes and David Degrazia regard utilitarianism as a form of “situation ethics”. (***ibid.* p.8**). They see a utilitarian as a person who has no sympathy for the notion that certain kinds of actions are intrinsically wrong, but who rather holds that certain actions, such as lying, may be wrong in certain situations and yet right in others. In other words, these philosophers maintain that, for the utilitarian, the circumstances in which an action is performed determine its rightness or wrongness since the consequences of the action varies with the circumstances. Thus, they

say, utilitarianism holds the morality of action as a function of the situation confronting the agent, hence “situation ethics”

The *placebo* and the Utilitarian Theory

How would Utilitarian Theory help the medical researcher resolve the ethical dilemma in using the *placebo* in his clinical tests? According to utilitarianism, the researcher will have to consider the consequences of his actions. If he believes the results of his overall medical experiment when using the *placebo* will produce an over balance of *good* over *evil*, then he will consider his action morally right, regardless of the demands spelt out in the UNESCO’s *Universal Declaration of Bioethics and Human Rights*, *The Nuremberg Code of Ethics in Medical Research* and the *Helsinki Code* cited above. He might need to argue that the “*situation*” under which the tests are done require that concealing the truth from the patients is the only way to get them agree to participate in the experiment. He would argue that no patients could willingly offer themselves for a *placebo* when they are surely suffering from ailments they badly want to see cured!

It will be a different matter, however, if the consequences of the experiment turn out tragic, which is the main weakness of the utilitarian theory. There is no way of telling in advance what the consequences of the action will be until it has been performed! In administering the *placebo* the clinical researcher is gambling with human life! This is unacceptable.

Kant’s Theory of Categorical Imperative

Kant formulates the categorical imperative in several ways. However, only two of these formulations are relevant for the purpose of this paper. The first formulation of the categorical imperative states: “Act only on that maxim through which you can at the same time will that it should become a universal law” (Kant, 1964). The second formulation states: “Act in such a way that you always treat humanity, whether in your own person or on the person of any other, never simply as a means, but always at the same time as an end” (*ibid*). The second formulation holds more relevance to this paper because it emphasizes more the *respect for persons* which the use of the *placebo* ignores. The *categorical imperative* requires that every human being be treated as an end in himself and never as merely a means to an end. Human beings should be respected impartially, without exploiting anyone

The *Placebo* and the Categorical Imperative

Now, how would the medical researcher benefit from Kant’s categorical imperative theory to resolve the dilemma in the *placebo* experiment? The researcher might wish to ask the questions: What motive does he have when he deliberately lies to the “control group”? Would he wish this act of lying to become a universal law? Would he wish to be given a *placebo* if he attended hospital for medical treatment? Would he wish treating people as means and not as ends

in themselves become a universal law? To what extent does the administration of the *placebo* respect human dignity and human rights? If the answers to these questions do not satisfy the guidance offered by the *categorical imperative*, then using the *placebo* in his research methodology is morally wrong.

Conclusion and Recommendations

Since the formulation of the Nuremberg Code, medical research using human subjects is guided by well established codes and regulations to ensure safety and observance of dignity and other human rights. This paper has highlighted a few sections of three of these codes, i.e., UNESCO'S *Universal Declaration of Bioethics and Human Rights*, the *Nuremberg Code* and the *Helsinki Code*. The continued use of the *placebo* seems to contravene almost every guideline contained in all the three.

Researchers continue to conceal the truth during experimentation with the *placebo* on the grounds that unless they lie to their "control group" they would hardly secure patients willing to come forward for tests. At first, this sounds an attractive reason, until one invokes the guidelines contained in the three international Codes discussed above, all of which emphasize human dignity and respect for persons, together with Kant's *categorical imperative* which requires that every human being be treated as an *end* in himself and *never* as merely a *means* to an end.

The above evidence weighs heavily against administering the *placebo* to patients in the "control group". Therefore, there is no justification in its continued use in modern medical research and recommendation is hereby made for its prohibition.

References

- Kant, Immanuel: 1964, *Grounds of the Metaphysics of Morals*, trans. H.J. Paton, Harper and Row, New York.
- Mappes Thomas A. and David DeGrazia: 1996, *Biomedical Ethics*, McGraw-Hills Inc., New York.
- Mill, John Stuart: 1897, *Utilitarianism*, Longmans, Green and Co., London.
- UNESCO: 2006, *Universal Declaration of Bioethics and Human Rights*, Paris.
- World Medical Association, "The Helsinki Code", reprinted in Thomas A. Mappes and David DeGrazia, pp. 199-200.
- _____, "The Nuremberg Code of Ethics in Medical Research", reprinted in Thomas A. Mappes and David DeGrazia, *Biomedical Ethics*, McGraw-Hills Inc., New York, 1996, pp.198-199.

Bioethics Teaching in African Institutions of Higher Learning

Jude M Mathooko,
UNESCO Regional Bioethics Documentation & Research Centre,
Egerton University, PO Box 536, Egerton, Kenya. E-mail:
mathookoj@yahoo.com

Abstract *This paper focuses on the status of bioethics teaching in African institutions, and the role of UNESCO in advancing bioethics reflections in Africa and worldwide through the Global Ethics Observatory (GEObs), the normative instruments, and activities such as the training of ethics education teachers. Institutional committees in bioethics to guide teaching and research should be formed in all universities and should be independent and pluridisciplinary in their purpose and membership; should evaluate research planned and conducted from an ethical perspective; should give approval before any research commences; should put into place procedures for following up and monitoring research; and they should ensure there is a declaration in all research proposals that ethical matters have been considered. The question on why there are so few bioethics courses taught in Kenyan Universities is addressed and the following constraints cited: (i) human capacity to teach bioethics: Very few lecturers/curriculum developers have been trained in bioethics, (ii) limited awareness of its existence since it does not feature in most curricular, even in Secondary and Primary education, (iii) abstract in its application: No clear boundary of what is ethical or not, and (iv) meagre availability of resources for teaching bioethics. Some of the recommendations arising from this paper are (i) Introduction of a core course in bioethics in all universities to be taken by students taking Medicine and Life Sciences, (ii) UNESCO should support and facilitates a model International Postgraduate Bioethics Certificate Programme, (iii) Cascade Bioethics Courses from the university level to primary level, considering levels of comprehension in the subject matter, and (iv) Universities should initiate diffusion and dissemination processes of bioethics and human rights to communities.*

Key words: *Public universities, Bioethics Committees, capacity building, academic programmes*

Bioethical issues are relevant to individuals and societies as a whole (Cheek, 1992) and it is a discipline worth focusing on in our institutions of higher learning. As future citizens, students will need to make decisions not only about their own destiny but also about those that society should take. With the rapid advancement in science and technology, it is important to review the direction and principles that underlie future scientific endeavours and what impact these decisions will have on individuals and societies. One of the challenges in the development of bioethical reflection is the content surrounding bioethical issues which are complex to comprehend. This is because the content is made up of personal, social and emotive aspects as well as specific biological information. Coupled with this challenge is the question of the methodologies and resources to deliver the seemingly abstract content to the students. Africa is very diverse in its ethical voices and culture. Therefore, teaching bioethics cannot adhere to the western tradition of science education that highly values reason, knowledge, and cognitive aspects of knowing. The pedagogical approaches therefore should be different, delivered using diverse cases that address the aforesaid diversity. Furthermore, bioethical contexts, because of the associated uncertainties and complexities, require more holistic teaching approaches that take into account feelings, aesthetics and affective dimensions. Feelings are individualistic and should be explored through activities designed to clarify and analyse the issues (Conner, 2000).

In order to address issues of teaching of bioethics in universities and other institutions, UNESCO has promoted the development of curriculum and resources for bioethics teaching and information dissemination. It has engaged experts from the member states into the preparation of a core course in Bioethics. The content of the course covers the articles in the Universal Declaration on Bioethics and Human Rights (UNESCO, 2005). Therefore, a student who goes through the course will be able to comprehend the declaration and also be exposed to a wide spectrum of bioethical reflection. Teaching approaches for the course will involve use of video/movie, role play, group discussions, and use of ethical dilemmas or cases. The Ethics Teacher Education Programme will further provide the pedagogical skills for handling the teaching of bioethics. Further, UNESCO has established the Regional Bioethics Documentation & Research Centre at Egerton University, Kenya, to support its efforts in the region on bioethical reflections. The objectives of the Centre are to promote an integrated research in bioethics; to create a platform for networking and information sharing among the regional institutions of higher learning on bioethical issues; to create a regional database on bioethics research; and to contribute to education and capacity building through training, research and documentation in the field of bioethics. In addition, Egerton University Chair in bioethics is also promoting bioethics through its mandate: organizing and promoting an integrated system of research, training, information and

documentation activities in the field of bioethics, an instrument for facilitating sub-regional and regional collaboration between high-level, internationally recognized researchers and teachers, and progressively setting up of an intra- and inter-regional network of research in bioethics, collating information on bioethics issues related to contemporary research projects, and the establishment of a rapid and systematic mechanism for the transfer of knowledge and information.

Research, as a systematic method consisting of enunciating the problem, formulating a hypothesis, collecting the facts or data, analyzing the facts and reaching certain conclusions either in the form of solution(s) towards the concerned problem or in certain generalizations for some theoretical formulation, generates information for theorizing or generalizing knowledge (Kothari, 2004). However, the collection of the data, if it uses human beings as research subjects, should engage ethical approaches which should not infringe on the individual's and/or community rights. Effective quality assurance in research therefore depends largely on the availability of highly qualified researchers who are conversant with research ethics, hence the need for capacity building in ethics. Very little emphasis is being put on research ethics and the few Research Ethics Committees (RECs) which ought to offer guidance for researchers in the institutions have no legal standing.

The time for African institutions to incorporate bioethics in the curricula is now. The question on whether there a place of Bioethics in the Institutions of higher learning in Africa is also very appropriate. With the rapid developments in science, technology and innovations in the world, Africa institutions should ignore bioethics at their own peril. Teaching bioethics in institutions of higher learning in Africa will create awareness that bioethics can be applicable in shaping operations and encouraging good practices in the increased research activities, the pros and cons of the introduction of alien products; globalisation and the resultant intense inter- and intra- cultural interactions among human beings; and the emphasis of Science, Technology and Innovations (ST & I) by governments. All these call for well coordinated ethical approaches.

This paper considered three universities in Kenya: Egerton University (EgU), University of Nairobi (UoN), and Masinde Muliro University of Science and Technology (MMUST). All courses and programmes given in these universities' current catalogues were scrutinized to isolate the courses bearing the words "ethics" or "bioethics". Additional information was obtained through interpersonal contacts and consultations. One experience was that it was extremely difficult to obtain information on bioethics teaching in African universities from the Internet. Therefore, the outputs of this paper are not exhaustive and have room for more data. One of the findings was that no university in Kenya has any undergraduate degree programme on bioethics. In addition, no Department of

Bioethics exists in any of the public universities. Other findings of the study were:

1. Very few courses on Bioethics/Ethics are offered in Kenyan public universities.
2. The majority of courses with ethical/bioethical dimensions are taught in the final year (4th. Year) of study at Egerton University. At the University of Nairobi, they are concentrated in Year 3 of a 4-year programme, with a good number also in the final year (4th. Year) of study. Furthermore, in the Masinde Muliro University of Science & Technology, ethics/bioethics courses are concentrated in Years 2 and 4 of study (Table 1).
3. Many of the science and medical programmes did not offer ethics/bioethics courses.
4. The majority of the ethics courses are taught in Religion and Philosophy (Table 2), with limited bioethics in their content.
5. Nearly all bioethics/ethics courses are theoretical and academic without reference to practical examples or cases.

It appears from the foregoing findings that considerations should be made to incorporate bioethics in the curricular and to identify the appropriate window within the study programme when bioethics should be taught to students: Should bioethical/ethical courses be taught in the beginning or in the final year of a degree programme? (Mathooko, 2007). It is proposed that bioethical issues should be included in all the years especially in Medical programmes.

Table 1. Allocation of Bioethics/Ethics courses in undergraduate Academic Years: Egerton University (EgU), University of Nairobi (UoN) & Masinde Muliro University of Science & Technology (MMUST). YoS = Year of study

YoS	Number of Courses, (%)		
	EgU	UoN	MMUST
Year 1	1 (10.0%)	2 (8.3%)	1 (11.1%)
Year 2	1 (10.0%)	5 (20.8%)	3 (33.3%)
Year 3	1 (10.0%)	11 (45.8%)	1 (11.1%)
Year 4	7 (70.0%)	6 (25.0%)	3 (33.3%)
Year 5	-	-	1 (11.1%)

Table 2. Main Disciplines in which ethics/bioethics courses are distributed. *Not offered, - Information not available.

Discipline	EgU	UoN	MMUST
	%	%	%
Education	17.2	6.9	11.1
Medicine	10.3	10.3	-
Biotechnology	*	-	11.1
Biochemistry	3.4	0.0	-
Biomedical Science & Technology	6.9	-	-
Commerce	6.9	0.0	11.1
Gender	3.4	0.0	*
Communication	3.4	3.4	11.1
Philosophy	10.3	10.3	11.1
Religion	34.5	55.2	22.2
Engineering	3.4	0.0	11.1
Law	*	3.4	*
Anthropology	*	3.4	*
Sociology	0.0	3.4	22.2
n	29	29	9

Another key question emanating from the findings and which may be asked is: Why are there so few bioethics courses in Kenyan Universities' Programmes? This could be answered through the identification of the constraints which make bioethics not be considered. These include limited human capacity to teach bioethics. Very few lecturers/curriculum developers have been trained in bioethics. As a discipline, there is limited awareness of its content and aspects of focus since it does not feature prominently in Secondary and Primary education. This is further complicated by the abstract nature of bioethics in its application and teaching methodologies. Meagre availability of resources for teaching bioethics (e.g. books, E-library facilities, among others) is an indisputable constraint.

It is therefore recommended that:

1. the UNESCO core course in Bioethics to be introduced in all universities, to be taken by students taking Medicine and Life Sciences. The Ministry of Higher Education, Science & Technology should therefore support and facilitate the teaching of Bioethics.
2. Universities should form Bioethics Teaching Committees to oversee Bioethics teaching, assessment, and research.
3. Universities should build capacity for teaching bioethics through training, collaboration, and exchange of staff.
4. with support from UNESCO and Universities' which have bioethics programmes already, Kenyan universities should develop Bachelors and Masters Degree Programmes to train students and build capacity for teaching Bioethics in Universities and Middle Level Colleges.

5. UNESCO should support and facilitate a model International Postgraduate Bioethics (IPGB) Certificate Programme for the sub-Saharan region.
6. An extension training programme in bioethics involving health care personnel, community organizations and actors involved in the field of health should be developed and implemented.
7. E-library and E-learning in bioethics should be initiated and supported in selected centres such as the Regional Bioethics Documentation and Research Centre at Egerton University, Kenya.
8. Bioethics Courses should be cascaded from the university level to primary level, considering levels of comprehension in the subject matter.
9. Subject matter for teaching bioethics should be drawn from the Universal Declaration on Bioethics and Human Rights (UDBHR).
10. Universities should play a key role in the diffusion and dissemination processes of bioethics and other UNESCO normative instruments focusing on the well-being of human kind.

In conclusion, the Ethics Teacher Education Programme, the core course in Bioethics and the formation of Bioethics Committees are some of the positive steps towards building capacity for bioethics teaching in the Universities. There is need to train lecturers and introduce them to the resources and methods of teaching bioethics through demonstration of teaching skills. With the rapid advancement in science and technology, bioethical reflections should occupy a central position in our teaching, research and in the general development. More information on Bioethics Curricular from various institutions in the world can be obtained from the Global Ethics Observatory (GeObs) website (www.unesco.org/shs/ethics/geo).

Acknowledgments

I acknowledge all those persons who assisted in providing the data.

References

- Cheek, D., 1992. Thinking constructively about science, technology and society education. Albany, NY: State University of New York Press.
- Conner, L., 2000. The inclusion of social issues in the Science and Technology Curriculums in N.Z. and the implications for teaching. *Pacific Asian Education* **12**: 19-30.
- Kothari, C.R., 2004. Research methodology: methods and techniques. New Age International (P) Ltd, New Delhi.
- Mathooko, J.M., 2007. Teaching and institutionalization of bioethics in Kenyan universities' curricula. Paper presented during the Ethics Teacher Education Training, 9-13 July 2007, Egerton University, Kenya.

United Nations Educational, Scientific and Cultural Organization,
2005. Universal Declaration on Bioethics and Human Rights.
UNESCO, Paris, France.

Legal approaches in Bioethics in Italy

Nunzia Cannovo^o, Vincenzo Graziano^o, Mariano Paternoster^o

^o*Dipartimento di Medicina Pubblica e della Sicurezza Sociale –
Università degli Studi di Napoli Federico II –
drncannovo@libero.it, via Pansini 5, 80131, Napoli; tel/fax:
00390817463468*

Abstract *This paper discusses the connection between bioethics and law in Italy. Bioethics operates within the limits of biolaw. Like in many countries, the challenge is for the legislative system to keep pace with scientific discoveries. Previously, bioethics was the prerogative of the National Bioethics Committees, but currently it has been taken over by ad hoc scientific committees. In spite of all these, we conclude that whatever the scope, law can not take over bioethics.*

Key words: *Bioethics, legal practices, biolaw*

Introduction

The issue of the relationship between bioethics and law is a rather ancient one, retroactively datable to the first philosophical speculations about the relationship between law and science, as well as between law and medicine in particular⁷. In extreme synthesis, the question to be posed could be the following: “Should law get interested in bioethics? Is it rightful that bioethics be subject to juridical rules?”. The answers should not be taken for granted, as they influence the epistemological interpretation of bioethics itself. In general, this latter is considered as an interdisciplinary science, drawing from and contributing to the fields of medicine (intended as both research and praxis), of ethics as well as of law. Bioethics⁸ intends to trigger a reflection about the innovative perspectives concerning birth, life and death, which are available on the «market» of individual choice thanks to the progress in biology and medicine, and which becoming the area for a new meeting-encounter between thinkers with a different background. There is not only a divide between philosophical and directive bioethics, but also between lay and religious world. To stem this inner conflict is the task of biolaw. From the conceptual point of view, it should endeavour to regulate the behaviour of arbitrary use of the prodigious scientific abilities by means of threatened sanctions. individuals and organize the collective ones, in order to preserve society from an In fact, biolaw limits bioethical action, caging it into arid mechanistic patterns which obey pragmatic rules rather than moral ones.

⁷ The doctrine of natural law is an example.

⁸ Lecaldano, E.: 1999. *Bioetica. Le scelte morali*, Laterza, Roma-Bari

Bioethics and law

While drawing up the law, the jurist is at the centre of a triangle whose vertices are represented by :

1. the situation and the opinions received by the scientific community;
2. the framework of the scientific position provided to him/her by epistemology and by the argumentations of ethics;
3. the general and fundamental principles of his/her regulation, which, the case being, are interpreted and seen in the light of the economic and social interests at stake, taking into account the superior value of a compromise accepted by everybody or by the majority.

This is why the legislative system in Italy is certainly slower in its decisions than the explosive development of new scientific discoveries. In order to fill this gap, there is the judiciary's intervention: within a judgement, it identifies directives to promote the common interest in order to guarantee an equal social life of the community. A relevant example hereof is the debate about therapeutic obstinacy regarding the case of the Englaro family. The judiciary stepped in to fill a regulation gap. Both the judgement of the Court of Cassation (no. 21748 of the 16th October 2007) and the draft laws about anticipated directives and thus about therapeutic obstinacy, are trying to objectivize - through questionable scientific interpretations - issues with a rich ethical matrix, imposing a standardized way of reasoning. The effect of this is interference with the people's intimacy in establishing interdictions, instead of avoiding such borderline situations to be reached. Another related example is the research of a scientific framework allowing to formulate a list of motivations justifying euthanasia, without having tried to alleviate the individual's suffering in the terminal phase. It is easy to issue a law imposing a series of interdictions; what is difficult is to avoid that people are caught in borderline situations that compel them to infringe these prohibitions. The purposes of juridical and ethical science, though within the essential mutual contribution against the background of bioethical interdisciplinarity, are different and should remain so. The justification of a codified legal obligation appears by virtue of the power conferred to an authority which is the sole entitled to establish the boundary between crime and correct behaviour. The justification of a moral duty, on the contrary, springs from inexhaustible sources of rational argumentation which are not based on an assumed power, but on the power of the reasoning itself, and "in this sense it implies an equal decisional relationship, while law consecrates a forced, vertical and hierarchic relationship⁹".

⁹ Petrelli, F.: 2002. La bioetica tra filosofia, medicina e diritto. *Dialegesthai. Rivista telematica di filosofia*, anno 4 on: World Wide Web: mondodomani.org/dialegesthai/>, [33 KB], ISSN 1128-5478.

The role of ethical committees

The activity of linking the worlds of law, bioethics and science in Italy had been the prerogative of the National Bioethics Committee (CNB), which – unfortunately – in the last years has been outclassed by ad-hoc technical-scientific committees instituted by the various ministers of Health of the last years. The CNB's prerogative consisted in being a multidisciplinary organism featuring a high competence and above all presenting itself as a pluralist body, independent from political parties. The present situation has caused an impoverishment of the parliamentary debate concerning bioethics, whose place was been taken in by technicalism.

Conclusion

Bioethics cannot be restricted within the limits of law, as in compliance with its ontological statute it must have the opportunity to open up to meditations with a constantly widening scope; otherwise it is at risk of exhaustion. The laws have to be grounded on a mature bioethical reasoning. Law, however, cannot take the place of bioethics.

Closing speech

By Prof. Sylvester C. Chima

*Programme of Bio & Research Ethics and Medical Law,
College of Health Sciences, University of KwaZulu-Natal,
Durban, Republic of South Africa*

E-mail: chima@ukzn.ac.za or chimasc@hotmail.com

Distinguished Guests, Ladies and Gentlemen, it is my pleasure to stand before you today in order to give a closing address to this important international meeting. Let me start by saying that after listening to the deliberations of this conference over the last three days, my conclusion is that: 'Africa can only ignore bioethics at her own peril'. This quotation, paraphrased from a speech given by the Director-General of UNESCO in 2007, may have challenged and inspired the hosting of an International Conference on Bioethics with the theme of 'Bioethical perspectives and Practices in Research, Medicine, Life Sciences and Related Technologies in sub-Saharan Africa.' This conference hosted by the UNESCO Regional Centre for Documentation and Research on Bioethics at Egerton University gathered researchers, scientists, observers, and guests from Sub-Saharan Africa and other parts of the world with an interest in bioethical issues in Africa. During the three days, a total of 27 papers were presented in 10 thematic areas, ranging from Ethical Implications of Human Research, Legal Approaches in Bioethics, Ethical issues in Animal Experimentation, Genetically Modified Organisms and Products (GMO foods), Biodiversity and Environment, Biopiracy and Bioterrorism, Complementary and Alternative Medicine (CAM), Ethical Dilemmas in Medicine, Bioethical Issues in African Cultures and Religions, and the Teaching of Ethics in Africa. I am pleased to note that this meeting has attracted local and international participants from Kenya, Nigeria and South Africa, Canada and Italy. All participants must be complimented on the high quality of the presentations and the amount of work and effort put into the preparation of papers and discussing these very important issues.

Ladies and Gentlemen, I would like to summarize the achievements and deliberations of this conference in terms of the items agreed upon and the way forward in the domestication of bioethics in the region.

There were four major agreements by all participants at the conference, which represented the major outcomes of the conference designed to contribute to the progress and awareness of bioethics in sub-Saharan Africa.

Immediate Outcomes:

- (a) There will a Conference Proceedings published under the auspices of the UNESCO Regional Research and Documentation Centre at Egerton University
- (b) Participants resolved to publish a multi-authored book based on selected papers delivered at the conference and elected three participants to co-ordinate the book publication exercise.

Future Outcomes:

- (c) Participants resolved to initiate a mechanism for the hosting of a similar conference on Bioethics biennially in Sub-Saharan Africa
- (d) Participants also agreed to explore the possibility of establishing a journal for the publication of African ideas or perspectives in the area of Bioethics.

With regard to the Domestication of Bioethics in Africa, my observation is that, outside of UNESCO we should explore the mechanisms for modifying African regional and national laws or incorporating the ideas and suggestions raised at this conference into local laws. Towards this end, it would be desirable to establish standing committees or sub-regional workshops on domestication, to look into important issues raised during the debate and plenary sessions at this conference. This would include workshops in the areas of:

- (i) Ethical issues in GMO foods and organisms in Africa
- (ii) Ethical issues in Traditional or Complimentary and Alternative Medicine in Africa
- (iii) Ethical issues in human Biomedical Research in Africa
- (iv) The Teaching of Bioethics in Africa

Resolutions from these workshops or discussion forums could be compiled and included in a proposed African Union (AU) Directive on Biomedical Research in Africa similar to the European (EU) Convention on Human Rights and Biomedicine, Oviedo, 1997. This will enable African countries to continue to protect their citizens and vulnerable population groups and also promote a forum for debate and domestication of Bioethics in Africa. On my own part, I would be willing in collaboration with my institution, University of KwaZulu-Natal, South Africa, to host one of the workshops directed towards achieving these laudable goals.

Finally, I would like to express my profound gratitude to our hosts Egerton University and the UNESCO Regional Bioethics Centre located at Egerton University. I would also like to thank the Ministry of Education through the Kenya National Commission for UNESCO (KNATCOM) and the office of the UNESCO Regional Advisor for Social and Human Sciences in Africa, Nairobi, Kenya for facilitating this conference, and all here today. As we all depart o our various institutions, I wish each and every one of us a safe journey home, and I urge us to apply whatever we have learnt at this forum in our work at our various institutions. Ethics impacts on all aspects of human life and endeavors, and this conference should not be the end of ethical analysis and discussion. UNESCO as an institution should endeavor to extend their activities to all of Sub-Saharan Africa. We should also remember that other organs of the United Nations such as the WHO and UNAIDS also have extensive interests on ethics. As African researchers and scientists we should explore and use these opportunities for collaboration. We should not forget the African adage, which says: 'If you want to go quickly go alone, but if you want to go far, go together.'

With these few remarks, I now declare the International Conference on Bioethics held at Egerton University from 12-14 August 2008 officially closed.

Thank you and God bless you.

Annexes

Programme

Theme

Bioethical Perspectives and Practices in Research, Medicine, Life Sciences and Related Technologies in Sub-Saharan Africa

VENUE: ARC Hotel, Egerton University, Kenya, 12th -14th August 2008

Overall Coordinator: Prof. JM Mathooko

Co-coordinators: Dr. JK Kipkemboi & Dr. IN Wagara

In-charge of Registration & Reception: Ms. JW Mutahi

Chief Rapporteur: Dr. JO Ouma

Floor & Communications Coordinator: Dr. SM Mwonga/J Muthee

Security & Transport: Mr. B Guyo

TUESDAY, 12 AUGUST 2008

0800 – 0900 **REGISTRATION**

Chair: Prof. JM Mathooko

Rapporteur: Dr. JO Ouma

0900 - 1000 - Introductory speech by the Chair, UNESCO Bioethics
- Speech by the Vice-Chancellor, Egerton University
- Opening Speech by the Chief Guest Prof. Karega Mutahi, PS, Ministry of Education

[Photo Session]

1000 – 1030 **TEA BREAK**

1030 – 1130 **Keynote Speech I.** *The Role of Bioethics in Shaping the Science, Technology and Innovations Agenda in Kenya* [Prof. CM Kiamba, PS Ministry of Higher Education, Science & Technology]

1130 – 1200 *Ethical Dilemmas in Medicine* [Dr. Bill Fryda, Director St. Mary's Mission Hospital, Nakuru]

- 1200 – 1230 *Ethical Dilemma in Medicine: Is the Use of Placebo in Drug Research a Justifiable Lie?* [Dr. S Monyenye, University of Nairobi]
- 1230 – 1300 *Informed Consent in Kenyan Hospitals* [Prof. Moni Wekesa & Dr. M Shieshia-Odwori]

1300 – 1400 **LUNCH**

Chair: Prof. Moni Wekesa

Rapporteur: Dr. T Nganda

- 1400 – 1500 **Keynote Speech II:** *Ethical Implications in Human Research* [Dr. MK Wasunna, Director, KEMRI, IBC Member]
- 1500 – 1530 *Overriding patient autonomy in medical practice: Best interests, necessity, therapeutic privilege, and public policy* [Prof. SC Chima, University of Kwa Zulu-Natal, RSA]
- 1530 – 1600 *Probiotics and Nutritional Intervention Research in Sub-Saharan Africa: What are the ethical considerations?* [Drs. PN Njeru, S. Mbugua & E Kamau-Mbuthia, TRF, Max-Rubner Institute & Egerton University]
- 1600 – 1630 *Ethical Issues in Substance Abuse Research* [Ms. J Kimani, NACADA]
- 1630 – 1700 *HIV/AIDS: a bioethical hard blow to Human Dignity and Human Rights* [Dr. P Chummar, Catholic University of Eastern Africa, Nairobi]
- 1630 – 1700 *Understanding the roles through which the state participates in HIV/AIDS vaccine research* [Ms. EA Oduwo, Research Assistant, Biomedical Ethics Unit, McGill University, Canada]

WEDNESDAY, 13 AUGUST 2008

Chair: Prof. SC Chima

Rapporteur: Prof. A Kahi

- 0900 – 1000 **Keynote Speech III:** *Ethical Issues in Animal Experimentation in Science* [Dr. Idle Farah, Director General, National Museums of Kenya]

1000 – 1030 *Animal Experimentation and Research: Developing challenges and ethical considerations in biomedical research* [Drs. FN Mbai, RM Ngure & BS Dunbar, EU/UoN]

1030 – 1100 **TEA BREAK**

1100 – 1130 *Biosafety Issues in carrying out Agricultural Biotechnology Research in Kenya* [Dr. R Soi, Kenya Agricultural Research Institute HQs, Nairobi]

1130 – 1200 *Bioethical Issues Related to Genetically-Modified Products* [Prof. SA Abdulrazak, Secretary, National Council for Science & Technology]

1200 – 1230 *Genetically-Modified Food Products: Ethical Dilemma and Implication for Food Security* [Prof. AJ Sigot, Masinde Muliro University for Science & Technology]

1230 – 1300 *Stakeholder's perception of genetically modified organisms* [Prof. Moni Wekesa & WM Kyalo]

1300 – 1400 **LUNCH**

Chair: Prof. AJ Sigot

Rapporteur: Prof. J Matasyo

1400 – 1430 **Keynote Speech IV: Legal approaches in bioethics** [Mr. AD Rachier, Advocate of the High Court of Kenya]

1430 – 1500 *Use of Indigenous Plants in Sustaining Health and Livelihood in Africa* [Dr. ST Kariuki, Egerton University]

1500 – 1530 *Research and Development of Traditional Medicines: Ethical Dimensions* [Prof. C Wambebe & K Gamaniel, International Biomedical Research in Africa, Abuja, Nigeria]

1530 – 1600 *African Traditional Medicine in Italy: Ethical-Deontological and Medico-legal considerations about its application* [Ms. Cannovo *et al.*, University of Studies of Naples Federico II, Italy]

1600 – 1630 *Experiences in Herbal Medicine Practice* [Prof. JW Mwangi, University of Nairobi]

1630 – 1700 *Plants as sources of Traditional Medicine: Ethical implications on unregulated and uncontrolled use* [Dr. WA Muia, Egerton University]

THURSDAY, 14 AUGUST 2008

Chair: Prof. JW Mwangi

Rapporteur: Dr. AW Muia

0900 – 1000 **Keynote Speech V: *Bioethics Teaching in African Institutions*** [Prof. JM Mathooko, UNESCO Bioethics Chair, Egerton University]

1000 – 1030 *Bioethical Issues Pertaining to Teaching and Learning in African Institutions of Higher Learning* [Prof. EM Standa, CS/CEO, Commission for Higher Education]

1030 - 1100 **TEA BREAK**

1100 – 1130 **HIV/Aids – A Major Medical Ethics Dilemma** [Dr. DK Ngotho, Egerton University]

1130 – 1200 *Ethics of Using non-human Primates in Biomedical Research* [Dr. Kariuki, Institute of Primates Research, Nairobi]

1200 – 1230 *Bioethical Issues in the Islamic Religion* [Mr. Abdalla Kheir, Imam, Kenyatta University]

1230 – 1300 *Bioethical Issues in African Cultures and Religions* [Dr. Fr. SN Mbugua, Egerton University]

1300 – 1400 **LUNCH**

Chair: Dr. M Theuri

Rapporteur: Fr.Dr. Stephen Mbugua

1400 – 1430 *Towards a more effective regulation of Human Biomedical Research in African Communities* [Prof. SC Chima, University of Kwa Zulu Natal, RSA]

1430 – 1500 *Biopiracy: A New Threat to Biodiversity in the 21st Century* [P] Rongoei, Egerton University]

1500 – 1530 *Is there an African Bioethics?* [Dr. K Mbugua, University of Nairobi]

1530 – 1600 *Is there Need for a Code of Ethics for Researchers?* [Prof. M Kinyua, Moi University]

1600 – 1630 **CLOSING CEREMONY [Chief Guest: Prof. G Godia,
Education Secretary, Ministry of Education]**

**[TREE PLANTING AT THE BIOETHICS SQUARE,
BOTANIC GARDEN]**

List of Participants

1. Ms. Elizabeth Oduwo
McGill University, Kenya
Email: akothliz@hotmail.com

2. Mrs. Hawa Mavura
Egerton University, Kenya
Email: hmavura@yahoo.com

3. Prof. Jude. M. Mathooko
Egerton University, Kenya
Email: mathookoj@yahoo.com

4. Dr. John Nkinyangi
UNESCO Nairobi Office
Email: John. Nkinyangi@unesco.unon.org

5. Dr. Isabel. N. Wagara
Egerton University, Kenya
Email: inwagara@yahoo.com

6. Samuel. M. Mwonga
Egerton University, Kenya
Email: smwonga@yahoo.com

7. Prof. Sylvester. C. Chima
University of Kwa Zulu-Natal, Republic of South Africa
Email: chima@ukzu.ac.za

8. Dr. Theuri M. Mathew.
Egerton University, Kenya
Email: theuris2001@yahoo.com

9. Dr. J. Ouma Omolo
Egerton University, Kenya
Email: ojoonearth@yahoo.com

10. Prof. L. M. Mumera
Egerton University, Kenya
Email: dvcafegerton@africaonline.co.ke
11. Prof. R. A. Mwonya
Egerton University, Kenya
Email: mwonyar@yahoo.com
12. Dr. Fiona. N. Mbai
Egerton University, Kenya
Email: fionambai@gmail.com
13. Dr. Jane N. Mburu
Egerton University, Kenya
Email: jnmburu@yahoo.com
14. Dr. Moses Rotich
Egerton University, Kenya
Email: rotichmak@yahoo.com
15. Stephen K. Gikuru
Egerton University, Kenya
Email: skgikuru@yahoo.com
16. Dr. Joseph. W. Matofari
Egerton University, Kenya
Email: matofari@yahoo.com
17. Prof. Ngure Raphael. M.
Egerton University, Kenya
Email: ramuch68@yahoo.com
18. Ms. Mobagi Diana
National Environment Management Authority (NEMA), Kenya
Email: dianasoila@hotmail.com
19. Fr. Dr. Stephen M. Ngari
Egerton University, Kenya
Email: ngaristephen@yahoo.com
20. Prof. Moni Wekesa
Moni Wekesa & Co. Advocates, Kenya
Email: moniwekesa08@gmail.com

21. Prof. Asenath J. Sigot
Masinde Muliro University of Science & Technology, Kenya
Email: sigot@africaonline.co.ke
22. Prof. Charles Wambembe
International Biomedical Research in Africa, Nigeria
Email: wambembe@yahoo.com
23. Dr. Francis. K. Njonge
Jomo Kenyatta University of Agriculture and Technology(JKUAT),
Kenya
Email: francisnjonge@yahoo.com
24. Dr. Julius Mathara
Jomo Kenyatta University of Agriculture and Technology(JKUAT),
Kenya
Email: juliusmaina_2000@yahoo.com
25. Prof. E. M. Standa
Jomo Kenyatta University of Agriculture and Technology(JKUAT),
Kenya
Email: che@wananchi.com
26. Prof. A. K. Kahi
Egerton University, Kenya
Email: a.kahi@egerton.ac.ke
27. Mr. Benson O. Obwanga
Egerton University, Kenya
Email: obwangaz@yahoo.com
28. Dr. Paul Chummar
Catholic University of East Africa, Kenya
Email: pchummar@gmail.org
29. Dr. Samuel. T. Kariuki
Egerton University, Kenya
Email: stkabuito@yahoo.com
30. Anne C. Kipkorir
Egerton University, Kenya
Email: cherrainne@yahoo.com

31. Humphrey Muiruri
Egerton University, Kenya
Email: humkah@yahoo.com
32. Amana Juma
Egerton University, Kenya
Email: Amana_juma@yahoo.com
33. Francis Mwangi
Egerton University, Kenya
Email: frankimwangi@yahoo.com
34. Dr. Fredrick. K. Waweru
Egerton University, Kenya
Email: fkamwa2002@yahoo.com
35. Dr. Christine Wasunna
Kenya Medical Research Institute (KEMRI), Kenya
Email: cwasunna@kemri.org
36. Mr. Ambrose Rachier
Kenya Medical Research Institute (KEMRI), Kenya
Email: lawtechs@rachieradvs.co
37. Racheal W. Njoroge
Egerton University, Kenya
Email: rawanjo67@yahoo.com
38. Majambo Jarumani
Egerton University, Kenya
Email: majamboj@yahoo.com
39. Michael W. Ojiambo
Ministry of Education, Kenya
Email: michaelojiambo@hotmail.com
40. James I. Muthee
Egerton University, Kenya
Email: jamesim@egerton.co.ke

41. Vivian N. Waithaka
Jomo Kenyatta University of Agriculture and Technology(JKUAT),
Kenya
Email: vwaitbaka@apd.jkuat.ac.ke
42. Prof. Mwaniki. S. Ngari
Egerton University, Kenya
Email: msngari@yahoo.com
43. Joyce Nduhiu
Egerton University, Kenya
44. Prof. Josphat Matasyoh
Egerton University, Kenya
Email: josphat2001@yahoo.com
45. Dr. Karori Mbugua
University of Nairobi, Kenya
Email: karorim@yahoo.com
46. Dr. Douglas K. Ngotho
Egerton University, Kenya
Email: dkngotho@wananchi.com
47. Dr. Anastacia. W. Muia
Egerton University, Kenya
Email: wairimumuia@yahoo.com
48. Dr. Nzula Kitaka
Egerton University, Kenya
Email: nkitaka@yahoo.com
49. Dr. Kibet Ngetich
Egerton University, Kenya
Email: k-ngetich@yahoo.com
50. Prof. F. K. Lelo
Egerton University, Kenya
Email: eupra@wananchi.com

51. Dr. Titus. N. Nganda
Egerton University, Kenya
Email: tnnnganda@yahoo.com
52. Bora Guyo
Egerton University, Kenya
Email: bogusa71@yahoo.com
53. Wilkister. N. Moturi
Egerton University, Kenya
Email: Moturi33@yahoo.com
54. Prof. Hellen Mondoh
Egerton University, Kenya
Email: ngombesa@yahoo.com
55. Dr. Moses Aloba
Egerton University, Kenya
Email: malobo@dndi.org
56. Prof. Z. A. Ogutu
Inter-University Council of East Africa / VicRes, Kampala, Uganda
Email: zazogutu@yahoo.com
57. Prof. A. L. Deng
Egerton University, Kenya
Email: agerkuei@yahoo.com
58. Dr. Mwose Nzwili
Kenya National Commission for UNESCO (KNATCOM) , Kenya
Email: m.nzwili@yahoo.com
59. Dr. Boniface Wanyama
Kenya National Commission for UNESCO (KNATCOM) , Kenya
Email: bwwekesa@yahoo.com
60. Peter Koome
NACADA
Email: pkoome@yahoo.com
61. Dr. Julius Kipkemboi
Egerton University, Kenya
Email: j_kkipkemboi@yahoo.com

62. Dr. S. O. Obure
Egerton University, Kenya
Email: sobure2000@yahoo.com
63. Mr. Harrison K. Macharia
National Council for Science & Technology (NCST), Kenya
Email: harimacharia@yahoo.com
64. Ms. Kabura W.
Egerton University, Kenya
Email: rmkabura2@yahoo.com
65. Prof. H. S. K. Mwaniki
Egerton University, Kenya
Email: henrySKmwaniki@yahoo.com
66. Prof. Julius K. Mwangi
University of Nairobi, Kenya
Email: mupal02@yahoo.com
67. Ms. Anne Kahihia
Kenya Wildlife Services (KWS), Kenya
Email: akahihia@yahoo.com
68. Dr. Reuben Soi
Kenya Agricultural Research Institute (KARI)
Email: reubensoi@gmail.com
69. Priscah J. Rongoei
Egerton University, Kenya
Email: rongoeipj@hotmail.com
70. Dr. Thomas Kariuki
Institute of Primate Research/National Museums, Kenya
Email: tkariuki@africaonline.co.ke

Members of the organizing committee

Prof. Jude. M. Mathooko – Chair
Dr. Mathew M. Theuri- Member
Dr. Samuel M. Mwonga- Member
Dr. Josiah O. Ouma- Member
Dr. Isabel. N. Wagara- Member
Mr. Bora Guyo- Member
Dr. Titus Nganda – Member
Mr. Mames. I. Muthee- Member
Dr. Julius Kipkemboi – Member

Support staff:

Ms. Joyce Mutahi
Ms. Lucy Musyoka
Ms. Winny C. Seronney
Ms. Suzan Obura