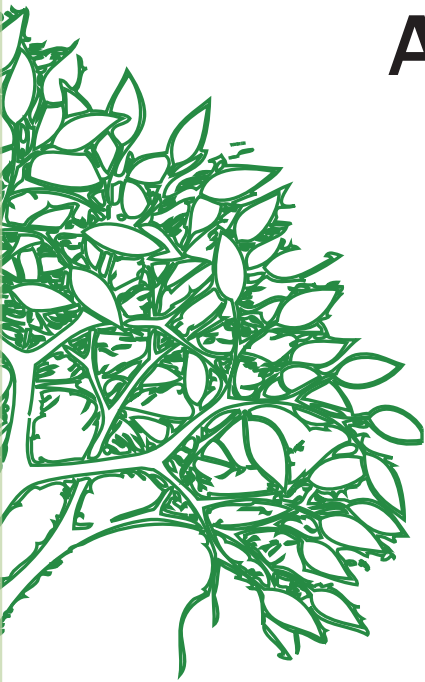


UNESCO Bangkok
Regional Unit for Social and Human Science
in Asia and the Pacific

Asia Pacific Perspectives on Medical Ethics



Asia-Pacific Perspectives on Medical Ethics

Asia-Pacific Perspectives on the Medical Ethics. Bangkok: UNESCO Bangkok, 2008.

vi + 115 pp.

1. Medical Ethics. 2. Research Ethics 3. Human Rights 4. Bioethics. 5. Asia and the Pacific.

ISBN 978-92-9223-219-1 (Electronic version)

© UNESCO 2008
Published by the
UNESCO Asia and Pacific Regional Bureau for Education
920 Sukhumvit Rd., Prakanong
Bangkok 10110, Thailand

Chief Editor: Daniel Calderbank
Editor: Darryl R.J. Macer
Cover design: Alessandra Blasi
Design/Layout: Celia H. Thorheim

Printed in Thailand

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SHS/08/EP/002-1

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ACRONYMS

AIDS: Acquired Immune Deficiency Syndrome
ARV: Anti-Retroviral Medicines
CHRB: Convention on Human Rights and Biomedicine
CIOMS: Council for International Organizations of Medical Sciences
COMEST: World Commission on the Ethics of Science and Technology
ELSI: Ethical, Legal and Social Impact
HES: Human Embryonic Stem
HIV: Human Immunodeficiency Virus
HUGO: Human Genome Organization Ethics Committee
IBC: UNESCO International Bioethics Committee
ICN: International Council of Nurses
IDHDG: International Declaration on Human Genetic Data
IVF: In Vito Fertilization
IRB: Institutional Review Board
NGOs: Non-Governmental Organizations
NHMRC: National Health and Medical Research Council (Australia)
OECD: Organization for Economic Cooperation and Development
PGD: Pre-Implantation Genetic Diagnosis
REC: Research Ethics Committee
RMI: Republic of Marshall Islands
RUSHSAP: Regional Unit for Social and Human Sciences in Asia and the Pacific
SARS: Severe Acute Respiratory Syndrome
UNAIDS: Joint United Nations Programme in HIV/AIDS
UNDP: United Nations Development Programme
UNESCO : United Nations Educational, Scientific and Cultural Organization
US-FDA: US-Food and Drug Administration
WHO: World Health Organization

PREFACE

The pursuit of health is a natural drive for survival found in all living organisms. The development of medicine and ethical norms to guide the conduct of the medical profession has been seen in every society over the course of history. UNESCO has made ethics of science and technology one of its five priority areas and the International Bioethics Committee of UNESCO was established in 1993 to deliberate on issues raised by the pursuit of advanced medical research. This volume offers perspectives from people in a range of countries across Asia and the Pacific on medical ethics, many of whom are actively involved as members of the UNESCO Asia-Pacific School of Ethics.

UNESCO's programmes in bioethics aims to strengthen the ethical link between scientific advancement and the cultural, legal, philosophical and religious context in which it occurs. UNESCO's strategy in bioethics has been to act as a standard-setter on emerging ethical issues, to disseminate information and knowledge and to help Member States build their human and institutional capacities. The standards include the Universal Declaration on the Human Genome and Human Rights, adopted by UNESCO's General Conference in 1997 and subsequently endorsed by the United Nations General Assembly in 1998. This was followed by the International Declaration on Human Genetic Data, adopted in 2003; and the Universal Declaration on Bioethics and Human Rights, adopted by UNESCO's 33rd General Conference in 2005.

This collection of papers is third in a series of books from RUSHSAP, UNESCO Bangkok offering perspectives on ethics in Asia and Pacific, with each focusing on a specific theme. These papers were originally presented during conferences on ethics in science and technology which UNESCO's Regional Unit for Social and Human Sciences (RUSHSAP) has been convening since 2005. Since intercultural communication and information sharing are essential components of these deliberations on the ethics of science and technology, the books also provide theme-related discourse from the conferences.

The First UNESCO Bangkok Bioethics Roundtable was held 11-15 September, 2005, as the first event in Bangkok to celebrate UNESCO's 60th anniversary. The UNESCO Bangkok office is the largest UNESCO branch office in the Asia-Pacific Region, encompassing 46 member countries. RUSHSAP is designated as the regional office for coordinating implementation of the UNESCO programmes in the social and human sciences sector in Asia-Pacific region, which includes the programmes on ethics of science with the Division of Ethics of Science and Technology in Paris.

The Sector's Programme on the Ethics of Science and Technology¹, being one of UNESCO's five priority areas, is designed to ensure that the world remains secure for everyone by placing the ongoing revolutionary scientific and technological progress within a context of ethical reflection rooted in the cultural, legal, philosophical, and religious heritage of the various human communities. This programme covers two primary areas of ethical reflection: bioethics (addressing concerns stemming from advances in life sciences), and ethics of science and technology (addressing other areas of applied ethics in relation to scientific and social developments).

The Bioethics Programme is part of UNESCO's Division of the Ethics of Science and Technology in the Social and Human Sciences Sector. It acts as the Secretariat of two advisory bodies: the International Bioethics Committee (IBC), composed of 36 independent experts, and the Intergovernmental Bioethics Committee, composed of representatives of 36 Member States. These Committees cooperate to produce advice, recommendations, and proposals that each submits to the Director-General for consideration by UNESCO's governing bodies.

The IBC is a body of 36 independent experts that follows progress in the life sciences and its applications in order to ensure respect for human dignity and freedom. It was created in 1993. The IBC provides a global forum for in-depth bioethical reflection by exposing the issues at stake. It does not pass judgment on one position or another. Instead, it is up to each country, particularly lawmakers, to reflect societal choices within the framework of national legislation, and to decide between the different positions. The

1 <http://www.unesco.org/ethics>

tasks of the IBC include:

- (1) To promote reflection on the ethical and legal issues raised by research in the life sciences and their applications, and to encourage the exchange of ideas and information, particularly through education;
- (2) To encourage action to heighten awareness among the general public, specialized groups, and public and private decision-makers involved in bioethics;
- (3) To co-operate with the international governmental and non-governmental organizations concerned by the issues raised in the field of bioethics, as well as with the national and regional bioethics committees and similar bodies;
- (4) To contribute to the dissemination of the principles set out in the Universal Declaration on the Human Genome and Human Rights, and to the further examination of issues raised by their applications and by the evolution of the technologies in question;
 - (ii) To organize appropriate consultations with stakeholders;
 - (iii) To make recommendations addressed to the General Conference, to give advice concerning the follow-up of the Declaration, and to identify practices that could be contrary to human dignity.

Since 1998, the IBC has had Statutes defining its mandate, composition, etc. The Director-General of UNESCO convenes the IBC at least once a year. Through its sessions and working groups, the Committee produces advice and recommendations on specific issues that are adopted by consensus and are widely disseminated and submitted to the Director-General for transmission to the Member States, the Executive Board, and the General Conference. The Director-General appoints the IBC's 36 members to serve in their personal capacities for four-year terms. The selection is made by taking into account cultural diversity, balanced geographical representation, and nominations from some states of qualified specialists in the life sciences and in the social and human sciences, including law, human rights, philosophy, education, and communication. The IBC has released a series of reports on particular themes in bioethics which can be accessed on-line. The most recent IBC documents are on informed consent and social responsibility, areas of medical ethics and public health ethics, which are also discussed in the papers in this volume.

I wish to thank the active discussion and participation of all who attended the UNESCO Bangkok meetings, many of whom are actively involved in the regional programmes.² A special thank you is due to Silvie Poeth and Daniel Calderbank for help in editing the papers, and to Frankie Keller for transcribing the discussion. The cover design is thanks to Alessandro Blasi and the book text layout was prepared by Celia Thorheim. We look forward to increased discourse on these papers, which is not to be seen as the final word on these topics, but rather as a means to catalyze a greater regional discussion of medical ethics and governance of medical practices according to accepted ethical, legal and social practices.



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² www.unescobkk.org/rushsap

Controversy over Medical Futility*

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Introduction

References to medical futility have a long history in the medical profession. Plato and Hippocrates commented on the proper response of physicians and patients in the face of medical limitation. Hippocrates advised physicians in such cases to refuse to treat those who are overmastered by their disease, realizing that in such cases medicine is powerless (Hippocratic Corpus, 1967). Modern medical technology has not only provided opportunities to save countless lives and relieve suffering, it has also fed people's compulsion to preserve life - even at a great cost and when most people would conclude that no good is served. Medical futility is also taking well established ethical principles, such as self-determination and the patient's autonomy into a new domain. For instance whether a patient's right to refuse treatment entitles them to demand more intervention that is deemed to be futile in the health provider's view. The decision to withdraw or withhold therapy in critically ill patients is complex. In practice, conflicts may arise when physicians and patients differ on the goals of treatment and care providers do not agree with patients or their families that requested therapies are in fact beneficial and resist such requests on the basis of medical futility. Dealing with futility in medical care requires not only an in-depth understanding of the patient's medical condition but also an intimate understanding of the patient's desires and those of the family.

Concept of Medical Futility

Medical futility is viewed very differently by various commentators and numerous definitions of futility have been proposed but none have been universally accepted. In one definition Nelson and Nelson (1992) described the concept of futility as any effort to achieve a result that is unreasonable or impossible. This definition was intended to cover treatments that: (i) will not serve any useful purpose; (ii) cause needless pain and suffering; and (iii) do not achieve the goal of restoring the patient to an acceptable quality of life. In another proposed definition futile treatments are those which fail to provide a benefit to a patient (in terms of comfort, well-being, general health, etc.) even though they may produce a measurable effect Schneiderman and Jecker, 1995).

In supporting physicians unilateral decision making Howard Brody (1992) notes that: "The physician must decide unilaterally whether a treatment possibility comes up to the mark as proper scientific medical practice... when an intervention is futile, the physician may and indeed should withhold it regardless of the patient's request. Someone who calls himself a physician, but who is constantly willing to compromise on valid modes of treatment in order to satisfy the wishes of the patient, is a fraud".

Following is also the statement of the American Medical Association: "The right of the patient to choose does not imply the right to demand care beyond appropriate options based on medical judgment and accepted standards of care..." (Council on Judicial Affairs, 1992). In other words, there is no professional or moral obligation to offer or provide treatment that is determined to be futile according to the standard of care.

Opponents of medical futility

The opponents of medical futility argue that the heart of the futility debate is a debate about power:

* Paper presented at the First UNESCO Bangkok Bioethics Roundtable, September, 2005

who should have it, and how it should be exercised (Rubin, 1998). Yet another commentator said that medical futility was constructed, in part, as a means of enhancing the physician's domination of a context wherein medical authority was threatened (Carnevale, 1998). They characterize medical futility as nothing more than a cover for the physician's reargued action to regain the dominance in decision making that they possessed before autonomy and informed consent shifted authority to patients and their families, a trend that emerged in the 1960s.

For instance, with reference to the fact-value distinction Susan Rubin distinguishes two kinds of futility - Evaluative futility and Factual futility. Evaluative futility; when futility operates as a primarily evaluative judgment, it is understood to mean that a treatment is inappropriate because it would just not be worth it. Factual futility; when futility operates as a primarily factual judgment, it is understood to mean that a treatment is ineffective because it would just not work. She endorses that even the so-called factual judgment of futility have evaluative components. Rubin argues "...that physician unilateral decision making on the basis of futility is a problematic and misguided approach to the challenge of setting appropriate limits in medicine". She believes we have been distracted from the meaningful debate about the underlying ethical conflict concerning fundamental differences in view and interest between patients, their families, and their physicians by mistakenly turning to the concept of futility. By rejecting the language of futility she urges us to argue more forthrightly and precisely about the moral appeals at stake between patients and those responsible for their care (Rubin, 1998).

Opponents are also concerned that the concept of medical futility may be seized on by some physicians as an excuse not to discuss with patients or surrogates their decision to withhold certain medical procedures and that it will also become a powerful tool for relieving physicians of the requirement to talk with their patients (Wolf, 1998).

Some Other Opinions

The above opinions lie at two extremes of the spectrum, one giving the physician the ultimate power of decision making about medical futility and another that denies the validity of such a concept in medical practice. There are other commentators who accept the concept of medical futility and believe that it should be addressed properly to solve the conflict between doctor and patient in decision making. They hold that "Because futility determinations... combine technical considerations, patients' values, and clinical judgments, the framework for these determinations should be one of shared decision making" (Lantos, et al., 1989). However, the practical question remains that if all parties involved (doctor/patient/family) profoundly disagree, is shared decision-making possible?

In another formulation, Tomlinson and Brody advocate physician authority over futility judgments, but suggest that this authority should be derived from an ongoing social dialogue. To answer the most important question: "Which value judgments physicians may use in deciding whether to meet patient's demands?" They propose a social mechanism to achieve mutually agreed-upon standards not simply a situation where doctors impose their values on patients. In that sense physicians can say "that treatment to preserve the life of someone in a persistent vegetative state is qualitatively futile, but done so on the basis of societal generated standard" (Tomlinson and Brody, 1990).

Finally in a detailed analysis of the issue, Robert Veatch categorized futile cases in three groups. First, those in which demanded treatment is physiologically futile, the second, those cases involving competition for scarce resources and the third, those in which the treatment would likely achieve the patient's goals although the clinician perceives those goals to be valueless. He argues that clinicians should unilaterally refuse the first but do not have legitimate roles in blocking access to the second and third. He proposes that use of scarce resources should be structured by a health system and the two last groups of treatment can produce results desired by the patient. (Veatch, 2005).

Conclusion: The Necessity of Policy Development

Existing controversy over the proper ends of medicine can be cited as an obstacle to regulating medical futility. A long lasting controversy over medical futility implies that doctors and patients will remain locked in a never-ending struggle. However, regulating medical futility will ease the tension in a clinical setting especially in decision-making at the end of life. A critical point nowadays, facing escalating health costs and scarce resources, is whether providing particular care which is deemed futile is in conflict with societal interest or not? Particularly in scarce resource communities, establishing just mechanisms to deal with medical futility may limit the use of expensive treatments of marginal benefit in order to assure that we can provide adequate medical care for all members of our society. Formulating medical futility cannot be developed independent of: i) medical facts; ii) normative values and; iii) socioeconomic considerations. Any attempt to develop an operational definition or guidelines must include patients' and families' opinions. What is needed is; neither excessive patient autonomy nor physicians paternalism. A genuine dialogue among all parties involved is crucial for policy development.

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Bioethical Issues in Nursing*

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Nursing is both an artistic and scientific profession which emerged in a more primitive era when a family unit was the primary source of health care for sick family members. Nursing became a recognised vocation as professional ethics developed, and in advanced societies it expanded into schools, factories, hospitals and into patients' homes.

The code of ethics for the profession developed in the 18th century

In 1893 Florence Nightingale developed the "Nightingale Pledge" which stated that:

- 1) A nurse will pass her life in purity;
- 2) Abstain from whatever is deleterious and mischievous;
- 3) Will hold in confidence all personal matters committed to her helping,
(Peterson and Potter, 2004).

These pledges formed the core code of ethics for nurses for many years. They were formalised by the International Council of Nurses (I.C.N.) in 1953 and have since been revised and reaffirmed at various times, most recently with a review and complete revision in 2005 (I.C.N. 2005). The elements of the code were:

1. Nurse and People
2. Nurse and Practice
3. Nurse and the Profession
4. Nurse and Co-workers

In this article I only reproduce the code concerning nurses and people. (I.C.N., 2005), which included:

1. Respect of human right values, customs and spiritual beliefs of the individual, family and community;
2. Ensure that the individual receives sufficient information on which to base consent for care and related treatment;
3. Hold personal information in confidence and use judgment in sharing this information;
4. Share with society the responsibility for initiating and supporting action to meet the health and social needs of the public in particular those of vulnerable populations;
5. Share responsibility to sustain and protect the natural environment from depletion, pollution, degradation and destruction.

* Paper presented at the First UNESCO Bangkok Bioethics Roundtable, September, 2005.

Ethical dilemmas in nursing for discussion are as follows:

1. As people migrate all over the world, unskilled labourers from under-developed or developing countries migrate to more developed countries. The nursing curriculum does not yet prepare nurses to serve multicultural clients;
2. The Thai government launched a “30-baht scheme For All” treatment policy in 2002. This policy caused the influx of a huge number of patients, both outpatients and inpatients, into hospitals - and with a smaller ratio of nursing staff to patients, important questions over the quality of care were raised;
3. The rapid increase in the number of elderly persons in Thailand has put major stress on health care. Eighty per cent of patients in medical units are elderly and hospitals have not yet provided facilities that are appropriate for these elderly people. Changes that are needed include the introduction of low-level beds, brighter wall colours, bathroom rails, etc. Nurses need to spend more time communicating with these elderly people as most of the care that is provided is just routine adult care.
4. For HIV/AIDS patients, even though stigmatization has decreased, there are some situations where HIV/AIDS patients still do not receive good care. For example, they may be placed in the corner of the unit because of tuberculosis complications. In a situation like this, these patients will feel social isolation. Because of a shortage of nursing staff the psychological and spiritual care is not sufficient for them.
5. In organ transplants there are some ethical dilemmas. Nurses who do not believe in organ transplants may have to ask for organ donations or provide care for organ transplant patients. Another dilemma is the high standard of care needed for the donor after the removal of organs.
6. Another dilemma to be concerned about is environmental pollution caused by the use of disposable medical and nursing equipment. Large numbers of disposable tubes, syringes, needles and bottles are thrown away after just one use. One can imagine how this will pollute our world because these, largely plastic items, are not bio-degradable.

The nursing profession is a profession dealing with human life. Therefore nurses need to practice good ethics and good standards. Ethical nursing dilemmas arise because of scientific, technological and social changes. Professional nurses should find the best way to provide safe, quality care, with ethical principles for the benefit of the patients under their care.

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Impulse of Ethical Research in Life Science and Health Systems: Foundation for development in sub-Saharan Africa*

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Introduction

Many people in the developing world, especially in sub-Saharan Africa, suffer from poor health and reduced life expectancy (Sanchez and Swaminathan, 2005). With just 10 years left to achieve the Millennium Development Goals (MDGs), a greater sense of urgency is needed by all sides if the targets are to be met (Sachs and MacArthur, 2005). Some sub-Saharan African countries are making substantial progress toward the MDGs as a result of improved policies, better governance, and the productive use of development assistance. But they could do with more adequate policy reforms and additional help. Scaling up efforts to meet the MDGs by 2015 present both opportunities and challenges (Commission for Africa, 2005). Furthermore, the role of research that contributes to the development of appropriate treatments and disease prevention measures is vital (COHRED, 2000; International Monetary Fund, 2004). However, a lack of resources and poor infrastructure means that many researchers in sub-Saharan Africa have a very limited capacity to conduct their own biomedical research. They therefore often undertake research in partnership with groups from developed countries. A sound ethical framework is a crucial safeguard to avoid possible exploitation of research participants in these circumstances (Nancy, 2004). My article will review and discuss four issues: (1) current public health related issues in sub-Saharan Africa; (2) what is the real problem?; (3) how might this problem be solved and moved ahead; (4) why do we need to promote and develop bioethics Education/Training in the context of ethics of research related to healthcare in African's universities and among Sub-Saharan communities?

Health-related issues in most of sub-Saharan African countries remains unfulfilled

The review of relevant health indicators in the majority of sub-Saharan African countries show that most, if not all of them are unfulfilled. Some examples to illustrate this sad situation follow: According to United Nations specialized agencies (UNICEF, WHO), among 27 million infants not immunized by DTP3 in 2004, one-third were in sub-Saharan Africa which represents less than 10% of the world's population; four million deaths of infants less than five years old are due to vaccine-preventable diseases. There is a stagnation of the reduction of both maternal and neonatal mortality and the rate of elimination of both maternal and neonatal tetanus is less than 50%. Furthermore, major outbreaks are still out of control in sub-Saharan Africa. For example, malaria and tuberculosis remain burdens and represent major public health issues in the majority of sub-Saharan African countries. The impact of HIV/AIDS on the development of sub-Saharan Africa is catastrophic. According to UNAIDS data, if no significant action is undertaken over the next decade, the percentage of the workforce lost due to AIDS from 2005 to 2020 will be multiplied by two and up to 30%. Unfortunately, a HIV preventive vaccine will not be available for the next 15 years.

This dramatic situation questions the real impact of the Alma Ata declaration (1978) on primary health care, 30 years later. Since of the eight goals set by the MDGs, three are directly related to health, (e.g: control/eradication of the burden of diseases: HIV/AIDS, tuberculosis (TB), and malaria), the success of these three goals are seriously compromised. Therefore, what will happen with emerging diseases?

* Paper presented at the First UNESCO Bangkok Bioethics Roundtable, September, 2005.

The WHO predicts that by 2020, two-thirds of diseases in the world will be related to non-transmissible diseases (e.g.: diabetes, cardiovascular diseases and other non transmissible chronic diseases)? These diseases will heavily increase Africa's burden.

What is the real problem?

The bottom line is the lack of financial and human resources, coupled with pertinent data on the sanitary situation. The limitation of resources in the context of the marginalization of sub-Saharan Africa with the fatal indifference increases the disparities/inequities in health between the North and South (Gap 10/90).

According to specialized agencies (OECD, UNDP, World Bank), the gap between the North and the South has multiplied by 30 over the last 20 years.

b) At the same time, there is also the absence of adequate health systems capable of delivering interventions to the most affected people in need.

c) The current situation on ethics of research related to healthcare in sub-Saharan Africa

Collaboration North/South, as discussed above is as follows: the lack of resources and weak infrastructure mean that many researchers in sub-Saharan Africa have a very limited capacity to conduct their own biomedical research. Therefore, most of the research, even in tropical diseases, is often undertaken in partnership with groups from developed countries and obviously not based on sub-Saharan public health priorities.

In the context of the globalization of economy and the absence of adequate structures in charge of ethics clearance of research protocol (REC, IRB) in most of the African countries (Sources Welcome trust, WHO, UNESCO), there is a real risk of conducting a clinical trial without minimal precautions and control (namely, informed consent, use of placebo, responsibility to adverse effects or incidents, sharing of benefits of clinical research after research completed and intellectual properties, etc.).

How to solve the problem and move ahead?

There is obviously no miracle solution to increase the health status of African people in the near future. However, some actions could immediately be undertaken which might lead, in a reasonable period of time, to the improvement of living conditions in sub-Saharan Africa. Specific research is required to help overcome these systemic issues in sub-Saharan Africa. The development of a health policy and systems research will produce knowledge which will lead to the real priorities, determine ambitious and pragmatic strategic policies and courageous and realistic action plans (with good cost/efficacy balance). Furthermore, African researchers need to consider the permanent dialogue, monitoring and evaluation based on scientific considerations in order to evaluate the real impact on the target population (vulnerable and poorest people) and adapt strategies and activities. Taking in consideration to the above points, I think that the strengthening of sub-Saharan health systems should be based on scientific research with well defined and accepted ethics values, regulations and guidelines. All of these measures will lead to good and appropriate research.

The implementation of the action plan should be executed step by step with the following three levels:

- Setting up scientific research based on the health systems in Africa;
- Strengthening Health Research Systems;
- Creating the means and tools to link research and action.

Why do we need to promote and develop bioethics education/training in the context of ethics of research related to healthcare in African's universities and among sub-Saharan communities?

One of the most important messages emerging from the reflections and reports published on African's development over the last five years, has been the necessity for a transition from short-term disaster relief to long-term approaches based on partnership, education/training and economic development that allow sub-Saharan African countries to build on their strengths and transform their economies (Juma, 2005; Commission for Africa, 2005). Central to this transformative agenda will be the role of science, technology and innovation, both as a driver of economic growth and healthcare improvement within these countries (Juma and Lee, 2005). In order to achieve this goal, more attention should be paid to the importance of building competence by education and the training of ethics of research related to healthcare in Africa's universities and among sub-Saharan communities. This will serve as a foundation for the development to promote economic growth through science and technology (Amonoo-Neizer, 1998; Juma, 2005; Commission for Africa, 2005).

There are at least three reasons to urgently implement solid learning of bioethics in sub-Saharan African countries:

- (a) Because the discovery of bioethics will enable individuals to acquire the concepts of heuristic methods in which the social and cultural context are essential;
- (b) Because progress in life science and technology disciplines have a direct impact on people's life on several levels. Social and economic choices relate to the definition of priorities, and the repartition of health resources: principle of responsibility and social solidarity. Also choice about the type of development includes the social impact.
- (c) Because bioethics encompasses health and research issues the discipline can constitute a framework including values of democracy, multidisciplinary and the respect of diversity, moral responsibility, and promotion of individual freedom, which lead to new types of organization of the collective life.

Furthermore, sub-Saharan Africa is more concerned about certain outbreaks (for example, hemorrhagic fever from the Ebola virus, malaria, tuberculosis, HIV/AIDS, etc). Indeed, the involvement of the African community in clinical trials and other research is a necessity to develop specific policies and new medicine in order to fight these burdens.

Conclusion

In sub-Saharan Africa where cultural identity has been denied through European colonization, the creation of research programmes - based on cultural and ethical concepts - must take into account other African specifics such as anthropology, sociology and the economy in order to help to solve some health problems and challenges related to Africa's development.

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Capacity Building of Research Ethics in China*

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Two thousand years ago a system of medical knowledge, now called Traditional Chinese Medicine (TCM), was established on the basis of the theories of Yin Yang and five elements, namely metal, wood, water, fire and earth. There is no tradition of human experimentation as well as human anatomy in TCM.

Medicine without the Tradition of Human Experimentation

According to a Chinese legend the Father of Chinese medicine (also the Father of Chinese agriculture), Shennong, "Tasted a hundred species of herbs and exposed himself to seventy kinds of poison a day" (Huainan Zi), or "Medicine originated with Shennong who tasted a hundred species of herbs." (Shi Ji, Records of Historians). However, traditional Chinese medical texts have no word for "experiment" or "research". Practitioners of traditional Chinese medicine (TCM) never performed human experiments in the modern sense in its 2000-year history.

There are two factors in Chinese culture, one epistemological, and the other ethical, that may explain why human experimentation was never invented in TCM. All three main schools of philosophy, namely Confucianism, Taoism and Buddhism, developed an internalist approach to epistemology, or "seeking the truth from within" - the concept that knowledge is gained from introspection rather than by observation. One of the founders of Confucianism, Mencius, first advanced the concepts of innate ability, which is acquired without learning, and innate knowledge, which is possessed without deliberation, and the thesis that "All is complete in me" (Chan, 1963, pp. 80, 82). The proponents of the school of xin (mind) argued that li is inherent in the mind, but it is concealed by wrong ideas, and li will be manifest only after correcting the wrong ideas (Chan, 1963, pp. 588-691). Taoists (Guang Zi) and Chinese Buddhists developed a similar internalist approach. The Zen Master Huineng taught that "Perfect wisdom is inherent in all people. It is only because they are deluded in their minds that they cannot attain enlightenment by themselves. Calmness and wisdom are foundations of my method." (Chan, 1963, p. 433). This internalist approach to the theory of knowledge has had a great influence upon traditional Chinese science and medicine.

The second factor incompatible with human experimentation is the ethical factor. The most popular Confucian ethical principle among the Chinese public is filial piety. According to this principle: "Hair and skin, which are imparted by parents, must not be damaged. This is the beginning of filial piety" (The Book of Filial Piety). How can you expose risks to your body that is imparted by parents for the benefits of others? (Qiu, 1992)

Phobia to Research and Experiment

However, these two factors are inadequate to explain the phobia to "research" or "experiments" among the Chinese public. Against this cultural background there has been a historical factor. Before the occupation by the Japanese army, the US medic, Dr. Lehman (Department of Neurology, Peking Union Medical College Hospital) recruited Jinrikshaw for two dollars a day to conduct experiments to induce epilepsy through the use of cardiazol. There was no disclosure of information and free consent. The whole process of the subjects' painful convulsion was filmed.

More serious is the Japanese Unit 731's inhumane experiments. The Japanese Army's Unit 731 headed

* Paper presented at the First UNESCO Bangkok Bioethics Roundtable, September, 2005.

by Ishii Shiro in Pingfang near Harbin was equipped with 4500 incubators and could produce masses of microbes, equivalent to 300kg of plague bacteria or 1000kg of cholera bacteria per month. The victims (the so-called “logs”) were recruited mainly from the secret prison in the Japanese Consulate and the city jail in Harbin. They were shipped in bags, wrapped in straw, or transported by special vehicles, to special prisons in buildings seven and eight by way of a secret tunnel that led from the administration unit’s office. From 1940 to 1945, at least 3,000 people died during experiments carried out by Unit 731.

These inhumane experiments included the following activities. (1) Bacterial experiments in humans: the victims were forcefully given plague, cholera, typhoid, diphtheria, or tetanus bacteria through flea bites, injection, or drinking bacteria-contaminated water or milk; (2) Live dissection: After being infected with bacteria, the victims were taken to operating tables. Without any anaesthesia, the artery in the neck was cut to drain the blood into a container and an incision was made from the thorax all way down to the lower abdomen. All the viscera and the brain and spinal cord were taken out for further examination; and (3) Human experiments in the field: These included bacterial and freezing experiments. Every year in the coldest months, some “logs” were taken outdoors, forced to soak their hands in cold water and then made to stay outdoors with wet hands below -20°C for long periods to study the extent of their injuries. A combined experiment was also undertaken to test the effectiveness of gas gangrene or anthrax in extreme cold temperatures. The victims were bound to a stake with their legs and buttocks exposed, and ceramic bacterial bombs were exploded near the victims. In one such experiment, all 10 subjects died of gas gangrene “in great torment” over a period of seven days. (Harris, 1994). I would like to point out that these crimes were committed by the Japanese wartime government, and have nothing to do with Japanese society today, nor the Japanese general public during the war time era.

Why was there no “Tokyo Code” in contrast with the “Nuremberg Code”? The reason is that it was covered up by the US government because it needed Unit 731’s data on human experiments. We can see that for Japan militarists, the value of Chinese human life “log” is lower than that of the Japanese, and thus, in their view, they did not deserve to be respected and be protected as Japanese nationals did. And as for the US authorities, data or information on germ warfare experiments was more important to them than retribution for the abuse of human life. Thus the victims in Unit 731 probably had less value than the victims of the Nazi regimes’ experimentation programme. We can see clear cut racism in the treatment of Unit 731 victims. All authorities should face history and reality, and give up double standards.

Imperative or Option?

Jonas argues that all non-therapeutic research involving human beings infringes the individual’s “primacy inviolability” in Kantian terms. He also objects to the use of a person as a means rather than an end (Jonas, 1967). However, it can be argued that the use of a person as a means rather than an end only in a case in which there is no informed consent. Voluntary participation in non-therapeutic research as a subject is an action for human solidarity and makes a contribution to science. Why should we not praise such altruistic action?

Suppose that there are two worlds. In World A there is no research involving human subjects. Consequently, there are no risks for human subjects. However, because there are no efficacious drug discoveries, there are higher risks and costs to the whole of society. In World B there is such research, so there are some risks for human subjects, but a lower risk for the rest of society. Which do we prefer: World A or World B? ²

Before the introduction of clinical trials into China, she fell into the World A category. The results of precluding human experimentation for a long period are serious. In the early 1950s, in a movement called “Learning from the Soviet Union”, Felatov’s tissue therapy was used throughout the country; some doctors even used it to treat pneumonia, with fatal results. During the Cultural Revolution officials of the Ministry of Health called for health workers to spread some favoured therapies (e.g. bitter), as though it could cure all diseases. Also, in promoting acupuncture anaesthesia, they demanded its use in 90% of operations. This led to negative consequences, including the death of patients. Although

² The Two Worlds’ argument comes from Professor Dan Wikler’s lecture at Harvard University.

we should not neglect valuable folk therapies which people discovered by trial and error for treating illnesses that doctors could not cure, if they are to become optional therapies in medicine, they must be tested on animals and humans by scientific methods. Apart from that, a few medical researchers tested herbs or new drugs on themselves. Following Shennong's example, some bare-footed doctors tested herbs without precautions and died of poisoning. Also many kinds of new drugs that had been manufactured were used in clinics without human experimentation and widely advertised in newspapers. The advertisements cited favourable responses of patients and physicians, intended to induce other physicians to use the drugs.

From our experience we have to agree with Engelhardt (1986) when he argued that one need not only fear the reckless use of humans in medical research, but that one should also fear the costs of reckless treatment - treatment not based on adequate research (p. 291), and that research is integral to a beneficent medicine, and medicine unexamined through systematic research may be a danger to patients (p. 292).

So the conclusion is that research involving the human being is imperative.

Setting SFDA

If research involving a human subject is imperative, how can we regulate it? In 1999 the State Drug Administration (SDA), was changed to the State Food and Drug Administration, (SFDA). After the SFDA was established Good Clinical Practice (GCP) Regulations on Drug Clinical Trials were promulgated. In GCP it is stipulated:

"All research involving human subjects must comply with the moral principles laid down in [the] Helsinki Declaration and CIOMS's International Guidelines on Biomedical Research Involving Human Subjects, i.e. justice, respect for [the] person, maximization of benefits and avoiding harms as less as possible.

"Strict review by ethics committee and normative process of informed consent are major guarantees of protecting subjects' rights and interests."

Almost 200 IRBs were set up according the regulation.

Rights of Human Subjects are stipulated as follows:

- Right to free participation and withdrawal at any stage of trial;
- Right to confidentiality;
- Right to be informed;
- Right to consent;
- Right to compensation when injury associated with the trial.

In March 2005 in a report of the national survey conducted by SFDA it was revealed that there were the following problems:

- Drug clinical trials conducted by unauthorized and unqualified institutions;
- Non implementation of GCP:
 - Malfunctioning of IRB
 - Revised protocols were not reviewed
 - Process and form of informed consent inadequate
 - Protecting subjects' rights and interests inadequate
 - Adverse events were not reported
- Inadequate monitoring and inspection
- Regulation on Monitor and Inspection of Drug Research is being drafted.

Case 1 shows that even if there is good GCP, the implementation can be different.

Case 1: New Drug for Osteoporosis

A US company requested a set of hospitals to conduct clinical trials of a new drug to treat osteoporosis which had been approved by the SFDA. The protocol presented by the sponsor includes: randomized, double-blind and control study. Both groups were provided with calcium and vitamin D. The duration of the trial was one year. The IRB of PUMC Hospital rejected it and suggested that the controls use the best proven therapy, but IRBs of other hospitals approved it.

In China the SFDA and the Ministry of Health are separate. The MOH drafted a regulation titled “Guidance for Ethical Review of Biomedical Research Involving Human Subjects” in 1998 and established its Ethics Committee on Biomedical Research Involving Human Subjects. This reviewed protocols in regard to programmes sponsored by the MOH. However, because of different opinions the draft has not been disseminated or published, although the draft was revised recently. Hopefully it will be promulgated as an official regulation on biomedical research involving human subjects.

Problems in Ethical Review Committee and Ethical Review

According to our experiences in attending ethical review committee (ERC) meetings and reviewing protocols, the problems in ERC and ethical review include:

- Therapeutic misconception is popular, research combined with treatment in particular.
- No non-scientist or non-professional members in the ERC;
- Members of ERC are mainly chairpersons of departments in hospitals, and chair/vice chairs of ERC are directors or vice-directors of hospitals;
- Only reviewing the protocols of international projects and not domestic projects. When PIs of domestic projects want to publish their papers, only then do they think of sending their protocol to ERC to be reviewed;
- ERC don't know how to review according to national regulations and international guidelines;
- Ethical review in some ERCs is just a rubber stamp: protocols are never rejected, no revision is made;
- In the protocol presented by PI, there was no content of an informed consent process, ERC only conducted a scientific review;
- Regarding the informed consent form, No clearly specified human subjects' rights existed, the title is “Notice to Subjects”;
- No monitoring after review;
- No monitor and inspection to ERC, etc.

Capacity Building Activities

From the discussion above it is clear that the capacity building in research ethics is a very urgent task for scientific regulatory bodies, as well as for bioethicists if the latter really want to leave their ivory towers and do something good for society. It is why my colleagues and I have spent a lot of energy and time to do capacity building in recent years. The following are some capacity building programmes and activities we have conducted in recent years:

- International Biomedical and Health Research Ethics Programme, sponsored by NIH: three workshops on biomedical and health ethics were organized by the Harvard School of Public Health and Shanghai Medical School, Fudan University, Research Centre for Bioethics, Chinese Academy of Medical Sciences (CAMS)/Peking Union Medical College (PUMC), and Centre for Bioethics, Huazhong University of Science and Technology (HUST) in Shanghai, Beijing, Wuhan, 2004-2005 respectively, The main organizers of these workshops are Zhu Wei, Zhai Xiaomei and Qiu Renzong respectively.
- Bioethics Leadership Programme, sponsored by the Chinese Medical Board (CMB): Three workshops on research ethics were organized by Peking University Health Science Centre (PUHSC) in Hangzhou, Chengdu, Xi'an, 2004-2005, The PI of this programme is Qiu Renzong.
- Chinese Centre for Disease Control (CDC) organized a series of training workshops on research ethics

focus on HIV/AIDS in Beijing, Yunnan, Anhui, Guangxi, Sichuan, Shanxi, etc between 2003-2005. The organizer was Zhai Xioamei.

Some provincial or municipal governments and institutions also took initiatives in capacity building, e.g. Shenzhen, Kunming etc.

Main topics of these training workshops includes:

- Historical Lessons
- Basic Ethical Principles
- Ethical Issues in Research Design and Selection of Subjects
- Informed Consent
- Confidentiality
- IRB and Ethical Review
- Responsibilities to Communities
- Ethical Issues in Clinical Trials
- Ethical Issues in Human Reproductive Research
- Ethical Issues in Genetic Research
- Ethical Issues in HIV/AIDS Drug and Vaccine Research
- Scientific Integrity and Misconduct

The teaching method at these workshops includes:

- Lecturing
- Case Discussions
- Exercise of Writing Informed Consent Form
- Mock Review
- Complete Questionnaires

Departments separate

The departments involved in human research including SFDA, MOH, the Ministry of Science and Technology (MOST) and the State Commission Population and Family Planning (SCFPF) are fall under State Council (central government) but are also separate. The Chinese Academy of Science (CAS) is also involved in human research. But only SFDA has GCP - MOH has a drafted GCP, which is not officially promulgated yet. So the central government needs an Ethics Committee or Commission, and a regulation covering all departments.

Cases of Research Ethics

The following cases highlight features of research ethics discussions in China in recent years.

Case 2: Treatment of Esophageal cancer

In 2003, volume 75 of a US journal paper: "Value of Radiotherapy after Radical Surgery for Esophageal Carcinoma - A Report of 495 Patients" was published by researchers at the Institute of Cancer Research, CAMS. The editor added a note in which he wrote that the paper had violated a very important ethical standard - patients were not informed and therefore they expressed their voluntary consent. Before the paper in the same issue there was an article titled: "Unethical Research: the Importance of Informed Consent", in which the author argued that it was a case of unethical research. He said it was understandable because it happened in an authoritarian country with political oppression, social control, violation of human rights and coerced sterilization and abortion etc. Another author complained and said that she could not understand why the research was labelled unethical, because she claimed she and her colleagues had been working hard to relieve patients' sufferings.

Case 3: Detoxification by Brain Surgery

In the past, numerous hospitals in China developed a form of treatment in which drug addiction was treated through brain surgery. The rationale being that a reward system exists for drug use in the brain and this system is located somewhere in the region of the accumbens septi. The theory was that if the part of the brain associated with drug addiction was successfully removed, the addiction - psychological addiction in particular - would be removed too. Altogether, 738 drug users underwent the operation in more than 20 hospitals across China. However, the part of the accumbens septi was identified in different ways, so what was removed during the operation was not universal in hospitals across the country. At an expert symposium under the sponsorship of the MOH on March 2-3, 2005, six hospitals reported their findings with different parts of the accumbens septi removed. All of them claimed that the efficacy rate was almost 85%. The symposium ended with the MOH's announcement that the surgery was to be prohibited. Meanwhile, the S Hospital in G Province successfully applied to the Provincial Bureau for Health for a research grant to treat drug addiction with brain surgery. They claimed there were 1,000 cases in which some part of the accumbens septi was removed and drug addiction was successfully treated. While recruiting human subjects they emphasized that there was no alternative to treat drug addiction except through brain surgery, and that the efficacy rate was almost near 90%. Many drug users went to the hospital to apply for surgery. They and their families were requested to sign a form admitting them to hospital and each patient had to pay 20,000-40,000 yuan. The follow-up time was only three months. Medics claimed that the efficacy rate was at least 85%.

Case 4: AIDS Drug Trial

A US drug company contacted China's CDC to request that clinical trials for a new drug for AIDS be conducted in China. They agreed to pay all the costs, the CDC agreed and the trial was conducted in Yuetan Hospital. When the staff went to Henan rural area to recruit test subjects, they discovered that AIDS patients were eager to participate in the test. One standard of enrolment was a cell count CD4 below 200, but some subjects were only 50. The trial revealed that the drug was not so effective, and two subjects died after they returned home, but it was not related to the drug, e.g. one of them died from suicide. The advocate claimed it was fraud, and complained to the CDC. The latter invited the ERC of the Centre for HIV/AIDS Prevention and Control to investigate the case. At the meeting researchers, four representatives of subjects and the advocate were requested to present their testimony on the process of informed consent. The detailed description of the informed consent process presented by the researchers was not questioned by subjects and the advocate. So the ERC concluded that there was no serious violation of ethical requirement of informed consent. But the advocate was not convinced. Nevertheless, the researchers should have been more alert when the AIDS patients were in a desperate situation (before the government was committed to providing free anti-virus treatment to the AIDS patients). The patients had a therapeutic misconception and they were more likely to express consent without carefully reading and considering the meaning of the information the researchers had disclosed. They were also afraid of losing a rare opportunity to be treated free of charge. In this circumstance, the researchers should have been more careful and explained the information to prospective subjects to help them understand the implications of the test.

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Current State of Research Ethics in Developing Countries: Where Do We Stand?*

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Introduction

Two thirds of the world's total population lives in developing countries, so the disease burden is high in these countries and their requirement for biomedical research is proportionately significant (Editorial, 2004). A wide discrepancy is found between the burden of disease in developing countries and the quantity of bio-medical research that is committed to combat the diseases of these developing countries (Gilman and Gracia, 2004). In this regard, it is noteworthy to mention that 93% of the world's burden of preventable mortality occurs in developing countries, but too little research is focused on health problems in those countries (Sumathipala et al. 2004). In the developed world, particularly in Europe and North America, bioethics has already achieved a strong position in health sciences. On the contrary, the situation is quite dissimilar in many developing countries (Ogundiran, 2004). However, the main objective of this article is to illustrate the current situation on ethical issues in bio-medical research in developing countries along with focusing on the ways and means to ensure its implementation.

Inadequate knowledge and awareness on research ethics

In developing countries, one of the key difficulties faced by ethical review committees is the limited number of people trained in medical ethics. Even researchers are not well exposed to the principles of research ethics. In some countries, although there are a few training programmes in research ethics, these are still insufficient to meet the growing need for an ethical review process (Bhutta, 2004).

In a recent study, conducted among a group of Bangladeshi physicians, it was revealed that the biomedical researchers, particularly medical practitioners did not possess sufficient knowledge about ethical components of research ethics (Hossain et al. 2005). Moreover, in developing countries, obviously the need for training and education in basic research ethics has grown over the past few years. Research organizations and educational institutes are facing the challenge of providing this training due to limited resources and lack of training kits (Rivera et al., 2005). Most of the ethical review committee (ERC) members in developing countries have little opportunity to be educated on how to determine the application of broad ethical codes in certain cases, for example, those related to the standards of care to be provided to participants during and after clinical trials (Hossain et al. 2005).

Exploitation of research subjects

It is a common practice in developing countries to carry on bio-medical studies like clinical trials without taking informed consent from human subjects, which is a serious offence according to the Helsinki Declaration and the Nuremberg Code. It becomes possible because study subjects are easily exploitable

*Paper first presented at the First UNESCO Bangkok Bioethics Roundtable, September 2005.

due to their illiteracy, poverty, unemployment, lack of consciousness etc.

The Helsinki Declaration has already established the ethical principles for research with human subjects worldwide and it has focused on a vital issue that the well being of human beings should always come before the interests of science and that of society. Research proposals must include this commitment, both in developed and developing countries, but in some developing countries such as Argentina, Brazil and Mexico, much of the population face odd experiences, great injustices, including a lack of equal access to health care (Angeles-Llerenas, 2004).

When a multinational research project is conducted in a developing country, in most cases, the investigators or sponsors from the powerful industrialized country or the giant pharmaceutical company look after the ethical matters. Therefore, a possibility exists to exploit subjects (Macklin, 2005).

Some pharmaceutical industries are offering opportunities for studies in developing countries as well as achieving economic profits, but at the same time these studies carry the risk of perpetuating and even intensifying unjust situations and violations of human rights (Angeles-Llerenas, 2004). Partnerships between developed and developing countries in biomedical research have led to concerns regarding the potential exploitation of resource-deprived subjects. This is because the willingness to volunteer can be influenced by expectation of adventitious benefits, which may make human subjects accessible to unethical research (Hyder et al., 2004). Actually, it has become a common phenomenon that investigators often exploit the disadvantaged and poorly educated subjects in developing countries.

Research ethics in scientific publications

Sometimes even scientific journals, particularly in developing countries, publish articles without asking the author(s) about ethical issues relevant to the performed study. It should be one of the prime responsibilities of the journal editors to monitor the submissions of the papers to their journal and whether there is protection of the subjects' rights in the paper. The editorial process is now widely accepted as the control mechanism for preventing scientific misconduct and preventing the publication of unethical materials (Cowell, 2004).

A study was conducted to observe the ethical issues included in instructions to authors in Brazilian medical journals. Out of 29 journals, 79% contained no recommendations related to ethics. Only 15 wanted the required ethical information to be included in the text, and two wanted a letter from the authors about how ethical standards were followed. The study concluded that Brazilian scientific journals showed little concern for the ethical aspects of scientific research in human subjects (Sardenberg et al., 1999).

Ethical review process and the procedural delay

Although there is a strong demand for sustainable research ethics committees to provide an ethical review of human subject research in developing countries, many developing countries do not have such committees or bodies (Macpherson, 2001). In developing countries, ethical review systems are unfortunately at a relatively early stage of development, and are not so effective. In Pakistan, a recent review of 47 leading health science institutions, showed that only 25% had established full-time ethical review committees (ERCs) and that there was no national ethics review body (Bhutta, 2001). Simultaneously, a review of the status of health ethics among several countries in South East Asia indicated that although a central mechanism for ethical review existed in these countries, it had no adequate capacity at an institutional level (WHO Regional Office for Southeast Asia, 1999).

Selecting individuals from civil society, lawyers or journalists for ethical review work is not so easy, particularly if such work is on a purely voluntary basis. Institutions in developing countries have difficulties in appointing and maintaining ERCs due to limited manpower. Zulfikar A Bhutta from Aga Khan University, Pakistan, stated in a paper that one consequence of the situation is that middle-grade staff may be required to review applications from colleagues in positions of relative seniority and authority. He explained that even if these individuals are appointed, the lack of a culture of questioning and confronting authority, especially at different academic ranks, can pose problems (Bhutta, 2004).

Simultaneously, a review of the status of health ethics among several countries in South East Asia indicated that although a central mechanism for ethical review existed in many countries, it had no adequate capacity at an institutional level (WHO Regional Office for Southeast Asia, 1999).

A study was carried out in some developing countries among 670 health researchers on the issues of ethical review and informed consent. About 44% of the respondents reported that their studies were not reviewed by a developing country ERC or Ministry of Health and one third of these studies were funded by the US. The respondents said that, during the review process, issues such as the need for local language consent forms and letters for approval, and confidentiality protection of participants were raised by US IRBs in significantly higher proportions than by host country IRBs (Hyder et al., 2004).

A few developing countries, including India, Uganda and South Africa, have formulated their own national ethical statements. However, national and international guidelines will not be effective unless countries have appropriate mechanisms for their implementation. Another obstacle to conduct research in developing countries is the complex process of ethical approval for studies from ERCs (Gilman and Gracia, 2004).

Prior to starting a study, taking ethical clearance from an appropriate authority remains a thorny obstacle for researchers in developing countries due to widely practiced corruption, bureaucratic complication, procedural delay and so on, which distract researchers from fulfilling necessary formalities.

Shortage of budget for ethical review

In most cases, international agencies fund clinical research to the institutes of developing countries, but they do not provide the costs for the operation of an ERC. Therefore, the financial burden of such activities falls upon the institution itself. As a result, members of institutional ERCs are often expected to undertake ethical review activities in addition to their own duties, without compensation for their time or effort. This situation creates understandable backlogs in processing of applications and reduces the number of people willing to devote their time and energy to the ethical review process (Bhutta, 2004).

Ethical versus scientific review

Since a significant relationship has been established between scientific and ethical review processes, scientifically unsound research is by definition unethical to undertake. It is not acceptable to undertake unethical research for the purpose of attaining good scientific knowledge. So it is desirable that ERC members should be aware of the scientific design and merit of planned research (Bhutta, 2004). Some of the guidelines show that the role of the ERC should extend to a full scientific review, or at least to ensuring that a scientific review has taken place (CIOMS, 1992). In some cases, there is a lack of consensus regarding the optimal level of scientific knowledge required of ERC members (Bhutta, 2004).

Research ethics: Developed versus Developing countries

It is a common trend that developed countries often design and develop clinical research protocols implemented in Third World countries. In recent years, common practices prohibited in developed and sponsoring countries, such as studies among patients with placebos even though best proven treatments exist; the distribution of drugs unapproved in their country of origin; withholding of existing therapy in order to observe the natural course of infection and disease; redefinition of equipoise to a more bland version, and denial of post-trial benefits to research subjects, are widely seen in developing countries (Kottow, 2002).

Recommendation and conclusion

The current situation of bioethics, particularly research ethics in developing countries, should be improved. Professional and technical assistance and political motivation, both from national and the international community, are vital to changing the situation. We recommend practical strategies to ensure ethical safeguards to human subjects involved in biomedical research in developing countries.

At the same time we encourage initiatives for more research.

More innovative training and education on research ethics should be offered to the prospective researchers in developing countries. A more comprehensive approach to bioethics should be incorporated in formal ethics education in all health-training institutions in developing countries. Further support for ongoing training programmes on ethical issues related to research is essential. Information technology and the Internet can be a good opportunity to build up a rich resource setting for developing countries in the research ethics sector.

In recent years, an increased trend has been observed in international clinical research involving collaboration with developing countries. The role and responsibility of the research ethics committees should be wider and more comprehensive. Local ERCs should be equipped with appropriate financial support and such resources should be built within the projects. A permanent budget for the core ERC costs should be allocated before starting a new study. In addition to ERCs, checkpoints such as scientific journals can also play a vital role in implementing ethical aspects to biomedical research.

Studies with human subjects and ethics remain a paradoxical burden on the researcher in the developing world. This should be resolved. But until then, considering the huge disease burden of the developing world which is to be researched out, we suggest peeling the potato with a fingernail until a knife is available.

The good news is that in some developing countries the situation has improved in recent years with the development of national guidelines for the ethical conduct of research, training of staff and trainers in bioethics. Moreover, several institutions are now developing own training programmes in the research ethics sector and gradually achieving international recognition.

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Informed Consent in Health Research: Current State of Knowledge among Physicians in Bangladesh*

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Introduction

All studies which involve human subjects should be conducted in accordance with the following basic ethical principles namely autonomy (respect for person/subject), beneficence, non-maleficence (do no harm) and justice (Indian Council of Medical Research, 2000). Ethical considerations should not be considered as legal considerations. These are moral considerations that must be kept in mind when undertaking work on, or with human subjects (Khanam, 1998). The purpose of bio-medical research involving human subjects is to improve the diagnostic, therapeutic and prophylactic procedures, and the understanding of aetiology and pathogenesis of diseases (Subrahmanyam, 1999).

Informed consent is a decision to participate in research, given by an individual who is well informed about the research, who has adequately understood the information, who has arrived at a decision without having been subjected to coercion, undue influence or inducement, or intimidation. For all biomedical research involving humans the investigator must obtain the voluntary informed consent of the prospective subject or, in the case of an individual who is not capable of giving informed consent, the permission of a legally authorized representative in accordance with applicable law (Kafiluddin, 2004). An important code of ethics was the Nuremberg Code of 1947. According to this code any research should not proceed on human subjects without voluntary consent (World Health Organization, 2001). This was a consequence of a trial of physicians, who had conducted cruel experiments on prisoners and detainees without taking any consent during the Second World War. The code was designed to protect the integrity of the research subjects, and also to emphasize the voluntary consent of those involved in the research (Kafiluddin, 2004).

The World Medical Association, in association with the World Health Organization, developed an expanded and revised code of ethics called the Declaration of Helsinki to guide physicians in research involving human subjects. In 1975, the 29th World Medical Assembly held in Tokyo, adopted a revised declaration (Helsinki Two), which changed the emphasis from "clinical research" to 'biomedical research involving human subjects' (World Health Organization, 2001).

Ethical codes of conduct should be followed not only when interventions or experiments are planned, but also when social and public health related work is undertaken using only interviews or observation (Khanam, 1998). Every experimental study should be ethically acceptable, subjects should be aware that they have to participate in an experiment, should know how their treatment will be decided and what might be the possible consequences, so that they may withdraw from the trial at any time, and should freely give their informed consent (Abramson, 1999).

Research codes of conduct suggest that the experimental subjects should be fully informed and receive accurate information (Zikmund, 1999). In many countries, informed consent is mandatory for studies on human subjects, unless there is a valid contraindication (Abramson, 1999). The Nuremberg Code of ethics stressed that all subjects involved in the research should have a legal capacity to consent (Tanzania National Health Research Forum, 2001). In non-experimental studies, ethical problems are usually less acute, unless the study involves hazardous test procedures or intrusions on privacy (Abramson,

* Paper first presented at the First UNESCO Bangkok Bioethics Roundtable, September 2005.

1999). As informed consent offers an imperfect safeguard to the study subjects, it should always be complemented by an independent ethical review of research protocols (World Health Organization, 2001).

This study was carried out as a pilot study to assess the current level of knowledge about the informed consent among a group of physicians in Dhaka, Bangladesh.

Objectives of the Study

The general objective was to assess the level of knowledge regarding informed consent as a component of research ethics among physicians from the Bangladeshi perspective. The specific objectives include:

To find out how much physicians know about the fundamental characteristics of informed consent, like the extent of its necessity and importance, documentation format (verbal or written), voluntary or involuntary in nature;

To assess the level of knowledge of the physicians regarding basic elements of informed consent such as explaining to the study subjects about the purpose of the research, expected benefits of the research and clean-cut description of possible risks and discomforts during the study;

To measure their knowledge about maintenance of confidentiality, rights, the well being of the study subjects and compensation for any disability or death during the study.

Methods and Materials

Types of study: Descriptive type, cross sectional study.

Study place: National Institute of Cardiovascular Diseases (NICVD), Sher-E-Bangla Nagar, Dhaka, Bangladesh.

Study period: 16th January 2005 to 15th February 2005.

Study Population: Physicians who were enrolled in the postgraduate courses of all (1st 2nd, 3rd) parts under cardiology and cardiovascular surgery departments of NICVD.

Sample size: The physicians (postgraduate students) who were available during the data collection period. A total of 46 medical doctors were selected conveniently and purposively.

Sampling technique: Non-probability convenience sampling.

Research instruments: A self-administered structured questionnaire. Maximum questions were designed in the Likert scale for measurement of the knowledge-level.

Data analysis: Data was analyzed in a computer by using the SPSS system.

Results and Discussion

The following table illustrates the opinions of the respondents regarding some important components of the informed consent (Table 1). All the physicians (100%) agreed that informed consent is essential. Among them only 65% agreed to that strongly, while 35% just agreed. Most of them (52% + 41% = 93%) commented that study subjects should give informed consent voluntarily. All the respondents (72% + 28% = 100%) remarked that the purpose of the study should be mentioned in informed consent. The majority (39% + 52% = 91%) of the physicians mentioned that the description of expected benefits by the research should be included in informed consent. Though 9% remained confused whether all possible risks/hazards to the subjects should be mentioned clearly in informed consent, most (76% + 15% = 91%) of them were aware of it. While 33% were uncertain if informed consent should include the terms of compensation in case of loss, disability or death of study subjects, but more than half (54%) were strongly in favour of that. Interestingly, all of the physicians thought that the study-subjects should have their confidentiality and/or anonymity ensured. Moreover, 39% (24% + 9% + 7%) did not know

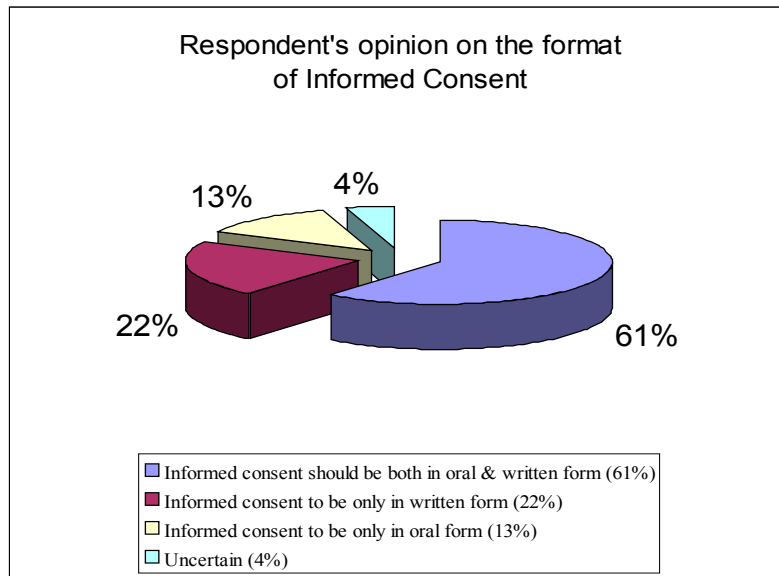
that study-subjects reserve all rights of withdrawing themselves from the study, anytime. On the other hand, 61% (48% + 13%) thought that the subjects have rights to withdraw themselves from the study at any time or at any stage. Most of them (43% + 52% = 95%) either strongly agreed or just agreed that the well being of study subjects should be prioritized over the interest of science. However, 4% disagreed with this. Almost all physicians (except one) stated that an individual can choose freely to participate or not in any study. More than 59% (50% + 9%) were not aware of an important aspect that consent forms need to be submitted for ethical clearance.

Table 1: Respondents' Opinion about Informed Consent (Likert scale based)

	Strongly agreed	Agreed	Uncertain	Disagreed	Strongly disagreed	Total
Informed consent is essential in any bio-medical research						
	30 (65%)	16 (35%)	-	-	-	46 (100%)
Informed consent should be given by study subjects voluntarily						
	24 (52%)	19 (42%)	1 (2%)	2 (4%)	-	46 (100%)
Purpose of the study to be mentioned in informed consent						
	33 (72%)	13 (28%)	-	-	-	46 (100%)
Description of expected benefits by the research to be included in informed consent						
	18 (39%)	24 (52%)	3 (7%)	1 (2%)	-	46 (100%)
Description of discomfort & risk of the study subjects to be mentioned in informed consent						
	35 (76%)	7 (15%)	4 (9%)	-	-	46 (100%)
Compensation for disability or death should be described in informed consent						
	25 (54%)	-	15 (33%)	6 (13%)	-	46 (100%)
Study participants should be assured about their confidentiality						
	40 (87%)	6 (13%)	-	-	-	46 (100%)
Study subjects have rights to withdraw himself/herself from the study at any time/stage						
	22 (48%)	6 (13%)	11 (24%)	4 (9%)	3 (6%)	46 (100%)
Well being of the study subjects should get priority over the interest of science						
	20 (44%)	24 (52%)	-	2 (4%)	-	46 (100%)
An individual can choose freely to participate or not in any study						
	21 (46%)	24 (52%)	1 (2%)	-	-	46 (100%)
Informed consent to be submitted to ethical review committee for approval						
	14 (30%)	5 (11%)	23 (50%)	4 (9%)	-	46 (100%)
In case of children, consent to be obtained from parents or legal guardian						
	30 (65%)	16 (35%)	-	-	-	46 (100%)
In case of married woman, husband should be consulted for consent						
	12 (26%)	23 (50%)	4 (9%)	6 (13%)	1 (2%)	46 (100%)

Figure 1 illustrates that the majority (61%) of the respondents were in favour of informed consent both in the oral and written form, while 22% suggested it be written only. Only 13% mentioned that informed consent should only be in the oral format.

Figure 1: Forms of informed consent



Conclusion and Recommendations

The results show that although the majority of the physicians were conscious about informed consent, a large number of them did not possess sufficient knowledge about basic elements and fundamental characteristics of informed consent. As this particular group of physicians were enrolled in postgraduate medical courses, they had to conduct studies among patients/human subjects to complete their thesis/dissertation as a part of their course. So, prior to starting a study or thesis, it was important for them to be properly trained and knowledgeable in ethical issues of research.

One priority should be to include more details of research ethics in the syllabus of undergraduate and postgraduate medical courses, particularly in developing countries. Dissemination of information regarding necessary elements of informed consent may be conducted through various workshops, seminars and training programmes for the scientists and researchers, who are working in the medical field involving human subjects.

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Utilization of Traditional Knowledge and Support of Access to Health*

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1. Introduction

The last century has brought many achievements in medicine, especially in regard to control of certain infectious diseases, the tremendous developments in immunology leading to organ transplantations and most recently the progress in decoding the human genome. In spite of these accomplishments, both health service consumers and practitioners are not always satisfied. The conventional medical system is often in trouble. At the same time, non-conventional medicine receives great interest from the public and an increasing number of conventional medical practitioners. Its consumption is not limited to certain social classes or to certain countries.

2. Traditional (indigenous) medicine vs. alternative and complementary medicine

Traditional medicine is something pertaining to the core of all cultures, since the dawn of humankind. Traditional healing is not only the solitary source of health care for the majority of the world's population, particularly in rural areas of Asia, Africa and Latin America, it has started recently to be appreciated also as a potential source of remedies for illnesses considered hitherto incurable. The importance of traditional healing methods for indigenous groups is, however, not only practical, it is more often related to a particular cosmology and cannot be dissociated from religious concepts.¹ Traditional health systems take into account physical, mental, spiritual, social and ecological dimensions of well-being, fundamentally trying to restore the balance, which by being disturbed is causing the disease. Treatments are designed not only to address the symptoms but to restore the state of equilibrium within oneself and the environment.

Traditional medicine is based on the principle that each individual has his/her own constitution and social circumstances, which result in different reactions to the causes of disease. Different people may receive different treatments even if, according to modern medicine, they suffer from the same disease.

This "holistic" approach to the patient as a unity of mind, body and spirit is one of the reasons traditional medicines are getting increasingly popular in developed countries as well, in spite of the relatively well established conventional health care systems. Traditional Chinese medicine, acupuncture and moxibustion, meridian therapy, Ayurveda, yoga, and Unani medicine are formalized diagnostic and therapeutic systems with a history of millennia, recognized mainly in their countries of origin and elsewhere. Other therapies, such as homeopathy, reflexology, aromatherapy, osteopathy, Bach Flower healing, naturopathy (and iridology), hypnosis, medical astrology, pendulum diagnosis, transcendental meditation, colour therapy, may be relatively new but their principles are founded in the laws of nature and extensive clinical experience of dedicated observers.

They are perceived to be more natural, less risky and emphasize the preventive aspect of medicine and the personal responsibility in the maintenance of one's health. Therefore, the educated public, which is increasingly concerned about the adverse reactions of allopathic drugs, is choosing them more and more. In palliative and geriatric medicine, neonatology and obstetrics also find wider acceptance. Therefore they are alternative or complementary to mainstream western medicine. According to WHO

¹ Director General of The National Institute for Research in Traditional Medicine and Pharmacology, Mali

* Paper presented at the First UNESCO Bangkok Bioethics Roundtable, September, 2005.

figures, over 50% of the population in developed countries have used complementary or alternative medicine at least once (Canada - 70%; France - 75%; Germany- 90%)¹. This compares to 80% of the population in developing countries who still use traditional medicine for their everyday health needs. Combining these figures, we can see that the great majority of humankind uses forms of healthcare that are mainly outside of, or subordinate to mainstream biomedicine. Surely, the term “alternative” may be considered moot when a majority is creating the trend.

3. Recognition and integration

However, traditional health practitioners remain marginalized and their recognition by health authorities has only begun in several countries, in spite of them being 50-100 times more numerous than allopathic health care providers. In Uganda there is at least one traditional healer for about every 300 people, compared to one Western-trained medical practitioner for every 10,000 people in urban areas and 50,000 people in rural areas, respectively.²

Traditional healers are usually integrated and accepted in the community in Uganda. They are influential in reaching and changing the behaviour of low-status, stigmatized patients, who often avoid public providers or are neglected by the public health care system. Traditional healers are, in terms of primary health care, accessible to the community looking for the root causes of disease and illness (which are sometimes spiritual). They also often play a role as a mediator between spirits and humans.

Also from the economic point of view, traditional medicines are preferred, being less expensive. This trend is particularly evident in countries in transition, where traditional remedies have become the major resource for health as funds dwindle for pharmaceutical products used in conventional medicine.

According to the WHO, the degrees of recognition of traditional healers by the formal, governmental health system are: 1) fully integrated, as in PR China, Korea and Viet Nam; 2) included, but not completely integrated, as in a number of developed and developing countries, and; 3) tolerated. However, in most of the countries, traditional healers are usually informal, unrecognized by the government, and do not interact with the rest of the health care system. Recently, central and local governments and non-governmental organizations have recognized the potential of integrating traditional healers into their primary health care systems. Such examples include Bolivia, Brazil, South Africa, Ghana, Malawi, Mongolia, Nepal, Tanzania, and Uganda, to name a few.

Cote d'Ivoire is a West African country which was considered one of the most peaceful and prosperous in the region until civil war erupted in 1999. In 2004, Cote d'Ivoire was in position 163 (out of 175) on the UNDP human development index scale.

Tropical infectious diseases represent the biggest public health care problem, particularly malaria. Recently HIV/AIDS has started to spread due to war and the refugee movement.

Before colonialism, Africans developed a variety of ways to prevent and heal diseases. These included environmental controls as well as herbal treatments. Africans had also developed a range of medical and spiritual practices to deal with different forms of spiritual and corporal diseases. Medicine men or juju priests dispense charms, tell fortunes and give advice on how to avoid danger. They also bless grisgris, necklaces that ward off specific evils.

Since 1995 the government has decided to integrate traditional medicine into the national public health care programme, complementary to modern medicine, and in 1996 three laws regarding the protection of traditional medicine were proposed. These refer to authorization of practice for traditional medicine (TM) in Cote d'Ivoire; creation of a national organization of traditional healers and establishing a code or practice for the healers. These laws are still to be debated and approved.

Traditional medicine became a priority in the National Plan for Sanitary Development, the government recognizing it as a major component of the cultural heritage, to which the population will always be attached. A National Programme for Promotion of Traditional Medicine was launched in 2004 and

2 <http://www.who.int/mediacentre/factsheets/fs134/en/>

the plan of action for 2004 -2009 has been published. The main objectives are to effectively integrate traditional medicine in the national health care system, to assure good quality and affordable traditional medicines and to promote research into this ancestral field.

The programme, consisting of several academics, focuses on four areas of activity: research of the diseases treated; research of the plants and methods used; identification, education and supervision of traditional healers, and; public relations and communications.

Côte d'Ivoire does not have official training facilities or programmes for traditional medicine, however, a module of training in traditional medicine was due to be introduced into the curriculum of two medical schools in 2005. University students are encouraged to research topics related to traditional healing practices for their graduation thesis. In a related development, retired and respected professors are using their authority to convince young African doctors, trained in Europe, to have some disdain for traditional medicine.³

Mongolian Traditional Medicine (MTM), while rooted in ancient systems of healing such as Ayurveda, Tibetan Medicine and Chinese traditional medicine, has its distinctive features which have been developed in accordance with the particular geographic and climatic conditions of the country and the nomadic lifestyle of its people. MTM has been practiced successfully for centuries in the heart of the Asian continent until it was officially ignored for more than 70 years during the 20th century. Since 1989 traditional medicine, considered to be an important health care resource and an essential part of the nations' intellectual property, has become increasingly popular and the government of Mongolia is committed to continuing the development of MTM, working to incorporate it into official health care services.

The main areas of action of MTM are cardio-vascular, neurological diseases and digestive tract ailments, however it is believed that all manner of physical, mental and psychological disorders can be cured through the use of herbs, mineral water, metals and animal parts. The medicines are administered according to one's metabolism, the weather and the season. Acupuncture and massage are also considered to be important parts of the treatment process (Bold and Ambaga, 2002).

In 1990 the government made development of MTM a priority and in 1996 it announced its support for incorporation of remedies used by traditional medicine into the mainstream health care service system. A draft policy on the development of MTM was discussed at the Conference on National Policy on Traditional Medicine in 1998 and was adopted by the State Great Khural Parliament on 2 July 1999. This document covers nineteen areas of work over the next 10-to-15 years, including structure and organization of hospitals, capacity building of traditional medicine personnel, producing safe herbal medicines in line with good manufacturing practices, exploring possibilities of curing critical diseases with traditional methods and applying traditional medicine to ambulance services and primary health care.

The health insurance fund pays for inpatient treatment, including the use of traditional methods. The health minister has praised the contribution of traditional medicine to the public health care service, medical supply and intellectual property.

4. Further challenges

In order to assure safety and efficacy for consumers, more research is needed to prove the age-old validity of remedies. Protocols for clinical trials should be designed according to the specifics of the tested substances and the cultural sensitivities of the people who have used the therapies for generations.

The growing interest in herbal medicines stems partly from the fact that they are made from plants harvested from nature and there is an association of natural resources with human well-being and health. At the same time, great care should be taken to insure sustainable use of natural products, both

³ From the discussion held on 10 October 2004 with the members of the National Programme for Promotion of Traditional Medicine at the Ministry of Public Health and Population in Abidjan, Cote d'Ivoire.

vegetable and animal, since many traditional medicines originate from endangered species.

About 25% of modern drugs are based upon plants first used traditionally. In recent years famous cases of biopiracy have made the headlines. Pharmaceutical companies undertaking research in the herbal pharmacopoeia of indigenous groups have patented products without acknowledging the original information. In terms of intellectual property rights, the present international system does not seem to fit the specific laws governing the ownership of traditional knowledge, including that for healing purposes.

5. Conclusions

Traditional practitioners are often the only source of medical care. They provide a large, accessible, available, affordable human resource pool. They practice under the authority of the community, drawing ancestral knowledge through initiation processes, rather than formal education. Traditional knowledge is often part of their culture and closely guarded.

Cultural and spiritual values are decisive in choosing and/or accepting non-conventional therapies. Culturally appropriate research methods are needed to validate TM practices. Traditional healers should be trained in a respectful manner. Prejudice of the conventional medical practitioners against traditional healers persists across the globe. Collaboration is possible and has yielded valuable public health benefits. Recognition from governments of the importance of TM is spreading. The importance of cooperation between the two sectors needs to be emphasized. A system of "medical pluralism", a new paradigm, "like the two wings of a bird" is needed. Policy and infrastructure development will be needed according to varying priorities in different countries.

There are some ethical questions remaining:

- Should age-old wisdom prevail over modern double-blind clinical studies?;
- When should one forgo modern treatment, especially when it is still experimental, and embrace alternative therapies, including spiritual ones?;
- The cost - should non-conventional methods be covered by health insurance, what about countries where coverage is limited or nonexistent?;
- A trust relationship with the practitioner is the basis of healthy communication, therefore reciprocal acknowledgement between practitioners is highly recommended;
- Are environmental aspects taken into consideration when using natural medicines?;
- Are indigenous groups benefiting from the results of pharmaceutical research stemming from their knowledge and biological resources?

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Avoiding Biopiracy? Protecting Traditional Marshallese Medicinal Knowledge and Plants*

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There is a worldwide trend, particularly in developing countries such as the Marshall Islands, to both recognise traditional medicinal knowledge and to incorporate time-tested traditional medicinal practices into the modern health care system (WHO, 2003). However, to effectively bring about such recognition and integration requires that traditional medicinal knowledge make a transition from the protected, often “secret” domain, to the public so that it can be documented and scrutinized. This raises concerns about “biopiracy” (Shiva, 1997): healers and researchers express strong reservations that both the once closely held knowledge of healers and genetics of medicinal plants will be exploited and lost to external commercial biotechnological and pharmaceutical interests. This paper describes the success and challenges of a collaborative project which aims to provide public access to the specialized knowledge in the use of 56 plants by female healers in the Marshall Islands, while both preserving the private right to the ownership of the formulas, and the security of the common, free and self-regenerative species of medicinal plants of the Marshall Islands.

Background

The Republic of the Marshall Islands (RMI) is in the region of the Pacific known as Micronesia. The country consists of an archipelago consisting of a double chain of 34 low-lying limestone islands and some 879 reefs located between 5o and 15o N. latitude and 162o and 173o E. longitude in the west-central Pacific Ocean just north of the Equator and west of the International Dateline. The two island chains are the Ratak (Sunrise) Group in the east and the Ralik (Sunset) Group in the west. The country includes 29 true atolls, each with numerous small islets surrounding a central lagoon, and five low-lying limestone reef islands without central lagoons. Few if any of the islands have elevations three metres above sea level. If the individual islets that compose each atoll are included it has been estimated that there are over 2,000 low-lying limestone islets or sand keys in the Marshall Islands. Land is precious and vulnerable, the total estimated land area of the archipelago is only 171 km² (70 mi²), which is scattered over some two million km² (750 mi²) of ocean (Merlin et al. 1994). Nineteen atolls and three of the low-lying limestone islands are inhabited. As of 2004, the population of RMI was estimated to be about 65,000. Urban centres have developed on Majuro (pop. 36,000) and Ebeye (pop.13,000), the former being the capital and commercial area and the latter accommodating the workforce serving the US Kwajalein missile testing base.

The first voyagers sailed to this central region of the Pacific between 2,000 and 4,000 years ago. Encountering a parallel-chained archipelago, they settled on its atolls and islands, calling it Aelon Kein Ad - “These our atolls”. According to their own stories the people shared their home with inhabitants of the unseen or spiritual world (ri-anij), spirits of the land (jetōb), hidden folk from the land(ri-menanuwe and noniep) as well as those from the depths of the sea (rikijet), most of whom are culturally attributed as inspiring and contributing to their knowledge systems. As in many other Pacific Islands, a fine-tuned social organization and culture evolved in the Marshall Islands where rights, roles, reciprocity, cooperation and respect governed the ways of interaction and behaviour of the major clans (jowi), sub-clans (bwij), and families (nukin eo). Custodianship and protection of the limited land, the waters of the lagoon and the ocean-side reef were of vital importance. Chiefs (irooj) were the overall landowners and custodians within a matrilineal system. Along with their mediators, they carefully orchestrated and managed society, ensuring that all, according to rank and requirement, were provided for. Like other traditional

* Paper presented at the First UNESCO Bangkok Bioethics Roundtable, September, 2005.

societies, there were clans who held specialized knowledge. Along with medicinal practitioners, these included diviners, astrologers, canoe builders, navigators, farmers, fishermen, genealogists, storytellers, sorcerers, magicians and warriors.

Traditional Medicinal Knowledge

Marshallese traditional medicinal knowledge has been constructed and accumulated over time. Guarded through a traditional system of copyright, it is also regulated by customary ethics. It has always been protected by a private family unit, or a clan and only gifted to carefully selected apprentices. Expert healers were carefully trained for years until they reached a level of mastery. They were held in tremendous respect in the community, and the sacred nature of their medicinal knowledge, passed on as a legacy to succeeding generations, was regarded as both an inherited right and great responsibility.

The healer's role was to provide medical help to all who required their care: and both medicinal knowledge and the healing act itself were regarded as inspired and assisted by spirits and the spiritual world (Petrosian-Husa, 2004). For this reason, adherence to taboo (mo) was strictly observed as an integral part of the cure (Kabua-Fowler, 2004).

In the past, the reciprocal system of Marshallese society meant that treatment was freely offered but always rewarded - the gift of something sharp, such as a needle or fish-hook sufficed as appreciation in most cases. Healing a critical illness would be regarded as an act of kinship with the healer being given land or adopted into the family as a close relative. Medicinal knowledge was also closely guarded in order to maintain the purity and efficacy of the method of administration. Thus protected, it would avoid the abuse of the healing power by "outsiders" who might aspire to acquire the knowledge for their personal advancement in social or material prestige.

Modernity and Globalization

Although there are indications in the Marshall Islands that traditional medicinal knowledge continues to be passed onto the younger generation (Taafaki et al., 2005), two features of modernity - urbanization and out-migration - are seen as having a negative impact on the cultural transmission systems that survived in the past. The influence and easy availability of western education and life-styles have increasingly pervaded the once remote far-reaches of the Pacific. Moreover, post-World War Two events in the Marshall Islands, including nuclear testing, has necessitated and prompted the relocation and out-migration of many Marshallese people away from their traditional lands and settlements to new islands, urban areas and overseas. Independence and modernization efforts have increased access to formal education at all levels and provided opportunities for islanders to work in the urban centres of Majuro and Ebeye. Travel and migration, mass communications and allopathic systems of medicine are now a feature of modern life, especially in the urban centres.

Modernization has also disrupted and fragmented the knowledge-transfer systems that ensured the perpetuation of the traditional knowledge of the past. Those healers with the desire to pass on knowledge, or indeed those with the potential to receive training in the healing arts, may no longer be physically present in the atoll communities. Traditional knowledge has also been de-valued in rapidly urbanizing areas where there is an increasing pre-occupation with modern public and private sector development, a focus on western formal education, wider exposure to western media and involvement in other non-traditional activities. Most of the younger generation no longer has the time, interest or commitment necessary to learn, or follow, the medicinal remedies and associated practices and taboos from their elders. As a result, the very specialized cultural knowledge, which has been accumulated over hundreds, if not thousands of years, in close contact with the atoll environment, is over time, being lost.

Documenting Marshallese Traditional Medicinal Knowledge

Detailed documentation of Marshallese traditional medicinal knowledge began in 1998 with informal conversations with women about the medicinal uses of the trees, shrubs and other plants. In the course of the discourse, serious concerns were expressed that their knowledge system might not survive into the future. To begin to address this situation, a study was initiated to gather and record information on

Marshallese traditional medicinal knowledge in an attempt to preserve the very rich component of the culture before it is lost or diluted. To do so it was necessary to bring medicinal knowledge out or away from the closely held secret knowledge systems of the clan or family, into the public domain. There was also the anticipation that, once recorded, effective traditional Marshallese medicinal practices and medicines could become formally acknowledged as a compliment to the modern health care system in the Marshall Islands.

A grass roots group of women was formed comprising the following groups: traditional leadership; the private sector; government; the National Council of Women, and; the University of the South Pacific Centre. Initially self-funding, the collective was determined to collect and record the medicinal uses of plants of the Marshall Islands. Together they organized and supported the First Herbal Plant Workshop in 2001.

The first step in the workshop process was to show respect to, and take permission from, the spiritual world, including past healers - spirit forces recognized as inspiring or granting medicinal knowledge. A roro or chant was called, asking these forbears to allow the secret knowledge of the past to be written down for the benefit of the future. Living traditional leaders were also present as an indication that they, as traditional custodians of knowledge, were granting their assent to the transition from the private to the public domain.

Two Hawaiian traditional healers played a critical role by relating how the Hawaiian people had lost much of their traditional medicinal knowledge because it had been replaced by modern medicine and had not been sufficiently recorded. It was stressed that this loss was due to the secrecy and power or mana associated with traditional medicine and the reluctance of healers to pass on information unless the recipient was worthy. Based on the Hawaiian traditional healers' experience, they suggested that if Marshallese medicinal knowledge was not recorded immediately, then much of it would be lost forever. The Marshallese would then suffer the same fate of cultures, such as the Hawaiians, New Zealand Maoris, Australian Aborigines and American Indians. The very active movements to revive dying cultures and to record information regarding these groups has come almost too late. This passionate and emotional presentation, together with the cultural permission granted through the roro and by living traditional leadership, together with the assurance that their contributions would be recognized and attributed in any publication, enabled the Marshallese participants to unanimously commit to becoming active players in the recording, preservation and application of Marshallese medicinal knowledge for the benefit of future generations.

Once the transition from the past to the present was concluded, the research process was started by the participants, who were either recognized expert healers or contributors familiar with medicinal folk knowledge. Either individually or as small groups, they completed questionnaires (Thaman, 2001), which, though designed in English, was translated into Marshallese to ensure full access by all participants. The questionnaire had two sections. The first section asked the respondents to list the 25 plants they considered most valuable in Marshallese medicine, what they were used for, and what parts were used. The second part asked them to record those medicinal plants from different categories (e.g., trees, shrubs, vines, ferns, grasses, etc) that were in short supply, rare or disappearing.

Analysis of the data began immediately after the workshop concluded. It revealed an initial profile of sixty-one medicinal plants. Of these 37 were considered by at least one respondent to be rare or threatened, with over one-third being listed as threatened, very rare or locally extinct.

Over the next year a working group comprising a small group of expert healers and other contributors, including traditional leaders and members of families who own specific medicinal knowledge as well as those well versed in general Marshallese folk medicine, met weekly at the University of the South Pacific Centre in the Marshall Islands. The working group systematically worked through 61 plants verifying which plants corresponded to the Marshallese, and in the process identified a small number of non-plant species, such as coral, pumice, crabs, snails, etc, that were also used in Marshallese medicine. The expert healers shared their knowledge about how they used each plant, or part of the plant, for medicine, and which, if any other plants were used in combination with the primary plant. Other group members asked probing questions on treatments and contributed their own knowledge about each plant and its use, drawing on personal experience or family or clan held information learned both in the

Marshall Islands and, in some cases, other cultural contexts. Each session was recorded and the notes entered into a master document. Any clarifications required by the recorder would be brought back to the next meeting of the research group. Over the course of the first year, a total of 131 uses were identified for 51 of the plants identified by the respondents to the first questionnaire

A second Marshall Islands Medicinal Plants Workshop was held in 2002, this time with funding from the Canada Fund, which enabled healers from more remote atolls to participate in the process. At this workshop, Marshallese expert healers and other contributors were joined by traditional healers from Fiji, who shared their own experience in using medicinal plants and promoting traditional medicine. Participants worked in groups to examine and verify the uses and recipes collected over the previous year and added new plants and recipes to the collection.

Over the next two years, the submissions from each group were examined and carefully edited at weekly meetings of a smaller research focus group. Those recipes that were similar to those already compiled, not fully described or which could not be fully verified by expert healers or prepared from the instructions were eliminated. In the process, knowledgeable members of the focus group, in association with available healers, added new recipes. An ethnographer at the national Historic Preservation Office joined the working group in 2003. Her questions, translation and interpretation of the accounts of nineteenth century German ethnographers who had recorded the pre-modern era use of Marshallese plants and the beliefs of Marshallese people were documented. This added another valued dimension to the group's consultation and discoveries.

In all, eight expert healers and fifty-four other contributors participated in the project. At the end of the research period 275 formulas or recipes of medicines using 56 plants providing remedies for 138 conditions were documented. Of these 272 used only plant material and three formulas were found to be a combination of non-plant and plant material. No medicinal use of sea plants, other than coral, were recorded in this study.

Given the fragile atoll environment of the Marshall Islands, the range of uses of the 56 plants identified in this study are extraordinary. The diversity of treatments is testimony to the creativity and resourcefulness of Marshallese healers, who through inspired dreams and careful experimentation have used their limited resources for the care of the health of members of their isolated communities.

Safeguarding the Sources of Traditional Medicinal Knowledge

Throughout the process, every effort was made to respect, acknowledge and safeguard the sources of each contribution to the collection. The formulas or recipes now belong to the individual expert healers, other knowledgeable contributors, groups of contributors or, if a folk remedy, to the Marshallese people in general as their intellectual property. The naming was also intended to serve as a copyright in the hope that this would avoid the exploitation of the knowledge once secretly preserved and now shared and made public for the wider benefit of future generations of Marshall Island people.

Subsequent analysis and discussion of the research also identified the need to know more about the extent to which cultural knowledge transmission is in progress in the Marshall Islands and how this knowledge can be safeguarded. Many outside observers see the loss of knowledge as rapid. Marshallese respondents, however, while acknowledging the loss of systems which were once a natural passing on of knowledge and skills from one family member to a capable apprentice in the younger generation, feel more confident that their medicinal practices are alive and well and that their knowledge systems can survive.

Key to this survival is the legal protection of the traditional knowledge and the plants themselves. While the second workshop established a non-governmental organization to protect and promote Marshallese medicinal knowledge and plants, as the manuscript became closer to publication, the researchers became increasingly conscious of the vulnerability of the knowledge of traditional medicine they were in the process of removing from the protection that secrecy afforded under the traditional copyright system by introducing it into the public domain.

The global climate of development and exploitation by commercial biotechnological and pharmaceutical

interests has raised questions regarding “Eurocentric [sic] notions of property and piracy” (Shiva, 1997), described as the basis for the framing of the International Property Right laws of the GATT and the WTO. The impulse to discover and colonize appears to have been extended to interior spaces, with attempts to claim and manipulate, monopolize and patent not only unscripted, and therefore unprotected, traditional knowledge but also the genetic codes of life forms - from microbes and plants to animals, including humans (Shiva, 1997; p.3).

Given this climate, concern over the loss of traditional knowledge in the Marshall Islands transformed into concern over the loss of the ownership of the knowledge itself as well as the communal ownership of the plants of the Marshall Islands and the loss of their habitats. Researchers into Marshallese traditional medicine thus recognized the need to focus attention on the extent to which the Convention on Biodiversity had been implemented in the RMI and what legal measures the Marshall Islands has in place to protect the rights of the people to their specialized and folk knowledge and also what measures existed to ensure the space and freedom of the diverse species of medicinal plants to continue to evolve naturally in the Marshall Islands.

The RMI joined 157 nations as a Signatory of the Convention on Biological Diversity in 1992 at the Rio Summit. The Convention calls on parties to respect, preserve and maintain the knowledge and innovations and practices of indigenous and local communities and to encourage their customary uses of biological resources in a sustainable way. It recognizes the role of indigenous and local communities in the conservation and sustainable use of biological diversity and in addition recognizes their entitlement to receive a share of the commercial or other benefits derived by others from their ideas and innovations or from genetic resources under their control or stewardship.

The goals and guidelines of the Convention on Biodiversity were used to create an RMI National Biodiversity Strategy and Action Plan. Published in 2000, the Strategy and Action Plan prioritizes twelve goals based on the assessment of the urgency of the problem, the numbers of people affected, achievability and their potential contribution to sustainability. The goals were set by participants at a National Workshop - drawn from all outer atoll communities and urban centres and included traditional leaders, representatives from local governments, women’s groups, youth and faith-based organizations. The goals fell into four strategic themes:

- A -Conservation of Biodiversity and Biological resources
- B -Protection of the Marine Environment
- C -Traditional Culture and Practices
- D -People and Biodiversity

The ethics of care, cooperation work and self-reliance are heard in the voices of the participants in the Strategy and Action Plan workshop (Table 1). Also noted is a sincere wish to preserve traditional custom, knowledge and the desire to acquire the skills necessary to be able to do so. The ranking of priorities also reflects a lack of awareness of the importance of identifying and implementing legal mechanisms, except for the more traditional imposition of fines.

Table 1: RMI Biodiversity Priorities

Rank	GOAL	Goal #
1	Activate traditional mo (taboo) conservation sites	A1
2	Training and capacity building towards conserving resources	B1
3	Apply traditional knowledge and skills	C1
4	Impose fines and penalties on those who destroy our resources	A2
5	Sustainable fishing practices	B2
6	Self-reliance through traditional values and cultures	D1
7	People taking the initiative in planting trees and crops	A3
8	Population awareness	D2
9	Institute learning of the culture through the traditional ways of passing knowledge from elders to the young, through schools, community meetings and workshops	C2
10	Work cooperatively and justly with one another	D3
11	A move towards more uses of local products	C3
12	Clean up the environment	D2

Constraints to Safeguards

As a Small Island State, the Marshall Islands has an economy that is aid dependent.

The present population of 65,000 has a GDP per capita of \$2,250.00 (EPPSO, 2005). It also has the lowest number of college graduates in the Micronesian region (EPPSO, 2004). Though cash strapped and capability stretched, the Marshall Islands government's recognition of the importance of the Convention resulted in the establishment of an Office of Environmental Planning, Policy and Coordination in 2003. However little additional internal funding is available to support the implementation of the provisions of the Convention.

Additional constraints are noted by senior managers at the ministerial and agency level. The first is that the steering committee responsible for coordinating the activities for implementing the articles of the convention is comprised of senior managers of ministries and agencies who have multiple responsibilities (Muller, 2005; Barker, 2005). The committee meets rarely and thus coordination becomes a challenge. Secondly, the Marshall Islands has a transient professional workforce, consultants come and go and capable Marshallese move from agency to agency. "Starting over" with new staff becomes the norm and the continuity for follow up on implementing measures are lost in the change-over. These changes in the professional workforce at the implementation level especially hinder sustained measures with respect to information management and monitoring essential to protecting biodiversity, legislating intellectual property rights and material transfer agreements, controlling invasive species, especially those invasive plants that are smothering medicinal plants, monitoring bio-prospecting, creating opportunities for communities to register their traditional knowledge and conducting public education and awareness programmes.

While the RMI is in the process of ratifying the Convention on Plant Genetic Resources, bioprospecting is recognized as a real threat and the country recognizes it has not moved fast enough on legislation to protect intellectual property rights (Muller, 2005). Regional initiatives to document medicinal plants in the Pacific Islands (DaSilva, 2005) and measures taken thus far protect both intellectual property rights, such as the Mataatua Declaration on the Cultural and Intellectual Property rights of Indigenous Peoples and the Treaty declaring a Life-forms Patent Free Pacific (LFPFP) have been slow to reach any real level of awareness in either the Pacific Region or the Marshall Islands.

None of the Pacific Island States are party to Intellectual Property Rights Treaties (DaSilva, 2005; p.38)

and Pacific nations haven't moved forward towards the goal of a LFPFP since the idea was first described 10 years ago. Although signed by NGOs (in the southern Pacific), no NGO in the Marshall Islands is as yet party to it (Mead, 2005). Organizations can, however, still sign on to both initiatives to protect intellectual property and life-forms as valid symbols which can be used as a rallying point should interest in this area reach a critical level of interest (Petaru, 2005). At present in the region there are strong interests against having a LFPFP. These interests are the pharmaceutical companies, agricultural and university research institutes who voice concerns about the impact protective mechanisms will have on their research and commercialization activities as they seek new drugs, herbicides, and plant growth hormones (ibid).

Special provisions for Small Island States enabled representatives from the RMI to attend regional and international meetings, including the Annual (now bi-annual) Convention of Parties (COP) to gain information and skills on the Convention and its implementation. Also, the proposed island biodiversity programme of work, to be coordinated by the South Pacific Regional Environment Programme (SPREP), will offer some financial incentives for the Marshall Islands to implement the goals of the country's National Biodiversity Strategy and Action Plan. Though ratification of the Convention on Plant Genetic Resources is underway, legal safeguards within the RMI remain outdated and limited in scope. To date there has been no review of environmental legislation or drafting of laws specifically intended to implement the Convention on Biodiversity and nothing exists to prevent the exploitation of traditional knowledge or the plant life it depends upon.

Along with legislation, capability to implement the goals, information management and monitoring skills needs to be strengthened and public education initiatives within the public school system and by community-based organizations, activated.

Steps are required to create awareness of those in the Marshallese medicinal knowledge community of the protections afforded by the Convention. While these have been described in English (SPREP, 2000) the articles and subsequent initiatives and agreement remain difficult to access, especially by non-English speaking community groups who may wish to register their knowledge.

Early publication of the compilation of Marshallese traditional herbal medicine and the description of the plants that support it has become a priority for the researchers as it is, in itself a protection of both the cultural knowledge and the biodiversity. Under US patent laws, no invention can be patented if described in publications more than one year prior to the date of the patent application. However this too becomes a challenge for an NGO in a Small Island State, as publishers express strong reservations about investing in publications considered to have a low market appeal. Those compiling the results of their research into Marshallese Traditional Medicine and Medicinal plants are asked either to self-publish or raise their own funds to support professional publication. In various ways this hampers their next efforts to establish conservation areas, plant nurseries and prompt the legislative processes necessary to protect vulnerable national cultural and biodiversity resources.

Those women who shared their once closely safeguarded and private traditional knowledge released it willingly for publication in an ethical spirit of care for others. Safeguarding it now becomes the duty of the public domain through its governance and legal mechanisms. Detailed systematic research and documentation of the medicinal uses of plants found in the Marshall Islands is regarded an important first step in both the conservation and evolution of traditional knowledge into a system that can be integrated with modern health care in the country. It also has the potential to be a catalyst to raising awareness of the need to use the force of legislation and education to ensure that the knowledge remains with those who have generated it and moreover that the plants, upon which the system relies, remain safe and freely available to those who need and use them.

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Market-driven Biomedical Research: A Major Challenge to “Everyday Bioethics”*

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“Frontier bioethics has been focused almost exclusively on recent developments in biomedical sciences, for instance [in] organ transplantation, genetic therapy, cloning, use of stem cells, pre-implantation diagnosis, and transgenic technologies, which lead to unheard-of events and new moral categories. Everyday bioethics, less remote from the experience of ordinary people concerns the daily persistent conditions of most of the world’s population, often difficult and sometimes tragic. [Even] among people who ignore the latest progresses of science, moral reflections on birth, gender relations, justice and autonomy, disease and health care, the interdependence of species, and death have a very long history - as long as that of humanity. These reflections guide today, wittingly or unwittingly, the decisions of all individuals, social groups, and communities, because “it must be shown that all men (sic) are ‘philosophers’, by defining the limits and characteristics of the ‘spontaneous philosophy’ which is proper to anybody”.

- Giovanni Berlinguer Lancet (September 18, 2004)

1. Some Pertinent Questions from the SARS Epidemic

During the SARS epidemic of 2002-2003, the microbial agent involved (SARS coronavirus) was swiftly identified and sequenced in a remarkable collaboration between otherwise highly competitive laboratories in Asia, Europe, and North America (World Health Organization. 2003). These early exchanges however very soon gave way to a mutual wariness at the point when intellectual property claims were filed for the pathogen’s sequences and other patentable findings with commercial potential (Gold, 2003; Editorial, 2004; Simon et al., 2005).

Notwithstanding the rapid success in isolating (Peiris et al., 2003) and sequencing (Ruan et al., 2003) the SARS coronavirus, the epidemic quickly subsided in the absence of reliable diagnostics, vaccines, or efficacious therapies. WHO gave much credit to institutional responses such as isolation, contact tracing, ring fencing, and quarantines (i.e. centuries-old techniques)², with lesser mention of personal risk avoidance and the possible contributions of seasonality effects or cross-reacting immunity from related endemic micro-organisms (Ng et al., 2003). Most importantly, the economic and financial stakes involved (Chan, 2003) ensured that SARS would not be a “neglected disease”.

A number of pertinent questions arise from these observations, which could be asked more generally of emerging biomedical technologies:

- How important are biomedical advances (including genomics) to population health and to patient care (distinguishing perhaps between knowledge-based practices and coping responses, as opposed

* Paper presented at the First UNESCO Bangkok Bioethics Roundtable, September, 2005.

2 Brundtland, G.H., Director– General, World Health Organisation. 2003.: “SARS can be contained despite the absence of robust diagnostic tests, a vaccine, or any specific treatment. When awareness, commitment, and determination are high, even such traditional control tools as isolation, contact tracing, and quarantine can be sufficiently powerful to break the chain of transmission ...”. WHO website (Accessed 5 July, 2003).

to consumable commodities?)³; what is the relative significance of genetics in the aetiology (and social ecology) of health and disease?

- What are realistic expectations of the advances that genomics can contribute to disease control, diagnostic aids, and treatment? In what ways can pathogen genomics be most useful in epidemic control strategies?
- What are the likely trajectories of genomics R&D in the foreseeable future, given the current modalities for funding of biomedical research, the associated regimes of patents, intellectual property rights, and market-driven product development, and the chronically unresolved problems of neglected diseases of the poor?
- What would be an enabling environment for the realization of the useful potential of genomics? For an equitable harvest of benefits and a humane deployment of genomic technologies that can avoid the emergence of a marginalized genetic underclass and the imposition of arbitrary, constructed norms?
- What are acceptable processes and institutions for dealing with these policy and ethical issues, at the community, national, and international levels?

2. The Social Ecology of Health and Disease

Among public health practitioners, it is by now conventional wisdom that there is only a modest overlap between the “healthcare sector” (in the narrow sense), and the “determinants of health” (Marmot, 2005). McKeown and Record (1962) advanced the thesis that the historical decline of infectious mortality in the 19th century (among the early industrializing countries) owed little to medical science and its derived technologies. In England and Wales for example, the mortality rate from a major killer, respiratory tuberculosis (TB), had declined by more than 85% between 1838⁴ and 1945, well before the discovery and isolation of streptomycin in 1947 by Waksman and Schatz (one of the early antibiotics effective against the tubercle bacillus⁵) and well before the widespread availability of BCG vaccination from the 1950s onwards. Clearly, other factors had been paramount in the decline of TB mortality in England and Wales, and McKeown and others went on to identify food intake and nutritional status, and from about 1870 onwards, potable water supplies and environmental hygiene as the key factors in the secular decline of infectious mortality⁶.

Mortality by itself of course is an inadequate metric of population health status. Nonetheless, the recent efforts to invent more discriminating measures of disease burden which take into account morbidity, disability and functional capacities, and quality of life (Daly’s, Qaly’s, Hale’s for example) have not seriously

3 While vaccines and efficacious therapies were not speedily available at the time (1998– 1999), the knowledge that Nipah encephalitis was linked to a newly recognised paramyxovirus which could be transmitted through close proximity to live, infected pigs but not via insect vectors, fomites and suspended airborne particulates, or contact with raw or prepared meats (ascertained from virological studies, field epidemiology, and clinical medicine), allowed for its rapid control in humans, even as this control decimated the pig farming industry in parts of Southeast Asia.

4 Tuberculosis mortality in England and Wales in 1838 was nearly 4000 deaths per million population (age– adjusted to the 1901 population).

5 Robert Koch’s discovery of *Mycobacterium tuberculosis* in 1882 had little effect on the rate of decline of TB mortality.

6 R.C. Lewontin gives lesser weight to potable water supplies and sanitation, at least among the early industrializing countries, but may have downplayed the synergistic effects of diarrheal disease and malnutrition on childhood mortality, especially in poorer countries: “The history of tuberculosis is the history of nearly all the major killers of the nineteenth century. Whooping cough, scarlet fever, and measles, all with death rates in excess of 1,000 per million children, and bronchitis, all declined steadily with no observable effect of the discovery of causative agents, of immunization or of chemotherapy. The sole exception was diphtheria which began its precipitous decline in 1900 with the introduction of anti– toxin and which was wiped out in five years after the [US] national immunization campaign. The most revealing case is that of measles which killed about 1,200 in every million children in the nineteenth century. By 1960, despite the complete absence of any known medical treatment, it had disappeared as a cause of death in Britain and the US while in much of Africa it remains the chief cause of death of children. The causes of the tremendous decline of mortality from infectious diseases in the last 100 years are not certain. All that is certain is that “scientific medicine” played no significant part. Water supply and sanitation are not involved, since water-borne diseases have not been the major killers. The suggestion that a reduction in crowding may have reduced the rate of transmission of respiratory diseases is not altogether convincing, since measles remains pandemic although it kills virtually no one in advanced countries. The most likely explanation, both for the historical trend and for the differences between regions of the world today, is in nutrition, although hard evidence is not easy to come by.”(New York Review of Books, January 25, 1979).

undermined McKeown's thesis, notwithstanding the evident efficacy of some modern therapeutics and procedures when used under controlled, favourable circumstances. Biomedicine (in the sense of consumable commodities as opposed to knowledge-based practices and coping responses) at best has contributed modestly to improvements in population health in the course of human history.

Even when effective therapies exist for responding to major public health emergencies, there can be non-technical political and economic barriers to these available options, most dramatically revealed by the ongoing campaigns for affordable essential drugs, in particular, for anti-retroviral treatment for people living with HIV/AIDS.

A broader perspective on aetiology and the coping responses of human societies towards illness and infirmity was clearly needed and it was articulated at the International Conference on Primary Health Care (PHC) in Alma-Ata, USSR in September 1978. The Primary Health Care vision and the practical requirements for its implementation were of course the distillation of prior cumulative experiences from countries such as China, Bangladesh, Cuba, and India.

Its intellectual lineage however (one branch of it, at any rate) was already evident in the writings of Rudolf Virchow (Taylor and Rieger, 1985), and this has been further enriched in the last several decades by diverse influences from Thomas McKeown (1971), Rene Dubos (1959), Richard Levins (1996), Paul Farmer (1992), Michael Marmot (2004), Vicente Navarro (2004), and others. Along with this increasingly sophisticated and nuanced understanding of aetiology (Krieger, 1994), the "multi-sectorial approach" - the institutional and somewhat bureaucratic expression of the "new public health" - now appears as overly static, rigid and compartmentalized.

A social ecology of health and disease captures better the dynamic, interactive complexity, and the interpenetrating unity of the social, natural and created environments which embed the health and disease experience of individuals and populations⁷.

3. Molecular Medicine: Justifiable Exuberance or Premature Genohype?⁸

Dr Francis Collins, Director of the US National Human Genome Research Institute had earlier declared that the benefits from mapping and sequencing the human genome: "Would include a new understanding of genetic contributions to human disease and the development of rational strategies for minimizing or preventing disease phenotypes altogether"⁹, with further prospects of "genetic prediction of individual risks of disease and responsiveness to drugs...and the development of designer drugs based on a genomic approach to targeting molecular pathways that [have] been disrupted in disease [pharmacogenomics]"¹⁰.

Five years on, in October 2004, the US National Academy of Sciences (Institute of Medicine) convened a conference in Washington, DC on Genomics and the Public's Health in the 21st Century at which participants reflected upon the modest progress which had been achieved in the interim.

Regarding cancer treatment, where hopes had been raised for dramatic advances in therapy, Dr. Gilbert

7 Levins, R. and Lewontin, R.C. 1985. *The Dialectical Biologist*, Cambridge, Harvard University Press. For an overview and discussion of theoretical currents in social epidemiology, see N. Krieger. 2001. *Theories for Social Epidemiology in the 21st Century: An Ecosocial Perspective*. *Int J Epidemiology*, Vol. 30, pp. 668– 677. See also, Kelman, S. 1975. *The Social Nature of the Definition Problem in Health*. *Int J Health Services*, Vol. 5, p. 625; McNeill, W.H. 1977. *Plagues and People*, Oxford, Blackwell; Epstein, P. 2000. *Is Global Warming Harmful to Health?* *Scientific American*, August. <http://www.sciam.com/2000/0800issue/0800epstein.html>.

8 Genohype, expressive phrase introduced by N.A. Holtzman to denote the overblown expectations of the benefits that genomics can confer on patient care and population health. Holtzman, N.A. 1999. *Are genetic tests adequately regulated?* [editorial]. *Science*, Vol. 286, No. 5439, p. 409.

9 Collins, F.S. 1999. *Shattuck Lecture – Medical and Societal Consequences of the Human Genome Project*. *NEJM*, Vol. 341, pp. 28– 37.

10 Collins, F.S. and McKusick, V.A. 2001. *Implications of the Human Genome Project for Medical Science*. *JAMA*, Vol. 285, No. 5.

Omenn, a cancer specialist and president-elect of the American Association for the Advancement of Science was quoted as saying that despite an “avalanche of genomic information... cancers remain a largely unsolved set of medical problems [for which] we continue to rely on highly toxic drugs”¹¹. Herceptin, for HER2-positive metastatic breast cancer, and Iressa, for non-small cell lung cancer were two recent additions to the cancer armamentarium which had benefited from advances in molecular cancer biology. These new therapies however were not free from significant (and among a minority of patients, potentially life-threatening) complications either, affecting the liver (Iressa) or the heart (Herceptin). More generally, genomics had made little impact on primary care medicine.

Indeed commentators like Richard Lewontin and others¹² have argued that aside from the relatively rare Mendelian disorders such as cystic fibrosis, phenylketonuria, and Huntington’s disease where high penetrance genotypes are involved and allow for easier study of the associated molecular genetics, the overwhelming bulk of common chronic diseases (diabetes, coronary heart disease, cancers) have much more complex aetiology which may include a familial component in addition to social, economic, psychological and biological factors.

The relationship between genotype (DNA sequence at the gene locus of interest) and phenotype (manifest traits) therefore becomes correspondingly murky and contingent so that the proportion of cases that can be attributed to susceptibility-conferring genotypes in a given population is typically small for common diseases such as breast cancer and colon cancer¹³.

Even when the molecular genetics are tractable, the translation of knowledge of molecular pathogenesis into efficacious treatments is quite unpredictable. It took 70 years for instance for streptomycin to become available for TB treatment, from the time *Mycobacterium tuberculosis* was identified by Robert Koch as the microbial agent involved. More encouragingly, protease inhibitors (used in combination therapy along with reverse transcriptase (RT) inhibitors for treating HIV/AIDS patients) became available in the mid-1990s, i.e. about 10 years after the discovery of HIV-1. On the other hand the molecular (genetic) basis of sickle cell anaemia was elucidated in the 1950s (Ingram, 1956), and palliative therapy has only recently become available (Charache et al., 1995).

Similarly, there has been little advancement in the treatment of cystic fibrosis (CF) fifteen years after the cystic fibrosis trans-membrane regulator (CFTR) gene was identified and cloned in 1989 and details of the molecular pathogenesis worked out. By 1993, gene therapy treatments for CF patients had begun and early studies reported some success with adenoviral vector-mediated gene transfer. On subsequent review and further testing however, the earlier findings now appear equivocal in the wake of more stringent study protocols which did not replicate the earlier results¹⁴.

4. Market-driven Biomedical Research and Product Development

Given that there has been quite limited success thus far with gene-based therapies, and few promising candidates on the horizon, commercial interest is likely to shift towards genetic testing for “disease susceptibility” alleles in line with a “paradigm shift” towards “predictive medicine” (genetic profiling of individuals for assessing risk of future illnesses). This has the added attraction that mass markets

11 Patients have yet to benefit from genome research. Miami Herald, 12 October 2004, <http://www.miami.com/mld/miamiherald/news/nation/9895562.htm>.

12 Hubbard, R. and Lewontin, R.C. 1996. Pitfalls of Genetic Testing NEJM, Vol. 334, No. 18, p. 1192. (Correspondence NEJM, Vol. 335, No. 16, p. 1235 – Stern H.J., Maddalena A., Schulman J.D., Foulkes W.D., Bunn H.F., Stossel T.P., Forget B.G., Stamatoyannopoulos G., Weatherall D.J., Hubbard R., Lewontin R.C.). Even among the Mendelian disorders, Hubbard and Lewontin have pointed out the genotypic heterogeneity among persons diagnosed with hemophilia B, cystic fibrosis, sickle cell anaemia, retinitis pigmentosa, and conversely, the wide range of phenotypic expressions among persons with similar genotypes.

13 Holtzman, N.A. and Marteau, T.M. 2000. Will Genetics Revolutionize Medicine? NEJM, Vol. 343, No. 2, p. 141. (Correspondence: NEJM, Vol. 343, No. 20, p. 1496 – Sotos JG, Rienhoff, HY Jr, Block GD, Aulisio MP, Khoury MJ, Ference BA, Chauhan MS, Izumo S, Holtzman NA, Marteau TM).

14 Knowles, M.R., Hohnaker, K.W., Zhou, Z., Olson, J.C., Noah, T.L., Hu, P., Leigh, M.W., Engelhardt, J.F., Edwards, L.J., Jones, K.R., Grossman, M., Wilson, J.M., Johnson, L.G. and Boucher, R.C. 1995. A controlled study of adenoviral- vector-mediated gene transfer in the nasal epithelium of patients with cystic fibrosis. NEJM, Vol. 333, pp. 823– 831.

are involved, since the genetic testing for “disease susceptibility” may be applied in a routine manner as part of well-person (or well-child) care and screening. Accompanying this almost certainly will be corporate R&D aimed at producing “pills for the healthy ill” (the worried well)¹⁵, to carve out sizeable new markets not just for screening tests¹⁶ but also for “prophylactics” for those deemed to be “at risk” and consequently anxious for the availability of some (commodifiable) risk reduction options.

As early as 1996, Hubbard and Lewontin¹⁷ had cautioned that:

“Serious difficulties arise from the relative ease with which information on DNA sequences can be acquired, when adequate knowledge of its correct interpretation is lacking. This can be seen in relation to the so-called breast-cancer genes BRCA1 and BRCA2. These two DNA sequences have both been linked to increased susceptibility to breast or ovarian cancer. To date, more than 100 variants of BRCA1 and several variants of BRCA2 have been identified. Only a few of them however have been shown to be associated with tumour growth. They have been found predominantly among the small percentage of women who belong to families in which there is an unusually high incidence of one or both types of cancer or in whom breast cancer develops at an unusually young age. Yet about 90% of women with breast or ovarian cancer do not fall into these categories... it is not clear what a woman should do if she tests positive, since there are no effective measures of prevention (even such extreme measures as “prophylactic” bilateral mastectomy or oophorectomy provide no assurance that a tumour will not develop in the residual tissue¹⁸).

Despite the biologic uncertainties and the potential for discrimination and other social and personal problems, biotechnology companies have begun to develop tests for DNA variants thought to be linked to “cancer susceptibilities”...worried patients, encouraged by overly optimistic claims by researchers, biotechnology companies, and the media, may want to have genetic tests performed whose validity has not been established. At the same time, physicians may legitimately feel at sea about the meaning, reliability and predictiveness of the tests. [Given] the underlying uncertainty associated with the tests themselves and their actual prognostic value, [usually] no practical consequences can be drawn from the information gained, however the test comes out. In the meantime, the test results can have disastrous implications for the psychological well-being, family relationships and employability and insurability of those tested.

While busily seeking to create markets for its commodifiable biomedical outputs, market-driven R&D and its corporate sponsors will continue to ignore and bypass the diseases of the poor, a scandalous situation which has been well documented by Médecins Sans Frontières (MSF): of the 1,393 new drugs

15 Human Genetic Technologies: Implications for Preventive Health Care. 2002. A Report for WHO by GeneWatch, UK. Geneva: World Health Organisation, Human Genetics Program; Genetics and ‘Predictive Medicine’: Selling Pills, Ignoring Causes, by Wallace, H. GeneWatch UK, Briefing Paper Number 18, dated May 2002.

16 In anticipation of this expanded re- definition of “diagnosable disease”, global re- insurers are now shying away from insurance packages which provide guaranteed lump sum payments upon diagnoses of designated critical illnesses (typically, about 36 in number). The president of the Life Insurance Association of Malaysia (LIAM) K.H. Chia stated that re- insurers worldwide had stopped providing guaranteed premium terms, and local insurers would follow suit in 2004 by adjusting premiums on a year- to- year basis in accordance with their claims experiences: “This trend is already happening in countries such as Hong Kong, Taiwan, Britain, Canada, Singapore, Australia, New Zealand, and South Africa... Since diagnostic techniques have been improving significantly due to continual medical research, it is now possible to detect conditions earlier which are not necessarily life threatening. This leads to early payout of claims for a risk [for] which the protection is not intended to [cover].” (The Star, December 20, 2003). The Consumers’ Association of Penang however sees this as a convenient pretext for prematurely raising premiums, merely on the expectation of hypothetical and quite unpredictable future claims experiences (The Star, December 21, 2003).

17 Hubbard and Lewontin. 1996. *ibid*.

18 More recent evidence suggests that among women with a BRCA1 or BRCA2 mutation, prophylactic bilateral total mastectomy reduces the relative incidence of breast cancer at three years of follow- up (Meijers- Heijboer, H., et al. 2001. Breast Cancer after Prophylactic Mastectomy in Women with a BRCA1 or BRCA2 Mutation. *N Eng J Med*, Vol. 345, pp. 159- 64. In another study where BRCA1/2 carriers similarly underwent bilateral mastectomy (as well as oophorectomy in some cases), the relative incidence of breast cancer was also reduced after a six year follow- up (Rebbeck, T.R., et al. 2004. Double Preventive Mastectomy Lowers Risk in Women with BRCA1 or BRCA2 Mutations. *Journal of Clinical Oncology*, March 15, 2004.

approved between 1975 and 1999, only 16 (or just over 1%)¹⁹ were specifically developed for tropical diseases (such as malaria, sleeping sickness, Chagas' disease, kala azar) and tuberculosis - diseases that account for 11.4 percent of the global disease burden²⁰.

These diseases mainly affect poorer communities in countries of the South, which do not constitute a valuable enough market to stimulate adequate R&D by the multinational pharmaceutical companies.

An indication of their priorities was provided by the president of the Malaysian Organization of Pharmaceutical Industries (MOPI), Mr Lee Yee Chong who stated at a 2002 national health conference²¹ that the two top-selling patented drugs in Malaysia at that time were sildenafil (Viagra) and orlistat (Xenical, a slimming supplement), i.e. two lifestyle drugs.

5. Responding to Market Failure: Public Patents and "Open Source"

Prompted by this persistent market failure and the harm and misery caused by the neglect, MSF has recently launched the Drugs for Neglected Diseases Initiative (DNDi), a consortium that currently includes MSF, WHO/TDR, Oswaldo Cruz Foundation/Far Manguinhos (Brazil), Indian Council of Medical Research, Institut Pasteur (France), Kenya Medical Research Institute, and the Ministry of Health (Malaysia) as founding partners²². A principal aim of the consortium is to take the development of drugs for neglected diseases out of the marketplace and to encourage the public sector to assume greater responsibility for a needs-based research and development agenda.

In the US, Congressman Dennis Kucinich is engaged in an admirable but uphill struggle against Big Pharma. He intends to take it beyond research and development in proposing legislation: "That would create a new network of government labs for the research, development and manufacture of pharmaceutical products. When discoveries are made, the patents would be held by the government and nonexclusive licences would be attached to them. This would allow companies to compete to manufacture pharmaceutical products, just like generic drug companies do now. This would radically bring down the cost of drugs [and would also] increase the affordability of cures worldwide. We have watched the pharmaceutical industry fail on three counts: submitting fewer and fewer drugs to FDA for approval, creating 'copycat' drugs instead of truly new cures, and raising drug prices higher every year. Our current patent system is what encourages artificial improvements and keeps prices high. It seems clear that one of the keys to public health is establishing public patents²³".

The European Commission (Research Directorate) is also a significant funder of international collaborative research in the health sector, through its INCO programme. Researchers and research managers from the South have proposed that the fruits of such international collaborations could perhaps be similarly vested in international agencies (trustees) such as the World Health Organisation (WHO), to keep the

19 For 13 out of those 16 drugs, two were modifications of existing medicines, two were produced for the US military, and five came from veterinary research. Only four were developed by commercial pharmaceutical companies specifically for tropical diseases in humans (Kremer, M. and Glannerster, R. 2001. "Creating a Market for Vaccines", New York Times, June 1.)

20 Trouiller, P., Olliaro, P., Torreele, E., Orbinski, J., Laing, R. and Ford, N. 2002. Drug Development for Neglected Diseases: A Deficient Market and a Public Health Policy Failure. *Lancet*, Vol. 359, pp. 2188– 2194; Cohen, R. 2002. Neglected Diseases and the Health Burden in Poor Countries. *Multinational Monitor*, June 2002.

21 Health Ministry management conference – Facing the Challenges of Globalisation and the New Trade Agenda, October 10– 12, 2002, Penang, Malaysia. Pfizer (Malaysia) when contacted by phone (Jack Lee, December 3, 2003) acknowledged that Viagra was its top– selling lifestyle drug, but that other product lines such as Lipitor (cholesterol lowering drug) had larger sales volumes. Mr Jack Lee however declined to rank Viagra's sales volumes (or its profitability) among Pfizer's comprehensive drug list in Malaysia. Mr YC Lee similarly declined to comment further on his public remarks in October 2002.

22 WHO Press Release, June 25, 2003.

23 Kucinich, D.J. 2003. The Case for Public Patents. *The Nation*, June 19, 2003.

prerogatives within the international public domain²⁴.

At the moment, the EC's policy objectives are geared more towards the R&D needs of SMEs (small and medium sized enterprises), which lack the in-house R&D capacity of larger firms. SMEs, many of them innovative and dynamic, are viewed as the preferred vehicles for commercializing the outputs of EC-funded research in science, technology, and development.

This is not necessarily incompatible with the publicly-held patents and nonexclusive licensing as envisaged in the Kucinich initiative, or with other scenarios which the "open source" movement is actively deliberating, experimenting with, and promoting for knowledge-intensive industries. (The stereotypical model was pioneered by software writers for open-source applications such as the Linux computer operating system, but the generic ideas are now making inroads as well into the scientific publications and communications arena).

6. Concluding Remarks

Recent experiences with emergent and resurgent infectious diseases have cautioned us to retain a sense of proportion when considering disease aetiology as well as society's responses to such challenges.

A sense of proportion²⁵ is also essential for constantly reminding ourselves of our troubling capacity for

24 On September 3, 1999, US activists Ralph Nader, James Love, and Robert Weissman wrote to Harold Varmus, Director of the US National Institutes of Health "to ask that you enter into an agreement with the World Health Organization (WHO), giving the WHO the right to use health care patents that the US government has rights to under 35 USC Sec 202 (c)(4) of the Bayh– Dole Act or under 37 CFR 404.7, for government owned inventions. Under the regulations concerning government– owned inventions, the US government has an "irrevocable, royalty– free right of the Government of the United States to practice and have practiced the invention on behalf of the United States and on behalf of any foreign government or international organization pursuant to any existing or future treaty or agreement with the United States. 37CFR404.7(a)(2)(i)". With respect to government's rights in inventions funded by the US government through grants and contracts to Universities and small businesses under the Bayh– Dole Act, the US government has worldwide rights to practice or have practiced inventions on its behalf (37CFR401.14), and it may require that foreign governments or international organizations have the right to use inventions, under 37CFR401.5(d). As you must know, the US government has rights to a large portfolio of health care inventions that were invented with public funds. These include inventions in many HIV/AIDS drugs, such as government– owned inventions on ddI, ddC and FddA, and university and contractor inventions such as d4T, 3TC and Ritonavir, as well as drugs to treat malaria and many other illnesses. The private pharmaceutical companies that have obtained exclusive rights to market these products charge prices that are excessive and too expensive for many patients, including people in the United States and Europe. Most seriously, the hardships are particularly difficult in developing countries, where countries do not have high enough national incomes to pay for expensive medicine". Dr Varmus, in his reply dated October 19, 1999, stated that "Congress enacted the Bayh– Dole Act and the Stevenson– Wydler Technology Innovation Act (with later amendments, including the Federal Technology Transfer Act of 1986) to encourage the transfer of basic research findings to the marketplace. The primary purpose of these laws is economic development: specifically, to provide appropriate and necessary incentives [through exclusive licenses] to the private sector to invest in federally funded discoveries and to enhance US global competitiveness". A subsequent request dated March 28, 2001 and addressed to US Secretary of Health and Human Services Tommy Thompson was similarly denied.

25 During the SARS epidemic, there were loud laments about a societal (or individual) "overreaction" in the risk avoidance responses to the outbreak, with the resultant "collateral damage" on East Asian national economies disproportionate to the seriousness or severity of the epidemic of 2002– 2003. In Singapore for instance, 206 probable cases of SARS were diagnosed, of whom 32 died. Malaysia, which recorded five probable cases and two deaths from SARS nonetheless suffered comparable economic losses mainly in the travel and tourism, entertainment and hospitality sectors, as well as the health services industries. Clearly, this "collateral damage" overshadowed the direct human cost (lives lost, temporary or long– lasting infirmity, family and personal tragedies), when furthermore contrasted against the persistent, devastating, but all too often invisible plagues in poorer countries of the South: HIV/AIDS, tuberculosis, malaria, water– borne diseases and malnutrition, which collectively (and often acting in concert) cause more than 12 million avoidable deaths annually. Similarly, the continent–wide uproar in Europe over "mad cow disease" (bovine spongiform encephalopathy, BSE) and its putative human version, variant Creutzfeld– Jacob disease (vCJD), which has recorded less than 200 deaths in the fifteen years since the disease was first recognized in the late 1980s, seems grossly out of proportion.

selective anaesthesia²⁶, for “normalizing” human health disasters - especially when they occur among marginalized communities with a limited “voice”.

A social-ecological perspective of health and disease²⁷ teaches us to be wary of the extravagant claims of genohype, i.e. genomics as all-round panacea for the major health (and social) problems of humanity.

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26 Amartya Sen once observed that if poverty itself were contagious, it would speedily dispel the nonchalance and indifference of the privileged and sequestered.

27 Levins, R. 2003. The Re-emergence of Infectious Diseases on the Public Health Agenda. *Third World Resurgence*, July/August 2003, p.5– 10. See also Levins' award lecture for the Edinburgh Medal of Science, 1996. When Science Fails Us, <http://www-trees.slu.se/news/32/32levin.htm>.

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Social Discrimination and Health Disparity Across Generations: Are We Sufficiently Informed?*

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Background

The physical and social environments encountered from preconception to birth exert powerful influences on physiological function and risk of disease in postnatal life. Epidemiological evidence gathered from a variety of sources have confirmed that lifestyle diseases; such as heart disease, cancer, gastrointestinal disturbance, diabetes and various neuro-behavioural anomalies, need to be understood within the contexts of family and community life, socioeconomic status and preconceptional/prenatal development (Gluckman et al., 2005). In basic terms, epigenetic influences (that is, all the external environmental variables that regulate gene activity) modulate normal developmental processes. Since epigenetic effects are operative at any time during the differentiation of the gametes, the wellbeing and living conditions of both parents from the time of gamete formation to the conception of the offspring are crucial, as is the mother's situation during pregnancy and lactation. It is, therefore, important to highlight that the heritability of complex behavioural, dietary and other adverse epigenetic effects on development may permanently impose a vulnerability to mental and physical illness in the offspring, even to a second generation (Jiang et al., 2004). Manifestly, lower social standing provides fewer opportunities, less training and decreased flexibility in decision-making which, in turn, predisposes the body to stress-related physical and psychological disease. Being at the bottom of the social scale, whether provoked by poverty (lower income, lower education, poorer medical care, poorer housing), or advanced by harmful lifestyles (drug dependence, social disengagement, depression), is associated with high rates of morbidity and mortality (Singh-Manoux et al., 2003).

Numerous sources have established that the greatest effects on individual and community health result from environmental degradation and social injustice operating in concert. Lack of control over one's life synergises harmful dynamics of marginalization, alienation, resentment, depression and environmental deterioration. Self-trust, on the other hand, is empowering as it provides confidence from the freedom to construct solutions suitable for life's challenges (McEwen and Lasley, 2003). The present paper's objectives are to highlight equity issues as they affect human reproduction across generations and to update recent insights that sustain, or otherwise, the health-wellbeing continuum, as recently reviewed (Pollard, 2005). In order to reach responsible ethical positions, accurate biological information must be intelligible and communally accessible. It is in this context that I invite the reader to access my web portal at <http://www.bioscience-bioethics.org/> which provides free admittance to educational material in the area of stress physiology, reproduction, developmental toxicology and environmental science, and other useful links for those interested in bioscience ethics and bioethics.

Socioeconomic Disadvantage across Generations: The Situation

It is well recognized that events during gestation (as indicated by birth weight and placental weight) and infancy (as indicated by growth in the first year) are associated with the risk of lifestyle illnesses in middle and later life; however, equally compelling evidence that birth weight is associated with later socioeconomic disadvantage, is not so well publicized. For example, comprehensive surveys such as the 1958 national child development study, which correlated birth weight with social status in children resident in Great Britain (Bartley et al., 1994), provide us with challenges that demand just solutions regarding social deprivation and its consequences. The study established that children weighing under

* Paper presented at the First UNESCO Bangkok Bioethics Roundtable, September, 2005.

2,721 g (6 lb) at birth were more likely, if they survived to ages seven, 11 and 16 years, to be living in overcrowded households devoid of possessions and without sole use of basic amenities such as an inside toilet, hot water supply, and a bathroom (Bartley et al., 1994). Importantly, the association between birth weight and socioeconomic circumstance was found to be graded; that is, the lower the birth weight the poorer the living conditions after birth (Bartley et al., 1994). More recently, interest has focused on the origin and development of lifestyle diseases according to race as a social, not biological, construct. Overall, significant relationships exist between ethnicity/race and failing health and, conversely, health-promoting behaviour is inversely associated with self-reported racism (Paradies, 2006a). Fourth world indigenous groups and African Americans reported that racism typically preceded harmful health behaviours and chronic physical and mental lifestyle diseases, rather than vice versa (Paradies, 2006ab). For those not familiar with the term '4th world indigenous groups', it refers to all Indigenous peoples numbering about 250-350 million worldwide.²

In hindsight, it is patently obvious that if we are to address the combination of risks attributable to persistent developmental problems and socioeconomic disadvantage, experiences from preconception to birth through to adulthood, have to be taken into account. The following specifics relate to the Indigenous peoples of contemporary Australia but at the same time also expose the universality as described above.

Many Indigenous Australians experience levels of disadvantage and ill-health akin to the poorest nations on earth. Entrenched poverty, welfare dependence, social breakdown and unacceptably high rates of morbidity and mortality are reflected in intergenerational disparities in socio-economic wellbeing, lifestyle and access to health and other services. The current reprehensible situation, as commonly believed, is not only consequent on past inequities but also on present marginalization and neglect. Prior to the social upheavals caused by incoming Europeans, Aboriginal people lived in reasonable stability and enjoyed better health than that experienced in Europe at the time. As well as the loss of culture and land, the introduction into the country of infectious diseases such as smallpox, syphilis, measles, whooping cough, scarlet fever, tuberculosis and influenza has had dramatic impacts on Indigenous health and wellbeing. Despite progress being made, there's still a very long way to go before the goals of social equity, equality of opportunity and fair division of resources are reached.

From the Australian Bureau of Statistics³ we can access the following figures. Fifteen percent of households with Indigenous person(s) are considered overcrowded requiring at least one extra bedroom, compared to 4% of other households. The level of infant mortality in the Indigenous population is three times the national average. Babies weighing less than 2,500 grams at birth are classified as being of low birth weight; and in 2001, babies of Indigenous mothers were twice as likely to be of low birth weight (13% of births) than babies of non-Indigenous mothers (6%). In early to middle age (25-64 years) the morbidity and mortality rates from hypertension, cardiovascular, respiratory, renal and metabolic (diabetes principally) diseases are six to ten times higher than that for the population at large. High kidney failure rates can be attributed to chronic systemic malfunction resulting from hypertension and diabetes (Hoy et al., 2005ab).

Drug and alcohol abuse and high rates of unemployment are severe social problems within the Aboriginal communities. The Australian population, like many Western societies, most commonly uses and abuses legal drugs, particularly alcohol and tobacco; these drugs are associated with more chronic illness, disease, accidents, social problems, unemployment and days off work than all other drugs together (Brown et al., 1986; Johnson and Ait-Daoud, 2000). Aboriginal people in Australia also mainly use legally obtainable substances: alcohol, tobacco, analgesics, solvents and kava, although illegal drug abuse among urban Aboriginals has also been reported (Brady, 1992). In remote areas, availability narrows the range of substances used, however, alcohol, tobacco, inhalants (particularly petrol), kava, and methylated spirits are regularly available, even in remote bush communities. For reasons of general availability, cheapness and lack of access to other substances, the practise of inhaling volatile substances, specifically petrol, is more prevalent in remote Aboriginal communities than in urban or rural populations (Brady, 1992).

In January 2005 British Petroleum introduced into the market a non-sniffable fuel called Opal designed to reduce petrol sniffing in remote Indigenous communities. Opal is useful in mitigating petrol sniffing as

2 Indigenous node for the World Wide Web. Virtual Library [<http://www.cwis.org/wwwvl/indig-vl.html>]

3 <http://www.abs.gov.au>

it has low levels of aromatic compounds that generate the subjective feelings of pleasure and happiness - or "high" -pursued by the sniffer. The "high" is brought about by an artificially-induced imbalance of the brain's neurotransmitters that normally control emotional stability and when disrupted syndromes of depression and mania may develop, particularly following regular abuse (Pollard, 2003). Reduced engine emission of toxic substances such as benzene and sulphur also has environmental benefit. Unfortunately, cannabis abuse is on the rise as previous petrol sniffers switch onto what is more readily available.

Drug rehabilitation in combination with the relative remoteness of a significant proportion of the Aboriginal population has serious implications for health and wellbeing. Twenty five percent of Indigenous Australians live in remote and very remote areas of the country compared to 2% of the non-Indigenous population. Access to preventative health programmes and services such as health clinics, hospitals, schools, nursing homes, is more difficult in remote and very remote areas. As a consequence of neglect by disengaged adults and basic preventative medicine, Aboriginal children are at a serious disadvantage at school where entirely preventable or controllable health problems such as simple eye and ear infections, asthma and diabetes become chronic conditions seriously affecting quality of life issues early on in life. The Australian Bureau of Statistics also reveals that education is a long-term casualty of the living conditions of Indigenous peoples. Aboriginal school retention rate is 25-50% less than for other groups and university attendance in 2001 was 5% compared to the general population's 23%. As a result, Indigenous people are almost three times more likely than non-indigenous people to be unemployed or employed in a casual, low-income capacity. Neglect of education automatically reduces employment opportunities, which in turn undermines socio-economic status and community health.

It's no surprise, given existing conditions, that the average life expectancy for Aboriginals is 15-20 years below that of the general population. A comparative perspective shows that a person from Nigeria or Bangladesh can expect to live about ten years longer than an Indigenous Australian, or that a present-day Indigenous person has about the same life expectancy at birth as the whole Australian population had in the early 1920s (Howitt et al., 2005). Deaths from external causes such as accidents, suicide, homicide and assault, account for one in every six registered Indigenous deaths and this astonishingly high rate is considered a conservative estimate because of substantial under identification of Indigenous deaths (Howitt et al., 2005). Scandalously, suicide is two-to-three times more common among the Aboriginal and Torres Strait Islander peoples and five-to-six times more prevalent among Indigenous youths compared to non-Indigenous youths (Hunter and Harvey, 2002). Although Indigenous people constitute only 2% of Australia's population, they account for 20% of the prison population. It's not uncommon for young offenders to move through the depressing cycle from juvenile correctional services to imprisonment only to re-offend on release. The Royal Commission's recommendations into Black Deaths in Custody have helped to reduce suicide rates of Aboriginals under arrest; however, the striking imbalance of incarceration remains unchanged (see section on 'Circle Court for Aboriginal Punishment').

Despite popular belief, it's worth noting that victims of Aboriginal crime are mostly other Aboriginals. This was well substantiated when in May 2006 several hundred Aboriginal people were forced to live as refugees in their own community following gang violence on the streets of Wadeye, a remote Aboriginal community 250 km southwest of Darwin.⁴ Soul-destroying living conditions experienced by Indigenous Australians in some outback communities has reached such hopelessness that even the Vatican began paying attention when Pope Benedict XVI urged the Federal Government to actively address "the deep underlying causes of their plight". The Pope also expressed the opinion that the way to lasting reconciliation is through the healing process of "asking for forgiveness and granting forgiveness".⁵

4 Australian Aboriginal community wracked by gang violence plans evacuation. Canadian Broadcasting Corporation World News May 2006 [<http://www.cbc.ca/cp/world/060522/w052268.html>]

5 Archbishop discusses Pope's Indigenous comments. Australian Broadcasting Corporation Lateline May 2006 [<http://www.abc.net.au/lateline/content/2006/s1645758.htm>].

Intrauterine Programming: A Mechanism for Conveying Epigenetic Determinants Across Generations

From the biological perspective, health and ill-health are not alternative states; rather they are part of the same continuum where genetic and epigenetic influences sustain, or derail, normal reproductive processes triggering lasting legacies in the next and subsequent generations. As described in the introduction of this paper, we inherit more than just our genes from our ancestors. Inadequate control over the decision-making in one's life generates a destructive interplay of social, physical, economic and environmental (epigenetic) factors that undermines the determinants shaping the wellbeing continuum. Like all of us, foetuses have mechanisms by which they adapt to deteriorating environmental conditions brought about by parental distress, drug abuse, disease, nutritional deprivation and non-adaptive lifestyles. In essence, normal development is disrupted by harmful influences and for those surviving their prenatal challenges, the cost maybe a struggle with long-term health consequences. Adverse reproductive effects manifest themselves through reduced fertility, early miscarriage, foetal death, malformation, retarded growth and organ dysfunction together with the delivery of small, intrauterine growth-restricted, weaker, slower in development infants (Pollard, 2005). Growth-restricted infants also have a higher than normal risk of developing diseases of adaptation such as hypertension, ischaemic heart disease, diabetes, depression and increased vulnerability to drug addiction in adult life (Pollard, 2005).

The phenomenon whereby suboptimal intrauterine growth may alter foetal development is variously referred to as "foetal programming" or "developmental programming of adult health and disease" or just "programming" and occurs when the normal pattern of foetal growth is disrupted in response to unfavourable intrauterine conditions (Pollard, 2007). Transmitted via placental communication systems, particularly with glucocorticoid stress hormone involvement, adverse epigenetic influences impose foetal survival-enhancing trajectories in utero albeit at an increased risk of adult-onset degenerative diseases. Glucocorticoids can act directly on genes and indirectly through persistent differential effects on the hypothalamic-pituitary-adrenal axis which, in turn, influences the stress response throughout the course of postnatal life (Kapoor et al., 2006). Environmental stressors that cause permanent developmental dysfunction of the foetal brain are particularly disturbing. Intellectual and behavioural damage caused by prenatal exposure to poisons such as petrol, nicotine, alcohol, cocaine and marijuana cannot always be detected early in postnatal life with vital diagnosis being delayed until the children are expected to perform tasks involving attention processes such as learning and memory, and every day physical skills like eye-hand coordination essential in ball games and bicycle riding.

Foetal adaptation is subject to genetic resilience and if the limits of genetic adaptability are exceeded, foetal growth retardation and/or organ damage may result. Should epigenetic influences adversely affect the sexual differentiation of the foetal germ cells, then a changed genetic programme may be perpetuated in the offspring of subsequent generations creating a biological mechanism for the grandparents' lifestyle to effect health and wellbeing of their grandchildren. It is sobering to note that increased intergenerational risk of preterm delivery and low birth weight has been documented in African-American third generation children born of parents of high socioeconomic status (Foster et al., 2000). The final severity of the developmental damage depends on individual genetic predisposition and whether the defect can be transmitted to a subsequent generation. It should also be noted that certain behavioural anomalies may take more than a generation to discover. Conversely, reproduction under good conditions creates a positive force in shaping human identity across the generations.

Critical periods in intrauterine development are those periods during the development of organs, or organ systems, when they are most sensitive to external influences. Exposing an organ to a toxic substance or other disturbing influence during its particularly critical period, results in maximum developmental damage. It took the thalidomide tragedy of the late 1950s and early 1960s for scientists to fully realize that not all congenital malformations have a genetic cause. Of pregnancies that proceed far enough to be detected clinically, about 15-20% are subsequently lost by spontaneous abortion or miscarriage, usually during the first three months or first trimester. The majority of all spontaneously aborted embryos and foetuses have chromosomal abnormalities. This contrasts markedly with a 5% chromosomal abnormality rate found in stillbirths, clearly illustrating the natural in utero selection process that eliminates the majority of chromosomal damaged conceptions. The aetiology of human

malformations at birth includes mutant genes, environmental agents and a large category labelled unknown. The causes of most human congenital anomalies at birth are unknown because these, as for the majority of common disorders such as heart disease, diabetes and cancer, are multifactorially or polygenetically inherited; that is, result from a complex combination of intrauterine programming strategies in response to genetic and epigenetic variables.

Prenatal drug exposure, low socio-economic status, marital and family discord, maternal depression and paternal criminality have all been cited as risk factors for physical, academic, social and emotional problems in childhood (Biederman et al., 1995; McIntosh et al., 1995; O'Connor et al., 2002; Conners et al., 2004.). In circumstances of heightened, prolonged stress and weakened means of defence, the sufferer may seek the escape that mind-altering, psychoactive substances can provide. Simply expressed, those who become dependent on alcohol or drugs are using these substances as a medication to calm feelings of anxiety, anger, alienation or depression. Differences in overall reproductive health often have their origin in early life. For instance, an association has been made between chemically-dependent women seeking counselling for problems related to substance abuse, and their childhood sexual abuse (Bensley et al., 2000). Similarly, men are more likely to seek help for the consequences of sexual abuse (depression, alcoholism) than for the abuse itself and secondary school students who reported higher levels of emotional distress subsequently had the highest rates of substance abuse (Tschann et al., 1994).

We should never forget that poverty itself delivers emotional blows to children: poorer children at the age of five are already more fearful, anxious, and depressed than their better-off peers, and have more behavioural problems - a trend that continues through their teen years. The stress of poverty corrodes family life resulting in fewer expressions of parental warmth, more depression in mothers (who are often single and jobless), a greater reliance on violent outbursts and reduced quality time with the kids, all perpetuating social inequalities in health and wellbeing (Kristenson et al., 2004).

Challenging Social Discrimination and Health Disparity in Contemporary Australia

A: Government and Indigenous Communities in Equal Partnership

The differential allocation of risks and benefits for growth between differing socio-economic groups is central to addressing transgenerational equity issues. Both a harsh colonial history and self-sustaining inequities are responsible for many of the contemporary problems of Australian Aboriginal children and young adults. We know that children who have experienced a good prenatal environment and were well nurtured in their early years have better outcomes throughout their lives. They do better in school, have higher self-esteem, fewer social, health and behavioural problems and are less likely to become teenage parents, abuse drugs or be involved in crime. We also know that lack of control over one's life engages harmful dynamics symptomatic of marginalization, alienation, resentment, depression and environmental deterioration, and that these harmful dynamics are self-perpetuating across generations.

Persistent powerlessness in Australia's Indigenous populations is a shameful consequence of the failure of political, religious, health and legal institutions to bridge the gap between knowledge and effective action. Many lines of research have made the connection between unwanted births and the offspring's greater than expected risk of criminality (Levitt and Dubner, 2005) and that domestic violence and abuse is a strong motivation among women seeking an abortion (Glander et al., 1998).

Given scientific acumen and good will, it is possible to choose to prevent, postpone or skilfully control the worst consequences of poverty, depression, child neglect and drug dependence. The uneven distribution of common human (dare I say biological) rights has serious psychological, social and economic implications for the nation as a whole. We have the scientific evidence - what is required is the emotional intelligence to compassionately understand social and ecological systems. It is time to translate biological imperatives into ethical action and demand individual and collective commitment

in eradicating the worst consequences of poverty. Public acceptance that health begins well before conception and that each of us is custodian of the next and subsequent generations, would be a good start in the development of effective bioscience-bioethics education programmes. Given a just standard of living, preconceptional care should significantly reduce the social and health risks to future generations of children. Governments must give special attention to the education of young people so that they can exercise a responsible attitude to themselves and their children. It is imperative that we as a nation develop a practical and satisfactory scientific framework activating the acceptance of reproduction as a privilege, rather than a right; a right all too often trivialized.

Importantly, the allocation of health and educational resources should be on the basis of need, and disadvantaged minority groups, whether Indigenous or other, must be involved in designing and implementing the solutions. Muting the Indigenous voice is counterproductive since, as we have seen, self reliance is the key to good health and well being. All societies provide special rights to specific groups to ensure equal outcomes for all. That is why we have wheelchair access and designated parking for disabled people and diesel fuel subsidies for farmers. Health and living standards of Indigenous Australians are the worst in the developed world, so special measures are required to address the underlying causes of such severe disadvantage. In order to destroy inequality there must be a "fair go" for all Australians. Reconciliation is possible only when people make it their concern and actively work for it. In particular, biomedical issues concerning health and well being of parents and children need to be addressed and the provision of health and health education expanded for all.

Since this paper was written, Prime Minister Kevin Rudd has made an apology to Australia's Indigenous Peoples on behalf of all Australians. The statement was tabled in the Australian Parliament on Tuesday 12th February, 2008, and included for the first time the Indigenous "Welcome to [the] Country" ceremony as well as traditional British parliamentary rituals. The full statement read:

"I give notice that, at the next sitting, I will move: That today we honour the Indigenous peoples of this land, the oldest continuing cultures in human history.

We reflect on their past mistreatment. We reflect in particular on the mistreatment of those who were Stolen Generations - this blemished chapter in our nation's history.

The time has now come for the nation to turn a new page in Australia's history by righting the wrongs of the past and so moving forward with confidence to the future.

We apologise for the laws and policies of successive Parliaments and governments that have inflicted profound grief, suffering and loss on these our fellow Australians.

We apologise especially for the removal of Aboriginal and Torres Strait Islander children from their families, their communities and their country.

For the pain, suffering and hurt of these Stolen Generations, their descendants and for their families left behind, we say sorry. To the mothers and the fathers, the brothers and the sisters, for the breaking up of families and communities, we say sorry.

And for the indignity and degradation thus inflicted on a proud people and a proud culture, we say sorry. We the Parliament of Australia respectfully request that this apology be received in the spirit in which it is offered as part of the healing of the nation. For the future we take heart; resolving that this new page in the history of our great continent can now be written. We today take this first step by acknowledging the past and laying claim to a future that embraces all Australians.

A future where this Parliament resolves that the injustices of the past must never, never happen again. A future where we harness the determination of all Australians, Indigenous and non-Indigenous, to close the gap that lies between us in life expectancy, educational achievement and economic opportunity.

A future where we embrace the possibility of new solutions to enduring problems where old approaches have failed. A future based on mutual respect, mutual resolve and mutual

responsibility. A future where all Australians, whatever their origins, are truly equal partners, with equal opportunities and with an equal stake in shaping the next chapter in the history of this great country, Australia.”

B: Circle Court for Aboriginal Punishment

New South Wales authorities have been staging trial pilot programmes of Circle Court as an alternative means of sentencing. The Circle Court, designed for serious repeat offenders, is a court overseen by a magistrate but supervised by community elders. It aims to involve the whole community in the sentencing-rehabilitation processes. The Circle Court begins by seating the presiding judicial officer, the offender, the defence council, the victim and other participants; such as the family and other interested persons in a circle. The aim of the court is twofold: to set a sentence plan for the offender and to address the underlying causes for the offence. The facts of the case are presented to the circle by the crown, followed by the defence after which the whole circle is opened up for a comprehensive discussion. Importantly, the offender must also address the circle, perhaps after a statement by the victim about the impact of the crime is made. The bringing of offender and victim face-to-face has several beneficial effects not least increasing the programme’s success rate. The circle then examines what must be done to heal the victim and the offender and, more broadly, underlying issues in the community that are causing serious problems and examine ways of addressing them. At the end of these deliberations, bail conditions are set for the offender such as curfew, work programmes, abstention from alcohol, cognitive behavioural therapy, anger management, and any other penalty deemed appropriate not excluding imprisonment. Some members of the circle, perhaps with the involvement of other community members, will take responsibility for seeing that the offender completes the sentencing plan.

The immediate good news is that circle sentencing has slashed recidivism rates in all locations since the scheme was first introduced in 2002. The strength of the Circle Court is the close kinship between the elders and the accused where the circle is built on trust and respect. Within the circle context it’s understood that to break the law you break the law of the traditional owners of the land as well as the Australian court. This excellent outcome reinforces the fact that the crime rate is not contingent on ethnicity but contingent on socioeconomic disadvantage and lack of control in one’s life (Goodman et al., 2005). As stated previously, transgenerational change has to be forged out of the entire life-death and renewal cycle; not from short-term fixes.

C: Healthy Country, Healthy People: Gaining from Aboriginal Adaptability and Creativity

As the reader has seen, the founding of white Australia was at the expense of Indigenous people flourishing, the loss of which is a major cause of social unrest, chronic ill-health and spiritual distress. Clearly, redressing Indigenous health is an ethical issue that demands special consideration. Indigenous Australians believe that they have been in Australia since “Dreamtime”, or “Creation”, when their land was shaped by their spiritual ancestors. These ancestors, or first people, journeyed across the country creating the landforms, plants, animals and diversity. They brought with them laws to live by: ceremony, kinship and ecological knowledge. They taught Aboriginal people how to live in the land and look after the country.

“If you respect the land,
then you will feel the land,
Your experience will be one that you
cannot get anywhere else in the world.”

*Brian Baruwei -Wurrkbarbar clan,
Aboriginal traditional land owner.*

Although it will probably never be known precisely when the first human footprint was made on Australian soil, it is hypothesized that the first people migrated from the South East Asian region more than 50,000 - probably 60,000 - years ago. At that time much of the world’s water was frozen into ice sheets and the level of the sea was more than eighty meters lower than it is today. This made the passage

for the first boat people from Asia to Australia much easier. Since the Pleistocene coastline extended out so much further than it does today, most of the earliest camp sites are, regrettably, underneath the sea. Among Australia's Indigenous peoples many cultures exist and Aboriginal people identify as both Indigenous and, whenever possible, also as a member of their language group; that is, coming from a particular place/country each identifiable by its own creation stories. It is estimated that at the time of Captain Phillips's landing at Sydney's Botany Bay in 1788, there was a population of about three million Aboriginal people speaking about 250 distinct indigenous languages, each with their own country and culture. Almost all of these languages - many of which have since been lost - are related indicating that they are descended from a single ancestral language spoken by the first settlers.

Most importantly, prehistory teaches us that the first Australians were some of the earliest representatives of *Homo sapiens* who, through millennia, were able to sustain fitness by adaptively evolving a holistic framework of country, community and appropriate conduct. At the same time as successfully adjusting to profound environmental and climatic changes (with accompanying loss of substantial tracks of their land as the polar ice caps melted and the seas rose), Aboriginal Australians also developed a rich and varied culture. This culture, over many thousands of years, supported thriving populations in some of the harshest areas of the world's driest inhabited continent. Significantly, sustainable practices allowed them to exploit and survive in a wide range of environments where modern European land/water management practices bleakly failed. In modern times, scholars, increasingly, are warning us that the nature/culture dualism, which serves to separate humanity from the rest of the biosphere, is the primary cause of current ecological crises. We are warned to directly acknowledge that the natural environment is not an endless resource just for the taking and must figure out a better relationship that underpins an ecologically sustainable and just ethics. Just ethics, or eco-justice, implies challenging extant values and assumptions, particularly those that have supported ecologically damaging practices. It promotes living in harmony with nature rather than its conquest and exploitation. This is precisely where Australia's Indigenous peoples can assist if we are to intelligently confront the oncoming challenges of climate change and global warming.

All over the continent thousands of archaeological sites and natural landmarks reveal in astonishing detail animated evidence of Aboriginal life. Prehistoric Australians had widespread trading networks, were skilled in understanding the laws of physics (note boomerang and didgeridoo technology), and devoted much energy to ceremonial life. Above all it was creativity of spirit, rather than material resourcefulness that prehistoric Australians excelled in. Home-grown society was organized to allow ample leisure time for matters of the mind such as art, ceremonies, music and dance. Their "written" prehistory can be "read" by marking out cultural sequences of engraved rock paintings, ornamental artefacts and ways of honouring the dead. For instance, the earliest burial site in Australia dates back 60,000 years ago, and includes ochre scattered over the corpse. Red ochre was the most highly prized pigment in prehistoric Australia, and pieces from deposits created by ancestral spirits were essential for use in rituals. Long expeditions were therefore made to these sites, or sometimes the special ochre was obtained by barter.

The earliest art predates the post-glacial rise in sea level and development of estuarine conditions and depict ancient geometric figures, concentric circles, animal tracks and lines that have weathered back to the same dark colour as the parent rock; a process that takes many thousands, even tens of thousands, of years. Great antiquity is also demonstrated by the dynamic representational style of art that resides in the World Heritage sites of Kakadu and the Kimberley in the Top End of the continent. Amongst these motifs there are realistic depictions of land animals, including the extinct Thylacine or Tasmanian tiger, pecked-out small, insignificant humans and imposing early spirit figures (Figure 1). Much better known, however, is the later estuarine art dominated by fish and crocodiles portrayed in a unique x-ray style in which the skeleton and internal organs of creatures are shown as well as the external features (Figure 2). The significance of these ancient galleries were not kept secret for they were prominently placed high up on rock shelters or on groups of massive boulders from which they could be seen from the vast plains below. Consequently, these natural landmarks percolated with spiritual significance provide us with a record of the evolution of the land and its people over the last 50-to-60 thousand years. To the reader who wishes to learn more about the prehistory of Australia and its people Josephine Flood's book (Flood, 2004) is an excellent source of information.

As described elsewhere in this review, the coming of white people almost extinguished Aboriginal society; however, now the time is right to assess both ancient and modern insights with a view to integrating the essentials of healing and well being. Traditional wisdom supported by rapidly growing research-based understanding, particularly that of stress physiology, have identified key factors in the generation and maintenance of physical, psychological and social well being. By integrating contemporary biological insights with a sense of responsibility, we should be capable of harnessing our collective pool of flexible intelligence in order to further evolve our altruistic instincts already embodied in our genes.



Figure 1: Examples of some of the oldest surviving rock paintings in the Northern Territory done in red ochre (varieties of iron oxide minerals such as haematite) which when worked in water produces a strong pigment that penetrates deeply into the rock surface. In a dry climate and over thousands of years the silica in the rock forms a glaze on the surface effectively sealing the images. Top: images depict a black wallaroo with a joey in her pouch, small human-like figures and imposing spirit figures with too many fingers or exotic head dress (Katherine Gorge, Nitmiluk National Park; Jawoyn country). Bottom: part image of Thylacine long extinct on the mainland (Ubirr, Kakadu National Park; Binini and Munguy country).

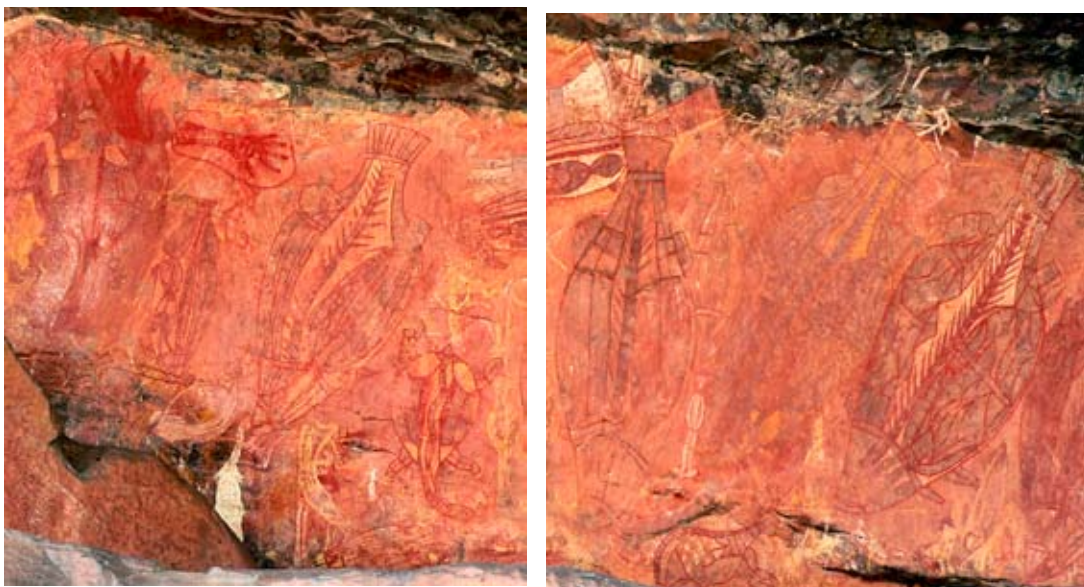


Figure 2: Ancient galleries of unique X-ray art record the traditional cultures and evolution of the land and its people over the last 40,000 years. On the right panel the human is insignificant compared to the animals (Ubirr, Kakadu National Park; Binini and Munguy country).

Concluding Remarks

If society's priority were to maximize avoidance of preconceptional prenatal and neonatal harm, the most efficient route would be through improvements to the general quality of life, by eliminating the worst environmental pollution and the stresses of poverty, which impair responsible parental care. The root causes supporting the cycle of domestic violence, drug and alcohol abuse, unemployment and juvenile detention demands recognition. In communities where the prevailing culture is such that violence is acceptable, change brought about by introducing the Circle Court innovation, for example, has provided hope for a new beginning. Change is not easy, especially in outback communities where typically everyone knows everyone else and the community has more often than not to deal with kin-based loyalties and a divided sense of obligation to their kin and to the protection of women and children. In these instances, the establishment of outside agencies dedicated to dealing with issues of sexual and physical violence can be a life saver as impartial service offers an opportunity, for women in particular, to lodge a criminal complaint without fear of retribution.

To focus on what is a safer, healthier place for families and children means engaging with these families as well as engaging outside services. That means to act proactively with the community in question rather than the usual reactive response once the situation has descended into crisis point. Immediate justice for victims of abuse is very important but justice is best extended with a view to the longer-term by promoting systemic change. What governments do profoundly affects the lives of people; therefore, we need to step back from short-term, poll-driven political goals and assess community values that guide aspirations for freedom, stewardship, ethics and justice. Programmes that have been found to be effective in reducing gang violence are anger management counselling, parental support through inter-generational mentoring involving respected elders, the establishment of men's groups, bonding through meaningful activities such as team sports, and other community-based initiatives such as dry (alcohol free) zones and keeping children safe off the streets at night. The stumbling block, typically, has been funding to initiate and maintain successful community-based programmes; especially new initiatives geared towards lifting self respect and community empowerment.

Issues of stress reduction, environmental quality, housing and workplace safety and educational reform, do not need to be uniform; rather the framework should incorporate regional diversity and pluralistic problem solving in tune with ethnically diverse populations. Part and parcel of consciousness raising is that all voices are heard, acknowledged and valued. It seems fitting, therefore, to close with the words of one such voice "with respect comes attitude"⁶

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Islamic Codes in Medical Ethics

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"In the Name of Allah, the compassionate, the merciful"

Introduction

The revival of genuine ethical merits is a vital requirement for establishing an Islamic state in society. Islam, as a perfect and comprehensive divine religion, not only provides guidelines for the personal lives of its followers, but also, in order to attain its ultimate truth, has various cultural, economic, juridical and governmental aspects. Because of these ethical methods, Islam exerts a great influence as a rule on all aspects of human life. Ethics as a kind of knowledge that deals with human beings, and their mental and spiritual improvement and inward purification has essential differences with conventional sciences, and is second to theology, in terms of status, necessity, and rewards.

The mission of ethics is to identify the various potential of humans and help us attain a balance between various desires of self, in order to find the way toward his deserved perfection. Hence, spiritual and moral edification should accompany, or even precede all kinds of education and direct them. Although it seems that there is no connection between the two, material and physical sciences are a necessary prelude to what serves ethics and human perfection.

Ethics

Morality is defined as: "Conscientious inspirations which are a force other than reason and emotion, dictating inwardly and determining do's and don'ts." So, a moral deed is one inspired by conscience. As Kant has put it: "Moral act is an act that is taken as a duty which is determined by conscience." Essentially, man is born liable and inwardly responsible. "...and [we] enjoined on them charity ..." (21. 73). The honourable prophet of Islam says: "I indeed was appointed to perfect moral virtues" which means that he considered it as one the most important objectives of his divine mission.

Medical Ethics and the necessity of discussing it

Although there is no specific chapter in ethics for medical ethics, considering the differences in professions and their social status and that each profession deals with its own problems and concerns, medical ethics can be defined as: "The science that is concerned with those behaviours and rules that should be observed by all in medical professions." Medical ethics is as inseparable from the world view as is the ethics itself. Therefore, nearly all races have believed in medical ethics since ancient times, although each has justified its necessity in a different way.

History of Medical Ethics

For centuries, the medical profession has been subject to moral advice and professional regulations, as is known with Indian and Egyptian physicians who observed ethical precepts. Medical ethics had substantial importance in ancient Greek civilization. According to Hippocrates, "The basis of medicine is a cordial and humane treatment". The most important contribution of Hippocrates in medicine has been his belief in ethics, which is reflected, in his famous oath.

There are provisions regarding the medical profession in Hammurabi's charter, which dates back to 2,200 B.C. This charter, carved into a piece of stone discovered in the Shush region in the early 19th century, is now kept in the Louvre Museum in Paris.

As can be deduced from ancient Iranian texts such as the Avesta, which includes several provisions and rules about physicians and medicine, when other nations lacked specific organization in this field, there were written considerations of ethics of medicine in this part of the world. There were various laws and regulations concerning health, physicians and veterinarians' rights and duties, and about medicine and surgery.

Medical ethics has enjoyed more significance under the sublime teachings of Islam, because medical sciences are highly regarded in Islam.

So far as to be equated with religious knowledge "There are two kinds of knowledge: Knowledge of the body [medicine] and knowledge of religions." and it is considered as one of the three main requirements of all human societies. Imam Sadeq made the following statement: "As no society can do without three things: a pious knowledgeable scholar, a benevolent obeyed chief and, a trusted insightful physician".

Muhammad Zakariya Razi (aka. Rhazes), one of the greatest physicians of the Islamic world, has written a book, titled "The Spiritual Medicine" about the principles of ethics, and Abu Ali Sina (Avicenna), the famous physician and philosopher of the East, has a book titled "On Ethics". Some researchers attribute a treatise to Rhazes, who is said to have written it for one of his students who had become the physician of a lord, to advise about observance of principles of ethics regarding physicians and the medical profession.

Medicine and Medical Ethics

Familiarity with spiritual issues is one of the most vital requirements of the medical profession. Islam considers spiritual and psychological treatment of the patient as more important than treating his/her bodily pain and illness. Establishing a spiritual link between the patient and God is one of the main duties of a physician. The medic should first of all try to lift morale and inspire hope and self-confidence in their patients, through mentioning the point that only God is health-giving.

A physician has many comprehensive responsibilities including those toward:

- God
- His/ Her mentor and the issue of education and learning
- Conscience
- Patient
- Society

1. A physician's duties and responsibilities toward God

It was quoted from Jesus Christ that: "Leaving the treatment of a wounded or ill person is certainly equal to helping the assailant, since the assailant wanted to kill or maim that person, and the one who has left the wounded has not wanted his betterment."

Therefore, medicine is not like other professions and jobs to be used as a means to attain wealth and power, since the main feature of every job is that the owner can perform it and get the benefits or not perform it and leave those benefits, but medicine can be considered a divine mission and a moral,

religious and humane duty for the physician who has spent years of time and effort to attain the status, and hence, has no right to neglect his/her duties and not fulfilling this mission is certainly an offence.

2. A physician's duties and responsibilities toward his/her mentor and the issue of teaching and learning

A physician, either as a learner or as a teacher, should observe the dignity of knowledge and first of all try to edify' and purify him/herself and learn and teach in order to comply with God's will. Principles that a physician should be committed to, after purifying him/herself, include:

1. First of all they must edify him/herself and attain a high level of knowledge;
2. Consider practical education more important than oral education;
3. Should be aware of his/ her poor ability and knowledge when compared with God and remain humble;
4. Observe regularity and discipline;
5. Teach like an affectionate and sympathetic father;
6. Observe the principle of graduation and repetition in learning and teaching;
7. Have an acquaintance with rhetoric and related skills;
8. Have courage in accepting reasonable objections;
9. Increase encouragement to learn and teach and act as a role model;
10. Observe justice and fairness;
11. Remain pious and virtuous;
12. Avoid wicked company.

3. A physician's responsibility to edify him/her

Being endowed with humane virtues and Islamic qualities is necessary for a Muslim physician. Benevolence is so important in medicine that any negligence, omission, deception or hypocrisy is considered a crime. A real benevolent person:

- Does not commit treason;
- Is not self-centred;
- Sympathizes with others.

4. Physician and patient

A doctor is the only one who can help the patient. The patient's only hope is in the doctor's skill. He/she should console the patient and take the responsibility of treating the patient's mental and physical ailment with compassion and love. A physician's most important duties toward patients include:

1. Good treatment and compromise;
2. Serious endeavour to solve the patient's problem;
3. Avoiding discrimination between the poor and the wealthy;
4. Distinguishing medicine from business;
5. Paying attention to the patient and attracting his/ her trust;
6. Upgrading one's knowledge and skills;

7. Trust worthiness;
8. Piety and avoidance of taboos;
9. Observing divine limits in giving orders to the patient;
10. Observing confidentiality;
11. Recommending preventive measures.

5. A physician's social responsibilities

Legally, a physician is responsible to society and government. It is emphasized in Ahadith (narrations) that no one can enter the profession without adequate approved knowledge and skills. A physician, while promised spiritual rewards in the after world, should be able to afford his/her reasonable needs through a sufficient salary. Of course, excessive inclination toward financial issues will result in commercialisation of medicine and make it a means of amassing wealth and power.

And finally, we end this part with a quote from Imam Khomeini (BA), who had an insightful and wise view regarding this profession: "You should not taint this profession with material, worldly interests, or else you will have worked and not [have been] blessed by Allah's blessings. Do it [your job] as a divine profession, for God's sake, and its being divine and getting a reward for it are not incompatible. These are not incompatible."

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Gender Foeticide: Exploring Beyond Medical Ethics*

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The serious gender gap

Foetal foeticide based on gender selection has posed a major problem for doctors, society, government and religious institutions in the Punjab and other regions of northern India. In 2001, the highest seat of Sikhs, the Akal Takht at the Harmandar Sahib, announced an edict forbidding any termination of pregnancy based on gender selection. The Indian State passed legislation against female foeticide in 1994. Activist groups have tried hard to stop foeticide but it continues, with Punjab having almost the largest number of ultrasound facilities in India per 1,000 people of the population. The 0-6 year old female-to-male ratio has steadily fallen in the Punjab and stands at 793:1,000 in 2001 against the national ratio of 927:1,000 female-to-male ratio. In 1991 this ratio was 875:1,000 in Punjab. No one quite knows how this will be reversed. It poses some considerable questions about ethics related to medical opportunities and whether they should be freely available. It also requires a multi-disciplinary approach that sees the problem as wider than the scope of medical ethics and brings in various civil society actors in a coordinated approach.

Determining Foetal Gender

Ultrasound scanning and amniocentesis were introduced as part of medical diagnostics to diagnose foetal abnormalities. Amniocentesis is an invasive technique, requiring a sample of amniotic fluid from the womb. It is usually informative at 16-18 weeks of pregnancy when it is safer to draw out amniotic fluid. Foetal cells from this fluid give important Chromosomal information. It can also give information about the gender of the foetus. Ultrasound scanning is a non-invasive technique. It gives information about foetal development and can give useful information about some forms of abnormalities. However at 15 weeks, it can also give information about gender.

Ultrasound equipment costs from US\$11,000 to \$45,000. There is a considerable demand for it in India. In fact even small towns have a private ultrasound facility. People access these facilities for gender determination of the child. The law requires that the sonographer does not reveal the gender of the child. However the official report of the sonographer does not need to reveal the gender. It could simply say that the foetus is normal while the sonographer can verbally advise the parent.

Gender Selection Abortion

Once people find the foetus is a female, the next step some take is abortion. Abortion for gender selection is against the law in India. However, the mother can pretend that she does not know the gender of the foetus and demand abortion on any of the other criteria. Even if the doctor is privy to the real reason for the abortion, the doctor can claim not to have known the reason for the abortion.

The Law

The first law relating to abortion was passed in 1971 as Medical Termination of Pregnancy. Prior to this abortion was illegal in India and abortions were carried out by back street clinics or quacks. The law was brought in to give legislative form to increasing liberalism in Indian society. However the number of gender selective abortions led to a rethink and introduction of the pre-natal Diagnostic Techniques Act in 1994. This was followed by the Preconception and Pre-natal Diagnostic Technique (prohibition of sex selection acts) Act 2003.

* Paper first presented at the First UNESCO Bangkok Bioethics Roundtable, September 2005.

The main features of these laws are:

(2) Subject to the provisions of sub-section (4), a pregnancy may be terminated by a registered medical practitioner:

- (a) Where the length of the pregnancy does not exceed twelve weeks, if such medical practitioner is, or:
- (b) Where the length of the pregnancy exceeds twelve weeks but does not exceed twenty weeks, if not less than two registered medical practitioners are of an opinion, formed in good faith, that:
- (i) The continuance of the pregnancy would involve a risk to the life of the pregnant woman or of grave injury to her physical or mental health; or:
- (ii) There is a substantial risk that if the child were born, it would suffer from such physical or mental abnormalities as to be seriously handicapped.

In the Pre-natal Diagnostic Act 1994, the following is significant:

Determination of sex prohibited in an amendment in 2003 and act changed to pre conception and pre natal... on and from the commencement of this Act:

(a) No Genetic Counselling Centre or Genetic Laboratory or Genetic Clinic shall conduct or cause to be conducted in its Centre, Laboratory or Clinic, pre-natal diagnostic techniques including ultrasonography, for the purpose of determining the sex of a foetus;

(b) No person shall conduct or cause to conduct any prenatal diagnostic techniques including ultrasonography for the purpose of determining the sex of a foetus.

It added in vitro sex determination as banned in the list in 2003.

Cultural Issues

The reasons behind the high gender based abortion rate are the desire for a male offspring and the dowry. Despite legal attempts to outlaw the dowry, the practice has increased in Indian society. Traditionally the dowry was practiced in upper castes. However, with increasing economic change in all sections of Indian society, the dowry became prevalent among all castes. Dowry is now endemic in Indian society and given to the groom when a daughter is married. It is a significant economic burden upon the family. Moreover daughters leave the family home and therefore form a net financial burden upon the Indian family system. Indian society has not found an economic or significant cultural value for girls within the family except when they come in as daughter-in-laws. Indian culture can be extremely cold in decisions such as foetal foeticide.

Around 60 years ago, infanticide of newborn female infants was not uncommon in Punjab. This practice began to decrease significantly when religions and state made it a crime. The Sikh religious hierarchy condemned such a practice and its ban was written into the Sikh code of conduct. Killing of newborn infants was treated as a murder. However since a loophole in the law has emerged through abortion as a legal right, female foeticide has emerged back into society. The market has simply responded to the demand.

Discussion

The issues around this subject involve several different aspects which I will discuss:

- The role of medical fraternity
- The role of paramedical services
- The role of law
- The role of law enforcement agencies
- The role of the state

- The role of religious institutions
- The role of NGOs

The role of the Medical Profession

The role of the medical fraternity is the most obvious yet it continues to be the most difficult to regulate. A doctor is required to obey the law and to follow guidelines that are based on moral responsibilities. A doctor is not supposed to abort a foetus simply on the grounds of wrong sex.

However many doctors have continued with these practices despite moral and legal constraints. There is a lucrative market. A doctor is considered to get 250-500 rupees from the centres for every illegal scan. Abortions cost between 3000-5000 rupees. Many abortions are done in unhygienic places where the incidence of infection is high. Doctors feign ignorance about gender reason for an abortion.

It now requires the Indian medical fraternity to start pointing fingers at such doctors. However the Indian medical fraternity does not have a reputation for taking quick and difficult decisions on professional misconduct. In the United Kingdom, the government has introduced a culture of constant revalidation by colleagues and a willingness by colleagues to point out concerns about serious misconduct. Public pressure and a vigilant press have added to this. Perhaps there is a need for a similar system to be introduced in some disciplines of medicine such as obstetrics and gynaecology.

The role of paramedical and diagnostic services

The role of ultrasound clinics has greatly increased the incidence of foetal foeticide. Can these services be brought under some scrutiny given that the law and the law enforcement services have failed. In a country such as India, the level of corruption makes most regulatory practices unworkable, unless public scrutiny is significant.

The guidelines for registration of ultrasound facilities, the duties and obligations of those working there or in genetic laboratories prohibits anyone connected to associate or help in carrying out detection or disclosure of sex of the foetus in any manner. Every single detail of the pregnant woman has to be recorded. Yet foetal gender determination carries on remorselessly.

Perhaps there is an argument to control the market in some aspects of economy. Also the number of ultrasound machines could be regulated by statistical indicators other than demand and price. For instance, the state could put a limit to numbers of purchase and sales of ultrasound machines. Since they are largely used to determine foetus gender rather than other medical diagnosis in India, the number of machines can be related to the ratio of female to male births in a region. According to L Chitty, University College, London, (2000) there is no indication for routine ultrasound scanning and can be reduced on an indication basis.

Regulatory bodies can cope with a small number of machines as public accountability increases. This may be against the free market economy that India has adopted. However, the restriction for controlling the market has national and moral reasons rather than political or economical reasons.

The role of the Law

The law has unfortunately enabled gender abortion. However the balance between rights based on liberal values and the need to narrow access to abortion is a fine one. The law cannot go back to the pre-abortion days. Moreover, in societies such as India, the law is not the sole solution. It merely enables society to take action against a social problem. It is up to the state and society to implement the law.

India tends to resort to legislation as the first measure to deal with a problem. However, society then remains frustrated at the non-implementation of the law. The law has to be complimented with other social institutions or preceded by mass campaigns.

The role of law enforcement institutions

In the field of violence against women and dowry deaths, law enforcement agencies eventually resorted to setting up special cells in cities such as Chandigarh which were specialised to deal with infringements. The plan seems to have worked to some extent.

A fall in the female-to-male ratio could lead to significant problems for India in the future. It will create a crisis in population growth. However it could also increase issues of law and order as there will be more single young men with little prospect of marriage.

The State has to see this problem as a serious state issue if it wants to deal with the foetal foeticide problem other than in a moral context. If the State considered this to be a serious future problem, then it will have to set aside resources to deal with it. It would appear that the State sees female foeticide as a moral issue and some have cynically suggested that it sees a possible population reduction in the future. However the consequences of a surplus number of single young men does not seem to have been thought through.

In Punjab, law enforcement agencies need to set up foetal foeticide units. It would be difficult to make this work if it is linked to gender violence units as the complicity of women in foetal foeticide is a primary cause for the problem. The gender violence units depend on the victim reporting to the crime unit and then a raft of legal provisions have made it easier as well as simpler for conviction.

A foetal foeticide unit needs to work differently as the victim is neither the pregnant mother, nor the ultrasound unit. The victim is the foetus, society and the State. Consequently the “awareness” of the crime has to be accordingly adjusted.

The role of the State

The State in India is set in its working methods. It rarely works as a multi-disciplined unit. It also fails to bring in various institutional powers in society into state led action.

Clearly the State alone cannot function in dealing with problems in society that are rooted in cultural mores and compulsions.

To deal with the ethical dimension of foetal foeticide, the State needs to bring in religious institutions, law enforcement agencies, NGO's, the medical profession and politicians to work with common responsibility on this problem.

Currently, the enforcement authority on gender foeticide consists of a Joint Director of Health and Family Welfare as the Chairperson, an independent woman representing women's organisations and an officer of the Law Department of the State Government. However there needs to be wider involvement of civil society, particularly religious and cultural representative groups.

This has been tried in society orientated issues in the UK. For instance, after the London bombings, the government embarked on a wide consultative exercise with religious communities and set up a multi-discipline task force with police officers, community leaders and religious institutions as well as NGOs involved. The foetal foeticide issue cannot be seen simply as a medical ethics issue, but an issue arising from medical ethics to a wider responsibility.

The role of religious institutions

Religion plays a significant role in the lives of people in Indian society. However the institutions are rarely brought into solving problems. Instead they have frequently been exploited for political gain.

The edict by the Akal Takht Sahib in this case is significant. However the Akal Takht has no legal enforcement power nor does it have institutional framework to deal with a problem such as a major campaign within society.

Ideally the state should have responded to the edict by bringing in the Akal Takht to assist in the

coordination of a public campaign. However, in the paradoxes of Indian statecraft, while politicians willingly exploit religious leaders, the State tends to maintain a rigid secular approach. A change in this could significantly help in dealing with social and cultural problems that have a cultural root.

The Akal Takht cannot set about a mass campaign itself, it has to work through the statutory body the Shiromani Gurdwara Parbhandik Committee (SGPC) which has vast resources at its disposal. The SGPC has shown little inclination to give life to the edict although it has the infrastructure to do so.

The role of NGOs

NGOs in Indian society generally tend to be middle class based organisations with a secular orientation. As a result they rarely work with religious institutions and do not generally incorporate the wider civil society in their work. There remains a considerable gap with activist NGOs and society. They tend to lobby the government for legislation and implementation. This has not worked for dowry and is unlikely to work for foeticide.

NGOs need to put aside their political alignment to secularism and have to work closely with religious institutions. In many other fields of welfare work, religious figures and NGOs working together have made a significant difference.

Conclusion

Foetal foeticide is not merely a medical ethical issue. It has significant ramifications for society now and in the future. The female to male ratio has already fallen very low. This may have an unintended benefit for women as it could reverse dowry giving from male to female as the shortage of marriageable female partners becomes evident in a decade. However, the imbalance could also cause unrest and civil disturbances in a country with an increase in the number of single young men. Their energies seek outlet in violence or related activities. It could also increase diseases such as AIDS as prostitution will increase.

Traditional approaches such as enactment of the law and hoping for the medical profession to regulate its members' action is unlikely to work. There needs to be a multi-faceted and multi-disciplined action led by the State.

The State has to recognise the problem and encourage various institutions to work together to deal with female foeticide. The law enforcement agencies need to set up a special unit, the State needs to work with religious and other civil society representatives to campaign within society. There is also the argument to restrict the number of ultra sound scanners and relate sales to statistics on female to male ratios. This problem cannot simply be categorized as medical ethics. It requires recognition as a major social problem.

Human Rights and Gender Equality*

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Introduction

"It is rare to be born as a human being; rarer to be born without hunchback, blindness, deafness or infertility; and it is a great boon to be born as a woman."

These are the sayings of some of the great thinkers of Tamil Nadu, a state in the southern region of India. A study proves that although women are empowered in various ways in India, there are many blocks on their movement and society has to go a long way to achieve equality in the practical sense of the word. Worst is the plight of the transgender persons who are not treated as human beings at all by society. They are deprived of most of the rights given to citizens by the Constitution of India. The question comes to mind: "Are transgender persons not among the citizens of India?"

This paper deals with two important groups, namely, women and transgender persons, and their status in Indian society. The discrimination faced in medical services is only the tip of the iceberg and thus this paper looks at social ethics. Though women occupy 50% of the world's population, and compete with men in all spheres, their status remains second to men. Nobody has thought about the third gender, the transgender persons and shown any empathy or concern for their improvement.

The primary sources for this study are the Universal Declaration of Human Rights (UDHR), the Indian Constitution, regulations, interviews with the transgender community and women in Chennai, published works and newspapers.

The UDHR and Indian constitution give a detailed account of the fundamental rights given to citizens, who include women and transgender persons too.

Universal Declaration of Human Rights (UDHR)

The Universal Declaration of Human Rights (UDHR), consisting of 30 Articles, was adopted and proclaimed by the United Nations' General Assembly Resolution 217(iii) on 10, December, 1948. The Preamble states that the recognition of the inherent dignity and the equal rights of all members of the human family is the foundation of freedom, justice and peace in the world. But the disregard and contempt of human rights have resulted in barbarous acts. It also specifies that the people of the United Nations have reaffirmed their faith in fundamental human rights, in the dignity of the human person and in the equal rights of men and women. No doubt, the UDHR is one of the landmarks in the recognition of the protection of rights of every individual without any distinction. To those who have money, might and power, these rights are not questioned and even not often needed. For the weaker section of society, these rights are essential, but they are unable to enjoy them because they cannot fight money and power.

Deeper analysis of the articles of the UDHR make one believe that all people of the world can lead a happy and peaceful life, if the articles are really adopted. But why is there chaos, confusion, anarchy, assault, in almost all parts of the world? It is mainly due to the non-practice of UDHR. What is in paper should be followed in practice. The failure leads to violence, servitude, sufferings and suppression. Let us remember these articles.

* Paper first presented at the First UNESCO Bangkok Bioethics Roundtable, September 2005.

Article 1 of the UDHR states that all human beings are born free and equal in dignity and rights. They are endowed with reason and conscience and should act towards one another in a spirit of brotherhood. All have the right of self-determination. They can determine their political status and pursue their social, economic and cultural development.

Everyone is entitled to all rights and freedom without any distinction of colour, creed, religion, language, sex, political or other opinion, national or social origin, property, birth or other status (**Article 2**). Even in the 21st century people in various parts of the world suffer due to the many differences mentioned above. Though caste is not referred to in the UDHR, people have faced different kinds of problems arising due to caste, which cannot be eradicated in India.

Everyone has the right to life, liberty and security of person (**Article 3**). There are innumerable instances in which many lives had been taken unnecessarily, and the liberty of the people was not valued; and security of persons is a misnomer.

No one shall be held in slavery or servitude. Slavery and slave trade shall be prohibited in all forms (**Article 4**). Though slavery in the real sense of the word does not exist in many parts of the world, many men, women and children are kept in servitude as bonded labourers, servants, maids and so on.

No one should be subjected to torture or cruel, inhuman or degrading treatment or punishment (**Article 5**). In the modern world, people with money and power go to any extent to achieve their goals which results in inhuman, cruel or degrading treatment.

Everyone has the right to recognition everywhere as a person before law (**Article 6**). It is sad to note that many people do not even have their own identity.

All are equal before law (**Article 8**). This statement sounds nice but it is impracticable in every society.

No one shall be subjected to arbitrary arrest, detention or exile (**Article 9**). There are many cases of women, untouchable castes (*Dalits*) and the under privileged who are being victimised.

Article 12 stresses that no one shall be subjected to arbitrary interference with his privacy, family, home or correspondence, nor to attacks upon his honour and reputation.

Everyone has the right of freedom of movement and residence within the borders of each state and has the right to leave any country, including his own, and return to his country (**Article 13**). There are many cases of exceptions to this right.

Everyone has the right to a nationality (**Article 15**). We find cases of people who do not have national citizenships.

Men and women of all ages have the right to marry and found a family, without any limitation due to race, nationality and religion (**Article 16**). In India in many orthodox families, even today daughters have no right to choose their partners.

Everyone has the right to own property and no one shall be arbitrarily deprived of his/her property (**Article 17**). But there are many cases of confiscation of property and under payment too.

Everyone has the right to freedom of thought, conscience and religion (**Article 18**). The violation of this right could be well understood in many contexts.

Everyone has the right to freedom of peaceful assembly and association (**Article 20**).

Everyone has the right to equal access to public service in his/her country (**Article 21**).

Everyone as a member of the society has the right to social security (**Article 22**).

No person arrested shall be detained in custody without being informed.

Everyone has the right to work; every one, without any discrimination has the right to equal pay for equal work (**Article 23**). Unemployment, under employment and unequal payment are common features in all parts of the world.

Everyone has the right to rest and leisure, including limitation of working hours and periodic holidays with pay. (**Article 24**). Though the Factory Acts are favourable to the labourers, in actual practice they do not enjoy these rights due to various reasons.

Everyone has the right to security in the event of unemployment, sickness, old age or other lack of livelihood in circumstances beyond his/her control (**Article 25**). Though in western countries such safeguards are there for affected people, India has to go a long way.

Everyone has the right to an education (**Article 26**). Every government wants to educate their children. But the socio-economic condition of the downtrodden in India deprive many children of their right to an education.

Everyone has the right to freely participate in the cultural life of the community (**Article 27**). In the case of India, sometimes, the cultural activities of one community result in communal disharmony.

Everyone has duties to the community (**Article 29**). This aspect is forgotten by many people, as they talk only about their rights and privileges.

Indian Constitution

The Preamble of the Indian Constitution ensures social, economic and political justice, liberty of thought, expression, belief, faith and worship; equality of status and opportunity.

Article 14 of the Indian Constitution guarantees all citizens "equality before law." It protects people against discrimination among equals. It is as same as Article 7 of the UDHR.

Article 15(3) permits special protection to women and children.

Article 17 provides abolition of untouchability. Though this Article condemns untouchability, the latter continues in many parts of India. In many villages the practice of "two glasses and two plates" continue confirming the prevalence of untouchability. The condition of the dalit women in many villages in Tamil Nadu is very pathetic. Another form of untouchability is seen with the treatment given to transgender people.

Right to freedom is assured in **Articles 19-22**.

Article 21 provides that no person shall be deprived of his life or personal liberty. All other rights will lose their values in the absence of protection of life and personal liberty.

Article 22 provides protection against arrest and detention. But there are many instances of penalisation of women, transgender persons and dalits.

Right against Exploitation is assured in **Articles 23 & 24**.

Persons cannot be forced to work (Article 23). Women, both educated and uneducated are forced to do many different kinds of jobs. Indian women who work as maids in rich families are subjected to humiliation, rape and violence. Even well educated women in the private sector are put to shame by their employers when they are asked to do unwanted things.

Article 24 specifies that no child below age of 14 years shall be employed to work in any factory, mine or in any other hazardous employment. Female children are forced to serve as maids in houses, and as workers in match and cracker factories. It is sickening to note that minor girls are forced into prostitution.¹ In the UDHR, Article four specifies the right against exploitation. Though law has been passed against child labour, it is prevalent in various forms and goes untouched by law.

Article 25 of Indian Constitution provides that all persons are equally entitled to profess, practice and

¹ The New Indian Express, 10th January, 2007.

propagate religion. India, a nation of numerous religions faces many challenges due to differences among followers of religions. Conversion, communal clashes, fanaticism and orthodoxy affect the peace and unity of the country. Fundamentalists of every religion wait for an opportunity to attack other religions. Women also face problems because of this.

Legal rights

Civil rights include the rights to self-determination, liberty, equality, privacy, freedom of thought, conscience and religion, freedom of opinion and expression, marriage and family protection, equality before law, prohibition of slavery and the slave trade, and freedom of movement. Political rights include the right to vote, compete and contest elections, take part in government etc. Cultural rights include the right to education and rights relating to science, art, music and culture. Social rights include rights to security, motherhood, childhood, adequate standard of living, physical and mental health. Similarly, economic rights include rights to self-determination, work, just and favourable conditions of work, formation and joining trade unions, equal wages and remuneration for equal work. A deeper analysis of these rights would reveal the ignorance of women regarding their rights and even if they are aware of their rights, how helpless they are and how they are prevented from enjoying the fundamental rights.

Women's Rights

Gandhi's dream of "Ramarajya", where a woman with all her jewellery could travel alone even at midnight, remains a utopian dream in India. The safety and security of women remains questionable. The life style, wants, means, treatment of three categories of women - upper, middle and lower classes - are not the same. Ethical codes are not followed and also violated especially in the case of poorer and depressed classes of people.

Their sufferings cannot be described in words. They lack awareness, care and concern. Women face ill-treatment. They do not even know the meaning of human rights.

There should be no need to mention women's rights separately. But the necessity arises when they are not treated on par with men in a civilized society. The torture and humiliation undergone by women necessitate special regulations to eradicate the evils. The position of women all through the ages reflect their pathetic condition. Female infanticide, sati, child marriage, prostitution, the Devadasi system, dowry system, polygamy, widowhood, divorce, property rights, illiteracy, unemployment and under employment that are prevalent in Indian society speak for the gender inequality. Sex determination tests have resulted in female foeticide.

The declaration of International women's year in 1975, and 8th March as Women's Day created an awakening in the whole world for the cause of women. The Indian Constitution assures equality before law (Article 14), no discrimination on the grounds of sex (Article 15), equal opportunity for all (Article 16), equal justice (Article 38), equal pay for equal work for both men and women (Article 39), and property rights (Article 300A).

The Indian Census Report of 2001 shows that for every 1000 men there were only 933 women. The reason for the lower number of women in India is the prevalence of various social evils affecting the women folk of India. Though the evils existed from very early times, it must be accepted that the British rule in India and the enlightened reformers of India were responsible for social changes curtailing the evil effects of some of the practices mentioned above. Many regulations have been passed by the government in the 19th and 20th centuries.

The Sati Prevention Acts of 1829 and 1987 helped to save widows being burnt on the funeral pyre of their dead husbands. But cases of sati are still reported and sometimes remain hidden from records. A recent case of sati reported in a newspaper states that Vidyavati, aged 40, jumped onto the funeral pyre of her husband Lalchand Lal Lodh of Rari village in Fatehpur district in Uttar Pradesh.² These are to be

2 The New Indian Express, 20th May, 2006.

condemned.

Though a widower becomes an eligible bachelor after the death of his wife, widows are looked down if they want to remarry. Though Iswar Chandra Vidyasagar and many others fought for widow remarriages and the British government in India also passed the Hindu Widow Remarriage Act of 1856, widows are still not in a comfortable position. In recent times, educated and employed widows boldly decide their lives but they are few in number.

The Child Marriage Restraint Act of 1929 was passed to end the practice of marriage between minors or between a minor girl and an adult or old man and vice versa. Child marriage has been a cause for increasing number of widows in India. The introduction of the Prevention of Child Marriage Bill of 2004, provides for the appointment of Child Marriage Prevention Officers by the state government. Child marriages are performed secretly in some parts of India. Some cases of child marriage are being reported in papers and journals. A recently reported child marriage took place at Sampur in Orissa State on 6th October, 2006.³

The Hindu Marriage Act of 1955 gave women the right to divorce, and to declare the second marriage of a man illegal when the first wife is alive. Under IPC 494, it is a punishable criminal offence. But we encounter many people of all ranks and position who do not bother about this act and have more than one wife - and not many first wives seek legal assistance to punish the husbands. They are silent victims and blame fate for their miserable life.

The 1961 Dowry Prohibition Act was passed to save the parents and the bride from the dowry menace. Taking or giving dowry, or abetting to give or take dowry continue to be offences and the offence relating to dowry is non-bailable. This act was amended in 1984 and 1986 to the benefit of the bride's parents. In spite of it, the dowry problems and dowry deaths persist. The affected brides are subjected to physical and mental torture which leads to bride burning and suicide. Leading newspapers and journals report the number of cases of dowry deaths every year. Many more cases go unreported. Due to dowry harassment, a young bride in a slum set herself ablaze in Chennai recently which affected an area full of huts.⁴

Women have been deprived of the right to own property. The Hindu Law of Inheritance Act of 1929 recognised the right of inheritance of women for the first time. But the Hindu Women's Right to Property Act of 1937 opened a new chapter in the life of Hindu women in getting some share in the family property. The Hindu Succession Act of 1956 introduced some benefits to women in inheriting property. It is a boon to a Hindu widow to get a share in the property of her husband. But in real life they face many challenges to enjoy this right.

The Immoral Traffic (Prevention) Act of 1956 and Act 44 of 1986 made it possible for any female victim of suppression of immoral traffic to seek justice in the court against the offender. Once again, though the law is in support of women, many women are forced into prostitution and even if they want to get out of it, they are unable to do so because of obvious reasons. In some countries, prostitution is legalised and the sex workers get support and safeguards from the government. But it is not so in India. It is shocking to know that the fathers and brothers of young girls have sold them to flesh traders.⁵ Worse than that, there are many cases of child abuse reported, hushed up by the parents. Various sociological and psychological factors are involved in this.

The Indecent Representation of Women (Prohibition) Act was passed in 1986. Women are exhibited indecently in the media. Women are to be blamed and punished, if the indecent representations have been made with their approval. They are used as commodities in the television, cinema, newspapers and periodicals. As it has become an occupation, much goes unnoticed.

In some places in Tamil Nadu female infanticide takes place even with the mother's approval. It is due to the inability of the parents to provide education, food and basic facilities, and above all a dowry.

3 Dinamalar, 8th October, 2007.

4 The New Indian Express, 12 September, 2006.

5 The New Sunday Express, 11th March, 2007.

Even the propertied classes want sons to continue the family business and carry on the family. Recent research showed that daughters are better entrepreneurs and take better care of their elderly parents. Tamil Nadu's Infant Mortality Rate (IMR) is higher than other states in India. Kerala records the lowest rate. India cannot shine if millions of girls are prevented from being born. It is shocking to know that eleven baby girls were starved to death in Andhra Pradesh state last year by their own parents in a tribal village near Hyderabad. The tribal people in the village feel that daughters are a burden and sons an asset.⁶ They have no shame or guilt over the death of their female offspring. The Cradle Baby System introduced in 1992 by former Chief Minister Jayalalitha is a move in the right direction to help save female babies.

It is sickening to see in newspapers every day that cases of rape and gang rape are being reported. Some emotional parents are satisfied with the marriage of their daughters with the rapists. The affected girl's feelings are not respected. Most of the culprits are police officers, and men with money and power. Many cases of rape have taken place when women were in police custody (e.g. the case of Chidambaram Padmini). Severe beatings, inserting pins and sticks in sensitive parts of the body, giving electric shocks, using cigarette butts to burn the skin etc, are some of the measures that have been used by the police towards female suspects. Though All-Women Police Stations have been introduced in some areas in Tamil Nadu, women continue to suffer.

The National Commission for Women under Mrs Mohini Giri's Chairpersonship has asked for the Rape Compensation Fund. It is shocking to know that many young girls are raped by people known to them.

At home, the work environment, police stations and even in public places, women face physical and verbal violence. A recent survey (2005-2006) reveals that there are increasing cases of wife-beatings in Tamil Nadu.⁷ Married women in Tamil Nadu have been found to be more vulnerable to spousal violence (42%) than their counterparts in the other southern states of India. It is higher than the national average of 37% of women suffering from spousal violence. But Bihar tops the list at 59% and Tamil Nadu stands seventh in the country. The survey shows that women with little or no education experienced more violence. The better educated women are less abused. Breaking all ideas of modernisation and gender equality, it has been revealed that 41% of married women have been abused by their husbands in Chennai in Tamil Nadu. The state government has to take steps to implement legislation against domestic violence. Apart from domestic violence, when caste and communal riots break out, women are the worst victims.

Though constitutionally everybody is independent and free, it is not so with single women. The widows, spinsters, unmarried, divorcees and single mothers face ordeals in society. They are physically, mentally, emotionally and financially abused. They are not looked at with dignity or decency. Society wants them to be dependents. "Eve teasing" is another evil practice in Indian society which has brought misery to the lives of young girls. Eve teasing ranges in severity from sexually suggestive remarks to outright groping. Though an act has been passed to protect women from eve teasing, the evil practice continues in one form or other. "Ragging" in educational institutions is another practice harmful to both boys and girls. Ragging means doing an act which causes, or is likely to cause physical, psychological or physiological harm or apprehension or shame or embarrassment to a student. Some student victims of ragging have taken their own lives.

In industrial and agricultural sectors, women do not get equal wages. They work hard in spite of their responsibilities to the family and their children, but they are not paid equally. They are ill treated and harassed and sometimes sexually abused at work. Rural women suffer a lot from the absence of basic facilities such as water, firewood, toilets, and so on. The miseries of Dalit women cannot be explained in words. Crimes against underprivileged women are increasing. As they are illiterate, they do not even know their fundamental rights.

There is no doubt that there is an increase in the literacy and employment levels of women in India. They compete with men at all levels. But only a minority of women are innovative and ready to face

6 Deccan Chronicle, 14th March, 2007.

7 National Family Health Survey- III, The New Indian Express, 4th March, 2007.

the challenges. The rural and Dalit women have a long way to go to reach the target. The formation of Self Help Groups (SHG) has been successful in creating an awareness among women to know about themselves and earn an income of their own.

Transgender persons

Laws have been passed to safeguard the rights of men, women and children but the Central and State governments have failed to take note of a different kind of people in society. They are the transgender community. Some of them are born eunuchs and some change their sex due to changing psychological conditions. Men and women who leave their homes and transform themselves into women are called transsexuals who do not enjoy any fundamental rights in society and they can become a laughing stock.

When interviewed, Asha Bharathi and Priya Babu, two educated transsexuals expressed their agony. They wondered why their parents could accept physically and mentally affected children, but why they are not able to accept their transgender children and show care, concern, sympathy and empathy. When people love and do not want to part with their pets and take very good care of their animals and birds, why do they not care for their own transsexual kin? An in-depth study of the transgender reveals many pathetic facts about this psychologically, physically, economically and socially offended community. Though they live the life of a woman, they are not categorised as women. They are insulted, teased and tortured. Their families disown them. Society misuses and abuses them. Their sufferings are inexplicable. Most of them are forced into begging and prostitution.

They are deprived of their basic rights as citizens of a country. They are not recognised and face problems and ill-treatment when they claim ration cards, passports, driving licences, property rights, admission to schools and colleges, entry into occupations etc. Even entry into a public toilet is denied to them. They want the government to recognise Sex Reassignment Surgery as is done in Singapore, Malaysia, Denmark and Thailand. They feel sorry that they cannot even adopt a child legally.

Transgender people have their own rules and regulations, festivals and ceremonies. They have their organisations in different parts of the country. As they are not included in the two common genders (male and female) and treated as a different gender, they face misery and humiliation.

After a long battle, Indian transgender people got the right to vote and stand in elections. But they are not happy that they are identified as "female" in the ballot roll. They want a separate identity as the third gender. In Salem, Radhika, a transgender contested a poll as an independent in a local election in October 2006. Elizabeth, an American transgender campaigned in favour of her.⁸ When Kamala John, a transgender was elected mayor in Madhya Pradesh, a case was filed against the election. It is heartening to note that transgender people receive full recognition in Thailand and Malaysia and their counterparts in India appeal to the government to give them equal status.

The life of a transgender is full of misery. They earn their living by visiting shops and homes, singing and dancing and prostitution. Because of illegal and unhealthy sex, the transgender suffer from AIDS and related diseases and when they go to hospitals, they are humiliated and denied medical treatment. Gokila, a transsexual was admitted to a hospital for severe stomach pain. When the doctors and other medical staff discovered that Gokila was a transgender, they refused treatment and teased and humiliated her. Plans are in the pipeline to organise a rally to create awareness among the general public about the condition of the transgender and gain the attention of the government about discrimination towards transsexuals⁹

Police atrocities against transgender persons prove their pitiable status. They are treated as objects of pleasure and fun and it is sad to note that the transsexuals undergo torturous treatment in the name of sex, at the hands of police officials of different ranks. A case of self-immolation in front of a police station by a transsexual in Chennai was recorded on 12 July as the victim chose to commit suicide over

8 Dinamalar, 4.10.2006.

9 Deccan Chronicle, 8th October, 2006.

sexual harassment suffered at the hands of six police officials in one station where he/she was illegally imprisoned.¹⁰ The probe ordered by the judges proved the guilt of police who were responsible for the death of an innocent human being.¹¹

Santhi, a poor Tamil girl who won a silver medal in the 2006 Asian Games, was disqualified because she failed a gender test. Overnight this test made the great winner, a laughing stock and she felt deserted and desperate but for the support of the chief minister of Tamil Nadu.¹²

Back in the past, two transgender people succeeded in getting two posts in a government office as computer assistants. However, they could not continue for more than two months because of the sad conditions prevailing in the office environment. Even the educated do not understand the position of these people. They are even denied rental accommodation by landlords.

It is heartening to note that the Tamil Nadu AIDS Initiative (TAI) organises conventions to unify transgender people and encourage them to fight for their basic rights as citizens of the country.¹³ As many transgender people are affected with AIDS, the TAI takes interest in creating awareness among the transgender community on AIDS and how to protect themselves.

While celebrating Transgender Day (Aravanikal Dinam) on 18th January, 2007, the Transgender expressed their awareness to the problems of humankind and launched a campaign "We too are for a healthy society" with the help of the Tamil Nadu AIDS Initiative in Chennai and 14 other districts of Tamil Nadu from 18-24 January. They took part in tree planting, play presentations, and visited a paediatric ward in a hospital in Chennai.¹⁴ On the 24th the transgender association submitted a memorandum to the Tamil Nadu government seeking basic rights and privileges such as issuing ration card and driving licences to them.¹⁵ They celebrated Women's Day on 9th March at Chennai organised by TAI. Five hundred transgender participated in the event.¹⁶

Conclusions

Empowerment of women is possible by providing them with an education, health care, nutrition, economic independence, legal awareness, organisational support, and above all by respecting and making them take what is due to them. Most Indian women have dual responsibility. They are not only home makers, but also contribute to the family's economy. There should not be any bias or prejudice in dealing with them. With limited means, they work in agricultural fields, plantations and factories. They suffer because of malnutrition and a lack of health care. Though many regulations have been passed to improve the condition of Indian women, society as such has many constraints on allowing women to enjoy their basic rights. As women are also part of society, they have to realise their rights and responsibilities as citizens of the country and see that they are not ill treated any more. Gender inequality has produced the ideology of separate spheres for men and women, which has caused damage to both men and women. The attitude that man is a leader, woman as follower, man as producer, woman as consumer, man as strength, woman as weakness should change, as women have also shown their strength and capacity in various fields. In fact they are more successful than men in many fields.

The world now has an ever growing number of women participating in society as policy makers. However, nowhere in the world can women claim to have all the same rights and opportunities as men. The majority of the world's 1.3 billion absolute poor are women.¹⁷ Everywhere women continue to be victims of violence, with rape and domestic violence listed as significant causes of disability and death among women of reproductive age globally.

Similarly, in the so called civilized world, it is necessary to understand the problems of the third gender

10 The Hindu, 22nd November, 2006.

11 City Express, 27th February, 2007.

12 Anandavikatan, 7th February 2007.

13 The New Indian Express, 6th December, 2006.

14 The Hindu, 19 January, 2007.

15 Dinamalar, 25 January, 2007.

16 Deccan Chronicle, 10 March, 2007.

17 Deccan Chronicle, 8th March, 2007.

(transgender) that have been in oblivion enjoying no rights. Of late, they have tried to improve their basic conditions. They are to be given an education, employment and financial assistance so that they can lead a decent life. Society and the government should recognise them as citizens of the country. Their individuality is to be respected and they are to be treated as human beings.

Unless women and transgender persons of a country can enjoy their fundamental rights, it cannot be proud of its achievements in various fields, because human beings are the prime resources of a country and if they are not properly treated and utilised, any amount of success or achievement cannot be taken into account.

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Organ Donation: The Bioethical and Sikh Perspective

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Introduction

With medical advances organ transplantation makes it possible to prolong a patient's life. Organ donation is the removal of a specific biological organ of the human body from a person who has recently died or from a living donor, for the purpose of transplantation.

In the event of a sudden death, organ donation is a way to help others by allowing use of organs and tissues to save another life. If you die, your organs could help several people through organ transplants and many others through tissue grafts. For example, your liver could save the life of someone whose liver has been damaged through chronic illness or accident. A person who is attached to a dialysis machine could regain normal life after receiving one kidney. Organ donation does not disfigure the body.

Organs are usually taken only after death and it is usually done in a hospital where the tissues are matched immediately to a recipient in waiting. The grieving family members should be kept informed about every step. If a person dies in a hospital then the hospital contacts the family about organ donation. It is important to keep the family informed about your wishes.

Patients are matched to available organs based on a number of factors including blood and tissue typing, medical urgency, time on the waiting list to receive organs, and geographical location. The organs that can be transplanted include heart, kidneys, pancreas, lungs, liver, and intestines. The currently transplanted human tissues include bone, corneas, skin, heart valves, veins, cartilage and other connective tissues. Bone marrow is also transplanted.

Organ transplantation poses various ethical dilemmas some of which are special to the third world countries. In this paper I propose to examine some of these ethical dilemmas and I shall put forth the Sikh position on organ donation and transplantation.¹

A Sikh position on organ donation and transplantation

According to Sikh philosophy the human body is merely one form which the soul takes. The body and soul are distinct. There is the belief that the human soul goes through 840,000 incarnations before acquiring the human form. This cycle of birth and death is based on one's karma (one's deeds). On the basis of one's karmas one acquires a new form of life after death. The human form is just one of the many forms. Sikhism believes in the sanctity of life. It is not only the human life but also the other forms of life, e.g. animal life also which are equally sacrosanct and valuable. In the Sikh philosophy the human body is just a dress, which the soul wears, when the self transmigrates. One can argue that since this human body is just one dress - we need not lay too much stress on it and need not really bother about making extraordinary efforts to keep the human being alive especially when this dress has got damaged. We need not opt for organ transplantation or use external life support systems to extend the life of a person. In this connection Sikhism holds no doubt the soul transmigrates and the human form is just one such dress worn by it, but this human form is very important for the soul. It is only in the human form that the soul can attain self-realization. If this be so, it is every person's duty to look after his body and keep it healthy so that self-realization can be attained in this life only. Only due to one's good deeds in the past

1 I am thankful to Jathedar Joginder Singh Vedanti, Jathedar Singhji and Giani Jaswant Singhji for having discussed this issue at length and for their valuable suggestions.

life, one has got the human form. In order to achieve the goal of self-realization, one requires this body in a healthy condition so that it can achieve its goal.

Sikhism believes in the theory of karma and rebirth. One's ill health and damaged organ are all the result of one's past karma (Deeds done in past lives). In such a situation what is the role of the society and of the doctors? Even though it is due to past karma that a person is suffering, every effort should be made by the members of the society to cure the patient and prolong his life as is amply indicated in the life of the Sikh Gurus who considered helping the sick and curing them as a noble duty. Almost all the Sikh Gurus have cured the sick and the ailing, during their lifetime.

Cadaver transplantation

Indian cultures have reservations about accepting organ donation as a concept, for it is a religious belief that at death the body should have all its organs intact otherwise one will not go to heaven. Sikhism does not accept such a belief and therefore donating one's organs after death does not violate any religious injunction. On the contrary, Sikhism is based on the principle of service. By donating one's organs, one is serving others who need the organs and can live longer and lead a better life by receiving the donated organs. In fact there is a hymn in the Guru Granth Sahib, which states that an animal is better than me. When it dies its body serves in various ways and my body just burns without being of any use to anyone.

God, please bless me, I am even worse than an animal.

Nuroo murai nur kaam n aavai

When a man dies, he is of no use to anyone.

Pusoo murai dhuss kaaj suvaarai

But when an animal dies, it is used in ten ways. ||1||

Apunae kurum kee gath mai kiasa jaano

What do I know, about the state of my karma?

Mai kiasa jaano baabaa rae

What do I know, O Baba? ||1||Pause||²

Thus to donate organs is recommended. However, it being an instance of service, organ donation has to be voluntary and not mandatory. Presently, there are some Sikh organizations, which are introducing donor cards and making the Sikhs aware that we should donate our organs for the needy and thus are introducing the awareness of doing service both while alive and also after death. But it still requires that the donor make an affirmative statement during her or his lifetime that she or he is willing to be an organ donor. Still, it remains an opt-in system rather than the Spanish style opt-out system

Organ Donation by Living humans

The next question that we are faced with is whether it is permissible to donate one's organs while one is alive. In Sikh history, we have innumerable cases of Sikhs protecting the weak and oppressed and even sacrificing their own lives for them. In fact Sikhism is based on the principle of service to humanity even if it is at the cost one's life. So, the answer to the question: "Can one donate one's organ to save another's life, life of a person who is physically weak?" lies in the donor's intention. If the donor is donating his/her organ out of social pressure, this is not a case of service but rather it is unethical and irreligious. It would not be permissible according to Sikh tenets. The donor here is being victimized and injustice is being done to him. The Sikh Gurus have always stood against external force and pressure. On the other hand, if out of an intention of serving another person, someone is desirous of donating his organs in order to

2 Guru Granth Sahib (the religious text of the Sikhs), pp. 870.

prolong another's life, this would be a case of sacrifice and would be commendable.

Historically, when the forces of Banda Singh Bahadur were fighting the enemy, it was a fight for justice. The forces in the fort were surrounded by the enemy and as ration supplies were cut off, the soldiers started dying of hunger. One Sikh soldier who felt he was very weak and would die very soon, and was not able to fight any further because of hunger offered himself to be cut to pieces and parts of his body be fed to the other soldiers so that at least they could continue fighting and did not fall down due to hunger. This goes to suggest that ideally a Sikh should be ready to sacrifice his life, and also the organs of his body if that can help someone to live longer. Thus organ donation is commendable and the highest form of sacrifice.

Recently there was a case of muscular dystrophy in Hyderabad, India. The patient wanted to donate his organs. As far as he was concerned he would be dying very soon. In such cases the Sikh tradition would commend such a sacrifice. The intention of the patient was not to relieve himself of the unbearable pain but rather it was a noble intention of serving others in need of organs.

As far as accepting organs and blood donation, usually there are no restrictions. However, there are cases of patients who are leading a religious life, wherein these patients accept blood/organs only from those donors who are also religious. Such individuals refuse even acceptance of blood of non-religious people. In such cases the autonomy of the individual is to take precedence over the principle of beneficence or paternalism of the doctor/caretakers.

Brain Death

Brain death is defined as a complete and irreversible cessation of brain activity. Absence of apparent brain function is not enough. Evidence of irreversibility is also required. Brain death is often confused with the state of vegetation. Traditionally, death has been defined as the cessation of all body functions, including respiration and heartbeat. Since it has become possible to revive some people after a period without respiration, heartbeat, or other visible signs of life, as well as to maintain respiration and blood flow artificially using life support treatments, an alternative concept of "brain death" has emerged. By brain-death criteria, a person can be pronounced legally dead even if the heart continues to beat due to life support measures.

Is brain death acceptable in Sikhism? Ordinarily brain death is not death, for the jivatma (soul) is still in the body. Even though the brain is dead, there is evidence that other organs are functioning, A person is to be declared dead only when the breath leaves the body. Most organ donation is done after confirmation of brain death. However, if we accept the concept of service, then it is acceptable and even desirable that we sign the donor card stating that in case of brain death occurs one's organs should be used to benefit those who could live a longer and a meaningful life by receiving one's organs. If the concerned patient has not consented, then the proxy consent is not acceptable.

An important question arises in all cases of proxy consent, as to what is the motivating factor? Is it economic reasons, inability to take care of the patient, or an interest to help some other person who would benefit from the brain dead person's organs? Before proxy consent is acceptable the good intentions of the person who is giving consent have to be established. As it is not always possible to establish the good intentions, most often brain death as death is not accepted unless the patient had at some earlier time given his consent.

Sale of Organs

In a country like India, there is a need to have laws which are enforced strictly in order to stop the sale of organs. Due to poverty, the people of the lower economic strata are allured into organ donation for economic benefit. Organ donation is fast becoming an important bioethical issue from a social perspective as well. The fact is that the demand for organs and tissues far outstrips supply. Consequently, there has arisen a black market often referred to as the transplant trade.

The donors, especially those who are donating (selling) their organs out of financial necessity are

usually not informed properly of the implications of organ donation. Many volunteer for organ donation because of inadequate information. The Indian National Organ Transplant Act makes it illegal to sell human organs and tissues. Violators are subject to fines and imprisonment. Buying and selling of organs might lead to inequitable access to donor organs with the wealthy having an unfair advantage. However, in spite of such an act still there are innumerable cases of organ donation done out of sheer financial necessity.

In India, due to illiteracy, we are faced with various ethical and social problems relating to organ donation. At times, patients are allured and taken for a medical check-up telling them that this is mandatory for getting the promised job. In the hospital, their organs are removed without even informing them. In such cases, as the patient is not aware of the removed organ, he does not even take proper care. On the other hand, being a paternalistic society, very often the wife/mother is pressurized socially to donate her organs for her husband/child. There are hardly any checks/safeguards against such unethical practices. Even though the law is there, the culprits are rarely booked.

Summary

In summary, according to the Sikh religious tenets, organ donation from live patients, cadavers or brain dead patients is commended provided there is informed consent. Besides informed consent, the motivating factor should be service. Since organ donation should be done with the aim of service, under no circumstances is the sale of bodily parts allowed according to Sikhism.

Sikhism is based on the concept of service to the community. A Sikh should always be ready to help the needy. Thus, if by donating blood or an organ, one person can save the life of another person, it is in the service of humanity which is recommended. This would prolong the life of another person. There are certain ethical implications here too. Suppose a person donates their organ not out of a feeling of service but due to a dire need of money which they may get from the recipient of his organ. This sort of organ donation is really questionable, for a person is using their body as a means and is not recognizing the intrinsic worth of their body. They rather think that they have a right to their body and therefore donate it. The Sikh philosophy does not recognize a right to one's body. This body is a gift of God. It is our duty to preserve it and also to help in preserving and keeping others body healthy too with whatever means it is possible for us to adopt.

Growing human clones or genetically modifying animals so that their organs can be transplanted into humans in need of them is not permissible in Sikhism. The human clone would be grown and when there is need, the needed organ would be removed and the cloned human or the animal would be left to die. In such cases, the life of the clone or the animal is being disrespected and they are being treated as only a means and therefore this would not be permissible according to the Sikh Scripture. The principle of reverence for life is not only confined to the human sphere. Sikhism believes in the sanctity of all life forms and therefore xenotransplantation (transplantation of the organs from animals into humans), cloning, genetic engineering etc. which treat other life forms as a mere means to meet human ends are all questionable. We cannot use another living organism as a means to serve our personal purposes.

We can consider transplantation of organs from a person who is in a persistent vegetable state and had given the consent to use their organs if at all they were certain to stay in a comatose state or after their death. The latter would be a case of cadaver transplantation and here there would not be any adverse ethical implications.

Biomedicine - legal and ethical issues

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The Scientific context

Challenges of an age of science

It is little more than fifty years since James Watson and Francis Crick announced the discovery of the structure of DNA¹. This is the molecule that encodes the genetic information present in all living organisms. The research of Watson and Crick, published on 25 April 1953, signified the beginning of the modern age of biology and biomedicine².

In 2001, as an outcome of this discovery and by the rival activities of public and private sector bodies working on the Human Genome Project, a draft map of the human genome³ was published⁴. This map revealed that the total number of genes in the human species was approximately 30,000. An important aspect of contemporary biomedicine is the search to discover the operation of each of these genes, when isolated, and the significance of so-called “junk” matter in the DNA between the genes. Unsurprisingly, this “junk” (unlike a lot of that material that we see in the law) is not genetically worthless after all.

Few lawyers and social scientists have special skills in, or knowledge of, the physical sciences and technology. Most tend to be those who, as schoolchildren, excelled in subjects involving verbal skills. There have been exceptions. However, lawyers have not generally been trained in higher mathematics, still less in complex modern scientific theories and technological applications. For the most part, they only see these phenomena (if at all) in litigious disputes over intellectual property⁵ or contests over the admissibility of expert evidence⁶. Uncomfortably for lawyers, science and technology are now major driving forces of the world economy and global society. Moreover, they present important quandaries of a moral and ethical kind. Upon such quandaries, citizens often expect the law to speak with a clear voice.

Inter-related technologies

At the outset, it is important to realise how the most important modern technologies are inter-related. To win the Second World War, the Allies split the atom, harnessed nuclear fission, developed the atomic bomb and later created hydrogen bombs. For more than fifty years, the dangers that these weapons of mass destruction present have imposed on humanity an uneasy peace, safeguarded to some extent by the Nuclear Non-Proliferation Treaty⁷. In recent decades, the acquisition of nuclear technology (and also weapons) by more countries potentially symbolises the dangers for the survival of the human species inherent in the spread of that technology and the weapons that arise from it.

Yet it was to deliver such weapons that advanced rocketry was created to carry their payloads on intercontinental trajectories. This, in turn, led scientists to explore information technology, compacting

1 Watson, J.D. and Crick, F.H.C. 1953. “Molecular Structure of Nucleic Acid: A Structure for Deoxyribose Nucleic Acid”, 171 Nature 737-738.

2 See Watson, J.D. and Tooze, J. 1981. The DNA Story - A Documentary History of Gene Cloning.

3 When all the DNA in a particular organism is considered, it is called the genome.

4 (2001) 291 Science 1155; (2001) 409 Nature 813.

5 Aktiebolaget Hässle v Alphapharm Pty Ltd (2002) 212 CLR 411; Stevens v Kabushiki Kaisha Sony Computer Entertainment (2005) 224 CLR 193.

6 Clark v Ryan (1959) 103 CLR 486; Ramsay v Watson (1963) 108 CLR 642.

7 Treaty on the Non-Proliferation of Nuclear Weapons, 729 UNTS 161, entered into force 5 March 1970.

ever-increasing data in microchips of ever diminishing size. The advance of computer technology was later to make it feasible to perform the analysis of data about DNA and the genome. Without computers, the map of the human genome would not have been completed in its allotted time-zone, if at all.

It is in this way that the great scientific advances of the last fifty years are integrated. Nuclear fission gave birth to informatics. Informatics stimulated biotechnology. Biotechnology is now giving rise to neurotechnology and also nanotechnology which bridges living and inert materials. All of this has happened in about fifty years. Moreover, it has happened in ways that often go beyond the understanding even of an intelligent lay person.

There would not be many lay citizens who could truly say that they understand how nuclear weapons function; how computers work; and how genes develop and express themselves in the organs and tissues of living things. Yet we know from our common experience that such scientific and technological developments have occurred. We also realise that they present challenges to our species that sometimes require societal responses.

International responses to science

By chance, I have had opportunities, both at a national and international level, to examine the advance of information and biological sciences and the drafting of legal and ethical responses to address each. In the 1970s I chaired an Expert Group of the Organisation for Economic Cooperation and Development (OECD) developing guidelines to respond to transborder data flows and the issues for privacy and data security that they presented⁸. More recently, in the Human Genome Organisation and in the International Bioethics Committee of UNESCO ("IBC"), I have participated in ethical responses to some of the most important challenges of biomedicine of the current age⁹.

It would be impossible to describe all of the issues of biomedicine that confront us in our national legal systems. In common law countries, we know that, if the legislature or the executive government fails to develop legal responses to these challenges, there is no ultimate gap. In the end, the law is never silent. Where need be, it is the judges who will fill the omissions in the written law. If necessary, judges will express the legal principles that apply to a new situation presented by science or technology.

Because of the huge scope of the issues presented by biomedicine, their variety and complexity, I can do no more than to select a few topics so as to give a glimpse of some of the challenges that lie before us. In doing this, I will draw on my experience as a member of the HUGO and IBC bodies that I have mentioned; as a participant in the WHO and UNAIDS institutions that are responding to one of the greatest challenges to biomedicine that afflicts the world (the HIV/AIDS pandemic) and as a judge in a final national court. These insights may be helpful as providing at least some perspectives for the issues that should engage us as we reflect on contemporary advances of science and technology. We must do so in an age that is indelibly stamped by science and technology. I will deal selectively with some of the issues presented by advances in biomedicine. These will be:

- Intellectual property implications;
- Use of embryonic stem cells and cloning;
- Pre-implantation genetic diagnosis; and
- Issues in HIV/AIDS;

A reflection on these issues will give rise to some general conclusions.

Implications for intellectual property law

8 Organisation for Economic Cooperation and Development. 1980. Guidelines on Transborder Data Flows and the Protection of Privacy, Paris.

9 UNESCO, International Bioethics Committee has produced a number of (non-binding) international instruments, particularly the Genome Declaration and the Bioethics Declaration (see below).

Origins of intellectual property protection

One of the chief puzzles that flowed from advancing knowledge about DNA and the human genome, arose in the field of intellectual property law, especially the law of patents. Questions have been presented by the discoveries and inventions that arise out of the unfolding knowledge about the genetic makeup of human and other living species.

Should it be possible for those who identify the likely operation of genes (and their potential to contribute to therapies that prevent premature death and treat illness) to secure temporary monopoly protections under established patent law? Is patent law, originally devised in earlier times for mechanical and similar inventions, suitable to lay claim over the identification and manipulation of special features of living matter?

It is important to note that “in general, raw products of nature are not patentable. DNA products usually become patentable when they have been isolated, purified or modified to produce a unique form not found in nature”¹⁰. By and large, the quandaries presented by this topic are not puzzles of the lone scientist working in a laboratory bench. Commonly, the claims for patent protection are made by large institutions and pharmaceutical corporations. They are justified by the suggested need to raise venture capital to fund expensive and usually unpredictable scientific research. Without the protection of temporary monopolies, such bodies argue that funding will not be forthcoming to promote the research that will conquer disease. Yet it is the distortions that can be produced by intellectual property law that often give rise to the sharpest debates in the field of biomedicine. At risk is the actual focus of scientific exploration and the availability of the resulting products to people everywhere, not just in wealthy developed countries that can afford to pay the resulting licence fees.

The central idea in intellectual property law can be traced to ancient Greece.

In modern times, this body of law grew out of the monopolies granted by the monarchs in England and France. International legal protection was first considered at a conference held in Paris in 1883. Since that time, many national, regional and international developments have combined to create a global network of intellectual property law.

Watson and Crick sought no intellectual property rights in respect of their discovery of DNA or of its immediate applications. However, instead of devising a new and appropriate legal regime peculiar to advancing knowledge of the field of biotechnology, the old law of patents was invoked by others. This has produced less than perfect results.

Patents and biomedical advances

The Universal Declaration of Human Rights of 1948 contained a provision¹¹ that recognised the rights of scientists to enjoy protection for their intellectual property. The same instrument acknowledged the existence of competing human rights: such as the right to life, to health, to knowledge and the sharing of the benefits of scientific advances¹². Self-evidently, converting discoveries about the human genome from raw scientific data to beneficial therapies and tests is “potentially problematic and expensive”¹³. Mr Pascale Lamy, then European Union Trade Commissioner, observed in 2004¹⁴:

“Just take the example of the fight against AIDS: Some consider patients on pharmaceuticals a major obstacle to securing access for all to the newest and most efficient treatments, whereas others point to the fact that, without patents, it is unlikely that any treatment would have been

10 Human Genome Project, Patenting genes, Gene Fragments, SNPs, Gene Tests, Proteins and Stem Cells, United States Dept of Energy <www.ornl.gov/TechResources/Human_Genome/elsi/patents/html#2>.

11 Article 27.2.

12 Articles 3, 25.1, 27.1.

13 UNESCO, International Bioethics Committee, Report of the IBC on Ethics, Intellectual Property and Genomics (SHS-503/01/CIB-8/2 Rev, Paris, 10 January 2002), 8 (‘IBC IP Report’), 2.

14 Lamy, P. 2004. “Trade-Related Aspects of Intellectual Property Rights - Ten Years Later”, 38 *Journal of World Trade* 923 at 923-4.

developed at all”.

In recent years, a number of legal developments have caused concerns about the role that intellectual property law is playing in the field of biomedicine. For example, there has been a gradual disappearance of the previous global tradition of open science and the sharing of the outcomes of pure scientific knowledge¹⁵.

Domestic legislation in several developed countries, now demands that universities and research institutions secure intellectual property protections for their research¹⁶. This has happened at a time when humanity has come to appreciate the peculiarly intimate, pervasive and precious character of the genome of the species. It represents nothing less than the building blocks that make us what we are.

To the extent that scientific research is motivated not by curiosity but by profits, there is a danger that it will concentrate unduly on profit-making objectives. This is sometimes put vividly as “face creams rather than malaria and river blindness.” As well, abuse of intellectual property law has occurred. Thus, patents have been claimed over genetic sequences of uncertain utility¹⁷. As well, source materials for genetic investigation has sometimes been obtained from “donors” in poorer, developing countries. This has been so because of concentrated known areas of disease; rapid inter-generational reproduction; the easy means of collection; and low risks of litigation or demands for profit sharing. Concerns about such abuse led the HUGO Ethics Committee to demand that a fixed proportion of net profits of pharmaceutical companies should be devoted to repaying the benefits provided by donors in developing countries, in the form of their source of human genetic material¹⁸. So far this call has been unanswered.

Upholding basic rights and core values

Confronting the issues presented by patent protection in the field of biomedicine, the Nuffield Council on Bioethics of the United Kingdom concluded in 2002 that, on the whole, the provision of exclusive rights awarded for a limited period in the form of a patent system was ethically defensible because it had generally worked to the benefit of patients and society. Nevertheless, the Nuffield Council considered that “[I]n the particular case of patents that asserted property rights over DNA, consideration should be given to whether the balance between public and private interests has been fairly struck”¹⁹.

The Nuffield Council recommended that only genetic sequences that have been identified and characterised as beneficial should be capable of attracting patent rights and that the granting of patents over DNA sequences, as such, should “become the exception rather than the norm”. In effect, the Nuffield Council demanded a return to the fundamental principle that previously gave strength and legitimacy to legal entitlements to patent protection. This insisted that patents should only be available for “inventions” and not for the “discovery of something appearing naturally in nature”; that for patent protection something distinctly “novel” was required, not a matter of routine that was produced by computers; and that the product must be immediately “useful” without which, from a social point of view, monopoly protection (even for a limited time) could not be justified.

These reminders of the core components that informed intellectual property law need to be reinforced and insisted upon in international bodies such as the World Trade Organisation (“WTO”) and the World Intellectual Property Organisation (“WIPO”). There is a need to uphold these core values of patent law in the field of biomedicine.

15 Nicol, D. 2003. ‘Gene Patents and Access to Genetic Tests’, 11 Australian Health Law Bulletin 73 at 74; cf Cook-Deegan, R. 1994. *The Gene Wars: Science, Politics and the Human Genome*, New York, Norton, 28.

16 IBC IP Report, above n 13, 2. See also Kirby, M.D. 2001. “Intellectual Property and the Human Genome”, 12 Australian Intellectual Property Journal 61 at 74-75.

17 IBC IP Report, above n 13, 3. In Australia, the Australian Law Reform Commission (ALRC) has recommended that there be added to national patent law a requirement of “usefulness” as a precondition for the grant of a standard patent and in the certification of an innovation patent. See ALRC. 2004. *Genes and Ingenuity: Gene Patenting and Human Health*, Report No 99, 157 (Recommendation 6–3).

18 See HUGO Ethics Committee. 2000. Statement on Benefit Sharing (<http://www.gene.ucl.ac.uk/hugo/benefit.html>); ‘Genetic Benefit Sharing’, 290 Science, 49.

19 Nuffield Council on Bioethics. 2002. *The Ethics of Patenting DNA – A Discussion Paper*, 69 (para 6.2). See also para 2.10.

UNESCO Genome Declaration

In 1997, the General Conference of UNESCO adopted the *Universal Declaration on the Human Genome and Human Rights* ("the Genome Declaration")²⁰. That Declaration acknowledged that the human genome "underlines the fundamental unity of all members of the human family"²¹. It expressed the aspiration that "the human genome in its natural state shall not give rise to financial gains"²².

Those seeking intellectual property protection generally point to some "value-added" that, they claim, justifies monopoly rights. So how do we reconcile the advance of knowledge about the genome; utilisation of that knowledge for therapeutic and other purposes; protection of legitimate investments to this end; but ensure that the benefits will be available to all of humanity? These are major challenges before the world at this time. Within UNESCO, in September 2001, the IBC drew to the attention of the Director-General its view that "there are strong ethical grounds for excluding the human genome from patentability". It recommended that, in its review of the TRIPS Agreement, the WTO should clarify, in accordance with the provision of Article 27(2) of that Agreement, that the human genome is not patentable on the basis of the public interest consideration set out in that Article. The General Conference of UNESCO invited the Director-General to draw this advice to the notice of the WTO²³. In addition to these communications, a larger process of consultation amongst the affected agencies of the United Nations was established. An Inter-Agency Committee on Bioethics was created with a view to promoting further discussion of these issues, including those of intellectual property protection and the TRIPS Agreement of the WTO.

UNESCO Bioethics Declaration

These developments, in turn, led to the decision of UNESCO to initiate, through the IBC, preparation of a *Universal Declaration on Bioethics and Human Rights*²⁴ ("the Bioethics Declaration"). At the time, Madame Michèle Stanton Jean of Quebec, Canada, was the President of the IBC. At her invitation, I became the chairperson of the drafting group that prepared the text for this second Declaration.

The Bioethics Declaration sought to bring together the body of doctrine concerned with ethical principles that had grown in the healthcare professions since the time of the Hippocratic Oath in ancient Greece and the more recent body of doctrine, largely developed within the law, for the protection of fundamental human rights. The Bioethics Declaration contains several principles relevant to the specific topic of intellectual property law. Thus Art 14 ("Social Responsibility in Health") and Art 15 ("Sharing of Benefits") emphasise the importance in bioethical decisions of ensuring that all members of society share in the "benefits resulting from any scientific research and its applications"²⁵. The Bioethics Declaration also underlines the point that such benefits should be shared "in particular with developing countries"²⁶. Such principles represent the other side of the coin of assertions of national, individual and corporate interests often expressed in municipal and international law adopted to uphold economic investments upon biomedical tests and therapies.

Getting the balance right

Striking the right balance between protecting and promoting investments in these spheres, through intellectual property law, and ensuring that those investments are targeted at health conditions that are relevant to most of humanity and that any therapies are available at affordable cost to people everywhere, constitute major issues of importance for people in all countries. We need to ensure that national and international laws on patenting of biomedical advances conform to the principles endorsed by the IBC of UNESCO. This is the pointy end of a practical legal issue in which it is necessary for those who truly believe in the universality of human rights (and especially the right to access to the

20 Adopted 11 November 1997 by the 29th Session of the General Conference of UNESCO.

21 Article 1.

22 Article 4.

23 Resolution 31C/22 available on the internet at: <http://UNESDOC.unesco.org/images/0012/001246/124687_e.pdf>

24 Adopted 19 October 2005 by the 33rd Session of the General Conference of UNESCO.

25 Article 15(1).

26 Article 15.

best available healthcare) to raise their voices to counterbalance those who view such questions solely from an economic point of view and in terms of their own national and individual economic interests.

Embryonic stem cells

Pluripotent cells and their potential

Another development important for biomedicine, which the IBC of UNESCO has studied, is the use of embryonic stem cells in therapeutic research.

The research on this topic has focussed on human stem cells, particularly in the past those derived from the human embryo. The embryo is not a foetus. Still less is it an aborted or stillborn baby. In terms of size, an embryo is smaller than a full-stop on a typed page. Yet scientists have found that stem cells, obtained from the human embryo, have an ability to develop into more than one form of human tissue. If they are derived from embryonic cells, they may be totipotent (able to develop into all the different types of cells needed for a complete and functioning organism); pluripotent (able to give rise to most types of tissue but not capable of bringing an organism into existence); or multipotent (being able to give rise to particular tissue types).

Because of its very nature, an embryo must be able to develop in remarkable ways. It is this feature of embryonic cells that is thought likely to have specially beneficial consequences for medical research and therapeutic applications. Early experimentation on the repair of damaged cells has increased scientific attention to this potentiality. In particular, the apparent repair of damaged brain cells in patients with Parkinson's Disease or coronary cells following myocardial infarction has led to hopes that embryonic cell research will be useful for many scientific applications. Proponents of the research have therefore demanded that the use of embryonic stem cells should be encouraged and promoted because of their potential to result in therapies to combat forms of cancer and immune diseases, diabetes and diseases or injuries to the nervous system²⁷. Recent research, including work carried out in Japan, may suggest that embryonic sources will be less important for stem cells in the future than was thought in the past. It is unnecessary to decide whether this is so. For the moment we should assume that embryonic cells have a peculiarly valuable pluripotency.

In every national and international statement of human rights, respect is accorded to human life²⁸. There is a controversy as to whether such general provisions extend to prohibit the creation, preservation and use of embryonic cells for research; the extraction of particular cells for use in therapies; and the destruction of such cells when they are excess to needs.

Prohibitions and facilitations

Since the Human Fertilisation and Embryology Act 1990, the United Kingdom has authorised the use of supernumerary embryos for specified research purposes. In particular, the Act has permitted research use concerned with reproductive medicine and for the diagnosis of genetic and chromosomal disorders.

In 2001, the United Kingdom Parliament approved a law permitting the cloning of human embryos to derive stem cells, thus allowing the possibility of therapeutic cloning of human cells²⁹. However, in Australia, the Prohibition of Human Cloning Act 2002 (Cth) and the Research Involving Human Embryos Act 2002 (Cth) were enacted by the Federal Parliament as part of a package of laws aimed at the prohibition of human cloning and other practices deemed unacceptable to the lawmakers. Each of the Australian Acts was adopted by Parliament on the basis of a promise that an independent review would be conducted two years after such enactment.

27 UNESCO International Bioethics Committee. 2001. Report on the Use of Embryonic Stem Cells in Therapeutic Research (BIO-7/00/GT-1/2 (Rev 3), 9-13.

28 See eg Universal Declaration on Human Rights, Art 3; International Covenant on Civil and Political Rights, Art 1; African Charter on Human and Peoples' Rights (1981), Art 4; American Convention on Human Rights (1969), Art 4.

29 Human Fertilisation and Embryology Amendment Act 2001 (UK).

Such a review was duly established. It was chaired by a retired federal judge, the Hon John Lockhart QC. In December 2005, the Lockhart Review presented its report. The report recommended an end to the strict prohibition contained in the 2002 Australian legislation³⁰. It proposed a redefinition for legal purposes of the “human embryo”. It supported the introduction of a system of licensing for the creation of embryos for use for source materials for therapeutic purposes. However, the use of cloning and the experimentation with embryos for reproductive purposes was banned in Australia, and remains prohibited³¹.

Initially, the then Australian Government rejected the recommendations of the Lockhart Review. Following strong political, scientific and media reaction, a conscience vote was taken in the Australian Parliament. Consequently, amendments to permit therapeutic cloning and the use of human embryonic cells were enacted, albeit with only a tiny majority in the Australian Senate³².

The main arguments that assured this result in Australia were the recognition of the pluralistic nature of the country’s society; widespread reports on the potential utility of relevant research and experimentation; and the express conviction that experimentation would proceed in overseas countries whatever Australian legislation said. Interestingly, both the then Australian Prime Minister and the Leader of the Opposition (now Prime Minister) voted against the amending Act, although each acknowledged respect for the contrary views.

International debates and bans

In the international community, the global debates on the regulation of experiments using embryonic stem cells have frequently been driven by countries and individuals that, to put it politely, have not always been at the cutting edge of the applicable science and technology³³. On the other hand, in recent years, the United States of America has also adopted a conservative position on these topics. Thus, federal funding of any activities involving use of embryonic cells was forbidden by federal law in the United States although, in that country, the actual authorisation of research on embryonic cells is generally left to the discretion of each State.

A handful of American States continue to prohibit such research. In 1999, the National Bioethics Advisory Commission recommended that federal regulation should be amended to permit research into embryonic stem cells obtained from supernumerary embryos. In August 2006, the National Institutes of Health in the United States issued Guidelines on the circumstances in which research could be conducted on that subject by federally funded scientists. One of the conditions to be observed was that no such scientist could destroy an embryo in order to derive cells for experimentation purposes. Such activities could therefore only be performed by privately funded scientists who might then pass the cells on to their publicly funded colleagues.

Critics suggested that regulations of such a kind were absurd, allowing to be done indirectly what was prohibited directly.

In a number of countries, the use for research purposes of embryos donated by persons following treatment against sterility and not intended for implantation (“supernumerary embryos”) is legally permitted. Often the conditions imposed for such use include a prohibition on research after the fourteenth day of the existence of the embryo and the consent of the donors who originally supplied the embryo. Such is the reported practice in Canada³⁴.

30 Australian Government Legislation Review: Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryos Act 2002, Report, Canberra, December 2005.

31 Prohibition of Human Cloning for Reproduction Act 2002 (Cth), pt 2 div 1.

32 In the Australian House of Representatives, the vote was 82:62. See Commonwealth Parliamentary Debates (House of Representatives), 6 December 2006, 127. In the Senate the vote was 34:31. See Commonwealth Parliamentary Debates (Senate), 7 November 2006, 48.

33 Thus, Honduras was the national sponsor of the United Nations ban on human cloning, reproductive and therapeutic. See Macintosh, K. L. 2005. “Human Clones and International Human Rights”, 7 University of Technology, Sydney Law Review, 134.

34 See IBC Report on Embryonic Stem Cells above n 27, p. 5 [19].

An elusive consensus

The source of objections to the use of embryonic cells varies between different societies. In some, the objection is explained by reference to religious beliefs. In others, it has been justified by reference to the unique respect owed to a particular human tissue which, at least theoretically, could potentially advance to result in a human being, who would then certainly be entitled to protection of his or her human rights. On the other hand, the IBC investigation of this topic discovered large differences in religious and major philosophical perspectives.

In some branches of Christianity (Roman Catholic and Orthodox), human life is treated as having commenced at the moment of conception. However, amongst other Christians, the appearance of the primitive streak or some later phase of foetal development are taken as ethically significant. According to most teaching in Judaism, life does not begin until about 28 days from conception. Much Islamic writing recognises the ensoulment of a foetus as commencing at the end of the first trimester (three months). Hinduism generally requires live birth as a precondition to full personhood and hence to moral and legal protection. Humanists commonly take positions according to the actual (as distinct from potential) capacity of an embryo/foetus to be viable and to live as a human being.

In the face of such radical differences in religious, philosophical and cultural understandings, it has proved extremely difficult, at the international level, to reach a consensus on this topic. As the recent Australian Parliamentary debates demonstrated, this is a topic that divides lawmakers as it does societies.

In such circumstances, the IBC concluded³⁵:

“Every society has the right and duty to debate and decide upon ethical issues with which it is confronted. Where there is fundamental disagreement, the society will have to decide where it stands on the issue either because the question involved relates to some fundamental value of that society or because practical considerations demand that the matter be resolved. The use of human embryos for deriving stem cells would appear to be one such issue. Human embryonic stem cells research ... is a matter which each community ... will have to decide itself. If the decision is reached after serious ethical debate, which allows for the expression of views in different directions, then this must be accepted if one believes in the principle of democratic resolution of public issues. Examples of this process are afforded by IVF for fertility treatment and pre-implantation diagnosis with embryo selection. There are differences of opinion on the ethical values involved and yet States have decided that these medical practices are permissible”.

When the IBC recommended the Genome Declaration, the document initially contained no explicit reference to cloning. The draft Genome Declaration was expressed in very general terms, inevitable in the product of an international consensus of the participating members. When, however, the governments revised the IBC draft, the final document saw the introduction of an explicit prohibition on reproductive cloning. Thus, Article 11 of the Genome Declaration states, with the added words italicised:

“Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted. States and competent international organisations are invited to cooperate in identifying such practices and in taking, at national or international level, the measures necessary to ensure that the principles set out in this Declaration are respected”.

Not everybody agreed with the notion that reproductive cloning of human beings should be absolutely prohibited³⁶. Critics pointed to similar expressions of revulsion when earlier forms of artificial conception first became available, such as AIH (artificial insemination husband), AID (artificial insemination donor) and IVF. They regarded as absurd the notion that children, born of such procedures, experiencing entirely different lives and environmental factors, would end up exactly the same as their donors³⁷.

35 Ibid, p 13 [53]-[54].

36 Robertson, J. A. 2001. “Why human reproductive cloning should not in all cases be prohibited”, 4 *Legislation and Public Policy* 35; Shikai, Y.M. 2002. “Don’t be swept away by mass hysteria: The benefits of human reproductive cloning and its future”, 33 *Southwestern University Law Review* 259.

37 Macintosh, 2005, 7 *University of Technology, Sydney Law Review* 134 at 135-136 describing the resolution of the General Assembly of the United Nations of 8 March 2005. This approved a Declaration, proposed by the Sixth Committee, to “prohibit all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life”. The General Assembly vote was 84 to 34 in favour with 37 abstentions.

They referred to the unreliable potential of revulsion or repugnance to cast light on ethical responses to modern technology. They also point out that earlier generations found much (particularly racial or sexual differences) repugnant in ways that would not be treated as acceptable today. Moreover, if, say, a country with a majority Christian population prohibited forms of cloning for biomedical research, it could not be assumed that similar prohibitions would necessarily be adopted in law by a country with a different religious or ethical tradition, such as [Buddhist] Sri Lanka or [Confucian] Singapore.

Hybrids, chimeras and transgenesis

Within the diverse cultural, religious and ethical viewpoints existing in the world, these considerations make it difficult to find identical responses to technological developments of this type. The most that can be expected is an insistence on serious ethical dialogue; a respect for different viewpoints; mutual engagement and a search for common understanding; and the creation of institutional ethics committees to focus and promote such exchanges.

One particular problem facing legal regulators on subjects of this kind is the speed with which developments typically occur in the field of biomedical research. Thus, until recently, there was much international consensus of the need for particular care to regulate or prohibit the creation of chimeras - hybrid embryos containing both human and animal genetic material. Various reasons have been advanced, including concern that such chimeras would involve human scientists in “playing God”, altering species definitions and debasing human distinctiveness. A practical source of opposition has reflected the concern that inter-species experimentation or transplantation might sometimes run a risk of introducing into the human species viruses to which other species have developed immunity but which cannot be combated by human beings.

Despite these considerations, in recent years experiments have been conducted to create transgenic animals such as the Harvard onco-mouse³⁸. This is a mouse into which an active onco-gene has been introduced from the human species in order to give the mouse a genetic disposition to develop cancerous tumours and hence to be specially suitable for laboratory testing of drugs designed to destroy or control human cancer cells. Even more fundamentally, in December 2006, the United Kingdom government proposed a total ban on the creation of any hybrid embryo containing human material, even for research purposes. Following protests from numerous research organisations, the government reportedly relented. In May 2007, new draft regulations were published setting out a list of techniques of inter-species experimentation that could be allowed, including the creation of “cybrid” embryos - which comprise human DNA implanted into an empty animal egg and human embryos that express certain animal genes or contain animal cells.

The report on this development in *Nature Medicine* in August 2007³⁹ expected that the draft regulations would be signed into law soon afterwards so as to permit two research groups in the United Kingdom to proceed with their research in the Stem Cell Biology Laboratory in King’s College, London. Critics of the procedure reportedly argue that the rules were too proscriptive rather than being excessively permissive. The debate indicates the level of scientific and legal complexity that issues of this kind now present to the law and to ethical debates. East answers are rarely forthcoming.

Pre-implantation genetic diagnosis

The facility of PGD and its uses

The complex character of the issues that are now arising in this field is illustrated by the regulation of pre-implantation genetic diagnosis. This is a topic that has lately been examined by the New Zealand Law Foundation Advisory Review Committee set up to promote debate in that country. I serve as a member of that committee which is centred at Otago University in Dunedin, New Zealand.

38 United States, National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, Report, 21 May 1975.

39 August 2007, Vol 13, No 8.

Pre-implantation Genetic Diagnosis (PGD) is a form of technology that has been developed as an alternative to pre-natal diagnosis for couples who are at risk of passing inherited diseases to their children. With pre-natal testing diagnosis (such as amniocentesis) being undertaken when the pregnancy is already established, if the foetus is discovered to be affected by a defined genetic disease, parents may be given the opportunity to consider whether to continue with the pregnancy or to terminate it and to try to establish a fresh pregnancy that will hopefully be free of the inherited disorder. The objects of PGD are to reduce the risks of passing on serious hereditary diseases; to reduce the burden and stress on the parents (especially the female parent) concerned; and to minimise the need for the termination of affected pregnancies.

Research towards technology in PGD began in the United Kingdom in the mid-1980s. Earlier technology had been developed for pre-implantation techniques in the context of animal husbandry, chiefly in order to breed animals of the preferred sex⁴⁰. The first successful human pregnancies using PGD were reported in 1990 for various X-linked or sex-linked disorders (where males, not females, are affected) with the selection of female embryos for implantation. In 1992, this experimentation was followed by a report of a live human birth after using PGD selection designed to minimise the risk of transmitting cystic fibrosis. In 2000, PGD was used in the United Kingdom to test a number of disorders caused by a single gene, namely beta-thalassaemia, sickle cell anaemia and muscular dystrophy as well as for various chromosomal disorders, including Down's Syndrome. In essence, PGD involves the creation of embryos; the performance of embryo biopsy; the analysis of biopsied cells; and the transfer of unaffected embryos to establish a successful pregnancy. PGD incorporates the use of IVF technology as part of the process.

In some societies where termination of pregnancies is absolutely illegal and where that law is enforced, PGD represents a potential means of circumventing the abortion law. Apart from anything else, it avoids the enormous trauma to the pregnant mother (and burden, in many cases, on the father and family) of any abortion procedures or the birth of a seriously endangered child. On the other hand, PGD has not yet become a widely used procedure, either in the United Kingdom, where it received early development, or in other developed or developing countries. Some people oppose it on moral grounds, suggesting that it denigrates people with disabilities and objectifies the process of human conception.

The reason for the inquiry in New Zealand was the rapid rise in popularity of PGD techniques in that country and the fact that New Zealand was unique, amongst the nations offering PGD services, in providing a commitment to fund the full cost of up to two cycles of IVF/PGD for people who use PGD to test for specified serious inherited genetic disorders. As an indication of cross-border cooperation, many of the PGD tests administered in New Zealand are contracted out to the IVF Unit at Monash University in Melbourne, Australia.

At the time of the New Zealand inquiry, the PGD tests were available for five major inherited conditions (namely Huntington's disease, cystic fibrosis, spinal muscular atrophy, beta-thalassaemia and fragile X syndrome). However, PGD could be approved in other cases on a specific instance basis⁴¹.

The New Zealand committee set about examining closely the scientific foundation and technological developments relevant to PGD facilities. This approach is consistent with the insistence that all modern legal and ethical investigations of biomedical issues should be based on a sound understanding of the relevant science and technology.

The controversies of PGD

As the New Zealand inquiry into PGD proceeded it discovered a number of important topics that would require attention. These included:

40 New Zealand, Law Foundation. 2006. *Choosing Genes for Future Children - Regulating Pre-Implantation Genetic Diagnosis*, Dunedin, 4 ("2006 Report"); Snelling J., Peart N. and Henaghan, M. "Pre-Implantation Genetic Diagnosis: Testing the Legal Boundaries" in Henaghan, M. (ed). 2007. *Genes, Society and the Future*, NZ Law Foundation, 27; Wee, R. and Dobbs K. "Legal Issues to Newborn Screening", *ibid*; Kerruish, K. "New Possibilities for Newborn Genetic Screening: Screening for Genetic Susceptibility to Common Disease" *ibid*, 295.

41 2006 Report, 5.

- The need for respect for the particular perspective of the Maori people of New Zealand concerning the sanctity of their Whakapapa (genetic inheritance) and anxiety that nothing should be done through PGD to reduce that inheritance, in all of its diversity;
- The need to consider whether PGD results in the denigration of people with disabilities or the suggestion that their lives are sometimes less worthy;
- The need to examine whether PGD should be available only to married couples or also to couples in de facto relationships; single women at risk wishing to secure a safe and viable pregnancy; and same-sex couples in a like position?
- The need to evaluate the health budget and competing health concerns, and also the public cost involved following the birth of disabled children. Can PGD be justified in a developing country or should other health concerns have a greater priority?
- The requirement to address the concern of religious groups that PGD involves a departure from the random passage of genes from one generation to the next and the introduction of scientists “playing God” to create human life in accordance with a preconceived notion of what that human life should be;
- The necessity to consider the question of what genetic conditions may be described as “disorders” and which of them is approved for PGD or not approved. Thus, will manifestations of baldness in a family be disapproved and excluded? Will the birth of several females to a couple warrant PGD to ensure a male birth, or vice versa? Will PGD lead to a postulate of “normal” genetics with the risk of reducing the human gene pool whose diversity has been an important protection to humanity against disease? Will developments in one country lead to demands for similar developments in other countries, despite different cultural, philosophical and religious traditions?

Different legislative responses

In the United Kingdom, a statutory regime has been adopted for PGD. It has been described as “one of the most liberal regulatory mechanisms in the world”. The Human Fertilisation and Embryology Act 1990 (UK) contains few express prohibitions. It delegates considerable decision-making power to the Human Fertilisation and Embryology Authority (HFEA). This Authority acts as a licensing body for purposes identified in the Act. There is no express reference to PGD in the United Kingdom Act. However, the Act prohibits the creation, keeping or use of an embryo except in pursuance of a licence granted under the Act. Such licences may be provided for “treatment services”. These are widely defined. They have included the safe provision of fertility services, ie by the exclusion of serious hereditary diseases.

Justifying this approach of openness and flexibility, the then Prime Minister (Right Hon. Tony Blair), in a foreword to the United Kingdom Government White Paper, *Our Inheritance, Our Future*⁴² wrote:

“Our country has a remarkable scientific tradition. The extraordinary achievements of Newton, Darwin and a host of other eminent scientists have both greatly increased the understanding of our world and improved the quality of life for everyone. Our record continues to be outstanding; with just 1% of the world’s population, we receive 9% of scientific citations. Nowhere has this record been more notable in recent decades than in bioscience and biotechnology. The discovery in Britain of the structure of DNA fifty years ago - perhaps the biggest single scientific advance of the last century - marked the beginning of a golden age of bioscience in Britain which continues today. It is likely to have as big an impact on our lives in the coming century as the computer had for the last generation ... The National Health Service should be able to respond to these advances so that the benefits of genetics and the more personalised and improved healthcare it will bring are available to all.”

The New Zealand Committee recommended close monitoring of the practices being adopted in New Zealand and the collection of national (or Australasian) statistics. It also recommended physical and mental examination of PGD children once born. It proposed comparative studies of the effectiveness of PGD for decreasing miscarriage rates and for increasing healthy birth rates. It recommended separate consideration of proposals for the introduction of comprehensive genomic screening for the entire population. It regarded such proposals as raising distinct and different ethical and presenting moral

42 United Kingdom, Government White Paper. 2003. *Our Inheritance, Our Future* (Cm 5761), [1].

questions demanding separate investigation and report. It also recommended further study of what single gene and complex genetic disorders should justify publicly funded PGD in New Zealand⁴³.

The issues concerning PGD, legal and ethical, are well-summarised in the New Zealand reports.⁴⁴ They demonstrate both the potential of biomedical technology to help people and to reduce suffering but also their capacity to present many and varied new issues, including legal issues, requiring the attention of judges and lawyers.

HIV/AIDS and Biomedicine

A colossal epidemic and actuality: For some people, especially in developing and poorer countries of the world, discussions of pharmaceutical patents, embryonic stem cells, PGD and like advances in sophisticated biomedical technology may seem remote, theoretical, non-urgent problems for law and policy.

In countries where the annual per capita expenditure on public health is extremely modest, say US\$100, theorizing about such issues will seem a trifle unrealistic. In such countries, there will be much more urgent biomedical problems. Chief amongst these, in many countries, will be the increasing incidence of malaria, tuberculosis and HIV/AIDS.

I will therefore turn to some of the biomedical and social dilemmas that face the world in connection with HIV/AIDS. This is an issue with which I have been concerned, during the history of the pandemic, since the early 1980s. I served on the inaugural WHO Global Commission on AIDS. I am now a member of the Human Rights Reference Group of UNAIDS - the inter-agency body of the United Nations, established to enhance the Organisation's response to the HIV virus. I have also been involved in the responses to AIDS of the United Nations Development Programme (UNDP) and the Inter-Parliamentary Union (IPU).

I can do no better in describing the dimension and urgency of HIV than to quote Justice Edwin Cameron of the South African Supreme Court of Appeal, in a recent address to the International Labour Organisation in Geneva⁴⁵:

"...[T]his epidemic is colossal. It is probably the biggest microbial pandemic to strike human kind in six centuries. Though the official figures are - rightly in my view - much contested, few deny that many tens of millions of people risk death from AIDS in the next decades - and that most of them are poor Africans.

UNAIDS estimates that nearly 40 million people world-wide are living with HIV - and perhaps 25 million have already lost their lives because of AIDS - in 2005 alone, an estimated 2.8 million. Changes in behaviour and prevention programmes (as well as the fact that the epidemic may have peaked) have reduced the incidence of HIV in many countries. Yet in the developing world, and particularly in Africa, the epidemic is still expanding. According to UNAIDS, Africa remains the global epicentre of the pandemic⁴⁶ ...

Within Africa, the sub-Sahara region has the highest infection rates in the world. While only 10% of the world's population lives there, nearly two-thirds (about 25 million) of the world's population with HIV resides there. The dark shadow of AIDS mirrors Africa's overall burden of disease. And its darkest reflection is in the deadly toll of AIDS. In 2005 an estimated 930,000 people died of AIDS in Southern Africa alone⁴⁷. Seen from some angles, the prevalence of my own country, South Africa, are the highest. Eleven per cent of the total population, 19% of the working-age population, and 33% of women aged 25-29 are infected with HIV. On every day of

43 2006 Report, above n 40, 58-59.

44 R (Quintavalle) v Human Fertilisation and Embryonic Authority [2005] UKHL 28; [2005] 2 WLR 1061; [2005] 2 All ER 555 (HL).

45 Cameron, E. 2007. "Legislating an Epidemic: The Challenge of HIV/AIDS in the Workplace", unpublished, 19 July 2007, ILO Geneva, 1-2 [3].

46 UNAIDS, Report on the Global AIDS Epidemic 2006, Geneva, 5.

47 Ibid, 15-23.

2006, approximately 1400 people in South Africa were infected with HIV and 950 died of AIDS.

We must humble ourselves before this [epidemic] in considering policy interventions that might alleviate it“.

For Justice Cameron, these statistics are not impersonal data. He is himself an openly homosexual man living with HIV. He gives a voice to the voiceless in this most urgent contemporary biomedical problem of the developing world. AIDS is a proper concern for all people for it remains a unique global challenge to human life and dignity.

Biomedical advances with ARVs: As a result of scientific and technological advances since the late 1990s, remarkable combinations of therapies (anti-retroviral drugs or ARVs) have become available for treatment of HIV/AIDS on a large scale. Anyone who has seen the effect that the administration of ARVs to people living with HIV/AIDS, medically prescribed and faithfully administered and monitored, will attest to the effectiveness of the drugs. They help to reverse weight loss, and restore economic capacity and the will to live.

This is why the Heads of Government of 189 countries, meeting in the United Nations General Assembly Special Session (UNGASS) on HIV/AIDS in June 2001, committed the world to reversing the epidemic and to providing ARVs, at affordable cost, to countries and patients everywhere. The result was the WHO 3x5 programme⁴⁸; the establishment of the Global Fund to support amongst other things the purchase of ARVs for distribution in developing countries; and the encouragement of national and international programmes designed to increase accessibility to these life-saving and life-enhancing drugs everywhere.

In parts of Africa, notably Botswana, there have been successful campaigns to provide ARVs to the population needing them. The ARVs are highly sophisticated drugs. If purchased at full North American costs, they would be unaffordable to all but a tiny fraction of people in the developing world. Treating HIV/AIDS as a most urgent public health emergency has permitted exceptions to be established for the use of generic copies of patented drugs and for the supply of licensed drugs through global subventions by rich countries to poor ones. Providing such drugs to the sick is but the first step. It remains necessary to monitor their use and to ensure that they are accurately administered without interruption.

Limits of biomedicine: HIV and prevention

Unfortunately, providing ARVs to the infected is not a complete answer to the HIV/AIDS epidemic. As was quickly discerned in a seminar held by judges of Zambia, patients receiving ARVs remain infected. Although their HIV viral load may fall significantly because of the effectiveness of the drugs, such patients remain capable of infecting others with HIV, principally through sexual intercourse. Generally speaking, nations (and the United Nations) have been ready to promote treatment and the availability of ARVs for therapy for the already infected. They have been much less willing to promote the strategies of prevention that have been shown to be effective in reducing the spread of the virus and the incidence of AIDS. Medicalising the AIDS epidemic is congenial for some. Tackling the vectors of HIV for prevention requires societies to take decisions that are often very difficult and painful for them.

It is in this sense that the biggest challenge presented by HIV/AIDS to developing countries, and especially in Africa, is the challenge of effective social and legal intervention. On this subject, most countries in the developing world have been neglectful towards, and apparently reluctant to tackle, the issue of prevention.

A study of those countries that have been successful in their strategies to promote prevention of the spread of HIV, and to reduce the rates of individual sero-conversion (such as the United Kingdom, Canada, Australia and New Zealand) will illustrate the steps that are essential to reducing the spread of HIV. Putting it simply, absent a vaccine and total cure, this can only be accomplished by behaviour modification. This, in turn, requires winning the confidence of the people most at risk; protecting

48 To secure access for three million persons in developing countries access to anti-retrovirals by 2005. The objective was partly, but not wholly, successful.

their human dignity; and convincing them of the need and utility to modify their conduct. Only such strategies have been shown to be effective in preventing further spread of the HIV virus, so dangerous to the individual and to society.

This message cannot be proclaimed often enough or loudly enough. Putting it quite bluntly, unless the strategies of prevention are energetically adopted, the numbers of people infected by HIV will continue to swamp the numbers of patients receiving ARVs. Those infected with HIV will continue to burden the health budgets and facilities to a growing and intolerable extent. The increasing numbers of patients on ARVs will remain a source of future infections. They will look and feel healthy. But they will remain capable of passing on the virus.

The present ARVs are likely, in many patients, to become less effective over time. New “second line” therapies will be even more expensive than the present ARVs. There is no certainty that they will be provided at a cheap cost. Rationality therefore tells us that there is no other option for developing countries but to step up the prevention strategy at the same time as they step up the treatment facilities. Yet, in Africa especially, an element of irrationality and reluctance has prevented most nations from taking the hard decisions essential for successful national strategies of prevention and behaviour modification.

Preventive methods that succeed: Studying the countries that have brought their rates of HIV sero-conversions down, it can now be said with a high level of certainty that the following strategies are essential and also effective. They are strategies in which lawyers, for once, can play a useful and constructive role in addressing a global epidemic:

- (1) Engage in mass education campaigns with candid information about HIV transmission for the entire population, especially the young who are most at risk;
- (2) Reform the law on commercial sex work (CSW) (prostitution) to promote empowerment of CSWs, education and insistence on the use of condoms;
- (3) Provide sterile injecting equipment for use by injecting drug users (IDUs). In Australia, this is available in most pharmacies. It has reduced Australian rates of IDU infections virtually to zero. The rates are ten times higher in the United States;
- (4) Repeal the criminal laws that punish consensual adult same-sex activity (MSM) (the so-called “unnatural” offences introduced into the criminal law during colonial days);
- (5) Enact laws to remedy discrimination against people living with HIV and AIDS;
- (6) Introduce courses in schools, colleges and universities to promote awareness and condom availability; and
- (7) Engage the affected minority communities at highest risk (CSW, IDU, MSM) in the foregoing strategies and keep them consulted at all stages.

Unless these initiatives are taken, all the anti-retroviral drugs and all the biomedicine in the world will not turn around the AIDS epidemic. This is the biggest biomedical challenge facing the developing world today. Malaria and also tuberculosis (which are often connected with HIV) is not far behind. It would be criminal if we were to ignore HIV.⁴⁹

Instead of tackling HIV/AIDS in the foregoing ways, that have proved effective in the developed world, too many countries have preferred the path of denial, neglect and pretended “morality” and “respectability”. This head-in-the-sand attitude will continue to reap a terrible harvest of suffering. It is particularly important that lawyers, who know the practical difficulties of securing behaviour modification, should speak up clearly about the urgency of preventative action.

49 Csete, J. 2005. “HIV/AIDS and human rights: We’ve only just begun”, 10 HIV/AIDS Policy & Law Review 1 (Canada).

National HIV/AIDS bodies should be adopting proactive strategies to remove the impediments (including the legal impediments) to prevention and therapy in the fight against AIDS. It cannot succeed if the fight is riddled with moralizing discrimination against the vulnerable groups most at risk and hamstrung by laws that place vulnerable groups outside the effective reach of safer-sex messages.

The difficulties of adopting the above strategies for prevention of the spread of HIV and AIDS are not underestimated. But none of us should ignore the price that will be paid for ongoing neglect and indifference.

The moves to criminalise HIV: Instead of taking the initiatives I have mentioned, many African and other nations have lately embraced a strategy of invoking criminal sanctions against those who knowingly infect others with HIV. Lawyers must explain why punitive strategies of this kind have only a tiny part to play in combating the spread of HIV.

To the extent that the law criminalises knowing infection of others with HIV, it introduces a significant penalty upon the individual's discovering his or her own HIV status. It thus discourages people from taking the HIV test. Yet taking the HIV test is often the first step towards self-awareness, behaviour modification and access to ARVs where they are needed. In 2001, Zimbabwe, Lesotho and Swaziland adopted laws to criminalise knowing transmission of HIV to another person. Uganda, Kenya and Sierra Leone are considering such a law⁵⁰. This spread of ineffective laws has launched the latest epidemic to hit Africa and the world. HIL (highly inefficient laws) may become as infectious in the developing world as HIV has been.

Large public resources will be devoted to prosecutions under these laws. Where the cohort of the sexually active population already infected with HIV is large, the net of criminalisation will be spread far and wide. Such laws are unlikely to have a large impact on actually reducing adult consensual or commercial sexual activity. In most developing countries, the resources will not be available to permit careful genetic analysis to distinguish an innocent accused from a guilty infector⁵¹.

I have participated judicially in court proceedings in Australia, confirming a conviction following a jury verdict for deliberate transmission of a dangerous disease (HIV)⁵². There may sometimes be a part for the criminal law to play in responding to wilful, deliberate or reckless infections of others. However, stepping up the criminal law to punish infections will constitute a drop in the ocean where truly effective strategies are required, but all too often neglected.

The urgent challenge: It is therefore essential and urgent that informed observers become teachers of the AIDS paradox. Paradoxically, the most effective strategy to contain the HIV/AIDS epidemic by behaviour modification is to protect those most at risk. Only this will secure their awareness and cooperation in reducing the incidence of sero-conversions. This may not be a popular message in some quarters. Wisely and prudently Bishop Desmond Tutu, Nobel Laureate, has admonished the all-too-human desire of people to have someone to look down on, to blame and to demonise. People in the developing countries have tasted the sting of such attitudes and discrimination in the past. They must not themselves be guilty of practising what they preached against when they were struggling for their own dignity and freedom.

Fresh government initiatives to combat HIV/AIDS are therefore needed. They should support and reinforce the efforts of WHO and UNAIDS that each teach the foregoing message. Pumping out more drugs and biomedicine is not the answer for prevention of HIV. Initiating law reform is. For once lawyers have a relevant role to play in combating this epidemic. But will we be courageous enough and imaginative enough and determined enough to do so?

50 Nature Medicine, Vol 13, No 8 (August 2007), 890.

51 Ibid.

52 In R v Reid (2006) 162 A Crim R 377. An application for special leave to appeal to the High Court of Australia was refused.

Conclusions

A global phenomenon

The present generation lives at an exciting and challenging time. The challenges of biomedicine are reaching the courts⁵³. They also present themselves to legislatures and policy-makers. They arise in the national, regional and global forums. It is vital that we should be aware of them and be able to respond effectively and justly to them.

There has been no occasion here to deal with all of the challenges that biomedical decisions present to us in the law. The challenge to intellectual property law is a universal one, although it affects developing and developed countries differentially. The challenge of embryonic stem cells research and pre-implantation genetic testing illustrate examples of experimental technology that are now arising frequently in developed countries. Whilst the challenge of HIV/AIDS is universal, its burdens fall most heavily on people in developing countries. This is especially so because of the reluctance of most of those countries to take the hard decisions of law reform essential to repel the pandemic by techniques of legal change essential to promote effectively the necessary behaviour modification.

Law in the rear, limping

Because biomedicine, its associated technologies and problems constitute universal phenomena of all humanity, we can all learn from each other. Unless issues such as I have raised are dealt with through expert consultation and public processes, judges, at least in common law countries, will resolve them as best as they can. They will do so by analogical reasoning, according to the general principles of the law. The response of the legislatures and the courts is, however, usually slow and hesitant. As Justice Windeyer said in the High Court of Australia forty years ago, the law does not keep pace with medicine. It marches in the rear, limping⁵⁴. Inter-disciplinary dialogue is essential. This chapter is offered as a contribution to that dialogue.

53 See eg *Cattanach v Melchior* (2003) 215 CLR 1 (“wrongful birth”); *Harrington v Stephens* (2006) 80 ALJR 791 [6] (“wrongful life”). See Teff, H. 2007. “Condoning Wrongful Suffering”, 15 *Torts Law Review* 5.

54 *Mount Isa Mines Ltd v Pusey* (1970) 125 CLR 383 at 395.



Discussion

Discussion and discourse at the conferences account for a significant part of the meetings. They are often wide-ranging and equally thought-provoking. Excerpts from some of the discussions are, thus, provided in the following pages. They are identified by the titles of the presentations after when they occurred.

Samantha M.C. Pang (Hong Kong) and Michiko Yahiro (Japan): How do Chinese and Japanese patients characterise the good nurse?¹

M.K. Tadjudin (Indonesia): I happen to be the dean of a school of health sciences which includes a programme in nursing. I believe that how a patient perceives a nurse also depends on how a nurse perceives a patient. Do you perceive the patient as a patient or a client? Because I believe there are some nurses who perceive their patients, the sick persons, as clients rather than patients.

Samantha Pang (Hong Kong): I think the question here goes to the value and the feeling of how we look at the patient. I think from a very paternalistic point of view, the patient is a patient, they are sick, so they need to be taken care of with a parental heart. The term client comes with consumerism and also out of the value of respect for autonomy. In Hong Kong, I can only say that both actually work, and it is more and more moving towards respect for the autonomy of the patient. That's why you have all types of conflicts, because client and patient views coexist in practice.

Grace (China): I just want to say this presentation reminds me of a movie. The name of the movie is "Patch Adams", starring Robin Williams. I don't know if anyone in this room has watched that movie? Actually, Patch, in that movie was a perfect doctor, and I don't think we can find that kind of doctor in our real life. As for a good nurse, I think a good nurse should be someone who respects patients, and as a real respect comes from carefully understanding your patients. And a nurse who can fully understand their patients should be a nurse who was once a patient. But, as you put in your presentation, sometimes people are so forgetful, so if I were a nurse and I was once a patient, but I am so forgetful, so I forgot I was once a patient. So how can I be a good nurse?

Samantha Pang (Hong Kong): I'd like to say that for all the descriptions, I am talking about something ideal. Here, I think we all agree that we have the good and bad, we are not perfect.

Paungphen Choonhapran (Thailand): Bioethics issues in intensive care nursing

Sarinya Sophia (Thailand): Let me talk as a Thai citizen. I just have one question that your paper is from your own experience and from the research that you get the information from the private or public hospital nursing system. The problem that I'm sure is not only in Thailand, but [in] many countries, is that the ratio of the nurse and patient is one to more than one thousand or whatever, in some countries, especially in the least developing countries. At the policy level, do you have any plan to solve or to handle this problem in Thailand?

Paungphen Choonhapran (Thailand): We have a nursing council and the nurse that has any kind of problem can write to the nursing council. I know that next year the government will get the budget to educate four thousand more nurses. But it's still not enough, because nurses in intensive care need more experience. They have to train for another one-to-two years.

Sarinya Sophia (Thailand): From my understanding, to be a nurse you need to study until you get a bachelor's degree, right? What about the assistant to the nurse? Are you training them for taking care of the patient?

Paungphen Choonhapran (Thailand): At the moment we try to stop that because from the research, it appeared that when we use the practical nurse, or aids in caring for the patient, the mortality rate will be higher.

Sarinya Sophia (Thailand): The case that you mentioned was for the private hospital - it's different, right, with the nurse? Because they are private hospitals, then sometimes there are more than two nurses to take care of one patient. But I am sure that in the upcountry outside of Bangkok or in the public hospital,

1 The discussion includes an edited transcript of the discussion made to all papers presented at the BBRT1 conference. In the case where no paper was available to include in this volume, readers are referred to the on-line abstracts for the entire conference. <<http://www.unescobkk.org/index.php?id=BBRT1>>

they have this kind of problem too, right?

Paungphen Choonhapran (Thailand): There is another problem that I am looking at. As I tell you that the nurses live with us. When the patient is more seriously ill so the patient on the ventilator moves out of the ICU, and they stay in the ordinary ward, it creates tremendous stress to the nurse, as well as to the patient and the relatives. I have a lot of complaints about this.

Dena Hsin (Taiwan): With a nursing background I studied bioethics. When patients are dying they are sent to the ICU. The ethics of ICU should be right for each patient at the right moment. So the goal for the ICU should be to preserve life, it is true, and only in the reversible situation we should put patients in ICU. If the patient's dying is irreversible, you shouldn't put a patient in the ICU. Most dilemmas come from that. It's very clear that we should have a guideline to use ICU resources in the proper way, because there's always a lack of resources in medical sociology. Also because of my background as a nurse, I really feel that about such dilemmas or the issues, we would like to have deliberate thinking about what is right, what is wrong and what is appropriate, rather than the emotional debates and distraction. This will solve the problem more effectively.

Paungphen Choonhapran (Thailand): Most patients who come into the hospital to die do not come into the ICU. They go to the ordinary ward.

Dena Hsin (Taiwan): The nurse in the ICU always has the dilemma as who should take the patient off the ventilator, is it a doctor or nurse? Older patients are struggling, and when should they stop aggressive treatment? So if the patient is dying, we can transfer the patient outside of the ICU, to go to a hospice. It's very clear, so if you can have a guideline like that, it would solve the problem. Also we have the similar situation in Taiwan. When patients are dying who are sent to the ICU, which is customary, we have to talk about the situation that is not appropriate. We hope that nurses shouldn't have to face that kind of dilemma in the future.

Mihaela Serbulea (Romania): This is related to that comment. I wanted to add to your recommendations maybe. It would be useful to make the general public aware of the limitations of the ICU, and not just bring terminally ill patients into the ICU in the hope that something could be done to save their lives there. There are limitations, and for the family of course it is painful to have the patient at home for dying but it is important to know that this is inevitable and that it is less painful for the dying person to be at home rather than in the hospital. I suggest general awareness is needed, not only education for the nurses who already know it, but for the public in general.

Alireza Bagheri (Iran): Controversy over Medical Futility

D.S. Sheriff (India): As an Islamic physician, what is your opinion about medical futility? Can you stop that? Can you practice it?

Alireza Bagheri (Iran): Actually it is important to understand the patient first. I hope it is possible to have a kind of shared decision making. To try to convince patients about the decision which the physician makes. If it is not possible then the second opinion would be the best option for us. This applies if the patient's wishes are not in conflict with social interest, especially in developing countries. The futility debate is not just for developing countries but developed countries as well. It is relevant to their health care system as well. But if there is no conflict between social interests and what patients request for the treatment, then it would be the best option to follow the patient's wishes.

John Weckert (Australia): I do have a concern about one aspect of your paper. That is that you kept referring to the physician making the decision, and if, in fact, there wasn't a satisfactory resolution between the physician and the family, then it would go to the ethics committee. Can you talk about how you see the role of the health team, rather than just the health care professional, because if we take into account the previous presentations about intensive care, the nurses have a critical part to play in this too, in my view, so I'd appreciate your comments.

Alireza Bagheri (Iran): Exactly, that is why I mentioned that it is better to have shared decision making. Having shared decision making is to have genuine communication with the patient, which, of course

includes patients and physicians, and also a critical role may be played by the nurses. Also I mentioned about the second opinion. The second opinion may be considered working as a team to decide about the course of treatment, or just referring a patient to the second opinion, if the patient has his own idea to go to another doctor. If there is still no ethics conflict at the hospital, then asking another doctor to join the session with patient and family to talk about the course of treatment would be a good option, of course.

Blaise Bikandou (Congo): Impulse of Ethical Research in Life

Miheala Serbulea (Romania): I wonder what do you think about the traditional medicines of Africa? How could they be used for public health purposes?

Blaise Bikandou (Congo): Such medicines are the original practice in Africa, so we think that is a priority. We are making guidelines to promote this traditional medicine because, like in Asia, we think that is one other traditional medicine to develop in Africa.

Wardatul Akmam (Bangladesh): I'd like to ask, how you take anthropological, sociological and economic aspects into account?

Blaise Bikandou (Congo): I think we can look for a translation to transpose a concept from Europe directly into Africa. For example, when you have a clinical trial in the United States, for example, if you have only one life lost, you should stop a clinical trial. In Africa, for example, with Ebola, there is 80% or 90%. For sickness and disease one treatment from 1940 was a very toxic arsenic. So, for these kinds of things we have to make a choice. That means of course we have to take care, but the core situation is not the same, regarding the situation in Africa, Europe, the United States, and even in Asia. Also, for example, for the anthropologists, the concept, in Africa if you set up a clinical trial in a village and you talk with the chief of the village and the chief says "yes, I agree", it is a bad thing to say individual consent because if the chief gives his authority, it is a bad thing to talk after to individuals, "I want you to..." Of course we have to make efforts to do our best to inform but we have to be careful.

Wardatul Akmam (Bangladesh): So you want to take into account the sociological and anthropological context when approaching all these things?

Blaise Bikandou (Congo): Yes.

Don Chalmers (Australia): The one memory I take from this interesting paper is the unacceptable gap in the treatment of children. I think we should as a community, always draw the line. This is simply an opportunity for our young. Do you have any ways that you phrase that problem to argue in favour of those children, in international agencies based on human rights? Or how do you go around addressing this problem? There is a part of the lawyer in me that sees that as a breach of human rights.

Blaise Bikandou (Congo): I have no good answer. That is a huge question.

Subrata Chattophyay (Nepal): Just a very quick comment: a friend of mine was employed with the WHO, working in the field of HIV a couple years ago, and he was very upset and kind of depressed given the scenario of HIV and all the problems in the African context. So recently there was an issue of drug sales to Africa. My question is, when we began to call for health for all by 2020 we are so hopeful about the whole scenario, especially in the African context. But now that we have AIDS coming up in such an alarming way and the question of AIDS medicines and vaccines, and the problems of war and famine and the conflicts, do you see or find any hope as far as Africa or the world in general is concerned?

Blaise Bikandou (Congo): This is an important question, but I do not know exactly how to answer. What I think is, although most disease is ecological, as you know. I think education and training could be the best way, because I don't know if in the short-term you can solve any problem. Of course it is not a big hope. I think the reality is that this country is very poor and we need to try to educate people, and so, maybe in 20 years or 30 years.

Subrata Chattophyay (Nepal): But the population needs help right now as well.

M.K. Tadjudin (Indonesia): Ethical Issues in the Face of Scarce Resources

Alireza Bagheri (Iran): I wonder in Indonesia, how do you evaluate your programme, including the principle of justice, whether your approach is based on distributive justice or do you have another approach to this issue? Especially considering urban and rural areas, how should you consider distributing facilities between these two?

M.K. Tadjudin (Indonesia): Well, as a person, the decisions are based more on politics than on a moral and ethical basis, because if you look at the resources allocated, then you can see that most of the resources are allocated more in the big centres of population. This is maybe because it is important for the politician to get the votes of the people.

So they support programmes which are more beneficial to people who are living in big population areas rather than on programmes in the rural areas. Formally we had family planning programmes, we have what we call self-service health first programmes which care for the people in the rural areas, but the support for this programme in the last few years has been diminished so the people in rural areas are having more difficulties in rural areas getting health care than people in the urban areas.

Yanguang Wang (China): Let us imagine if there are few patients and we need to choose one who will get a kidney transplant. One is young, one is old and another one is a very famous actor, and the one young girl has much money, which one would receive this kidney?

M.K. Tadjudin (Indonesia): We don't have that problem because we do not do much transplantation. Most of the people who want organ transplantation who can afford it go to China.

Wardatul Akmam (Bangladesh): You've mentioned that more research is required in this field, but my question is, is the research taken into account by the politicians? At the end they make the decisions so do they take into consideration the finding or the research works?

M.K. Tadjudin (Indonesia): That is why we have to educate the politicians. So I think the duty of the academics is to sell their findings to the politicians, and the NGOs. Then they can put pressure on programmes that we think will be more just and have more benefits for the people.

Wardatul Akmam (Bangladesh): I am asking this question because in Bangladesh, many research work on ethics takes place and many findings are there but they're not taken into account when actual policies are made.

Peggy Fairbun-Dunlop (Samoa): Thank you very much for this great reminder of the difficulties of being ethical when you haven't got much money to play with. My question is, in the Pacific countries a substantial portion of the health budget is provided by external aid, by aid donors. So I was just wondering, how ethical are aid donors in listening to what you think are the key problems or pushing your own particular research agenda or what they think are priorities? Is that an issue?

M.K. Tadjudin (Indonesia): Yes, it is an issue. Most aid programmes have their own particular issues. For some programmes it is difficult for us to get support.

D.S. Sheriff: Most of the corporate hospitals want patients to be in the ICU to earn money, so there is no question of their ethics. Do you have a corporate hospital culture in your country?

M.K. Tadjudin (Indonesia): We have only very few corporate hospitals in that sense, maybe some companies have their own hospitals but very few. So most hospitals in Indonesia are public government hospitals.

Peggy Fairbun-Dunlop (Samoa): I guess can I pursue the next bit of my question which is there a need for ethics courses within donor agencies? Seriously, what has been done within UNESCO itself or within the UN, Maybe Darryl will know?

M.K. Tadjudin (Indonesia): Well I do not know how many donor countries take these into account. Sometimes it is not the donor agency, like the USA will not support the programmes that include

abortion or something like that, so it's not the UN donor agencies themselves. As a response maybe other countries should be motivated to give more aid.

Darryl Macer (New Zealand): In response to Peggy's question on the ethics of donor agencies, the only UN organization with an internal ethics committee is FAO. WHO has one when necessary for receiving funds from external donors NIH and in fact, several years ago NIH held up grants as it forced the WHO to restructure its ethics committee. But many donor agencies have varying ethical guidelines. I have made some studies in the last few years on this and I haven't yet published it, but I think more and more should be brought into some coordinated programmes on how to coordinate ethics, for example the World Bank.

Xiaomei Zhai (China): Research Ethics in China: History, Status Quo and Issues

D.S. Sheriff (India): I found that when you are doing the ethics training it is in the interest of journals. Because as you said one of the publications which was considered unethical but editorially important. I don't know how they allowed the paper to be published when they have done some research on human subjects only for research purposes. So it must be asked, why did they publish the paper?

Xiaomei Zhai (China): It is a very good question. They often answer to why we publish this paper if it is an unethical paper, by explaining that it is very useful in science, it is a very good scientific paper. That is why. So it seems that if it is very useful in science, then they can compromise their ethical principles a little bit.

Neil MacPhee (UK): I am thinking of two things. I'm thinking of one word you used which is urgency because it is urgent, and the other thing I'm thinking of is scale, the size of the situation. I think we can relate what has happened in this case of surgery to other issues, for instance the release of genetically modified organisms into the environment. What we are considering doing with the release of the organisms is irrevocable. You cannot get them back once they are released. Once you do surgery on these patients you cannot undo that surgery. These are irrevocable actions. In the case of the surgery on the addicts, there are alternatives to that operation which might be successful and I'm not sure whether the doctors who carried out that surgery were aware of those alternatives. I think they ought to have considered the alternatives. When we are considering doing such no turning back actions, I think people should be aware of how important it actually is, and that it really is a gigantic and urgent issue. It is an immediate concern, a bit like a train coming towards you if you're stuck on the tracks. It's just a comment.

Xiaomei Zhai (China): I agree with you as we discussed during our meeting.

Jayapaul Azariah (India) In the case of informed consent do you have variation in language in different areas because there is a variation in language and dialects? Do you translate it and then back translate to see whether the translation has been made correctly?

Xiaomei Zhai (China): Yes, if the research project is when we obtained informed consent; it is very strictly done like this. After the informed consent for the procedures we will use a questionnaire to test if the patient has understood the procedures correctly.

Aamir Jafarey (Pakistan): I know several people from your country, several people from China and the USA who are developing very ambitious programmes like yourself and who have gone back to China. I hope are all working in developing research ethics. However, we, the developing world, cannot rely on the benevolence of the US NIH or the CDC for developing our capacity in research ethics or in bioethics forever. What is your centre in particular and the other agencies in China, doing to develop bioethics capacity in particular, indigenously? I know that you led a series of workshops in collaboration with other things but these workshops are two, three and four-day events. What other programmes like education programmes do you have in place to develop sustained capacity in bioethics that will produce bioethics teachers and ethical standards for China?

Qiu Renzong (China): Actually illicit drug use in China is illegal because parliament has a law to prohibit

that, so the drug user should be arrested by police and sent to prison. Almost 100 % of drug users will use drugs again when they get out of prison. This creates another option for surgery but this is subject to a lot of problems. So you see that each patient has to pay US\$20,000 to \$40,000. Actually in China, they develop experiments to use as a method also. A substitution serum, and we have visited one hospital to see a very good programme to stop drug use and the family who like to enter this treatment. So the government now tries to develop it into more than 200 clinics to use but still there are paradoxes or contradictions. On the one hand you have a law which puts the drug users into a penal institution; another, we try to develop this kind of serum.

Xiaomei Zhai (China): Yes, we just visited several sites for that and raised questions after that. Professor Qiu submitted a very good report, as well as the Minister of Health, who sent out a very good report. Now Professor Qiu just indicated those problems, that the government should pay more attention to this coverage, because in the centre, the excluded persons who couldn't get into that includes the rest of those drug users.

M. Al Mamun (Bangladesh): Informed Consent in Health research: Current State of Knowledge Among Physicians in Bangladeshi Perspectives

Amir Jafarey (Pakistan): I am surprised that among your conclusions and recommendations you want to expand this plan of 47 to the rest of your country. Because you have chosen a site of the National Institute for Cardiac Disease where you choose the best of your graduates and what I assume to be the best medical school graduates. If you choose other institutes also, you will probably have a difference there. I am surprised that your results are as good as they are because you say your medical schools do not teach research ethics, as is the case of Pakistan. Awareness is still quite good. If you're going to include research ethics education at the undergraduate level as you recommended, awareness will increase. But if you expand your study to other institutions, you probably will understand the other areas you need to focus on so that you can supplement your undergraduate education. That is one way, the other thing is I am sure that the Bangladesh Bioethics Council has already received a grant from the NIH and is educating post-graduate level students in research ethics in the region. My question is in such a densely populated area, how are you going to connect the undergraduates with the postgraduates?

M. Al Mamun (Bangladesh): Earlier I mentioned that this is actually a pilot study and we have a plan to expand this study among a large group of doctors. Regarding the syllabus in the undergraduate and post-graduate level, as you mention there is a big gap. Yes, I do agree, and actually in our country, on the undergraduate level there is a subject called "community register". While our teachers teach epidemiology, they spend some time also educating students regarding research ethics and research ethics issues. We believe that this is not sufficient and must be changed. However, at the post-graduate level there are two courses, MD and MS courses, and these are three year schools and these courses have three parts. In the second there is a subject in biostatistics as well. In that portion, research ethics may be incorporated.

Leonardo de Castro (Philippines): I just wanted to ask what the basis was for the informed consent form? Is there a national law or regulation or is it merely a policy in Bangladesh?

M. Al Mamun (Bangladesh): We have an organization, which I have mentioned already, the BMRC, the Bangladesh Medical Research Council. The organization looks at matters concerning ethical fairness. Post graduate medical students are not permitted to take any test from BMRC, because they submit the proposal to the concerned institute, and the institute itself has a committee to review that research proposal. I think this is a small gap because if they require their proposal to submit to BMRC, then they might be more aware regarding informed consent and other issues. The institute has a committee. They just review the proposal for the course, for degree purposes and they do not look at this as ethics.

Subrata Chattopadhyay (Nepal): We have a very similar culture and very similar history of ethics. What I was wondering is, in the part of Bengal where I come from, or in India in general, there is a strong resistance of the medical faculty regarding incorporating ethics. They think that ethics is kind of a

nuisance imposed on them, and at an institution level, the ethics board is made up only of physicians, and mostly their friends and colleagues. The process of clearance is therefore very fast. I don't see any ethics review board? I do not see any minister or religion, consumer advocate or environmental activist. So I am wondering how your institutional ethics board runs, honestly?

M. Al Mamun (Bangladesh): Actually this is a common problem in developing countries, we have the institution of BMRC. But there are bureaucratic complications. If some scientist submits a protocol for review, or for ethical clearance, they take a long time, and in our country it is a problem.

Anoja Fernando (Sri Lanka): I am not sure whether there are any members of ERCs from India in this room, but I will speak for Sri Lanka because you mentioned the developing countries. Now all the medical faculties in Sri Lanka have ethical review committees that they have had for a long time. They are functioning well and the faculties have a rule that none of the academics belong to faculty. Furthermore, you cannot conduct research or publish papers without approval from the ethical review committee. In addition to the faculty research committees, there are now government research committees. For example, the Sri Lanka Medical Association has one, where everybody else can submit proposals to these ethical committees. The Solon medical journal has a rule that nobody can publish research papers without prior approval. Also we are going ahead saying that no one can ever present research papers at academic meetings unless they have ethical approval. So it can be done. Some doctors and other people do believe it is a nuisance, but they do come around to see the point of the RC. It can be done.

D.S. Sheriff (India): I quite agree with Subrata. We have an ethical review committee, which is full of medical professors indeed, there will be the archbishop or the bishop, a legal expert, a social expert. All of them must review the paper and they are only given 15 minutes time to review the paper, so this occurs in most of the places in India.

M. Al Mamun (Bangladesh): In this regard I would like to mention that in our country only medical books need ethical clearance. But actually every institute should have separate ethical review committees and research review committees.

M Saidur Rahman (Bangladesh): Informed Consent in Health Research: Current State of Knowledge among Physicians in Bangladeshi Perspective

Zhai Xiaomei (China): I could understand well the situation you mentioned just now, as a similar situation arose in China four years ago. So we have to pay great attention in order to change this situation. It is a difficult situation to tackle from the beginning, however sometimes we say the spring of bioethics is coming, so I think the situation is changing a lot. We need to work on this.

M Saidur Rahman (Bangladesh): Thank you, that is the target and that is why we're here.

Amru Nazif (Indonesia): I am from Indonesia and I am almost sure that in Indonesia, although Indonesia is known as a corrupt country, that there is no such thing in the clearance of research proposals. Although I have to admit that everywhere else corruption is rampant but I am sure not in the process of clearance proposals. Because it is a select community. So what about in your country?

M Saidur Rahman (Bangladesh): May I ask you a question? Do you get the clearance quickly or are they interested enough to help you as soon as possible? Do they try to give you the clearance and things like that?

Amru Nazif (Indonesia): According to the procedure, nothing more, nothing less. But attaching this to bribery and corruption, I am sure it doesn't happen in Indonesia.

M Saidur Rahman (Bangladesh): I must mention one thing, NGOs and other organizations in our country, when they go for clearing the committee, the people on the clearance committee, the junior staff and I must mention the office bureaus and something like that. They think that this project is having a big fund from outside donors so they must try to fill their pockets as well. They do this as long as they can.

This is the situation and the reality and it may not be true for Indonesia. It should be improved.

Mihaela Serbulea (Romania): Utilization of Traditional Knowledge and Support of Access to Health

Irina Pollard (Australia): A short comment on this last paper, must it be and/or? Surely, age-old wisdom among clinical trials, up to date clinical treatment, and alternative therapies, but each can give so much to the other so that the totality is going to be so much better. So instead of antagonism, we need cooperation.

Lindsey Conner (New Zealand): I'm just wondering, given the ethical dilemmas of medicine we have heard already, and I know some of my friends are alternative healers, so can you comment on some of the countries' philosophies on how they instigate, professionalize or alert natural healers to the ethical principles around informed consent around alerting the patients to side effects or things that might happen.

Mihaela Serbulea (Romania): I wonder whether you refer to traditional healers or complementary, alternative medicine professionals. Traditional healers, I understand, are not often keen on being integrated. They have their authority in the community, they have their knowledge and they don't need to be acknowledged or recognized. Of course the government would like to license them in order to have evidence of who is doing what and how, but it is a problem yet to lure them to be sensitive to these kinds of issues. On the other hand, alternative medicine practitioners in industrialized countries have quite a rigorous system of registration and national exams and they have to pass strict tests to be recognized.

Maude Phipps (Malaysia): Thank you for your lucid presentation on the interplay and complementary use of traditional medicine with the orthodox western medical practice. I have some strong feelings about this, because I believe that there are some healers that have these skills over many generations perhaps, and they do know about the side effects of these medications, and on the other hand you have medical practitioners who are well versed in clinical trials and risk assessment kinds of things. However, in Malaysia I have noticed that sort of pseudo-medical professional or pseudo healers who are trained in neither, have found a niche in saying that traditional medicines are really good therefore they have come up with a lot of products. These are very illustrious people who actually commercialize and market thousands of medicines that are considered natural, are planted wild, etc. We have tested them in the medical centre. A colleague of mine is interested in this area and using some of the 2000 or so preparations that actually do not go under scrutiny of the Ministry of Health, because they are seen as supplements. We really don't know where they belong, but they are marketed and you can buy something very easily in the night market or sometimes in shops. Where do you see this and what practices are there in countries to actually regulate this practice? Because most of the time it does more harm than good. We are seeing a lot of cancer patients with third degree and fourth degree stage cancer where nothing can be done, because they have resorted to taking all these supplements and thinking it can cure them.

Mihaela Serbulea (Romania): It is indeed a very important question and this is why I emphasize that they need to be recognized and there needs to be a standard for them to produce products and to market them. Not just anybody who has dreamt up a product can come over and sell it, because people in desperate situations will buy it. So that is why it is necessary to have strict regulations, and for this reason, the government needs to understand that this niche exists. It is not only that they have to fund western medical institutions. They have to find a way of looking for these people who, for commercial or even for genuine reasons, but it's only under certain conditions or circumstances that the product works and they are not trained in giving the proper instructions to this. So it is an important part to be recognized by the health authorities in these respective countries.

Aruna Sivakami (India): It's not a question, it's a comment, and I am just adding to your paper when you have mentioned there must be mutual recognition and respect of practitioners. I don't think that a lot of the practitioners recognize the ethics especially when they give treatment for fallopian tube blocks. As my Malaysian friend pointed out, there are pseudo healers, like those who give advertisements every

day, making advertisements saying they have a cure for HIV/AIDS but they don't. People trust them and just spend their money. Usually it results in the deterioration of health. That alone is bad. I think at least 20% to 30% of the population take traditional medicines too. It is not just Arurveda that exists in India in addition to that there is what you call traditional medicine.

Irene Taafaki (Marshall Islands): Avoiding Biopiracy: Protecting Traditional Medicinal Knowledge in the Marshall Islands

Camille (UK): I'd like to congratulate you on your work. I think it's quite outstanding because obviously you have the trust of these practitioners. I think you should be very careful to publish traditional knowledge in anything that's going to help it to be retained. I've got a suggestion you may not have thought about, but the World Health Organization has been publishing items on traditional medicine for years. They've done, in Viet Nam for example, work on medicinal plants. These are all copyrighted and I think that once it gets into an official format like that, you will be better safeguarded. Secondly, there is nothing to stop pharmaceutical firms from nipping a bit of your bark and taking it away and making that into valuable medicine. So you do need regulations and biodiversity does cover that and I think you need to work with that to make sure nobody can develop anything from your plants, first of all without permission and secondly without reimbursement. There is also a difficulty because a change in agricultural methods has resulted in plants changing their nature. Herbalists are finding it very difficult and are having to go farther away to find plants and the same kind that still have the same power and energy to fill the prescriptions. I think you can perhaps pay some attention to that, and see that the cultivation is maintained. I'd love to have a copy of your book when it is released. I thank you very much for your efforts because really it's so very valuable and particularly that you have traditional healers who can specialize. I think working with women and children particularly is very important. Maybe your infant mortality and maternal mortality is zero?

Irene Taafaki (Marshall Islands): Well it's not, but one of the interesting things that have been raised by this is the difference of health in women in matrilineal societies and those in patrilineal societies. It starkly contrasts with, for instance, the experiences of African-American women in the United States who are oppressed both because of colour and also within the family. So a lot of things have been raised through this research. We are contacting WHO and we have a plan to publish and what I have neglected to say is that all the recipes that are contributed are ascribed to the people who have given them so that their ownership is completely safeguarded as far as we're concerned. The reason why we started this in the first place was also because the women wanted to have something in their hands. They saw how quickly traditional knowledge was being lost and so they wanted it written down, and we will have it translated into Marshallese, for the use of the people. It's in the interest of the international community, but the primary reason that we did this research was for the people themselves, because it's their project. So it was very easy for myself and my Marshallese counterpart. We planned this together with women's organizations because it's their project. It's not my project, it's their project.

Nat Tuivavalagi (Fiji): I just wanted to share my experience with this field because I am interested in the traditional paths of our ancestors and I am interested very much in the area of religion and spirituality. It is a very important topic that I am bringing up because a lot of scientists are not aware of this potential area of conflict. It is also why I mentioned yesterday that 80% of the questions that are coming back, we should be very concerned. We have to try and find out exactly what the people think so in this area I have mentioned about spirituality in Mattock. They believe in spirits. The importance of this topic at the present time is that Christianity is coming and Christians believe that the God that they worship is not just a God like when somebody from another part of the world talks about God. Christians don't believe we are talking about the same thing. We are talking about roughly the same subject, but we are talking about different spirits. A spirit that they bow to and worship. In Christianity, the spirit that they specifically worship is called Yahweh, which comes from the Judea world view. So this is a very important topic because it is a potential area of conflict. In many part of Asia, Christianity is coming. And previously, religion connected to traditional healers as we heard this presentation about the white and the black magic, but the other subject has not been brought up, the spirits that people worship. This can be a very important area, because once Christians know a different spirit has been worshipped, they are turned off. So the traditional way of beliefs may have some spirits that they worship. This is an area you should

look into: what are the spirits involved? I have attended some religious classes in the university and in the university context, and we are told not to get involved. The way we are just observing everybody, I feel that we are really missing the whole point of the religious experience that the people are talking about. So this is what I am getting into, and if we want to have a meaningful dialogue with indigenous people, we need to get inside what we are talking about. I heard yesterday somebody mention about not being aware of these things spiritually. What does it mean we don't have any reference to refer to? From the Christian concept, in mathematics when using the method of moving forward to solve the problems, if you are stuck and you cannot move forward, one method is to assume an answer and put it in place and move forward as if that was the answer. When we do that the picture gets lighter and we get a better picture of the real answer.

Irene Taafaki (Marshall Islands): Nat, I think I can reassure you that when I said "inspiration and dreams", the inspiration came from the spirits and we have a whole chapter on the description of all the spirits that influence the healing process. So it's only because of time that we didn't go into that, so it is fully acknowledged in the study. They are fully interconnected.

Nat Tuivavalagi (Fiji): I have nothing against your talk, but I am talking to this room full of scientists, and the need for interaction with indigenous beliefs.

Chan Chee Khoon (Malaysia): Market-Driven Biomedical research: a Major Challenge to Everyday Bioethics

Abnik Gupta (India): I would like to thank you for focusing on a neglected area of neglected disease. I come from the North Eastern region of India in the foothills area where particularly malaria is quite a major killer. Because of the attitude towards this, there are hardly any laboratories which can detect whether a person has a high fever, whether a person is having malaria or something else. Thanks to these tropical medicine developments we have good laboratories, but so many people die. We have lost many good people, even field workers who go to these areas and there is a surprising, even with a public demand, outcry for better medical facilities, you know, demands for a cancer institute, but nobody really focuses on this. I don't know how things will improve. I think at least we experience this great problem in our area.

Chan Chee Khoon (Malaysia): Let me just stress on malaria and the major convention on genomics on health and one interesting comment that was made. One of the participants mentioned that, you know for a long time they have been trying to come up with a malaria vaccine, without much success. But one participant mentioned that at about that time there was a promising chemical vaccine for malaria, but it had this characterization that there was only applications for a few months and after that I thought about it. Actually this is the ideal vaccine for commercial pharmaceutical companies because if you develop it, you can have a market among potential tourists in affluent countries who visit, and every few months they keep going back. You know some ten or 15 years ago, a Columbian biochemist made a promising tentative vaccine. He declared that if something really came out of it he would donate the copyrights and there were a few trials done in Africa but I haven't heard much about it ever since.

Abnik Gupta (India): In fact it would be ideal as you say because now when we go to those fertile areas, we carry all kinds of mosquito repellents; those repel the human beings also. It must be better to have the drug or vaccine that works for three months. But it has never come onto the market.

Mohammad Hasan Ghadiani (Iran): Islamic Codes in Medical Ethics

Aruna Sivakami (India): Do you mean to say there is no medical negligence, or medical abuses in Iran? If people are going to sincerely follow the medical ethics and the narrations of international ethics guidelines, if there are cases of medical negligence and abuses, is there a law? Do people take the doctors to the court of law? If so, how many cases are there regarding what medical abuses? If you can shed light on it, I will be happy.

Mohammad Ghadiani (Iran): If every physician works well and every patient was good it is not necessary

to order other measures. Medical negligence is separate from ethics. Negligence is divided into two kinds - one kind is scientific negligence, it's a problem for every patient - the doctor operates well, works well, but the patient works well but scientific surgery and drugs are not prevented. The second kind of negligence is not scientific, it is not ethical. Type one is separated from ethics, but type two is non-ethical.

Nat Tuivavalagi (Pacific Islands): I find your presentation very interesting, and I think you have a very important role to play in the development of your country. Firstly you are a professional and secondly, you are at the centre of the religion of your country. It seems like you are actually a participant of your religion. It seems as if you are at the very core of your being. But I am coming from a Christian background, and as one of our pastors likes to say, for us to remember the meaning of Islam, is supposed to be actually about all Muslims, irrespective of what all Islam means to all Muslims, that is supposed to be what Islam means to Christianity. But anyway, what I am interested in, in your country, for example, and in Islamic states as a whole: how do you deal with non-Muslims that live in your country? And how would you like these things that you have been talking about? How do the ethical codes in Islam deal with non-Muslims? What do you do from your viewpoint as a professional, and as a Muslim? How do you view this thing?

Mohammad Ghadiani (Iran): We have Muslims and non-Muslims in Iran. We have non-Muslims from other religions in parliament, for example, Christians and other religions. In hospitals, medicine is not different for us, patient, both Muslim and non-Muslim. In Islam we have "Yasu," a famous phrase is: "Yasu'a Maryam" mother of Jesus Christ. In Islam we have a wide vision about Muslim and non-Muslim people that is not much different for Islam. We must respect all the religions. The majority of people in Iran are Muslims, however we do have non-Muslim people also.

John Buckeridge (Australia): My question concerns your statement and the statement from an earlier speaker about deception and lying. Somebody said earlier that under no circumstance should a professional lie and you have said that the rules of Islam state that deception is forbidden. Now I can see why that might work in things like structural engineering where you are designing a bridge and if you try and deceive somebody, the bridge might fall down. But if you are a physician, can you think of any circumstances where it would be, not only appropriate, but morally right to lie? Can you see any situation in where it is morally correct not to tell the truth?

Mohammad Ghadiani (Iran): I spoke about ethics in medicine. Ethics is a general term used, but medical ethics is specialized. If a physician does not work for the patient, every situation is not ethical. If his patient work is non-scientific, it is not ethical.

Alireza Bagheri (Iran): Just some comments about the first question: malpractice as well as medical negligence. There are appropriate measures to tackle with those problems in the university level as well as the organization where Professor Ghadiani is working. If it is related to scientific/medical negligence, there is a committee to deal with the issue. But if there is any immoral practice by physicians, it may be dealt with at the level of university or hospitals. Of course, they distinguish these two categories differently, and they deal with them differently. Regarding your question, there is no attempt to convert people from their religion, because if they believe their own religion, as we believe in one, we don't like it if somebody tries to convert us to another religion, and we do know how they feel, if we wanted to try to do so. Furthermore, it is not ethically right to do so. But if there is a Christian, for example, a Christian doctor working in an area usually populated by Christians, the patients will go to that physician for therapeutic purposes. And if not, if they go to a Muslim physician, they will inform the physician that they are Christian and if there is any religious limitation and somehow they will inform the doctor and the doctor would know how to deal with it.

And the last question- I am a medical doctor, and I faced the situation which you raised. Any situation where there may be morally, I would like to say "morally tolerable" not acceptable, tolerable to lie. Again, I don't like to use this word, but we distinguish between withholding the truth and telling a lie. If the family asks the doctor to not disclose the patient's diagnosis, then the doctor will in somehow follow the family's wishes. Then it is the responsibility for the family to inform the patient about the diagnosis. I would say, usually, they don't lie. They may hold back the truth. It must be disclosed through the special channel which is the family.

Jasdev Rai (UK): Gender Feticide: Exploring Beyond Medical Ethics

Peggy Fairbairn-Dunlop (Samoa): I just had a quick question about the women getting abortions, are you saying that it is women making the decision to have the abortion, or do you think there are other factors involved in women deciding to have an abortion?

Jasdev Rai (UK): Inevitably the factors are cultural and economic, but the women are very strong and they always keep the family together in Indian society. They take responsibility for what is going to happen in the future. So women are voluntary participants in this. It is not that women see this as a problem against themselves, most women voluntarily participate in this abortion.

Peggy Fairbairn-Dunlop (Samoa): I guess I'm saying that the decision to have an abortion by many women is not from your own individual choice but from the pressures of the male within the household. That's why in a couple of papers today, I'd like to say that in human rights, these decisions are really male/female decisions in partnership and males should have equal opportunity to have the education to participate in this sort of decision making, rather than saying that it's almost only a woman's choice to have an abortion.

Jasdev Rai (UK): I agree with you. This is what I'm saying, that in India, what has happened is it has been women's organizations leading the battle and I think it has to be seen as a common problem. But it's a male and female problem, not just one gender issue. It's not just the responsibility of women, but the responsibility of men as well.

Irene Taafaki (Marshall Islands): I am wondering the extent to which the ease of abortion to women in the early 1970s, was prompted by women's rights movements or the desire of India to keep its population down because we were working in a rural development programme in western India in the early 1970s, and we were promised any kind of assistance as long as we would increase the numbers of people who would go in for abortions and family planning and remember the times where people were, both men and women, dragged off the streets to be sterilized. So I'm just wondering if that was more the case, rather than the women's rights issue?

Jasdev Rai (UK): There is a cynical view in India that one of the reasons why this has not been tackled is the state is not very interested because it is keeping the population down and as I said, some doctors cynically say that it is helping the state to keep the population down. It may be one of the reasons why realistic solutions have not been sought.

Ken Daniels (New Zealand): Governance of Donor Insemination (DI)

Alireza Bagheri (Iran): I wonder, is there any argument against DI if they compare the risks which are involved in the future of the child to force to stop using this technology? Is there any argument against using this technology based on the risks which are involved for the future of the child?

Ken Daniels (New Zealand): The non physical risks you mean? There is an interesting debate that goes on within professional and academic circles, that if a couple comes and says: "We want to have children, but we're not going to tell this child," whether you would have the rights to refuse them on the grounds that this would be potentially damaging to them and to their family relationship. It is a very contentious issue and I cannot think of hardly any of my colleagues who would say you can go as far as to take that kind of stand. I personally would like to go as far as that, and if we're taking the welfare of the child really seriously, I believe we've got good grounds for doing that. But it does infer a whole lot of other things about autonomy which creates other kinds of issues.

Irina Pollard (Australia): Maybe if the medical professional can balance risks they could say that donor insemination is the safest assistant reproductive technology. Then there are degrees of different risks like manipulations from the basic sort of biological perspective and that may drive social change and acceptance.

Ken Daniels (New Zealand): It comes back to the model I was trying to present about the biological and the psychological and the social, and how do we get that kind of balance? First of all, do we have a

commitment to a holistic kind of perspective? If we have, how do we get the balance right? I'm saying we haven't got the balance right in leaving the social dimensions out in terms of policy and legislation. We've left it to the professionals and we've actually moved somewhere along the continuum on that but how far do we go? Have we gone too far? Some professionals would say we have in countries like my own. I remember a professor of obstetrics and gynaecology saying to me not that long ago: "What you are doing in New Zealand is a dangerous experiment", in terms of opening all of this up and being quite frank. I wish I had been quick enough to say to him: "What you did when you started donor insemination in secrecy was a dangerous experiment."

D.S. Sheriff (India): In Indian communities, the husband says to the wife: "If you don't become pregnant to get a child within 12 months of time, I am going to divorce you." Then the wife without the knowledge of the husband goes to the artificial insemination doctor where she is impregnated. Unfortunately or fortunately she becomes pregnant and bears a child. As the child develops there is a medical emergency. The husband goes to the wife: "The child is not mine. It was your decision, you have to take care of the child." Do you face such situations?

Ken Daniels (New Zealand): The research from a number of different areas shows that in families where the children are conceived as a result of donor insemination, IVF and adopted, the parents are closer to and have better bonding with them than those who are naturally conceived. The item that is put forward for that is that these people have really struggled to have these kids, and they're going to make the most of it and enjoy it. There's always the risk with the bonding but I have yet to find anyone I have worked with in over 27 years who, when they get that child in their arms, doesn't feel as if they love and care for that child as if it is theirs.

Leonardo de Castro (the Philippines): Informed Consent: An Essential Requirement for Essential Health Research

Minakshi Bhardwaj (UK): I do not want to start a philosophy debate here, but the view you presented in your talk was based on just one aspect of the debate, who is the moral actor in health care research? But what about moral agents and duty of the actors to empower others? So when you say about giving autonomy to the non-autonomous, it means the duty of the autonomous to empower the non-autonomous. To become autonomous is an interesting question because if you read some of the recent literature where we talk about the concept of responsiveness, a new principle of responsiveness, in that regard will this question of autonomy to the non-autonomous hold true? I don't know.

Leonardo de Castro (the Philippines): I agree with the way you put it, but I don't agree with the way the paper puts it. The way you put it, the non-autonomous must be given assistance, affirmative action perhaps, so that they will become autonomous and able to exercise their self-determination. But I do not agree with the idea that the non-autonomous must be seen as not having to be asked about their desires and so on.

Minakshi Bhardwaj (UK): But they are still a moral agent though?

Leonardo de Castro (the Philippines): Yes, I agree, they are still moral agents and we should take for granted that they are moral agents and we should, as much as possible, try to on the basis of some other evidence, determine what they really would have freely decided for themselves.

Minakshi Bhardwaj (UK): But that's the part of capacity building, isn't it? Empowerment or capacity building because they don't know about it. We just cannot regard them as just being non-autonomous.

Leonardo de Castro (the Philippines): That's right, I agree with you.

Jasdev Rai (UK): Thank you for a very good presentation and explanation of what is going on at the international level. There are two aspects of research candidates, normally common people who become part of the research, usually students or people with economic problems. So there is in a sense autonomy already there, they are participating because of other external economic pressures. They are vulnerable people but there is no protection for them. Secondly, I think the statement from your own critical viewpoint goes on to reinforce the point I have been making. I do not think there is a concept

of universal norms. The concept of universal norms is a construction. Because in societies where an individual is born and thinks that the person is part of the society and there are mutual obligations, the concept of self-determination and autonomy, it isn't less relevant, but is less enforced. In societies where the individual rights are very strong, of course what you are saying has much meaning. That remains my whole problem with the concept of one driven universal norm, universal consent. It seems no different than the Judeo Christian ideal of the whole universal message. Now it's been perpetuated through a different idea of the universal norm. When is there going to be a general dialogue of you come to me and listen to what I have to say and I come to you and listen to you and what you have to say? Is there any chance that we have moved to that or do we continue to go on the concept of universal norms?

Leonardo de Castro (the Philippines): I think I can agree with you and say universal norms are constructs, that's what most of these ethical concepts are. In a certain perspective, they are constructs, they don't just lie there waiting to be discovered by us. There are things, I would say, we construct in the process of dialogue. They are not universal in the sense of being somewhere waiting to be discovered, or universal in the sense that it is something that everybody will agree on. But universal in the sense that they are within our sights. Let me give one example: as far as informed consent is concerned, if you think of informed consent as relating to the individual, and I do not necessarily agree with that, the autonomous entity need not be the individual. It might be within certain cultures, the family or it could even be something broader in other cultures. So it is up for discussion, I do not necessarily subscribe to the idea that autonomy must be understood in relation to the individual.

Aruna Sivakami (India): You were talking about vulnerability, autonomy and informed consent. In my opinion, informed consent has nothing to do with education. Autonomy has got nothing to do with education. Vulnerability has got nothing to do with education. Because sometime, in Kerala, where most of the population is very highly educated, researchers from one university from a different country came to Kerala, took the informed consent of autonomous people who are not vulnerable and they conducted experiments on them with a drug that was supposed to cure them from cancer. When it came time, the Indian Council of Medical Research (ICMR) rushed to the place to request the particular university not to continue with the research because the people were not really informed. Even though the university was arguing that they were well informed, they were not well informed according to the government of India.

Subrata Chattopadhyay (Nepal): You told us that exceptions are not the norms, and surgery, emergency and people who are sick can sometimes be considered as the exception. But if you think that the medical establishment is part of the reality and most of the people are not diseased or sick, that is part of the reality in a period of time. Now to illustrate the point I am giving an example. Imagine, just when crossing the road to this hotel, I had an automobile accident and I am bleeding and unconscious. Now there is not point or time for Darryl to contact my family back home in India. While I am unconscious and bleeding I was rushed to the hospital and it was found that I have ruptured my spleen. They have identified me as part of a conference for UNESCO and because he is in charge of the whole scenario, the telephone is given to Darryl. Now I have love and trust for Darryl that he will make the best decision given the scenario although I have no written "agreement" on the effort. Now if Darryl thinks he will be waiting for the response from my family to come here and make a decision, by that time I will be up in heaven or hell or whatever. So Darryl has to make a decision. Now if you take the informed consent as legally binding than Darryl will have to wait while I will be dying. Another point is that Darryl might not be legal, but I might be saved. What would you be doing?

Leonardo de Castro (the Philippines): I think Darryl will be dying. No, that is one of the exceptional circumstances that we speak of. I mean I do not really think that someone would consult Darryl. I don't think he would be in the legal position where he can be the one to make a decision. My point is that precisely that is one of the situations when exceptions could be permitted. In the USA, even emergency research is covered in certain regulations. We say if the situation is like this and like that, you need not consult maybe the relatives but there is a hospital institution that you should consult or something like this and so on and so forth.

Darryl Macer (New Zealand): I think like as Leo said, it would be a matter for the hospital ethics committee here and they would decide based on the presumption to keep you alive until they contact someone

they consider legally responsible.

Naoko Kimura (Japan): You've partially answered this I believe, but when informed consent is given through a chief or a leader in a group of people where that's their culture, in your opinion, do you think that should be accepted and respected by the group of researchers?

Leonardo de Castro (the Philippines): That is a difficult question to answer without the particulars of how things are in a community where such a chief makes these decision. You remind me actually of a case study, I think most of the people have had training in research ethics here. There was a research protocol where researchers from the sponsoring country come to this community and they want to be able to ask individual participants for consent. But the chieftain says: "Well, whatever I say goes." He doesn't have to consult anyone, he just calls everyone to a feast and feeds everybody. Everybody is drunk and he just says: "This is going to happen." But this is the way it goes in that community, but the way this story ends there is no settlement because the chief says: "Well, if you prefer to go to the individual subjects, you better go home, because this research is not going to push through." Unless I know in this particular community how things go - is it that this chieftain is so loud and so popular with the people that they really trust him making decisions? Have his decisions in the past been such that he has not taken advantage of the people? Has he not received money or other special considerations from external entities and then given permission for these external entities to conduct research on these people? I think you have to be guided by experience with this particular community.

Jurapon Pongwecharack (Thailand): This is not a question, just a comment on informed consent. I think there is a condition for informed consent. First of all there has to be a request of the information to be closed in the informed consent process. That is, the first thing that should happen. In order for the informed consent to be valid as you mentioned about the validity of informed consent, I think the participants have to understand. So the consent should be understood so that it is valid. And informed consent is not just a piece of paper, and should not be a "sign here please". That's not the point of informed consent. Understanding what is disclosed in the consenting person is the most important.

Le Dinh Luong (Viet Nam): Some Issues in the Implementation of International Bioethics Declarations in Viet Nam Practice

Yanguang Wang (China): You talk about from your presentation that informed consent is not paid attention to in research. Is this a fact? Not in medical fields, so I wonder how your country selects the human subjects for research?

Le Dinh Luong (Viet Nam): For example, when the patient comes to the hospital, medical doctors can take samples from them for testing, maybe for diseases. Afterwards doctors can use this data for their thesis, but no medical consent. But patients do not pay any concern about the flight of their genetic information, because they have no knowledge of this.

Shinryo Shinagawa (Japan): I heard in Viet Nam, article three of the Constitution is discusses human dignity?

Le Dinh Luong (Viet Nam): The term community understood in Viet Nam is for the whole nation, and not for only one individual. In the case, if there is some contradiction between individual and nation as a whole.

Shinryo Shinagawa (Japan): But as I remember article number one, human dignity, is only Germany. Article nine of the Constitution is protecting human dignity in Japan and India.

Le Dinh Luong (Vietnam): Dignity in our country is respected, but in this case if between one individual and the nation as a whole, some contradictions appear, we have to respect the dignity for the whole nation.

Sang-yong Song (Republic of Korea): I have two questions. You said some government decisions on bioethics were made. I wonder if they were just decisions issued by the government or legislation on bioethics? And second, do you have any NGOs related to bioethics which are critical of government

policy on bioethics?

Le Dinh Luong (Viet Nam): Firstly, the government decree is issued by government, but before that we have the whole process lasting months or even years for setting up the content of the decision. For example, the decision I mention here about GMOs, they didn't want to form the decision for two years. During these two years we had a lot of meetings and sometimes we had to finish them during the middle of the night.

Sang-yong Song (Republic of Korea): But was it passed in the parliament?

Le Dinh Luong (Viet Nam): I know the decree was issued already by government, but it was the decree of the parliament, I am not sure. And your second question concerns NGOs. I am one of the active members of one NGO because I formed it. You can find it on the website. NGOs are still not very strong in Vietnamese society and have very little influence on government decrees. Few NGOs are interested in bioethics, mainly focusing on the economy.



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