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### **Send papers to the editor in electronic form if possible.**

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*Deadline for the July 2008 issue is 31 May, 2008.*

## **Editorial: Philosophical Dialogues**

I invite readers to join the UNESCO Asia-Arab Interregional Philosophical Dialogues email group. The project is coordinated by UNESCO Bangkok and UNESCO Rabat offices. The yahoo group\* helps provide a forum for exchange of views in English and Arabic.

At present we have three working groups in the project:

- 1) Challenges of globalization to philosophy and democracy;
- 2) Philosophy facing the challenges of modern technology;
- 3) The roles of philosophy in war and peace.

We hope to publish volumes of papers that will be useful resources for philosophy teaching on these topics and to include papers from individual philosophers as well as papers the result of dialogue between members of the groups.

Please also note that we are planning to have working group meetings in person for in Seoul, Korea at the time of the World Congress of Philosophy (30 July – 5 August), and in Hiroshima, Japan (25-27 July, 2008). While we cannot support the travel costs of participants to this meeting, we promise that the events will be attractive and we encourage you to join so that a critical mass of philosophers can participate. More details of the meetings are below.

We also envision holding a dialogue meeting in South-east Asia in January 2009, to follow-up the 2008 and earlier meetings held in Rabat, Seoul and Paris. We are also open to suggestions of cooperation with other networks, and hosts to hold meetings of working groups. We also hope to use modern communication technology to enable dialogue.

In this issue of the journal we have a diverse range of papers, including a commentary on violence and war and evolution by Verma, and biosecurity concerns by Barr. Hans-Martin Sass proposes a 7R framework for guiding animal research with a special note towards corporate responsibility.

There is a paper by Narita et al. presenting descriptive data from Japan, as an illustration of how self-determination can be expressed in living wills. The paper from Lanre-Abass expresses an African critique of ART, and there is a paper describing recent bioethics issues in Pakistan.

Hope to see readers at the Philosophical Dialogues and Ethics of Energy technologies conferences in the next few months.

-Darryl Macer

\*<http://groups.yahoo.com/group/AsiaArabPhilosophicalDialogues>

For all below please contact: RUSHSAP, Email: [rushsap@unesco.org](mailto:rushsap@unesco.org)

**UNESCO Conference on Ethics of Energy Technologies: Energy Flow, Environment and Ethical Implications for Meat Production (Working Group 13)**, 24 July 2008, 9am-4pm, UNU-IAS, Yokohama, Japan

**Joint UNESCO-UNITAR Dialogues on the Role of Philosophers in War and Peace**, 26 July 2008, UNITAR, Hiroshima, Japan

**Joint UNESCO-UNITAR Workshop on Nuclear Dialogues and Ethics of Energy Technologies**, 27 July 2008, UNITAR, Hiroshima, Japan

**EWHA-UNESCO International Forum on Bioethics and Asian Culture**, 29-30 July 2008, Ewha Women's University, Seoul, Korea

**UNESCO Conference on Ethics of Energy Technologies: Ethical Views of Nature (Working Group 2)**, 3 August 2008, SNU, Seoul

**UNESCO Asia-Arab Interregional Philosophical Dialogues on Philosophy Facing the Challenges of Modern Technology**, 4 August 2008, Seoul National University, Seoul, Korea

**UNESCO Asia-Arab Interregional Philosophical Dialogues on Challenges of Globalization to Philosophy and Democracy**, 5 August 2008, Seoul National University, Seoul, Korea

# End of life self-determination: Attitudes of patients with ALS in a prefecture of Japan

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## Abstract

**Objective:** The objective was to survey patients' conceptions of autonomy or self-determination, and their feelings about participation in medical management decisions in the advanced stages.

**Subjects and methods:** Out of 116 patients registered on the intractable disease ("Nanbyo") system in Japan as a patient with amyotrophic lateral sclerosis (ALS) in 2004 in the Mie Prefecture, Japan, 21 gave their consent and participated. The author visited their homes from October 2004 to March 2005, performed examinations and semi-structured interviews. Fourteen (10 males and 4 females, 57.9±12.0 years old) were eligible for analysis on his or her diagnosis, communication ability or cognitive function, and were followed until all of the patients who had advance directives either died or revoked them (June, 2007).

**Results:** Nine patients indicated that they did not fully understand the word "autonomy" ("*jiritsu*" in Japanese). Substituting the word "self-determination" as an analogous word to "autonomy" and asking the question again, eleven patients provided a response about their interest in maintaining self-determination. When asked to provide a value for respect-level using percentages, 10 of 11 affirmed a high percentage of self-determination (89.1±17.6% [mean±SD]).

**Conclusion:** This report validates that some Japanese patients have a desire to control their treatment and management. While recognizing the small sample size, the authors suggest that neurologists involve their patients in medical management decisions regarding their ongoing care.

**Key words:** amyotrophic lateral sclerosis, motor neuron disease, advance care planning, advance directive, Japan

## Introduction

Individuals of any cultural background are hesitant to discuss their own death and dying when they have an intractable disease, such as amyotrophic lateral sclerosis (ALS), which requires special care to survive after respiratory or swallowing function deteriorates (1-7). Asian people, including Japanese, seem particularly more hesitant to discuss death and dying (8). Traditionally, patients and families have expected their physician to dictate what interventions he or she believes necessary with little discussion. In Japan, the proportion of patients in the advanced stage of ALS on mechanical ventilation via tracheostomy was more than 20% in 1997, and nearly one-third in 2004 (9,10). The high usage of mechanical ventilators is in part due to a good care system, "*nanbyo* (it means an intractable disease in Japanese)" system (11,12). It is difficult to determine when, by whom, and by what process the decision to initiate such treatment has been made for each patient. There have been recent reports about patients who want to decide the management of their own terminal conditions (13,14). In Japan, discussion about patients' involvement in decision making has increased since a presentation of the Guideline for the Process of Decision Making on End-of-Life Care by the Ministry of Health, Labour and Welfare of Japan, in May 2007 (15).

In the present study, our goal was to survey patients' perceptions and outcomes regarding feelings of autonomy or self-determination related to options of management in the advanced stages of ALS. Since 2003, the authors have provided care to these patients in our roles with the Liaison Council of the Networking for the Patients with Intractable Neurological Diseases in Mie Prefecture.

## Methods

Before implementing this study, the ethical and scientific validity was approved by the Ethical Committees at Mie University, School of Medicine, in accordance with the Helsinki Declaration. Each subject was informed by a written document that participation in the study was voluntary and their privacy would be strictly preserved. The registered numbers from the Institutional Review Boards at Mie University, School of Medicine are No. 291 and 476.

JMP ver. 5.1 (SAS Institute Inc.) was used for the statistical analysis. The study design was a cross-sectional study.

### First survey

Because of requirements related to patient privacy, we could not contact the patients directly. Public health nurses, as government staff at the nine Public Health Institutes, were asked to talk to as many patients as possible during their contacts in routine home visits or work at the institutes. In total, 116 ALS patients were registered on the "*nanbyo*" system in the Mie prefecture

in fiscal year 2004. It has been mandatory since 2003 for every patient on the system to have their own case sheet reviewed with them once every year from July to September. During their routine work, the nurses asked patients to participate in the study; 21 patients gave their consent to a visit from the authors, and participation in the study. After obtaining written permission by the responsible researcher, one of the authors (YN), visited each patient's home together with the public health nurse, performed physical and neurological examinations, and evaluated patient disability using the ALS Functional Rating Scale Revised (ALSFRS-R). Interviews were conducted from October 2004 to March 2005. Fourteen of the 21 patients surveyed (10 males and 4 females) were determined to be eligible for analysis based on their diagnosis, communication ability or cognitive function. Three of the 14 subjects were supported by a mechanical ventilator with tracheostomy (TMV) at the time of the interview, but they wanted to participate in the survey because of their history of decision-making. The mean age of the 14 subjects was  $57.9 \pm 12.0$  [mean $\pm$ SD] years old. (Table 1)

To assess how patients wanted to exercise individual self-determination in management decisions at the advanced stage of their disease, we performed semi-structured interviews at the patients' homes. Questions were designed to elicit patients' conceptions and wishes for management. Issues explored included their concept of self-determination and the desire to indicate their self-determination in regard to the management of their advanced condition. Each patient was asked if they knew and understood the word "autonomy" (*"jiritsu"* in Japanese, a relatively difficult word). The word "self-determination", as an analogous word to "autonomy", was used in the interview when the patient indicated lack of knowledge of the meaning of "autonomy". The interviewer then asked the patient to subjectively evaluate the level of respect expected to be given to his or her own "self-determination" as a percentage, with 100% as the highest level of respect and 0% as the lowest. Patients were also asked if they preferred another method to indicate their "self-determination".

#### *Follow-up survey*

We followed the 14 cases of the first survey in our clinic or indirectly via the Liaison Council of the Networking for the Patients with Intractable Neurological Diseases in Mie Prefecture, at least once a year. All participating patients with special documents of self-determination (advance directives) from the first survey were followed until they died or revoked their directives, that was until June, 2007.

## **Results**

### *First survey*

Nine patients indicated that they did not fully understand the word "autonomy" (*"jiritsu"*). Five of

them replied that they were hearing the word for the first time, even after having the word written in Chinese characters shown to them. Substituting the word "self-determination" as an analogous word to "autonomy" and asking the question again, 11 patients provided a response indicating their interest in maintaining self-determination related to care. When asked to provide a value for the level of respect expected to be given to their own "self-determination" using percentages, 10 of 11 affirmed a high percentage; the mean  $\pm$  SD was  $89.1 \pm 17.6\%$ . Seven participants indicated their respect level for self-determination as 100%. Three hesitated to face the issue, and chose not to respond to the question. Responses to the preferable method to communicate their self-determination were via a "document" by seven patients, with six patients stating they had "no idea" of a preferred method. One patient did not respond (Table 1).

Unexpectedly, two patients were found to already have self-determination documents during the initial interviews. In total, five patients had complete documents for self-determination at the first survey. Three patients (Nos. 1, 4 and 5) wrote an advance directive in conjunction with our team. One of the patients with TMV (No. 5) had started mechanical ventilation during a time when she was not competent to make her own decisions due to hypoxic encephalopathy, and was asked whether or not to accept tracheostomy and mechanical ventilation by her attending physician. Soon after the mechanical ventilation was initiated, she became competent again, and regretted that she was unable to participate in the decision-making process. As her clinical type of ALS was of the progressive bulbar palsy (PBP) type, she was still able to connect and detach the respirator tube to her tracheal cannula by herself, and did not want to use the ventilator except for sleep time. In the advance directive she developed in conjunction with the team, she clearly directed that the ventilator was not to be used in the daytime, even if her condition worsened. Two additional patients (Nos. 2 and 3) had already developed an advance directive document in their own manner, but both lacked items regarded as essential. One patient's document lacked the date it was developed, and the other patient's document had not been witnessed. Six other patients relied to some extent on their medical adviser (his or her attending physician) or family members to make appropriate decisions for their care.

None of the patients were reported to have major depression by their caregivers. We did not assess the patients using a depression inventory, but our subjective assessment of the patents during the interviews validated the impressions of the caregivers. When the participants were divided into two groups based on the possession of an advance directive document at the first survey, the ALSFRS-R score was

lower in patients who had such a document ( $10.2 \pm 12.6$  [mean $\pm$ SD]) than in those who did not ( $28.4 \pm 15.8$  [mean $\pm$ SD]) have a document ( $p=0.039$  by student t-test).

Table 1  
The demography and responses of the patients.

The data at the first survey were shown, adding the data at the follow-up survey in two rows at the right-end of the table. In the rows "Respiration" and "Respiration at the Outcome", "still spared" means that the patient's respiration was still not so deteriorated that he or she needed to use any artificial ventilation (NIPPV or TMV) or tracheostomy. The row "ALSFRS-R latest", indicates the score just before death or at the time of the most recent contact with each patient.

No.	Age	Sex	Respect Level (%)	Preferable Method	Advance Directive	ALSFRS-R	Communication	Respiration	Respiration at the Outcome	ALSFRS-R latest
1	66	M	100	document	+	1	letter board	NIPPV	deceased	1
2	64	F	100	document	+	8	communication aid	NIPPV	deceased	2
3	45	M	100	document	+	32	verbal	still spared	deceased	12
4	62	M	70	document	+	2	personal computer	NIPPV	TMV	1
5	68	F	100	document	+	8	writing	TMV (at sleep)	TMV (full time)	6
6	72	M	100	document	-	43	verbal	still spared	still spared	36
7	65	M	50	NR	-	44	verbal	still spared	still spared	38
8	53	M	NR	no idea	-	35	verbal	still spared	still spared	30
9	50	M	90	document	-	35	verbal	still spared	still spared	33
10	34	M	100	no idea	-	5	letter board	TMV	TMV	4
11	37	M	NR	no idea	-	29	personal computer	still spared	NIPPV	24
12	64	M	NR	no idea	-	27	verbal	still spared	deceased	13
13	65	F	100	no idea	-	0	letter board	TMV	TMV	0
14	66	F	70	no idea	-	38	verbal	still spared	still spared	35

NR: No Response

(at the first survey)

TMV: mechanical ventilation with tracheostomy  
NIPPV: non-invasive positive pressure ventilation  
ALSFRS-R: ALS Functional Rating Scale Revised

### Follow-up survey

Twelve cases were re-surveyed by interviewing the patients, families or healthcare professionals, and two cases were re-surveyed by telephone. In July 2007, ten patients were alive, and four patients had died since the previous interviews. Four patients with TMV were still alive, though their conditions had gradually deteriorated.

One patient (No. 11) had made a new written directive to resolve a conflict within the family that became apparent since the first survey. At the time of the follow-up survey in July 2007, a total of six patients had advance directives. Two patients (Nos. 4 and 5) revoked their directives and chose TMV, and have been alive for more than two years. The two patients coped with their new situation of dependency on TMV. One had changed his attitude, becoming very active in going out with his family and in exchanging e-mails, even as his physical condition worsened.

All four of the deceased patients had chosen not to be placed on mechanical ventilation. Three (Nos. 1, 2 and 12) died at home, and one (No. 3) died at a local hospital in June 2007 without any resuscitation, surrounded by family and the attending physician. These patients' families were satisfied with the domiciliary care support of public health nurses, visiting nurses, helpers, and home visits by physicians or members of the local ALS Association.

Two of the three patients who died at home (Nos. 1 and 2) had written advance directives, which were not used since an ambulance was not called. The patient who died at the local hospital (No. 3) had shared his advance directive document with the healthcare professionals and his relatives. Two weeks after his death, his wife and sister told us that the presence of the document reassured them that the patient's wishes had been honored, as the directions in the document were confirmed again among the patient, family and medical professionals thirteen days before his death.

### Discussion

The study location was Mie Prefecture, located on the east side of the Kii Peninsula in south-central Honshu Island, with a population of 1.87 million and an area of 5,776 km<sup>2</sup>. In the prefecture, there is one medical school, Mie University (a national university), and nine Public Health Institutes (local offices of the Department of Health and Welfare in the prefectural government). The prefecture is of intermediate size in population, area and economic activity when compared to all prefectures in Japan.

This study consisted of a small number of subjects, with a low participation rate of potentially eligible patients. The 21 initial participants in the sample were from a total of 116 ALS patients registered in the Mie prefecture in fiscal year 2004. By having the public

health nurses ask patients to participate it may have caused bias, as only people who were concerned with self-determination may have decided to participate. It is interesting that seven of 14 eligible patients preferred the use of a document to indicate their self-determination, five patients in the first survey already had an advance directive, and one patient developed a new advance directive document during the follow-up term.

This significant use of advance directives is exceptional, even when compared to reports from western countries (5,16). There is the possibility that participants' bias in favor of self-determination may have impacted the results. The existence of patients using advance directives in a relatively rural district in Japan suggests that patient culture may be changing. The environment may be diversifying from very conservative to highly autonomy-oriented, assisted by globalized information from the media and increased consciousness on the part of the individual concerning autonomy.

Some patients suffering from ALS seemed to think about self-determination in choosing options for medical management in the advanced stage of their disease, even though the word "autonomy" was still unfamiliar to some Japanese patients. The word "self-determination" is not as difficult to understand for people, and was used as an analogous meaning of "autonomy" in the context of this study. Patients may not understand the words used to explain their options, so it is important to ask if patients comprehend.

There is a study in the USA related to predictors and the course of elective long-term mechanical ventilation (LTMV) for ALS patients who were identified as hospice-eligible (17). Rabkin et al. followed patients monthly, for up to 55 months, and reported that patients who later chose LTMV were younger, had young children, had more education, and had a higher household income on average (17). In Japan, a new research program, Japanese Consortium for Amyotrophic Lateral Sclerosis (JaCALS), was launched in 2006 (18). This survey is prospective and is constructing a robust database on many aspects of ALS patients diagnosed by neurology specialists (18). The data from JaCALS will be available in several years. JaCALS does not cover highly private and delicate elements for Japanese patients, like patients' self-determination, income and educational background. We could not find any longitudinal reports about decision making in Japanese patients with ALS.

The patients who made advance directive documents had lower ALSFRS-R scores than those who did not make advance directive documents. Patients who thought about self-determination seemed to have chosen written documents rather than verbal expression to help them resolve their internal conflicts, rather than using advance directives as a legal document. Compared to western countries, the Japanese have a

relatively short history of personal contract plans especially in health care. Since the commencement of the Long Term Care Insurance and the new Japanese Guardianship plan in 2000, many Japanese may have recognized the meaning of contracts and that written documents are preferable in some cases (13). Although there is no legislation ordaining advance directives in Japan, a newly presented guideline is providing a cue to start discussion (15). Regardless of future efforts, we need to consider today how neurologists can advocate patients' rights to self-determination regarding their medical care.

### Conclusion

This preliminary report shows that some Japanese patients with ALS have a desire to control their own future treatment and management. Based on this finding while recognizing the small sample size, the authors suggest that neurologists need to take an interest in ALS patients' decision making; and to involve their patients, to the degree the patient wishes, in medical management decisions regarding their ongoing care.

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Disclosure: The authors report no conflicts of interest.

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## Violence and War

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The great philosopher naturalist Julian Huxley (1959) described war as an extremely rare phenomenon, found only in humans and certain ants called harvester ants, which live in deserts, amass a sort of property in the form of a grass seeds store in their nest for use in a dry season, when there are no grasses around.

The "Seville Statement on Violence", as quoted by Jones (2008), says, "It is scientifically incorrect to say that we have inherited a tendency to make war from our

animal ancestors.... that war or any other violent behaviour is genetically programmed into our human nature...(and) that humans have a 'violent brain'.". This statement was made jointly by 20 natural and social scientists, and was published in 1986 by UNO. Later it was adopted by UNESCO.

Since then views on this aspect of human behaviour have undergone a substantial change, and this change has been lucidly described very recently by Jones (2008). Jones refers to the book "Homicide" by Daly and Wilson, published in 1988. In this book, on basis of animal behaviour, anthropology, and pattern of violence and murder in modern societies, it has been inferred that the human brain has violent proclivities, which find expression in certain circumstances.

The main evidence in support of the human genetic proclivity for violence has been derived by Jones (2008) from the observations of Richard Wrangham, who has studied chimps in the wild for more than 30 years. Wrangham's observations on chimps, the closest living relatives of humans, as quoted by Jones: "Although chimps live in communities of around 150, they are rarely all found together. Instead they typically travel around their territory in parties of up to 20 animals. From time to time, a roaming party from one group will cross paths with a roaming party of another. If they are of equal size, there will be a lot of screaming and charging. When there is an imbalance of power, the larger party will often try to isolate and attack an enemy chimpanzee, sometimes holding their victim down while the frantically excited attackers hail down lethal blows". Jones proceeds to point out that a comparable phenomenon has been observed in primitive tribes, living in small bands. He says, "a small band of men leaves its home ground, sneaks up on the neighbours and tries to kill one or more of them.". Advantage of such incursions is obvious, namely extension of the home range and availability of more resources.

These instances remind one of territoriality so common among animals (Andrewartha, 1970). Verma and Saxena (2000) have pointed out, "Human nationalism and patriotism have their origin in the territorial instinct."

Such examples support the notion of proclivity for violence in the genetic makeup of humans. But Saxena and Verma (2007), from their discussion on morality and altruism, have inferred genetic proclivity for altruism, which is antithesis of violence. However, they say, "... (a person) often becomes so much obsessed with his personal ambitions and desire for social, economic or professional climbing that altruism becomes pushed to a back seat."

In the present state of knowledge it may be inferred that humans have genetic proclivity for altruism and also for violence, and which tendency finds expression is decided by the extant environmental influences. In this context may be recalled the Article No. 3 of the "UNESCO Universal Declaration on Human Genome and Human Rights", which reads as follows: "The

human genome, which by its nature evolves, is subject to mutations. It contains potentialities that are expressed differently according to each individual's natural and social environment, including the individual's state of health, living conditions, nutrition and education."

In humans the environment of an individual plays a more pronounced role in determining which genetic potentials would find expression than in other members of the animal kingdom. This is because of an extended period of psychological immaturity in humans (Rommel, 2006), and, in this period, a specially high capacity of learning and absorbing environmental influences in their behavioural pattern.

Both chimps and humans show two sorts of violence, inter-personal or in-group violence and inter-group violence, the latter war, if on a large scale. While wars are generally politically motivated, personal violence results from a personal urge for socio-economic rise or reproductive success.

Citing Wrangham, who has compared homicide rate in Europe from the twelfth century to the present, Jones (2008) points out that there has been a regular decline in in-group violence rate. This suggests that with developing civilization in-group conflicts have become increasingly infrequent. The time span for this change has been so small that it cannot be ascribed to evolution; it has to be through environmental influences. It may be added here that, with development of civilization, a finer function distribution takes place among members of a society, and, as a consequence a greater interdependence among the members and social coherence result. In these circumstances expression of the potentiality of altruism gets promoted.

Wars generally result from actions of a misadventurist and overambitious leader of a state, and underlying his action is the instinct of territoriality. Better understanding among states, realization and appreciation of interstate cooperation and coordination, and nations being led by leaders, who are aware of the highly destructive nature of modern warfare hampering development of civilization, and also of the extent misery wars cause to people, should avoid war-like situations. Enlightened voters will choose such leaders to lead their nation. Bioethics education in schools should help in this direction, as voters with such educational background will choose enlightened leaders. Besides removal of misgivings among various religious communities, and emphasis on need of healthy and compact societies through bioethics education will discourage in-group conflicts.

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## Beyond Biosafety: Biosecurity and the dual-use dilemma as ethical concerns

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### Introduction

Increasingly, bioethicists are turning their attention to the ethical and social challenges raised by the non-medical uses of bioinformation. One such challenge is biosecurity – that is, the attempt to prevent the deliberate use of the life sciences and biotechnology for political or criminal ends. As much of the literature on biosecurity has focused on the US, UK, or Australia (two exceptions being Enemark 2007 and Smithson 2007), there is a need, for reasons described below, to better understand Asian perspectives on these issues. Scientists, particularly in East and Southeast Asia, are understandably focused on preventing emerging disease outbreaks and on developing vaccines to treat re-emerging and existing diseases. However, in their focus on these important issues, it is possible that preventing deliberate disease outbreaks may be overlooked. Indeed, the fact that scientists are working so often with restricted agents as dengue fever virus, SARS, and avian influenza, is a reason to be concerned about the degree of biosecurity in the region. In this paper, I aim to encourage readers of *EJAIB* to begin to consider how they may contribute to these debates. Ethicists have much to contribute to this field of study since at the most basic level, biosecurity raises an age old ethical question: should we hold an agent morally responsible for the consequences of an action when those consequences were not intended and were, in some cases, beyond the agent's control?

### What is the difference between biosafety and biosecurity?

Many life scientists are familiar with the concept of biosafety. The term simply refers to laboratory

procedures and policies aimed at reducing accidental exposures. It includes instructions on how to work with, store, and export pathogens and toxins properly in order to avoid accidents that could be harmful to people, animals, and plants. Biosafety, in short, is about lab procedures, equipment, and the right handling of hazardous materials.

In contrast, biosecurity refers to the wider societal issue of the protection and control of pathogens and toxins to prevent their deliberate theft, misuse, or diversion for the purposes of biological warfare or terrorism. It includes researchers' personal knowledge, choices and behaviour, as well as society's collective responsibility to safeguard a population from the dangers of pathogenic microbes. Biosecurity, in short, is about measures taken to minimise the possibility of deliberate bioviolence.

There is some evidence to suggest that scientists are far less aware of biosecurity than biosafety (although part of the confusion may be that some countries use the same term to describe both meanings). A recent survey of over 300 Asian life scientists found that there was better awareness of laboratory biosafety issues compared to biosecurity and that overall, awareness levels and perceived threats about biological terrorism remained very low across Asia (Sandia 2006). Indeed, my own informal discussions with life scientists in China confirms this finding.

To help understand the notion of biosecurity and why it deserves ethical attention, it is necessary to examine one of the key elements of the biosecurity debate: the dual use dilemma.

### **The dual use dilemma**

The dual use dilemma simply refers to the possibility that the same scientific research or products which are intended for social good could also be used to threaten a population in a deliberate act of bioviolence. Two examples will help shed light on this idea.

One instance of a dual use experiment is the Australian mousepox tests (Jackson et al. 2001). Australian researchers modified the virus that causes mousepox in an attempt to make mice infertile. The hope was that they could limit the millions of dollars of damage mice inflict on Australia's grain belt. After their initial trials failed, researchers tried inserting an IL-4 gene (a cytokine that helps regulate immune system reactions) into the virus which they then administered to the mice. As a result, the researchers inadvertently created a recombinant virus which killed the mice, including 60% of those which had been vaccinated. Eventually it was discovered that the inserted gene had shut down the rodents' immune systems. Inevitably, researchers wondered if similar work could be done on smallpox or chickenpox to create a deadly modified form of those viruses that could overcome existing human vaccinations. The dual use controversy became worse when a team in the US duplicated the study with even greater lethality and

conducted similar experiments with cowpox, a disease which can afflict humans.

A second dual use example is the recreation of the Spanish Flu. In 2005, US scientists identified the sequences for the remaining unsequenced parts of the virus's genome and described the reconstruction of the virus (Taubenberger 2005; Tumpey 2005; von Bubnoff 2005). This allowed the benefit of testing the function of certain genes in the transmissibility and virulence of the virus which was a major scientific advance but had the consequence of risking that the recreated strain might escape, and/or that the publication of the full genome sequence gives any rogue nation or bioterrorist group all the information they need to make their own version of the virus. A number of experts in the US believed that the decision to publish the flu's genome was a mistake since it amounted to a blueprint of a weapon of mass destruction.

In both these cases, the knowledge and techniques generated by scientific inquiry had the potential for dual use: that is, they could aid in the fight against disease or be used to further spread it. The issue at stake thus raises fundamental questions about the role of science in society and the necessity of regulatory safeguards to protect innocent populations.

### **Security oriented regulation of the life sciences**

In many ways, biosecurity and the dual use dilemma provides a new angle on an old question: if a researcher's intentions are good – to contribute to scientific progress and to save lives – then can we hold the researcher responsible for the unintended and unforeseen malevolent use of their discoveries? (Kelly 2006; for more sustained philosophical analysis of this question, see Miller and Segelid 2006).

Currently, self-regulation within the scientific community is the most commonly advocated strategy to minimize the risks posed by dual-use research.

At the moment, editorial boards of medical and scientific journals have taken responsibility for judging, on a case-by-case basis, whether particular studies should be edited or withdrawn because the data or methods might have dual use implications. However, there are proposals that there ought to be an international pre-project and pre-publication review system to monitor research. Additionally, the Biological and Toxic Weapons Convention (BWC) Intersessional Meetings for 2008 will specifically address the appropriateness of codes of conduct for scientists as part of a larger 'web of prevention' to help combat the malign use of biological research.

Proposals for a review system have stemmed from studies such as the so-called Fink Committee in the US. This board named seven 'experiments of concern' that would, in their view, warrant, stringent review for dual use implications. These are projects that would do any one of the following: demonstrate how to render a vaccine ineffective; confer resistance to therapeutically useful antibiotics or antiviral agents; enhance the

virulence of a pathogen or render a non-pathogen virulent; increase transmissibility of a pathogen; alter the host range of a pathogen; enable the evasion of diagnostic/detection modalities; enable the weaponization of a biological agent or toxin (National Research Council 2003). Similarly, the Controlling Dangerous Pathogens Project (also conducted in the US but with international delegates) recommended that after a detailed questionnaire, the proposed project would be classified as either potentially, moderately or extremely dangerous. It is thought that most proposals would fall under the potentially dangerous category and would thus be reviewed at the local level. The other two categories (moderately and extremely dangerous projects) would require national and international scrutiny for their security implications (Steinbruner et al 2007).

Of course these proposals raise many questions about the norms of science and scientific openness. One study found that UK based life scientists believed that attempts to build a pre-project funding or pre-publication review system would potentially harm science, which in their view, was already subject to strict regulations and ethical review (Rappert and Dando 2005). Respondents to this study also indicated that in their opinion, scientific development and experimentation were in some sense 'inevitable'. Importantly, there was also a strong view that the pressure to publish (and thus secure further grant money) made it hard for researchers to not publish their work. Thus finding that many life scientists were unaware of the dual use risk and sceptical of security oriented review systems, the authors of this study concluded that is 'likely that large sections of the worldwide life sciences community have hardly begun to address the question of their responsibilities in regard to the dual-use potential of the results and techniques of their work' (Rappert and Dando 2005: 27).

As mentioned that the start, however, most of these studies have focused on the views of Western based scientists. There is little doubt that Asian countries will have their own perspective on these issues and that within Asia, there will be considerable variation in concerns and opinions. Compared to their counterparts in the US and EU, Asian based life scientists report that a lack of funds and equipment, as well as delayed shipments due to export controls are serious problems (Sandia 2006). Arguably, there is a danger that further security oriented laws may unfairly limit access to key samples and technologies, needed for genuine research purposes. And yet, as many East and Southeast Asian labs handle a high degree of dangerous pathogens, it also seems that the potential for misuse is also real.

Asian based policy-makers and academics have, to some extent, been involved in international efforts through the work of the BWC, UN, and WHO. Yet there is still relatively little input from relevant parties (ethicists, social and life scientists) to the wider

academic debates. Arguably, these voices need to be heard if only to confirm or to refute Western views of the importance of the dual use dilemma. Specifically, there is a need for better understanding of current biosecurity methods and review procedures across the region, both at institutional and national levels, as well studies into life scientists own views on the dual use risks of their work and their wider responsibilities for the how their research is used. Results from such studies can thus inform wider efforts to raise awareness and promote educational programmes to publicise the issue of biosecurity (as opposed to mere biosafety) and to aid in the construction of international codes and security oriented review systems which are sensitive to cost-benefit analysis and are able to perform objective judgments so as to not impede life saving work on vaccine development and the sequencing of emerging and re-emerging infectious diseases.

Of course nothing in this short paper denies the life saving importance of biosafety measures or the priority of research into infectious disease. But Albert Einstein is known to have been plagued with a sense of responsibility and guilt for how his work on atomic energy in the early 20<sup>th</sup> century contributed to the development of atomic and nuclear weapons (Einstein 1954). Potentially, life scientists today are facing a similar situation. It is hard to disagree with the statement that 'the human species is relentlessly acquiring power far in excess of its vision and is thereby posing monumental problems of prudential judgement – problems that society is not yet conceptually or institutionally equipped to handle' (Steinbruner et al 2007: 3).

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included, which were not covered by the Animal Welfare Act, the real number would be tenfold, at around 12 million [4]. Today, worldwide probably 50 million animals are used in research, not including microbes, insects and annelids.

Cultures represent different traditions and visions, but they share common concerns, intuitions and visions regarding health, life and environment as well. Among those common visions and goals are first and primarily the priority of human security and liberty to be defended and protected against unfavorable powers and seasons of nature, against dangerous animals and dangerous humans. But then there is also secondly an understanding of the close relatedness of humans and humanity to nature and natural laws and limits, including different forms of recognition, even compassion with other living beings. For example, mortality, suffering and disease are essential to all living beings, but visions of immortality, health and enhancement of health and happiness has been virulent in all cultures at all times.

A story told by Al Ghazali, the great Iranian scholar and unknown to the West, is the story of the prophet Moses who one day fell ill. His doctors recommended that he takes a special herbal medicine. Moses replied that God's will be respected; if God wanted him to suffer and be sick or even dead, then God as well could heal and make him feel better. The next day Moses' condition got worse and his doctors told him, that God had put healing powers into natural herbs and had given them the knowledge to know about those powers and to prescribe the most efficacious doses. Moses accepted the argument, took his medicine compliantly and got well, - a complex story narrating the relation between nature and culture, medical expertise, scientific inquiry and human solidarity more impressively than the best analytical essay. We humans of all cultures use nature to protect, to comfort and to cultivate our lives and communities.

Compassion and respect: Compassion and respect for the 'other', i.e. for fellow humans, in particular the weak and suffering, is one of the core principles in all cultures. But morally and metaphysically, nature and animals are included indirectly or directly. A German proverb holds 'Do not harm an animal for fun, as it feels pain just like you'. Even more encompassing is a Chinese proverb 'heaven and man are an integral one; as a result they are in constant pursuit of harmony between humanity and nature'. This Chinese proverb was recently prominently quoted by Pan Yue, Vice Minister of State Environmental Protection of the Peoples Republic of China [12]. Both proverbs are not just part of cultural history, but very much in the minds of people, educated and uneducated, in Eastern and Western cultures.

An indication of a transcultural sensitivity towards cruelty to animals, in particular to animals in research, has led to the widely accepted 3R's presented by WMS Russell and RL Burch 1959 in their book *The*

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## Animals in Research: 7-R Principles and Corporate Responsibility

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### Cross-cultural Consensus and Diversity

Culture and nature: Cultures are made and developed by humans, they are not natural. On the contrary, cultures overcome the obstacles, dangers, and cruelties of raw nature. Cultures manipulate wild plants and animals into cultured and farmed crops and animals for the benefit of humans and human communities. The term culture literally comes from *cultivare*, i.e. digging and working the soil. Cultures build houses and infrastructures to liberate humans and humanity from natural limitations, dependencies and uncertainties and to improve individual and collective health, life, and qualities of life.

Cultivation includes the cultivation [i.e. breeding, using, and manipulating] of animals, also the use of animals in research. In 1998, the official number of animals used in research in the US was estimated to be 1,213,814; but if rats, mice and birds would be

*Principles of Humane Experimental Technique*: replacement of sentient living animals with nonsentient animals or materials, reduction of the number of animals used in an experiment or procedure, and refinement of the techniques used in order to decrease the incident or amount of animal pain and distress [14]. The Indian term for 'do not kill' or in the broader sense 'do not violate' is 'ahimsa' and is based on the Hinduist and Buddhist notion which sees 'all living things as incarnation of a single life force' [13; see also the 2004 CPCSEA report to the Indian government]

Love your neighbor: 'Humane' techniques refer to directly to humans, indirectly only to animals. More prominent and more essential is the cultural, ethical and political responsibility and respect for humans, families, and communities. Ethics literally means ethos, customs, good behavior, respect for traditional models of human interaction towards friends and foes, within the family and community, towards the elderly, especially towards the weak and dependant, the poor, sick, suffering, and dying. Ethics is based on cultural traditions and experiences, enlightened by religious and philosophical teachings, often enforced by social contracts, regulations and laws. Sometimes the priority of reciprocal value-and-vision based interaction with and responsibility towards humans and human communities is so strong that nature, animals are no even mentioned in codes and rules for moral conduct. The Jewish prophet Micah defines the golden rule 'love your neighbor and go lowly before your God'; Jesus similarly said 'love God and your neighbor as you love yourself'. One of the five central commands in all fractions of Islam is 'to give charitably to the poor and sick'; animals are not mentioned. Confucian master Mohist even underlines responsibilities towards humans in contrast to animals in requesting 'treat humans as humans, do not treat them as you treat horses'.

But then there are very strong traditions in religious and philosophical teachings stressing the integration of respect for and compassion with the animal kingdom in all forms. Confucian master Mencius includes harmony with all nature into his 'doctrine of harmony' which has to lead into 'benevolence-oriented politics'. Theocentric and anthropocentric Judaism is very much aware of the Talmud teaching 'killing a mosquito on a Sabbath is a sin much greater than aborting a fetus'. Christian Saint Francesco Assisi holds that 'sun, moon, animals, plants and all creation are our brothers and sisters'. To demonstrate that age old traditions and teachings are still of cultural and political relevance, I again quote from the already mentioned keynote editorial of Vice Minister Pan Yue in 'China Daily' of July 7, 2006: 'Confucianism: All creatures stem from nature. It stresses that benevolence be shown to people and all other creatures, extending a spirit of benevolence to everything in the universe. - Taoism: Law of nature the supreme principle governing the universe and human society... believes that harmony

between nature and humanity is more important than good relations between people.- Buddhism: All living beings are born equal and have the right to live' [12].

When harmony is more important than manipulating nature in medicine and medical research, then extreme modifications of natural laws such as intensive medical care, heroic interventions, creating transgenic animals are morally questionable, even counterproductive to achieving harmony; this would be a genuine Taoist view. When suffering is an unavoidable and essential part of all forms of life according to Buddhist reasoning, then the goal of improving the quality of health and life and reducing suffering and pain, might not be the highest moral goal, rather the endurance and final escape from the wheel of karma, of suffering, of being born and reborn. Asian worldviews are more intuitive than argumentative; they rely more on direct experience than on principles; doing good and being compassionate is more important than having a correct argument or a principled answer to a complex challenge.

Care for the weak, the sick, the needy, the helpless: In medical ethics of all schools and traditions, we find a similar concentration on human solidarity with the sick and the suffering: Buddhist monks are very committed to and revered for serving the sick and the dying compassionately. All Christians will understand the rules of the charitable Order of St John 'serve your Lord by serving your Lords, the sick and the poor'. Ayurveda medicine intends to protect and to improve health; Asian medical cultures concentrate on family ethics, community health and human health enhancement and anti-aging. African traditional medicine uses the natural and spiritual powers of the visible and invisible world to heal and to protect fellow humans from evil spirits and evil diseases.

Cultivating nature: Global birds-eye perspectives on cultural traditions seem to confirm a dominant relevance of two interrelated concepts and visions: First above all, it is ethical that people care for each other, in particular for the sick and the poor; it is unethical not to care for the less unfortunate. Secondly, nature and animals are for the benefit of human life and human culture, but manipulation and exploitation should be done compassionately and responsibly in respect for the harmony of the world, but also indirectly for the benefit of the future of humanity. Cultural traditions such as the Abrahamitic monotheistic religions or the harmony-based Asian worldviews are not monolithic; they are diverse in themselves and some of their schools and concepts overlap or are identical with those visions from other traditions. In a globalized world, these complex identities and interactions of moral communities are often forgotten; but they are essential for personal as well as professional understanding of moral concern and moral visions, including those in medicine and in medical research.

Who has the authority to interpret moral imperatives: Let me illustrate the role of worldview and moral conviction by a recent case in family practice in Germany: A young Turkish patient suffering from low sperm count was been given medication by a German doctor. Three days later, he stormed into the doctor's office, throws the pills on the floor and shouts 'what pig can give a man medicine from a pig to make son'. The doctor had prescribed a mild remedy containing substances from pig pancreas. He could have prescribed other and definitely more potent medicines, but had followed routine medical practice to start with lowest intervention first. The Christian sect of Jehovah's Witnesses does not accept donated blood even in situations of life-and-death based on a strange interpretation biblical quotes. Physicians routinely respect those choices of competent adults. The Prophet Mohamed had not addressed medicines based on pig tissue or on shellfish, but he had forbidden to eat pork. Also the prophet had requested to strictly obey the rules of fastening during the month of Ramadan, but there is a variety of opinions, mostly supportive about the use of necessary medication, foods and liquids during times of illness. The Roman Catholic church supports organ donation but criticizes the use of embryonic stem cells in medical research and future clinical treatment. Who has the authority to interpret the validity of moral norms and moral teachings? This is a complicated question. As there are different positions in most moral cultures in increasingly more and more diverse continental and global societies, it would be wise to let the believer or consumer, i.e. the proband or patient, have the last word whether to accept or refuse certain medicine or treatment.

Actually, the fact that there is moral discourse on crucial issues in modern medical research, can serve as an indicator that reasonable and responsible people can have different opinions and that they should be allowed to follow their conscience and concern. Transparency in information and procedures to provide education are essential to let people make prudent decisions based on their personal views and visions, more or less closely supported by either one of the more influential ethics teachings and moral communities. E.g., extreme moral positions want to be informed and should be informed, if, how, and why certain drugs contain human blood, pig tissue, or are based on animal research, - competent and informed people have every right not to be associated, as considered by some, with those 'immoral' or 'forbidden' activities. Also, no one can or should be forced to involuntarily be involved in animal research activities in general, or more specifically in research on primates or (for pet lovers) in research using dogs or cats. Similarly, the respect for moral autonomy and individual value-based responsibility requires that we accept people's wishes not to accept medicines based on animal research or human research or containing animal or human substances.

#### **Four Categorical Moral Imperatives**

As far as animal experimentation is concerned, the basic conflict seems to be the use of non-human species for the benefit of the human species. Basic conflicts have basic roots; their solution or easement can be supported by basic guidance, which then in special situations needs to be refined. In a bird-eye's perspective, we can differentiate four cultural and ethical imperatives governing the individual and collective or regulatory resolution of the conflict. These imperatives are both cultural and moral, in as far as the enframing culture support specific ethical rules and requirements. These imperatives are also categorical, not hypothetical, not depending on certain situations, only in a limited way open to re-interpretation or adjustment.

Imperative I: The Kantian imperative requests categorically that you always should act according to rules and principles which can and have to be categorically the same for your fellow-humans too. In another version Kant requests to treat fellow-humans as ends in themselves not as means only. This is a reciprocal position similar to 'what do you want to be done to you, do it not to others'. Reciprocal ethics sometimes works among humans, but it does not work in interacting with animals. It is of no sense if I would request 'do not bite dogs, so they will not bite you'. Also, we would say to an animal 'treat me not only as a means, but always also as an end in itself'. We need other imperatives to treat animals 'ethically', i.e. according to value-based principles and virtues formulated by and for moral people for the humane interaction with animals and other forms of life. It will be a model already mentioned by Kant himself, the reasoning that a limited extension of solidarity and compassion beyond fellow humans only would strengthen the moral resolve towards people, and that being cruel to animals would create a slippery slope in decreasing or neglecting moral obligations towards humans.

Imperative II: Fritz Jahr, a German scientist, in 1927 in an article 'Bio-Ethik' [8; 18] extended the Kantian imperative to all forms of life 'respect each living being basically as an end in itself and treat it, if possible, as such'. Jahr's bioethical imperative was formulated at about half a century before von Rensselaer Potter's '*Bioethics-Bridge to the Future*' book in 1971, thus implementing the 18th century vision of British philosopher Jeremy Bentham 'it may one day to be recognized that the number of legs, the villosity of skin, or the termination of the os sacrum, are reasons equally insufficient for abandoning a sensitive being .. the reason is not, can they reason? can they talk?, but can they suffer?'. Most successfully and prominently in our days Peter Singer in '*Animal Liberation*' [22] has held the same categorical bioethical position. It is not a reciprocal imperative, rather an imperative of extending compassion and care to those who are unable to reciprocate or to protect themselves from harm, pain, and

suffering, i.e. vulnerable animals and other vulnerable living creatures. It is a respect owed to humans themselves that they treat other vulnerable forms of life compassionately somewhat or similar as they would treat other humans. They would harm the 'ahimsa' principle, i.e. violate the 'single life force' of which we all together and everyone individually is a part of, which is most directly understood in all Asian cultures.

Imperative III: The Sanskrit Imperative 'tat tvam asi' - literally means: it is you, the worm you step on, the fly you kill, the dog you beat, the guinea pig you use in research, the calf you raise for consumption, the Lesch-Nyhan mouse you have constructed and infested with a cruel human disease, the flower I break and then throw away carelessly. Other living beings are just like you, vulnerable, mortal, sensitive, scared; relieve their suffering; at least, do not contribute additionally to their suffering. Here are a few of the '10 Grave Precepts' of the Buddhist Mahayana tradition: '1. Affirm life, do not kill.- 2. Give, do not steal.- 9. Actualize harmony, do not be angry.- 10. Experience the intimacy of things.' These moral Imperatives are taught to humans, but include all suffering creatures, 'all things'. In the 'do not kill' command, supported and enforced by the 'doctrine of reincarnation', the rebirth of life in other forms of life depends on experiences in previous lives and hopes for a final escape from the wheel of karma and suffering in the great nirvana. This position in its pure form does not necessarily consider suffering, which is unavoidable anyway, as being bad or in need to be eliminated. Suffering and caring for those who suffer are the two most sensitive and most compassionate human actions. When suffering has a sense and a goal, then the urge to develop high tech medicines for the elimination of all sufferings and the enhancements of life are futile and not a priority. It is most difficult to justify any experiment on any living entity from an extreme purist position supporting this 'it is you' categorical imperative. But, there are quite a number of less strict versions of the 'it is you' principle. Philosophical vegetarians have to eat something. Informed consent or informed contract might broaden the platform from self experimentation based on the virtue of compassion with suffering humans and other living beings towards a model close to modern clinical trials, but using animals would be more difficult than using people, as they cannot rationally consent into a shared enterprise of compassion and humaneness, neither for the progress of human medicine nor for the progress of veterinarian medicine.

Imperative IV: Taoist reasoning mirrors human activity and morality to a perceived pre-given harmony, the One, the Tao, the Way, encompassing each and everything. Extreme and intense actions and goals are not harmonious, they destroy harmony or distract from harmony, they are selfish acts, uncoordinated with laws of nature, which have to form the laws of individual attitudes, human communities, and the harmonious

interaction of humanity with nature. Intensive care medicine fighting at the edges of mortality and using animals for human medicines can be seen as problematic and counterproductive for promoting harmonious interactions. Palliative care of the dying and self-experimenting of dedicated physician-researchers might be morally superior. Breeding dozens of varieties of goldfish for fun and human enjoyment might be more acceptable than breeding transgenic animals for extreme human research in human diseases. However, moral and cultural history shows that Taoist reasoning is closely intertwined in building harmonious communities and societies upon the model of perceived heavenly and global harmony. In the usual selective combination of Confucian and Taoist arguments, Mencius proposed 'benevolence-oriented politics' by saying that 'there would be an abundance of grain, if the sowing season was not missed, an abundance of fish, if they were allowed to breed unhindered, and an abundance of timber if logging was conducted on a reasonable basis' [12]. Such a 'rule of benevolence' towards cultivated nature would 'much improve people's lives' and create a 'harmonious society', defined by contemporary Chinese authorities by 'democracy and rule of law, fairness and social justice, credibility, vitality and energy, order and stability, and harmony between nature and humanity'. Harmony-based and ideal-nature-based concepts of orientation have historically and can contemporary allow for well reasoned and refined animal research for the benefit of humans and animals alike. The argumentation, however, has to be different than the one preferred in the Kantian or the Jahr model. It is not so much, what we do, but how we do it and how we live with it; the Tao Teh Ching holds: 'we make doors and windows for a room; but it is these empty spaces that make the room livable' [no.11]. Thus, we do animal research, but it is not this or that rule or design, it is the way we do it, with each other and with the animals. 'The highest form of goodness is like water; water knows how to benefit all things without striving with them.' In concrete term, this picture is translated into concrete situational ethics: 'In dealing with others, know how to be gentle and kind. In speaking, know how to keep your words. In governing, know how to maintain order. In transacting business, know how to be efficient. When making a move, know how to choose the right moment' [no. 8]. It is this concrete Asian strategic realism which translates general imperatives into situational action guides, not questioning that countries have to be governed, business has to be conducted, moves have to be made, but suggesting to do it in a civilized, compassionate and therefore successful way. Regulatory design and business strategy follow these rules, - a somewhat different model of being successful and being good than the analytical or weltanschauung-heavy Anglo-saxon or European model.

Imperatives and maxims are not refined and detailed prescriptions for single actions, rather general guides for differentiating between competing goals and risks and for choosing prudent solutions within a larger picture. The quotes on 'harmonious society', again not from a classic philosopher but from an acting Chinese minister show the actual relevance of classical teachings for contemporary orientation and policy decisions on the highest level [12], in particular given the extreme destruction of environment in the Chinese industrial and social revolution and the loss of self-understanding attitudes during the cultural revolution. As far as different parts of the world are traditionally guided by different cultural and moral systems of reference, it would be useful and successful to address major concerns towards animal experimentation in those traditionally dominant terms. However, as a result of globalization and exchange of cultural and moral convictions and ethics regulation by national bodies in more and more pluralistic societies and by transnational organizations, those transnational principles such as the principles of modern bioethics can and need to be applied as well. Even though these four categorical imperatives seem to be widely apart from each other, they are an expression of value-based concern for good moral action and cultivated and educated conduct by individuals and in moral and cultural communities. In practice and when applied to real-life situations, they are somewhat flexible, taking a special technical and moral situation into account when balancing different visions and obligations; as Thomas Aquinas would say '*quanto magis ad particularia descenditur*', - the more we face concrete real-life and differentiated challenges, we may not dispose of principles and virtues, but we have to adopt and refine them to the concrete challenge.

### Research Design

Different countries have regulated animal research, based on principles of 'no harm' or 'low harm'; not all animals are covered and animal research ethics rare is linked to research on human subjects. But animal research ethics can follow the same model as human research ethics, but need to implement a few concepts based on the different situation of animals and humans as probands and patients.

Four plus one basic principles: At the end of World War Two and after the cruelties in human experimentation by the Germans and Japanese, the Belmont Report in the United States established four principles of common morality which could be accepted by all fractions and moral communities in a pluralistic society such as the US: respect for humans: autonomy, nonmaleficence, beneficence, justice. Nonmaleficence, the old '*primum nil nocere*' do-no-harm principle, and beneficence, the old '*bonum facere*' do good principle in eliminating suffering, healing disease and improving the craft of medicine, were age old principles in all medical cultures; I have detailed that elsewhere. Both principles '*mutatis mutandis*' can

be translated into animal research ethics. However, as animals in research are not the beneficiaries nor their species (except in veterinarian research) are the beneficiaries, but as risks, and sufferings are associated with being a subject in research, harm will be done, but harm must be minimized. 'Minimal harm' has to be the principle; also, it needs to be remembered that harm, directly or as side effect, in practice rarely can be avoided neither in clinical research nor in clinical treatment. Also, the 'good' for research animals is difficult to determine; it would have been best for them not to be used in research. Therefore the 'do good' should be differentiated into 'keep happy' or 'do as good as you can'. The principle of respect for autonomy, such as e.g. detailed in informed consent, is relatively new and part of the individualistic post-enlightenment culture of the West, replacing traditional medical paternalism. It cannot be used in animal research, but the concept of 'respect for the proband/patient' can be used. Respect for animals in research would need to remember basic features of all forms of life, vulnerability, pain, suffering, angst etc. Thus replacing the autonomy principle by the 'respect and concern for vulnerability' principle would be the change of choice. Justice in human experimentation means that probands and patients should not be chosen because they are easier to get for reasons of poverty, low level of education, desperation, or because they belong to a minority group or are otherwise easy to exploit. Similar principles of fairness can and should be used in selecting special species or individuals for animal research. Thus, the four principles in animal research could read: respect for animals: vulnerability, minimize harm, keep happy, be fair. We have to differentiate harm and happiness in the research situation. I add a fifth principle, which I call the 'minimax principle'. As concrete situations never are confronted with only one single technical or moral issue, balancing various aspects, risk, benefits, costs, and uncertainties is basically the business of research design and implementation. We want to balance moral risk, uncertainty, cost, and benefit the same way we do with technical variables. We want to minimize what we do not like and at the same, as much as possible maximize the benefits and goals [16:205-214; 17:302-338].

Differentiating harm in animal research: Harm can have different forms, from severe physical harm to mental and psychological suffering, from pain to discomfort to the absence of enjoyment, to loneliness, feeling alone and abandonment, harm to life and survival. Other harm is directly related to breeding or conditioning design: genetic or other disorders or weaknesses resulting from breeding, disease resulting from infecting animals with human diseases, harm by crossing species borders by conditioning animals as carriers of human diseases or changing their genetic setup even more to make them suppliers of specimen, tissue or organs for human benefit. Also harm, pain,

and suffering definitely is different between species. But we don't yet know enough about those species-specific forms of pain, of harm and suffering. It definitely would be wrong to introduce human harm parameters into the animal kingdom. Based on species-specific differences, biologists differentiate roughly between microbes, insects, annelids and vertebrates. Quality and quantity of pain, comfort and discomfort is definitely different in these groups. Based on incomplete knowledge in nerve existence and sensitivity, we cannot define or determine what pain means to microbes, but there must be some form of cell-discomfort or distress associated with situations of stress, which in vertebrates and humans we would call pain. Insects have diverse or separate nerve systems, some more or less independent or integrated; how should we define pain? Annelids have sectoral, but also somewhat interrelated nerve systems; how do we define pain or compare their nerve associations with pain as we feel it? Vertebrates have central nerve systems, similar to humans; but already in humans individual recognition and anticipation of pain is different; how are these features species-specific similar or different. Do we owe more compassion to species which have become cultural companions to us over thousands of years of breeding and cultivation, dogs and cats? What do we know about the pain-and-suffering features of transgenic animals suffering from human diseases; how do they cope; how do they feel; how scared, lonely, desperate are they? And what about primates, about their emotional and sensual stress in research, additional to physical pain and captivity stress? Unfortunately, we do not know much, not enough to reduce unnecessary stress and suffering, not related directly to the experiment, which might influence the research. Also, different forms of pain associated with research might produce other outcomes in animals than in humans. What seems to be very clear is, that species-specific normal-life conditions, happiness and absence of harm requires more than regulations on the size of captivity containers, species-specific foods and drinks. Some species are sensitive to light, smell, noise, loneliness, day-night cycles, - do we know enough about these species specific sensitivities and harm features, - and if we know, do we or are we willing to reduce those harms, which are unrelated to the research itself?

A case study regarding regulatory uncertainty on which animals to protect and on what grounds: Regulations by the USDA did not include rats, mice and birds. The US District Court of the District of Columbia found that the definition 'animal' in the US Animal Welfare Act was arbitrary and in violation of the Act itself; it ordered USDA to change the rules; but a US Court of Appeals in the District of Columbia overturned the verdict on the ground that the plaintiffs 'did not demonstrate constitutional standing to sue and/or a statutory right to judicial review under the

Administrative Procedure Act [2]. Only in 2000 the USDA agreed to regulate rats, mice and birds [2; <http://www.labanimal.com/col/reg1100.htm>]. These and other legal quarrels demonstrate very visibly our cultural and moral uncertainties in dealing with animals and which principles and value to use in guiding animal research [1; 3; 7; 10; 11].

Our deficient knowledge in pain-and-harm features of the 'lower levels' in the animal kingdom might be caused by a lower level of concern for in species welfare having other models of neuronal signaling as compared to ours and those of vertebrates. In fact, animal research ethics, animal protection regulation and law, and animal welfare committees are primarily concerned with the welfare of vertebrates, and even more so with non-human primates. Except general convictions about the universality of suffering by Buddhist thought and harmony visions in Taoism, there is not much distinct and analytical reflection and assumption about pain in animals with nerve structures less centralized than those of vertebrates. How do we have to translate nerve conductivity in non-centralized animals into ethical concern and the language of compassion. In national and international regulations of medical research, microbes and insects are covered for the protection of human beings from infection and for the protection of the environment to avoid escape or release. Even animal rights activists do not seem to care much about the welfare of microbes, flies, and mosquitoes; also, they seem to care more about mice and rats in research than the fate of mice and rats in the wild or in the city. The absence of regulation of animal research based on moral concern for the entire animal kingdom is a fact which needs further ethical and cultural inquiry at another time; we will come back to this when discussing options in minimizing risk and maximizing benefits in animal research. The EC report on animal welfare committees rightly calls for replacing animal research by 'non-sentient material' [5:13]. Is *Drosophila* less sentient than a guinea pig or a primate? *Drosophila* can learn and remember situations in which sugar makes her happy and the absence of sugar unhappy; how would you translate 'happiness' and 'memory' of *Drosophila* into the 'sentient' language? What are the sentient levels of viruses and bacteria and living tissue cells? Research regulations routinely do not address the 'sentient' level of cells, microbes, and insects. Do they represent the non-sentient material the EC is speaking about? Buddhists and Hindi would disagree at least as far as visible living beings such as insects are concerned. How to define 'sentient' and 'non sentient'? Are there levels of sentiency, how can they be described in scientific terms and how can they be translated into moral terminology? These uncertainties call for future interdisciplinary research projects between biologists, physicians, neurologists, ethicists and theologians in the formulation of assumptions about pain and suffering in

the animal kingdom, which in turn might support or modify the design of existing research models and selection of species for specific research.

The EC community research report suggests to analyze and assess the 'ethical assumptions and frameworks of AWC's' [5:39] in order to find out about differences and shared assumptions; this would be a worthwhile project also to identify future interdisciplinary research into pain-and-suffering in animals of all level in the animal kingdom. A recent study on the 'Interpretation and Application of the 3 R's by Animal Ethics Committee Members' [20] shows inadequate understanding of the basic principles as a result of poor training but also differences in recognizing, defining, and reducing animal pain. An interdisciplinary research project is urgently needed and should be conducted on a global scale, studying and integrating assumptions in AWC's worldwide and comparing those with existing or developing attitudes towards all forms of life and assumptions about animal research in different moral communities and by ethics experts of different background.

Human cultures, irrespectively to general compassion with animals, have sometimes been very insensitive to animal pain and harm. Cock fights, dog fights, some forms of bullfighting and horseracing are examples that for fun and excitement we make animals feel pain or even being killed. But the middle-class girl loving and playing with her guinea pig, a night animal, all day long is not different from a family keeping a dachshund in an upstairs apartment, over time ruining his spine, or other families overfeeding bulldogs destroying their vulnerable cardiovascular system or others keeping German shepherd dogs suffering hip problems resulting from overbreeding. Of course, we kill (and even eradicate) viral and bacterial pathogens, we kill insects who carry them, rats and mice for 'good reasons' i.e. for the benefit of human life and health. Indeed, treatment of animals in research is embedded in these and other cultural attitudes towards animals in general and house pets in particular. Sometimes probably animals in research are better off than their brothers, sisters, and cousins in chicken houses or households.

Of particular sensitivity is research using non-human primates. There are strong objections against any use of primates in research benefiting humans. Two recent British 2006 studies took two different and opposing positions, one by UK Medical Research Council and the Wellcome Trust and the other by G Langley for the British Union for the Abolition of Vivisection and the European Coalition to end Animal Experimentation [21; 9]. These arguments are not reconcilable and indicate that a lasting cultural divide will be with us for a long time, based on different cultural and moral assumptions. The only solution to this divide seems to be to accept and let people choose for themselves while the public discourse continues in a hopefully understanding and compassionate manner. If we value

the moral autonomy of fellow humans and of different and specific moral communities, then we have to accept that they will have different positions in regard to support animal experimentation and to be involved in animal experimentation themselves, or accept the real and potential benefits from animal research such as medicines or medical products.

Cultivating animals: Selecting and breeding or even crossbreeding or genetically manipulating animals for research is just one part of using and shaping animals and other forms of life for the use of humans, human culture and humanity. For millennia, we have bred animals for farming and grazing, transportation, hunting and the protection of house and property. We have even been successful with selected interspecies breeding such as breeding mules. Varieties of goldfish have been bred for fun, varieties of dogs for different tasks and services, including for dogfights and for leading blind fellow humans. Some uses of specially bred animals have disappeared or minimalized, but these varieties are still kept in environment unfriendly, even unhealthy for their life and wellbeing, such as hunting dogs in city apartments or dachshunds in private homes with staircases. To directly design and create special species for studying human diseases in animal models or for changing enzymatic and other features in animals so that that organs might be harvested as replacement for human cells, tissue or entire organs falls in line with those traditional indirect techniques. When dachshunds had been bred for hunting dachs and fox, then the creation of transgenic animals for the study of human diseases follows the same pattern of using animals and modifying animals for human benefit [16:205-214; 19; 21].

Design principles in animal research: The ethical design of research using animals for human benefit could follow a set of principles which have been proven to be successful guidance in medical treatment and research, and in treating fellow humans in general. I mention four: compassion, vulnerability, solidarity and the minimax principle. These four principles can be used for both purposes, selecting the most appropriate animal model or species and selecting the proper course of research to reduce stress and harm. Compassion requires the reduction of unnecessary species-specific features which are not related to the specific research, rather to captivity and the artificiality of the environment. Vulnerability requires the reduction, compensation or treatment of distress and pain associated with specific research, also an awareness of new and very unique features in vulnerability of transgenic animals or animals carrying human diseases. The principle of solidarity may suggest compensating for distress and suffering by offering favors which do not or only minimally have an impact on research results. Compassionate killing is required by principles of compassion and solidarity. The minimax principle addresses a prudent balance of risk and benefit for the animal in ethical terms as part of the overall risk-benefit

calculations of the project itself. Salvi has suggested to accept animal cloning for clinical research but in support of profit motives in meat production [19].

Case discussion: Let's say that *Drosophila* and primates are both good models to study neurodegenerative diseases in humans. In such a case we have to find out, which aspects of research can be done with insects and which we unavoidably have to use primates. There would be a preference in the design of research on Alzheimer to put as much burden and suffering unto the *drosophila* probands, and as less as possible on the primates. Such a minimax solution would first of all be in line with century-old traditions that family and friends come first - in this case primates whose sentiments, fears and pain features we seem to know better than those of the insects. Secondly, it would protect what we know, minimize pain and suffering of animals quite close to us humans in the hierarchy of life. *Drosophila* has other forms of pain and distress, but those experiences of pain in insects and other forms of life, such as bacteria, are more remote from us, similar to those of a flower, I have picked and put into a vase on my living room table for my enjoyment. The assumption that a different pain experienced by *drosophila* has to be interpreted as pain of lower quality and quantity might be totally wrong; we would need to have more biological studies and more philosophical reflection and compassionate prudence and wisdom for an improved assessment. Fritz Jahr in 1927 already had such a research project [8; 18]. This would require to re-appreciate and to re-confirm traditional character traits for ethical professional conduct in medicine and medical research on the crossroads of physiology and psychology.

A good doctor, a good researcher, a good animal welfare officer: Following our model to translate basic principles and virtues in medical treatment and medical research into animal treatment and animal research, we can use character traits, virtues, and role models in physician's ethics to delineate character traits, virtues, and role models for researchers in animal experimentation. For this purpose, I just quote without further interpretation famous 17th century Confucian doctor Yang Chuan: 'Trust only those doctors who have the heart of humaneness and compassion, are clever and wise, sincere and honest'. I could use other more modern lists of physician's ethics as a blueprint, but the list of doctor Yang Chuan contains virtues which are indispensable and essential for responsible physicians in the care of their patients, and they are rarely addressed or even mentioned or supported in modern medical ethics, medical law and medical regulation. It is easy to re-write Dr. Yang Chuan's advice: 'Trust only those researchers who have the heart of compassion to all living beings, are clever and wise, sincere and honest'. It would be good, if creativity, smartness and cleverness in research design and implementation, wisdom and prudence in review

and in choosing between options, and above all honesty and trust would play a bigger role in research training and governance and would be honored appropriately. Just playing by the rules of regulation and oversight and protecting oneself and one's team from violating those rules on paper is not enough to be a good doctor and/or researcher and to earn the trust of other stakeholders and the community.

### **The 7-R Approach: Reduce, Refine, Replace, Rehabilitate, Respect, Review, Relate**

How can and should insights into cultural and ethical principles and requirements be introduced into animal research? Questions to be asked include: What alternatives to animal research do exist, which can or should be developed?; how can harm be minimized by refining design and implementation of research?; are there less pressing ethical issues when animals are used in veterinary research rather than in research benefiting human. These questions have already been introduced by national regulation in most countries; also, transnational bodies such as WHO, the EU and associations of industry and research have already issued regulation or self-regulation, guidance or guidelines; other countries have no regulations or regulations less clear or detailed and are tempting animal research teams to perform cruel experiments in those countries. It is my thesis that precise, open, and detailed Animal Welfare programs in research companies will contribute to more acceptable projects internally and to a better corporate profile in the public. Seshadri and others [21] have discussed the unfortunate facts that biomedical research, including experimenting with transgenic plants and animals, have found countries with low or no levels of regulation; a good and publicly visible corporate strategy and commitment of research companies will be able to counter the flight into such havens.

Animal research, of course, must follow external guidelines and regulation, but corporations also must set their own internal rules and principles, guided by specific corporate concern and mission. Of course, in order to be effective and trustworthy, corporate guidance and guidelines should be of global relevance and authority. High levels of self-regulation are always better than external regulation, as direct responsibility, immediate and direct capability for improvement, adjustment or refinement, self-interest and self-esteem are part of self-regulation. Animal welfare committees [AMC] on the local and national level have already been introduced in many companies and recommended by regulatory and oversight bodies. Novartis has subscribed to the widely used and noncontroversial 3 R's (reduction, refinement, replacement of animal research), originally proposed by WMS Russell and RL Burch in 1959 [14]. The 3-R approach has become the golden standard since by the EFPIA [6], the Council of Europe Convention ETS 123 and most recently

successfully been used in a report by an EC Community Research report 'Animal Welfare Committees in the European Research Area' [5]. As already mentioned, the Indian CPCSEA (Committee for the Purpose of Control and Supervision of Experiments on Animals) proposed and implemented a 4 R's set of principles – Replacement, Reduction, Refinement, Rehabilitation [13]; I use this 4 R's model to propose an extended 7 R's model for the use in animal research ethics and corporate governance on a global and corporate level.

The 7-R approach: I suggest to use the well-introduced and widely accepted 3-R model as a basis for the development of an improved and extended corporate 7-R model. In as far as animal experimentation is the result of a similar R approach to reduce, refine and replace human experimentation as much as possibly can be done responsibly in the development of safe and efficacious drugs and interventions for humans, it in itself relates closely to a broader moral strategy of reducing impact of subjects in research while keeping the goals and standards of medical research high. In the words of the EC report, the three principles require 'to Replace the procedure with a method or strategy which uses non-sentient material, to Reduce the number of animals used in the procedure, and to Refine the procedures so as to make animals suffer less' [5:13]. Of course, in order to be effective, the 3-R or 7-R model must be supported strongly by internal corporate policy, also not been confronted with financial or administrative shortcomings if the ethically better option is considered to be the option of choice. The 7-R approach includes the Replace, Reduce, Refine principles and the Indian Rehabilitation concept, but adds three more principles: Respect, Review, Relate, - either complementing or reinforcing goals and methods already expressed in the use of the first three principles. Of particular importance will be the integration of animal research into the overall corporate strategy, profile, ethics, and governance. It is more than a symbol when drug companies provide for rehabilitation and retirement centers for primates who have survived medical experiments for the sake of humans. Here are the additional three principles for implementing corporate ethics and governance beyond national and international rules and regulations, establishing research based drug companies as good corporate neighbors, also being concerned about the welfare of animals in research.

Respect: A special emphasis should be laid on species-specific forms of harm, pain, distress, as they are related to the captivity environment and to the research itself. Compassion and species-specific vulnerabilities need to be addressed and may lead to more refined species-specific refinements or even to a rare change of the animal model or an already established research design. A deliberate Respect for Animals principle will also allow recognizing specific local sensitivities in regard to animal experimentation

in general or the use of specific species or the moral and cultural acceptability of certain forms of research. Cosmetic research for the human benefit but associated with painful experiments on animals might not be acceptable in many cultures. Experiments for the development of medicines based on pigs in research might not deliver drugs which can successfully be sold in Muslim countries; transgenic animals might be perceived as against the harmony of nature, unnatural as they carry disease and pain reserved for the human race.

Given the controversies regarding animal research, respect has two sides: respecting the animals in a compassionate way and respecting different moral assessments of individual fellow humans and moral communities. Different interpretations of compassion and of our respect for forms of life in general and of animals and animals in research in particular are based on different assumptions; it would be unjust, unfair, and unreasonable to differentiate between lower and higher levels of argumentation or commitment or respect for humans and/or animals. We live in a world, diverse and rich in different values and value priorities. Moses Mendelsohn, a great European enlightened philosopher and devoted Jewish Rabbi once said: 'Brethren, if you really want to be close to God [wahre Gottseligkeit], then let us not lie about consensus, when diversity seems to have been the plan and goal of the providence. No one of us feels precisely the same as his fellow human; why do we cover ourselves in the most important fields of life like masquerade [Mummerei], when God gave each of us his own individual face?' [16:233]. The Respect principle allows each of us, and different moral communities, to hold different opinions on animal research and the use of medicines derived from animal research and animal products.

Review: Animal Welfare Committees are the instrument of choice to review and to improve animal research on the local level and to reconcile different approaches and to set standards on the national or transnational level. Corporate AWC's (Animal Welfare Committees) are indispensable as only they can develop, to experience, and to set standards on a global level and refine general corporate animal welfare policy for the local ethical and cultural environment. It is important that an open internal corporate discourse on methods, uncertainties, risks, shortcomings, and goals in animal research can be held and continued without financial or other pressure. As important is the communication-and-cooperation with outside partners in research, the information and exchange of experiences, the sharing of basic guidelines and procedures, a similar process of review and governance as is practiced in-house; also joint training sessions are very important. Corporate AWC's have to have access to all expertise within the corporation, preferably directly via members of AWC's or via consultants. But corporate AWC's need also outside expert advice; such an advice can be provided by experts in ethics and

culture or by members of moral communities, - the so-called and in IRB's reviewing CCT's in humans well established and well received 'community representative'. If necessary for internal corporate reasons, professional expertise in ethics and cultural attitudes can also be provided by outside consultants. It is my experience that 'lay people' from the outside (these lay include the so-called experts) provide a useful service within the committee as they introduce language and arguments which then can be directly integrated into the committee reasoning and decision making process. Lay people ask questions of ignorance which never will be formulated by pure and professional expert groups.

Relate: Animal research and animal research ethics are an integral part of medical and pharmacological research, including research in veterinarian medicine. It is beneficial for animal research as well as for the company to relate issues, solutions, even uncertainties, as transparently and as simple and well reasoned as possible. Interrelating corporate policy, corporate ethics, and corporate profile from the top level with all sections and department and with animal research lab's is the preferred design to develop and to guarantee one corporate mission profile. Such an integrated and well supported corporate mission profile serves a double purpose: leadership, encouragement, pride, and responsibility internally, and respect, understanding and support externally by the public and various moral communities, by the media, lawmakers and regulators, also by the outspoken critics of medical experimentation and in particular foes of animal experimentation. Towards ideological enemies of animal research only serious concentration on the basic mission of the corporation - of which animal research is for ethical and practical reasons one of the parts - will be persuasive and convincing and will show the shortcomings of simplifications by critics and their disrespect for suffering fellow humans and the great achievements and goals of modern medical research. In general, the Relate principle relates corporate profile and mission, research experience and design, corporate communication, cultural and ethical concern, stakeholder relations, and public opinion and information to each other, - not only a beneficial service for the corporation and the public profile, but also for improved future research design by integrating more and new input from internal and external sources into research design and policy. For national legislation and regulation it would need to relate rules and regulations to cultural and moral traditions, fundamental right issues, professional expertise, market rules, and public opinion and expectations. Similarly, international governance bodies would need to relate their recommendations and standards to global and local cultures, basic rights, market mechanism, and professional duties and possibilities.

## **7-R Moral Risk Reduction Guide in Animal Research**

In implementing animal research ethics into research design and corporate policies, action guides could be drafted for Corporate Profile, Regulatory Compliance, and Communication Competence. This best would be done in-house with critical assistance from ethics experts and experts from moral communities. Here is a Risk Reduction Scheme, which I have developed for other fields of integrating moral risk reduction into professional risk assessment and for the identification and possible reduction of uncertainties [13; 16; 17]. In this form, I have minimally modified for use in animal experimentation, in which animals are stakeholders but lacking the competence to be partners in decision making and design.

Research ethics risk reduction scheme:

1. Identify data and issues
  - 1.1. Collect technical (medical) data
  - 1.2. Collect animal data
  - 1.3. Collect value data
  - 1.4. Discuss data relations
2. Develop alternative options
  - 2.1. Establish reasonable options
  - 2.2. Refine options using 7-R principles
  - 2.3. Identify risk-and-harm features
  - 2.4. Discuss 7-R principles
3. Present preferred option
  - 3.1. Present research risk/benefit in selection
  - 3.2. Present animal harm/risk feature
  - 3.3. Discuss with stakeholders using 7-R's
  - 3.4. Discuss medical and moral uncertainties
4. Justify your selection
  - 4.1. Summarize reasons for selection
  - 4.2. Review AWC 's review using 7-R's
  - 4.3. Formulate objections to your selection
  - 4.4. Review in light of corporate profile

## **Implementing the 7-R Corporate Profile and Governance**

Animal research and animal research ethics are an integral part of the corporate mission in safe and efficient medical research and in the development of efficacious medicines for humans and animals. It is important that this overall mission guides and governs animal research internally and externally. A global corporate neighbor needs to have one global personality, virtue, and moral and professional profile. But this profile has to adjust to local sensitivities, cultures and customs, where those are particularly concerned with specific sensitive issues. If we as individuals are sensitive and cultivated, we individually will have to adjust to other customs, preferences and expectations, if we want to be perceived as educated and cultivated, as good neighbors, probably even friends. Similarly a civilized and cultivated corporate personality has to behave well without changing one's character for the reason to impress others or to be more

profitable. One has to share values and explain actions fairly and coherently. Of course, regulatory compliance with national rules, customs, guidelines, regulations, laws is a must, so is the respect for international rules and guidelines. But as no one lives by respecting rules and regulations alone, corporations should develop their specific character and their special culture exceed or transcending those customs or rules to become a well respected corporate neighbor, friend, helper.

Important for individual persons as well as corporate persons is a certain level of communication, competence and openness. Corporate persons tend to be suspicious of others, individuals, other corporations, pressure groups, the media; openness and dialogue, fair reasoning and arguing about what the mission is, why it is important, how it will be implemented, and what problems will have to be confronted, - that is the best way to deal with friends and foes, - both are stakeholders and partners in the local as well as in the global community. Communicative competence is more than reasoning; it includes personal involvement and compassion inside the company and outside. Much can be learned in training, in finding a mutual language and identifying mutual or different concerns, moral and technical. And much will be learned in communication-in-trust and cooperation-in-trust with partners and stakeholders, not a last with patients and prospective patients, - indirectly also in dealing with animals in a compassionate way which is more than most rules require.

Compared to the progress in methods and schemes of animal experimentation based on the traditional of Reduction, Refinement and Replacement, there has been no progress in methods and ethics of human experimentation, in particular as far as Controlled Clinical Trials are concerned. We are still using the 50+ years old model of soft-paternalistic informed consent and placebo groups, not introducing contract models for probands, researchers and sponsors due to the inflexibility of regulatory agencies. Also, we do not make use of recent pharmacogenetic knowledge regarding different types of drug metabolizers based on individual P-450 enzyme properties for individualized drug development and application. Extending the 3-R model towards the 7-R model for corporate governance and ethics will provide an even less controversial model in comparison to still unchanged outdated models in human experimentation supported by WHO, CIOMS, national regulatory agencies and subsequently by drug companies who have to follow regulatory rules [16:119-125; 17:302-338]. Unfortunately there does not seem to be any intention or moral concern in international and national oversight bodies and regulatory agencies for replacing unfortunate and outdated schemes of clinical pharmacological research on human subjects.

Jacob Burckhardt, the enlightened European thinker from Basel would agree with the saying of the Tao The Ching: 'We make doors and windows for a room; but it

is these empty spaces that make the room livable. Thus while the tangible has advantages, it is the intangible that makes it useful' [no. 11]. For our purposes we could say: We make rules and regulations for animal research; but it is our attitudes and compassion which make research livable; and we should add: let's review, refine, and replace outdated regulatory models and schemes in human experimentation as well.

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## Assisted Reproductive Technology in Cultural Contexts

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### Abstract

Recent developments in Western bioethics and biomedicine have called for the need to be culture-sensitive in handling certain bioethical issues. As a result of this anthropological turn in bioethics and biomedicine, there are cultural differences in moral attitudes such as disclosure of terminal illnesses, reproductive technologies, stem cell research, prenatal screening, genetic screening, therapeutic cloning, organ transplant, brain death, physician assisted suicide and so on.

This paper offers an examination of the socio-culturally framed ways of dealing with Western and African bioethics particularly as it relates to assisted reproductive technology. It focuses on the ethical issues surrounding assisted reproductive technology from an African perspective making special reference to their religious beliefs by drawing on the Christian and Islamic culture. Effort is made to distinguish between Western and African approaches to assisted reproduction stressing the fact of cultural diversity in issues relating to these reproductive techniques. It argues for the need to take social and cultural meanings embedded in various bioethical issues into consideration in arriving at different conclusions about issues in assisted reproduction in order to give room for adequate understanding.

The paper concludes by emphasizing the need to acknowledge cultural diversity in bioethics giving

reasons why this diversity is crucial and suggesting ways of handling this diversity.

**Key words:** Assisted reproductive technology, Cultural diversity, Artificial insemination by donor (AID), Artificial insemination by husband (AIH), In Vitro Fertilization (IVF) and Surrogate Motherhood.

### Introduction

Certain procedures developed by researchers in embryology, obstetrics and medicine, have altered or replaced natural human fertilization which involves the well known method of conception through heterosexual intercourse and initial gestation in utero. Among these procedures is artificial insemination by husband or sperm donor and in vitro fertilization using sperm of husband or donor and egg of wife or surrogate mother. This arrangement has raised many ethical issues in African culture and has been a source of conflict in religious ethics. Central to this conflict is the claim that this arrangement involves a third party in the sexual relationship, posed possible social and physical risks to offspring and displaced the traditional mode of conception and childbearing (Fletcher, 1986:535).

As a result of these conflicts, this paper examines the ethical issues surrounding assisted reproductive technology in Western and African cultures. It focuses on offering an account of assisted reproduction as embedded in Western culture as distinguished from the African culture. For the African, there appear to be widely shared expectations regarding motherhood. This norm contrast with that in the western world where assisted reproduction is practiced and widely accepted. This therefore paper offers a comparative analysis of assisted reproductive technology in Western culture and African culture focusing not only on Africa's societal norms and values but also their religious beliefs. It argues that given the whole idea of cultural relativism in ethics, moral principles derive their validity from cultural acceptance. Hence each culture's moral principle should be seen as unique to such culture. The paper concludes by emphasizing the need to acknowledge cultural diversity in bioethics and suggests ways of handling such diversity.

Many Africans conceive of bioethics as a Western phenomenon. This is particularly so when bioethical issues and questions are framed in such a way that makes it universally acceptable to all reasoning beings (Gbadegesin, 2001:24). The perception then is that bioethics is dominated by the West. This perception applies to the focus of research in bioethics in the West. So far as this issue of focus is concerned, there seems to be a conflict between what is of concern to the West and its technological breakthroughs, and what is of interest to African culture. For instance, through the use of the new assisted reproductive technology which Africans view as Western, biological motherhood has been separated into competing components of genetics

and gestation, a separation which has given rise to disputes over motherhood and its meaning in Africa.

So many social values promote assisted reproduction. A major one is the societal expectation from couples which sees having children as a natural and normal part of life. The consequence of this is that infertile couples are under pressure to reproduce and thus seek help through assisted reproduction. Many African women frown at the Western technique of assisted reproduction because it is alien to the traditional mode of conceiving and carrying a pregnancy. Also, this technique extends the boundaries of intimacy and of traditional notions of familial kinship patterns by dispersing what was once thought of as a unified entity (mother) and making it into something without a definitive aspect or dimension (Grayson, 2000:100).

However, the implications drawn from the social value promoting assisted reproduction are numerous. First, assisted reproduction has been described as a positive response to the needs of the infertile (Frith, 1998:817). Due to the frustration of infertility, Western medical science has responded by developing techniques designed to alleviate this health problem. Also, this medical technique is seen as mechanisms for extending people's reproductive choices; a benefit for both the individual and the society. Assisted reproductive techniques has the advantage of providing benefits for society as a whole because these techniques can help prevent genetically inherited diseases and advance scientific knowledge about the human reproductive system that could have, as yet unforeseen benefits (Frith, 1998:820). Lastly, some techniques (such as AID or egg donation) can also prevent the birth of children at risk of congenital diseases known to be carried by one of the parties who wishes to parent and other approaches such as surrogacy can protect women at risk of harm from pregnancy (Purdy, 2001,163).

### **Forms of Assisted Reproductive Techniques**

Assisted reproduction is of various types. One form is AID and egg donation in which sperm is obtained from a man who is not the prospective mother's husband, and is placed in her with the aim of initiating conception. In spite of the likelihood of inadequate screening for sexually transmitted diseases which is often a major problem of this technique, AID is described as a beneficial and well-established practice that can make up for male infertility and prevent serious genetic diseases (Mahowald, 1993). There is also egg donation by a woman. This requires hormonally stimulating a woman to produce multiple eggs; monitoring this development requires frequent blood tests and sonograms. If the stimulation is successful, the eggs are then retrieved from the donor by passing a needle through her vaginal walls (Purdy, 2001: 165). Although this technique has been described as risky

(Holmes, 1988), it has offered respite to some women notwithstanding.

Similarly, IVF technique requires a woman who desires a child either to undergo egg retrieval or to acquire an egg from a donor. Sperm (usually the husband's sperm) is then introduced to the egg in a Petri dish (Walters and Singer 1982). To increase fertilization rates, especially where sperm is known to be deficient in some way, a single sperm may be injected through the outer membrane of the egg wall. Any resulting embryos are placed in the woman's uterus when they have grown to four or eight cells; often multiple embryos are introduced to raise the odds in favour of pregnancy (Purdy, 2001:165). The woman then receives frequent injections of progesterone until the twelve-week point if she becomes pregnant. Although the success rate is low different clinics have different rates of success and some versions of IVF (such as that undertaken with egg donation) have better results (Consumer Reports 1996). Many people have expressed concern about the welfare of the offspring of IVF. Yet hundreds of thousands of IVF babies are born every year.

Another reproductive technique is surrogacy. Sometimes described as contract pregnancy, it involves impregnating one woman to gestate a baby who is to be raised by another woman (Purdy, 2001:168). Rodney Mowbray (1994:849) identifies three forms of surrogacy. The first occurs when sexual intercourse is used by the husband of an infertile woman to impregnate another woman for the purpose of bearing a child for the couple. A second method involves using artificial insemination of the surrogate with sperm provided by the prospective father. A third method, in vitro fertilization, uses sperm and eggs provided by the genetic parents to produce an embryo (a test-tube baby) that is then implanted into the surrogate. The last method which is sometimes referred to as gestational surrogacy is the most complicated form of contract pregnancy; it raises the ethical question of whether genetic relationship or gestational relationship bestows motherhood on a woman.

Modern assisted reproductive techniques call into question the main idea of personal identity, intimate relationships and the beginning of life. By dividing biological motherhood into two components of gestational and genetic motherhood, the negative consequence involves degrading pregnancy and exacerbating class differences and racial inequality (George, 1988:27-33).

For many couples however, procreation now includes the participation of additional parties such as health care professionals, surrogates, donors, and increasingly, the state. No longer belonging to the realm of private acts and decision making of couples, the procreative process of assisted reproduction has become a collaborative process that takes place in the public spaces of the laboratory and the clinic. Within these public spaces, assisted reproductive techniques

such as artificial insemination, in vitro fertilization, embryo transfer and surrogacy allow a multitude of individuals to participate in a couple's attempts to conceive (Grayson, 2000:100). Also, not only is birth a process mediated by the intervention of physicians but conception has become a more complex drastically mediated process as well. The 'private, all of love intimacy, and secrecy' of creating a child, has become a 'public act, a commercial transaction and a professionally managed procedure' (See Grayson, 2000:100).

Because the advent of Western reproductive techniques have succeeded in splitting reproduction into three components parts, (genetic, biological and social), this split raises numerous religious, social and ethical issues and consequently different responses from various religious sects in different cultures. Gbadegesin (2001) sees the need for these responses for according to him, 'every culture, even the most traditional one, must develop a response to the new technologies in health care' (Gbadegesin, 2001:25). Within the African culture, religion is the opium of the people. It is the lens through which Africans view various issues. Unlike the Western world where science and religion are separated, in Africa, religious factors play crucial roles in technology assessment. Responses vary among the Roman Catholics and the Protestants on the one hand and the Muslims on the other. This suggests the fact of cultural and religious diversity. Hence the need to examine these variations from the religious perspectives of the African culture.

### **Assisted Reproductive Technologies in Cultural Contexts**

Within the African culture are people of different religious sects and cultural attitudes. It is sometimes difficult to separate culture from religious beliefs. For centuries, a fundamental concern of African women has been the struggle over reproduction. African women have been carefully trained to want motherhood, to experience themselves and their womanhood, their very purpose in life through motherhood. But in spite of the artificial reproductive technique which was invented to serve as respite to the infertile African woman, the typical African woman still considers infertility a disability. For her, the experience of pregnancy is of utmost importance. Hence assisted reproduction seems inadequate as a technological device because it erases the whole idea of mothering experience and destabilizes the African traditional notion of the family. Franklin (1995:334) explains that the emergence of assisted reproductive technology that conflates with and displaces nature has disrupted naturalizing assumptions made about the categories of 'mother', of 'family' and of 'nature' itself.

While infertility is not considered a form of disability in the western world because of the available choice of assisted reproduction, in Africa, infertility is often

viewed as a form of disability. As Deane Wells (1987:374) claims, 'the inability to bring into the world one's own genetic children in Africa is a disability in the same way as is shortsightedness' Disability in this context implies reproductive impairment. Impairment can be defined as 'the expression of a physiological, anatomical or mental loss or abnormality--- an impairment can be as a result of accident, disease or congenital condition' (OTA, 1982). The issue of infertility is so important to the African woman yet assisted reproduction fails to offer respite because it detaches an African woman from the bodily experiences of pregnancy that she would actually want to undergo. In Africa, pregnancy is linked to the essence of being female for only in pregnancy is the organic functioning of one human individual biologically inseparable from that of another (Warren, 1992 212). Hence a typical African woman would want to experience pregnancy and childbirth. This explains the uniqueness of the gestational and genetic components of motherhood in African culture.

In Africa, the basis for determining natural parentage is genetics and gestation. It is also considered a definitive form of motherhood for the African woman because total ownership depends on gestational and genetic ancestorship. The African woman, like most women anywhere, prefers the gestation of her fertilized eggs in her body rather than the laboratory or in another woman. For her, what sits in her womb in form of the fetus is quite different from what sits in her mind in terms of the surrogacy arrangement with another woman somewhere. This seems to set the surrogacy arrangement on a par with the experience of pregnancy for the African woman. There is therefore need to reflect on the many ways in which the intrauterine environment and maternal behavior during pregnancy can influence fetal and later child development to acknowledge that the genetic and gestational components of motherhood need not be separated.

Apart from the fact that the new methods of assisted reproduction separates motherhood into two components and as a result abstracts the experience of pregnancy from the desiring mother, it also alters the traditional conception of the family; a practice which is alien to Africa where respect for biological ties is emphasized.

Modern artificial modes of reproduction threaten to produce greater emotional difficulties for family members affected or pose more serious ethical problems than those already arising out of long-standing practices such as adoption and artificial insemination. Although it is easier to keep secret from a child, the circumstances surrounding artificial insemination and egg donation, such secrets have sometimes been revealed with terrible emotional consequences for every member of the family involved. Alison Ward (1988) for instance compares the impact

of surrogacy on children to both situations. According to her,

There will always be pain for these children. Just as adoptive parents have learned that they cannot love the pain of their adopted children away, couples who raise children obtained through surrogacy will have to deal with a special set of problems. Donor offspring rarely find out the truth of their origins. But some of them do and we must listen to them when they speak of their anguish of not knowing who fathered them, we must listen when they tell us how destructive it is to their self-esteem to find out their father sold the essence of his lineage for forty dollars or so, without ever intending to love or take responsibility for them. For children born of surrogate contracts, it will be even worse: their own mothers did this to them (see Chesler, 1988)

An anthropologist notes that 'the family in all societies is distinguished by a stability that arises out of the fact that it is based on marriage, that is to say, on socially sanctioned mating entered into with the assumption of permanence' (Charo, 1988:104). If we extend the notion of socially sanctioned mating to embrace socially sanctioned procreation, it is evident that the new artificial means of reproduction call for careful thought about what should be socially sanctioned before policy decisions are made. In an attempt to explain what the family stands for in Western culture, Patricia Hill Collins (1990) tries to make a case for the possibility and necessity of more diverse definitions of mother and, by extension, of father and of family which will accommodate the different methods used to reproduce and introduce babies into families. Her argument is that we should find ways to acknowledge rather than diminish or ignore the participation of all parents in the process of assisted reproduction even if the effects is to destabilize previously held notions of the family. Redefining the traditional conception of the family brings us back to the problem of destabilizing the family unit created by reproductive technology.

Another ethical issue is that artificial reproductive techniques improperly treat children and women's reproductive capacities as commodities (Corea, 1985 and Holder, 1985). For instance, surrogacy not only reduces children to consumer durables and women to baby factories, it constitutes an unconscious commodification of children and of women's reproductive capacities; all of which is foreign to African culture. This arrangement substitutes market norms for some of the norms of parental love. Most importantly, it requires us to understand parental rights no longer as trusts but as things more like property rights – that is, rights of use and disposal over the things owned (Anderson 2007:244).

The most disheartening aspect is the surrogate act of leasing out wombs to other women as a means of income; the consequence of which is the introduction of the norms of commerce into parental relationship.

Margaret Radin (1987) for example condemns paid surrogate motherhood as devaluing women in general, mothers in particular and children universally by making them 'completely monetizable and fungible objects of exchange', meaning that any one may be replaced by any other and has no individual value in itself, so leading to 'an inferior conception of human flourishing' (Radin, 1987:1849). Treating children as commodities is not only degrading but also an unacceptable practice in Africa.

However, different African religious attitudes to relations between human beings and their perceived divine creator, influences responses to assisted reproductive techniques. In many Christian communities in Africa, for instance, it is considered offensive and a condemnation that one should assume to 'Play God' with human conception and birth as an impertinent human arrogation of divine power and authority. In other religions such as Judaism, there is a perceived partnership between humans and their divine creator so that individuals' God-given-gifts' of skills and initiative are properly employed in scientific advancement and in the cure or overcoming of medical impairments including artificial reproductive technique. In this tradition, the divine creator is described as acting in ways of beneficence, mercy and compassion and 'the human being is required to imitate God in this respect' (Steinberg, 1994:67). It is important to point out that it is typical of the Western tradition to attempt to 'play God' through various technological and scientific innovations.

However, religion permeates the whole aspects of the lives of Africans who hold various religious beliefs about assisted reproduction based on the Islamic and Christian injunctions in the Holy books (the Qur'an and the Bible). The typical African makes reference to religious arguments by citing the Bible or Quran in his/her approach to assisted reproductive technique on the one hand, or traditional African societal norms and values of motherhood on the other.

"Be fruitful and multiply". This biblical injunction occurs first in the context of the divine words of the creator to the newly created human beings (*Genesis* 1:27-28). Having offspring carries on and supports the work of creation. Procreation is good from the perspective of Christian ethics, both as divinely sanctioned and as a participation in creation (Demarinis and Dyck, 1986:499). Also viewed as good, as divinely sanctioned and created is the companionship of male and female, described biblically as destined toward a 'one flesh' union as wife and husband (*Genesis* 2:18-24, *Ephesians* 5:31). These two purposes of marriage and sexual intercourse, the procreative and unitive are generally affirmed in Christian thought and action, now, as in the past. It is noteworthy to point out that Western assisted reproductive technique undermines these unitive and procreative purposes of marriage when a third party is involved making every act of marital sexual intercourse public. The Roman Catholics

in Africa rule out AID and AIH as attempts to have children without the loving and unitive act of sexual intercourse with one's spouse.

The Roman Catholics view assisted reproductive technique as an unwanted interference with nature and what is perceived as God's will. According to them, this technique is a deviation from normal intercourse and in separating the unitive and procreative aspects of sexual intercourse, the reproductive process is devalued (Frith, 1998:822). Also, to introduce a party into the process of procreation is seen as defiling the sanctity of marriage and the family. Closely related to this is the treatment of the embryo. For the Roman Catholics, Western assisted reproduction puts the embryo at risk. Health problems might turn up as they develop (Holmes, 1988:140).

However, among some Roman Catholics, moral theologians and others, as reflected in Vatican council II, it is marriage that is intended to be procreative not every marital act. This is the generally held protestant point of view. However, there are Protestants as well as Roman Catholics who see AID as a threat to the relation that should exist between wife and husband: they should both bodily and lovingly contribute to their offsprings (Demarinis and Dyck, 1986:501).

Even within the Christian sect, diversity exists as to the issue of procreation. Some protestants who approve of AIH and AID emphasize the spiritual, psychological and physical bonds between the couple using artificial insemination and the child that results. In short, nurture rather than the one-flesh bond between two people is accented (Demarinis and Dyck, 1986:501). Although Roman Catholic ethical teachings and warnings against AID have dominated ethical debates on Western assisted reproductive techniques, significant opposition to their teachings also arise from some Protestant sources.

Joseph Fletcher (1986) was an early challenger of the prevailing negative view of AID in religious ethics. Basing his challenge on Christian personalism, he emphasizes placing higher values on the personal relationship of husband and wife than their biological relationship by supporting AID as a morally valid means to overcome infertility. Fletcher viewed the practice of levirate marriage (*Deuteronomy*25: 5-6) as a clear biblical exception to an exclusive claim of husband-wife reproduction. Further, he stressed that AID emancipated human beings from natural causality and determinism, therefore providing more humanly satisfying goals and relief of the emotional deprivation of childlessness (Fletcher 1186: 537). Indeed for Fletcher, we are more human in artificial reproduction than in natural reproduction.

Another major argument put forward by Fletcher in support of AID was that the protection of anonymity of the donor by physicians effectively discounted the idea that a third person was personally involved in the sexual relationship. The outcome of a desired

pregnancy outweighed in Fletcher's view, the minimal chance that anonymously donated sperm would be wrongly interpreted by husband and wife as a real intrusion in their sexual relationship (Fletcher, 1986:537).

However, Edward Reichman (2004) has suggested adopting assisted reproductive techniques on a case-by-case basis provided they do not entail Torah prohibitions. For him, the fact that the obligation to procreate, 'be fruitful and multiply' is the very first *Mitzuab* (commandment) in the Torah reflects its significance in the Jewish tradition. He identifies the procurement of the male reproductive seeds as a major legal obstacle that pervades all discussions of assisted reproduction. The prohibition against wasteful emission of male reproductive seeds (that is outside the contexts of natural intercourse) guides many of the rabbinic discussions on this issue. The majority opinion allows sperm procurement to treat infertility, since the ultimate objective is to produce a child and to thereby fulfill the commandment to 'be fruitful and multiply'. This is not deemed a wasteful emission.

Most authorities allow any interventions, such as artificial insemination or in vitro fertilization, using the gametes of a husband and wife and consider the resulting progeny to be the couple's legal child. When introducing donor gametes, however, either sperm or egg, authorities disagree as to the permissibility. Issues such as legal adultery and bastardy, the definition of maternity in cases of a gestational host (that is a woman who serves only as the gestational mother, while the egg was donated from another woman), and psychological manifestations weigh heavily in rabbinic discussions (Reichman, 2004:98).

In Islamic discussions, seeking treatment for infertility is encouraged since it aims for the good of procreation. Though the aim is good, the means of achieving it that involves assisted reproductive techniques elicits debate. From an Islamic perspective, IVF is only permissible under certain conditions. The woman's oocyte may only be fertilized with her husband's sperm only if they are still married. There must not be a third party such as an anonymous donor or a surrogate mother. Islamic teachings absolutely prohibit insemination of the woman's egg with the sperm of another man who is not her husband. Islamic scholars have addressed this issue of using sperm donors and have declared it comparable to adultery (Mirza, 2004: 109). They therefore regard it as a grievous crime and a great sin. Similarly, surrogacy is entirely illegitimate. As the Holy Quran states, "none shall be their mother except those who gave birth".

The act of giving birth bestows motherhood in Islam. The implication of this is that surrogacy or egg donation is not recognized in Islam. Donna Bowen (2001:233) describes the act of giving birth as detailed in the Quran. According to him, the act of bringing forth new life from the womb of the mother is the only

process leading to birth in the conception of the fetus. The Quran emphasizes the sacrosanct nature of life and the honorable roles of mothers. Women who conceive, give birth and sustain infants through the period of lactation are referred to as mothers in the Quran and are noted with respect. Muslims are therefore commanded to 'honor the mothers that bore you' (Quran4:1) and to show kindness to parents for with much pain his mother bears him and he is not weaned before he is two years of age (Quran31:14).

The implication of the above is that motherhood is not separated into genetic and gestational component, a consequence of Western assisted reproductive technology. Such separation is not mentioned and hence not recognized in the Quran. The womb is recognized as the only female reproductive organ, the uterus by extension and the importance of kinship and blood relationships (Hermansen, 2001: 522). The use of the term 'womb' in the Quran most often refers either to the generative function of the female reproductive organ (Q 2:228, Q3:6, Q13:8, Q22:5, Q31: 34) or to the importance of the bonds of kinship. Some of the above verses mention womb in the context of the legal implications associated with conception and birth. A consistent pattern of interpreting the Quran is to read the references to conception, birth and human development as evidence of God's creative majesty and care for human kind. The early life stages and aspects of human biology mentioned in the Quran include conception, fetal development and growth, childbirth, lactation and weaning.

In Quran 23:12-14, reference is made to fetal development and growth. Explanations of these verses express the view that 'sperm' and 'firm lodging' refer to sperm within the female reproductive tract, more specifically within the uterus. Prior to fertilization, sperm bind to the zona pellucida or outer covering of the ovum. Following such lines of interpretation, '*alaaqa*' could be a reference to this, that is to sperm 'clinging' to the ovum. However, *alaaqa* is also interpreted by some exegetes as 'blood clots' and taken to refer to 'something that clings to the uterus'. For those modern commentators who then extrapolate this interpretation scientifically, the 'blood clot could be taken to represent the fertilized ovum or early embryo implanting itself in the endometrium or uterine lining (Abdul Fadh Mohsin, 2001:231).

Nowhere is it stated in the Quran that fertilization using another man's donation other than one's husband is allowed. Similarly, no explicit reference was made to the act of implanting an embryo in another woman's uterus. These are acts which are allowed only between legal couples who consequently are described as parents in the Quran. Terms designating 'parents' in the Quran are '*walidani*' and '*abawani*' respectively. The dual form of *Walid*, "father, one who begets a child: (the passive *al-mawlud lahu* indicates "to whom the child is born"; *Walida* mother, one who brings forth a child (Giladi, 2001:20). Natural aspects of parenthood

are particularly identified throughout the Quran with maternal functions, pregnancy, giving birth, breastfeeding and weaning (see Q16:78, Q39:6, Q53:32, Q 58:2). Maternal emotions of love and solitude find emphatic expression in the Quranic story of Moses (Q28:7-13, Q20:38-40). As reproduction is implicitly presented as the goal of marriage (Q4:1, Q7:189), God made parents the reason for the servants to come into existence (Q4:36, Q6:151, Q17:23-24, Q 31:13-14).

The above Quranic references to conception and birth is not an indication that Islam opposes technology. In fact almost all sources, classical and modern, agree that the Quran condones, even encourages the acquisition of science and scientific knowledge. Most sources also argue that doing science is an act of religious merit, and to some, even the collective duty of the Muslim community. The purpose of rejecting some scientific views is not to promote alternative ones or to assert the authority of the Quran at the expense of the various fields of scientific knowledge. But 'the ultimate challenge in any religion or spiritual group is to be able to apply its teachings to the world in which its believers live. And issues relating to biotechnology are undeniably relevant to people of all faiths and religion' (Mirza, 2004:105).

Also, African religious and cultural beliefs concerning assisted reproductive technique do not suggest the devaluation of this technique. Rather it is a reflection of cultural diversity arising from religious divergences. Culture is an important aspect of people's lives and embedded as part of people's culture is their religious beliefs. Diversity exists about various bioethical issues and this is expected and should be allowed. Bioethical deliberations are like a 'theatre' which has its own cultural roles. Engelhardt (1996:vi) calls it 'a babble of conflicting bioethics' with the word babble illuminating the phenomenon of diversity of moral perspectives. Diversity constitutes both the most specific fact or feature of modern ethical thinking in biomedicine or bioethics and a challenge to it. Engelhardt wrote:

Moral diversity is real. It is real in fact and in principle. Bioethics and healthcare policy are yet to take this diversity seriously. Taking diversity seriously, Engelhardt diagnosed the danger there is a swarm of alternative ethics ready to give rise to a babble of conflicting bioethics. This circumstance constitutes the foundational moral challenge of all healthcare policy. It brings the very field of bioethics into question (Engelhardt, 1996:vii)

The above suggests recognizing the importance of diversity. Going by Engelhardt's historic account of the value of diversity, he tries to conceive of means to grasp what is common in different things by trying to provide an account of morality that should guide individuals when they meet as moral strangers to fashion healthcare policy. His aim is therefore to offer theoretically grounded guidelines that order chaos of

public moral attitudes, making fruitful collaboration of strangers possible.

Lending support to the value of diversity, Pavel Tishchenchenko et. al. explain that bioethics looks like a kind of a competition of storytellers or tragic poets in antic theatre. Public (spectators) is the agency that grants gifts (awards) of recognition to those whose stories mostly fit their internal moral predispositions. It is the way of permanent co-evolution of public moral identity and ideology of biotechnological progress. Differently put, bioethics theatre presents a specific form of cultural selection of competing for survival, multiplicity of moral values, styles of life, and world visions, and on the other hand, multiplicity of biotechnological projects of solution of human problems. This way, humanity achieves contingent, open to reappraisal normative structures that order and stabilize the stream of scientific progress in biomedicine (Pavel Tishchenchenko, et. al. 2006:226).

Continuing in the same vein, Pavel Tishchenchenko, et. al. (2006:8) describe bioethics metaphorically as a 'dining table' with place settings offering different menus: different methods (descriptive, evaluative and narrative), different ways of questioning power relationships (participatory, communicative, political) bring their ingredients together, find suitable recipes and set their part of the table nicely. They prepare a meal, to which a range of guests (those concerned, those involved, those affected) is invited. According to this metaphor, bioethics must be an open moral reflection, taking the plurality of cultural perspectives into account at all levels of scientific and hermeneutic methodologies. A key motif for understanding how different methodologies can work together is the pluriperspectivity of moral phenomena. They are social life-born not theory-born.

The recognition of diversity about bioethical issues however calls for ways of handling such diversity. First, there is need to acknowledge the fact that 'culture' is an important aspect of people's lives and that the features of a particular culture are unique to members of that culture alone. From this assumption, whatever beliefs, ideas, and values shared by all members of a particular culture will be seen as definitive of it. This underlying assumption can then be applied to various bioethical issues. Since bioethical issues cut across cultures, culture is intrinsically related to bioethics, hence bioethics should be seen as a social phenomenon. A reflective, culturally informed bioethics also questions bioethics actions in relation to cultural and social institutions (Elliot 2004 and Sharpe, 2002).

There is also need to pay attention to the variations in values and customs among different classes, genders, races and religions. It is noteworthy to point out that cross-cultural explanation of bioethical issues is important in disclosing apparently different moral standards and moral practices among different cultures.

Every culture has gone through processes of making its societal norms and values suitably specific. It is also an obvious fact that not all cultures have given the same answers to the same problems and often, many answers have emerged from within the framework of many different cultures such as the Western and African cultures on assisted reproduction. In all cultures, the interpretation and specification of norms, the reconstruction of traditional beliefs, the balancing of different values and negotiations are essential on an ongoing basis (Hoshino, 1997:28).

Coupled with the above is the need to respect every ethnic group or community's value system and worldview. All cultures are equally worthy of respect hence we cannot make objective judgments about cultures rather only ones from our particular cultural point of view. Gbadegesin (2001:26) has suggested a transcultural bioethics, a form of bioethics which is not specific to any single culture, but forms an arena of discussion in which people from diverse cultures can all take part on an equal footing. This according to him is important not only because bioethical issues transcend any single culture but also because transcultural bioethics facilitate intercultural understanding.

Also, since each culture finds its own uniqueness within its own cultural identity, it is imperative to acknowledge and not deny the differences that exist between cultures. There is therefore need to create international networks which effectively guide those aspects of science and technology which affect our life and death, including procreation but which will not lose sight of diversity in people's cultural beliefs. This becomes imperative because ethical reasoning on the same bioethical issue can justify different ethical conclusions. For instance the process of assisted reproduction generates ethical debates about issues concerning the beginning of life and alternative technique of procreation in every culture. But while it is acceptable and widely recognized in the United States it is not acceptable in Africa because it falls short of African cultural values relating to pregnancy and childbirth. We are again faced with the issue of cultural diversity.

Again, there is need to acknowledge the fact that biomedical developments carry with them social and cultural meanings that must be taken into consideration if the accompanying bioethical dilemmas are to be understood. Also, since bioethics is a specific form and concept of medicine just like predictive medicine and regenerative medicine, in order to be sensitive to these dimension of bioethics, bioethics should include a 'cultural approach' (see Daniel, 1999; Patricia and Barbara, 2004). Whether it is acknowledged or not, cultural diversity is real in principle and in practice and hence a major challenge to bioethics.

Thus this paper has examined recent developments in the field of Western bioethics. It offered a comparative analysis of assisted reproductive techniques in western

and African culture focusing on African societal norms and values including their religious beliefs. The paper argued for the need for culture-sensitivity taking into cognizance not only the facts of diversity and differences in the Western and African approaches to assisted reproduction but also the fact that a particular culture can only be understood on its own merits and not another culture's. I invite comments from Asian, and other, readers on their comparisons to African culture.

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## Bioethical Dilemmas in a Pakistani Context

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### Introduction

Since the dawn of the Industrial Revolution in the 18th century, science has had a profound effect on the way humans interact with, and act upon nature, largely through its applications in new technologies. On one hand science has brought about technologies that help save human and non-human life. Some of the dramatic examples are the kidney dialysis machine, artificial valves for sufferers of coronary heart disease, antibiotics, vaccines, new varieties of crops and a wide range of other drugs. At the other extreme, science can also breed technologies that are designed to deliberately hurt or to kill. The bitter fruits of this research include chemical and biological warfare, and also nuclear weapons, which are by far the most destructive weapons that the world has ever known.

Both the constructive and destructive technologies bred by science raise complex ethical questions. This is particularly true in the fields of biology and medicine where technologies such as genetic engineering, cloning, and *in vitro* fertilization give scientists the unprecedented power to bring about new life, or to devise new forms of living things. To address these ethical questions raised by technological advancements in biology a new subject i.e. Bioethics has emerged.

The term ethics is derived from Latin root *Ethos* i.e. character or *Ethikos* meaning arising from habit. Ethics is actually a branch of Philosophy concerned with the nature and ultimate value and the standards by which human actions can be judged right or wrong. It has sometimes been defined as a "particular systems of principles and rules concerning duty" [1].

Bioethics is "a means by which we organize complex information and competing values and interests and formulate an answer to the question 'What should I do?'" According to Darryl Macer, Bioethics can be defined as "the study of ethical issues and decision-making associated with the use of living organisms" [2].

Bioethics deals with the ethical implications of both biological research and the applications of that research. Although ethical issues have been faced in medicine and biology since ancient times, the large scale introduction of new technologies in recent times has reemphasized old issues and introduced new ones,

such as the withdrawal of life sustaining medical treatment, prenatal diagnosis, storage of frozen human embryos and the use of human and animal fetal tissue for scientific research. Needless to say, these are complex issues which warrant in-depth analysis by well informed scholars. There is absolutely no doubt that the study of bioethics can be enormously useful in focusing attention on problems that need to be confronted. However at the other extreme, it can become a name-calling argument between competing schools of thought such as the "pro-biotechnology" and "anti-biotechnology" which may reduce discussions to epithets and clichés.

The bioethical questions are in the form of ethical dilemmas. A dilemma implies that "there are good reasons for mutually exclusive alternate solutions to the problem". Disagreements on bioethical issues will always persist because we shall never have a single theory or method for resolving dilemmas because we derive our moral values from many sources such as religion, law, culture etc. However, we can work towards resolution of ethical disagreements through the following.

- i. Obtaining objective information.
- ii. Providing definitional clarity.
- iii. Using examples and counter examples.
- iv. Adopting a code of conduct.
- v. Analyzing arguments.

### Bioethics in Pakistan

New technologies pertaining to human health (e.g. Organ trade, Organ transplantation, reproductive health etc) plant / animal genetic improvement (e.g. Genetic Engineering, Tissue Culture, Cloning etc) and Industry (e.g. Cloning, Genetic Engineering) are recent introductions into Pakistan. Currently, however a number of organizations are actively involved in research in these areas. The introduction of these new technologies have highlighted the bioethical dilemmas associated with them.

Bioethical issues are sometimes raised by relatively low tech developments such as the introduction of "the pill" and other contraceptives technologies. Although not many people in Pakistan are bothered by the ethical questions associated with gene therapy for example, however, the use, abuse or non use of contraceptives have proved to be a divisive issue in Pakistan. The government, worried by explosive population growth rate has encouraged the use of contraceptives, however there have been opponents to the use of contraceptives since their very introduction.

In early days contraception was imagined as prohibited by the religious leaders and society. Many baseless rumors have been heard. Some were against the methods of birth control and others were against about the idea. But with the passage of time those people were guided through training and workshops. Many government and non government companies

were established for working on contraception. But still there is a controversy about contraception.

We are proud of living in the age of 'enlightened moderation', and brag about being the civilized lot, yet, when it comes to a choice between a baby boy and a girl, the majority of the couple opt for the former. According to a newspaper report 7000 girls are exterminated in India, largely because female fetuses are aborted after the sex determination tests. Female foeticide is also common in our country Pakistan as males are considered an asset in our society as well. Morally, legally, ethically and on religious basis abortion is illegal because it is said that it's a kind of murder of a human. And Islam forbids it. But on the other hand if a girl is pregnant in case of rape what will be her position in the society and who will be the responsible person for look after the baby born? Under section 338 abortion is illegal but it is allowed in certain cases when mother is medically unfit. But still there are 45 illegal centers in Pakistan who openly provide abortions.

Another bioethical issue which has emerged in Pakistan is the organ transplantation and the organ trade associated with it. Last year a newspaper report shocked Pakistani people which was "66% of the 2,000 transplants performed in 2006 were for foreigners which has given Pakistan a bad name as the 'organ bazaar of the world'". More than 50,000 Pakistanis are awaiting organs. About 2/3rds of those are awaiting kidneys alone. Other organs in need include lungs, pancreas, heart, and intestine. About half of those needing an organ transplant will never receive one, and most of those who do must first wait several months or years. Many people each day die waiting for organ transplants, and a new name is added to the Transplant Waiting List every day. The organs to be donated by the donors should be used in the country. A well organized committee must be there to handle all the related aspects of organ transplantation and donation, and that must also be responsible for the making the rules and regulations for the organ donations and transplantation.

Such other issues have also been raised by the media all over the world, but in our country they have not been introduced yet, like issues about stem cells research, cloning, GMO's and other advance technologies.

### **The Rising of Bioethics in Pakistan**

In 1984 Aga Khan University Karachi became the first Pakistani university to introduce biomedical ethics in the curriculum of medical students. Later on similar courses were also introduced into curriculum of the Nursing School of the same University. In the late 1990s, a journal "*The Pakistan Journal of Medical Ethics*" was started. However the same could not be published on sustained basis and is intermittently published.

There is a growing realization and a keen interest in highlighting, debating and addressing bioethical questions. Most international scientific journals are also demanding ethical review of research. International organizations such as GFBR are also attempting to create awareness in developing countries such as Pakistan. The GFBR selected Karachi, Pakistan as the venue for their annual meeting held in 2006.

In 2002, the Pakistan Medical and Dental Council (PMDC) published a Code of Ethics for medical professionals. The code was designed in the light of the Islamic Moral and socioeconomic principles. The basic principles already referred to have also been incorporated in the code. PMDC has also recommended that education in bioethics be made part of the curricula in medical institutions.

In 2004, Government of Pakistan approved a National Bioethics Committee (NBC) in the Ministry of Health. The NBC is "an advisory body dealing with all aspects of Bioethics in the Health sector in the country".

A Center for Biomedical Ethics and Culture (CBEC) has been inaugurated at Karachi University. The centre functions to explore the role of cultural social and religious norms in shaping indigenous value systems that are seminal components of human moral comprehension"[3]. CBEC is also training many professionals in bioethics.

Some of the religious institutions have also showed interest in bioethics in Pakistan. "This discussion is examined in light of law and the two major sources of guidance for Muslims i.e. Holy Quran and the Sunnah sayings and the ways of life of the Holy Prophet (P.B.U.H)" [4].

### **Conclusion and Recommendation**

1. In a country with low literacy rate one should expect low level of awareness about Bio-ethics issues. Awareness needs to be created at all levels so that people can formulate a "considered opinion" rather than blindly following others.
2. Bio-ethical issues should be openly debated through print and electronic media, Seminars, conferences and workshops should be held to encourage interaction between experts, academicians, researchers, students, policy makers etc.
3. The curricula of educational institutions including Universities, colleges and schools should include advanced or introductory courses on bioethics.
4. Every professional organization, whether it is related to Biological sciences or not must have their own Code of Ethics like Pakistan Medical and Dental Council (PMDC).
5. The government should know its responsibilities and should provide the necessary legal and regulatory frame work for dealing with bioethical issues and concerns. The government should institutionalize consultations among all state holders including legislators, policy makers, technical experts, Public representatives,

farmers and industry.

6. Ulemas and religious scholars should be consulted for their opinion while formulating laws or rules and regulations concerning bioethical issues.

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