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Send papers to the editor in electronic form if possible. Please use reference style used in News section, do not use automatic footnotes or endnotes. Papers are peer reviewed.

Deadline for the May 2005 issue is **1 April, 2005**.

Editorial: Across Cultures

- Darryl Macer, Ph.D.
Director, Eubios Ethics Institute
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This issue of the journal continues to include a wide variety of papers, in their views, content and topics. The authorship is from a wide section of global society, and the views reflect that. In the spirit of academic freedom Eubios Ethics Institute will continue to publish a range of papers, and these will continue to be freely accessible on the web. The papers from bioethics around Asia, Pacific and the globe will be available on the UNESCO Bangkok website as well as remaining on the University of Tsukuba website. Updated information will appear more readily in Bangkok, given my new location and the new editorial address there. The views in the papers published in journals and books of Eubios Ethics Institute may not be the views of the Institute but are those of the authors, and this spirit also is part of the respect for cultural and idea diversity by UNESCO.

In this paper there are several papers from persons in developing countries, as well as issues of cultural debate. Female circumcision is a controversial topic, and the article discusses some of the cultural aspects. There are also views on ethics in China, with comments also from persons outside of the country. It is important to have global and open debate on bioethics questions, so these papers are written in that spirit.

The preliminary draft UNESCO IBC Declaration on Bioethics is included for feedback, as this draft will be discussed at meetings of government experts in the coming months. The IBC has made much progress in the drafting, and we wait to see how government experts with a range of views will respond. Readers comments are welcome.

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Death's Doorstep

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Abstract

At around 25, the prospect of living to 100 may seem like a fine idea, but up here around 45, the idea is a lot less attractive. As science and medicine continue to barrel forward in their attempt to eradicate disease, millions of people will be living well into their 90s and beyond, but evolution is still sorely lagging behind so, in many cases, varying degrees of debility compromise the quality of those lives. More options must be made available to the individuals who will suffer the affliction of 'everlasting life' here on Earth.

Introduction

It has been speculated that by the turn of the next century, we will know the molecular basis for all genetic disease. This is meant to be the good news and carries the implication that we will eventually be capable of curing or controlling all these diseases. We are also diligently aiming to eradicate pathogenic causes of disease as well as cancer and any other disease of known or unknown origin that threatens us. Before long, there will be nothing left to die of and the chance to stand on death's doorstep will become ever more remote. Some say that unchallenged, the human being could potentially last 150 to 200 years. [1] Theoretically this may be true, but a visit to any nursing home or acute care facility provides compelling evidence to the contrary. Biology has clearly been outstripped by the advances made in science and medicine and individuals are suffering in the chasm. No effort has really been made to ensure the quality of these extended lives nor has provision been made to 'opt out' of this science experiment. With our heightened regard for autonomy in life, one might hope there would be more choices available to people nearing its end and wonder why there are not.

The Way We Were

Our attitudes toward death have changed over time. Before the middle ages, death was recognized as a fate common to all mortals and, as our destiny, was accepted calmly, with resignation or solemnity. The dying presided over the events surrounding their death, put their affairs in order and died simply and quietly at home. [2] Death was familiar, expected and didn't cause a great stir.

Subtly our attitudes changed however. We began to push death away physically and metaphorically, to weigh it down with notions of good and evil, of judgment and shame. It became macabre and associated with failure. Death became something to fear and avoid. In time, the dying delegated to family members the responsibility of executing their last wishes, thereby relinquishing their power and allowing others to "assume the burden of their ordeal". [2]

By the mid twentieth century, the physical place where death occurred became the hospital rather than the home and again power shifted, now to the doctors and the hospital staff, who came to dominate our final exit, determining when and under what circumstances a person would actually be declared dead. The criteria for death began to shift from cessation of cardio-respiratory function to brain function and even to the irreversible demise of certain crucial parts of the brain stem. [3] Controversy still surrounds the issue but it is a somewhat interesting side note that in death we would be content to be defined by our most basic organismal functions such as respiration and heartbeat, but in life we insist we are centers of consciousness and will only be defined ontologically, by our highest human functions. [3]

A Sea Change

In the mid-1960s, technological advance produced the means to support life artificially for indefinite periods of time. [1] Hospital visits became traumatic events, requiring visitors to brace themselves before entering the room where their loved one lay punctured by various tubes, breathing in time to the respirator. But something very interesting happened. Many soon realized that although possible, sustaining life in this manner was not desirable. We recoiled from the idea of prolonging life by mechanical means and death appeared preferable to interminable life. In our long trajectory away from death, we paused to reflect and concluded that we no longer wished to die a dehumanizing death in hospitals but rather to return home to die in the midst of our families. Further, our trust in the medical establishment was shaken and we took steps to exercise our autonomy, to take back the power of determining how our life would end. We wanted our dignity back. We wanted our destiny back. While we may now make scapegoats of the medical establishment for allowing such death-defying systems to exist, we would have been as vociferous in our criticism had they chosen to withhold available means of life support and accused them of not enlisting every accessible resource. The advent of this technology was so rapid that the mercilessness of it may have only been recognized after its implementation had already been effected. The quest for progress may to us, at times, seem myopic, but it is the role of science to expand the bounds of human knowledge, while medicine and technology provide the means by which to implement such expansion. The role of responsibly determining how best to utilize this knowledge falls to the rest of us.

In any event, the voice of the people was heard and the tide began to turn through the introduction of such devices as advance directives and living wills. Meanwhile, however, the standard of care came to include life support technology. It can be extremely useful in many cases and some individuals still aggressively demand it, even when futile. At this time, individuals must proactively elect to refuse life-sustaining interventions and advance directives are intended to ensure patient autonomy and consensual rights to treatment should their decision-making capacity become impaired. In their living years, it is often difficult for some to contemplate their own death, no matter how imminent or remote, so only a small percentage of people actually possess such documents, but it is a growing trend. [3] Unfortunately, these documents are being ignored by some in the medical profession. Such persons have been labelled paternalistic, but there is no reason to doubt the contention that the authors may not have clearly articulated their wishes for the particular situation they now face or may not have possessed sufficient knowledge to draft an unambiguous, informative document and there is still less risk to the career of the medical professional in choosing to sustain life. This is especially true when there is disagreement among family members or other loved ones as to which course should be taken or an actual material document cannot be produced. In time both sides can be expected to become more accustomed to this new practice and autonomy of persons should ultimately be respected in this matter.

Death and Dying

While dying in hospital became unattractive, death at home was often not the best option either. Constant care and monitoring is often required which family members may not be prepared to provide. Hospice formed to fill the great need of care for the terminally ill and offered the sought after alternative of death with dignity, which, it turned out, could often best be provided at home. They assist with end of life affairs and offer palliative care, fostering peaceful death and, if at all possible, attempt to afford the patient an opportunity to discover meaning in life and grace in dying. [4]

In the meantime, advances in science and medicine continue to increase the human lifespan. Medications are steadily becoming available to control chronic ailments and stave off heart attacks, strokes, high cholesterol and anything else that ails us. New breakthroughs are regularly reported in the news, leaving the impression that we can fight our diseases, triumph over nature and overcome death. Facing the double barrel of science and technology, our population will age but won't die.

In response to the burgeoning aged population, nursing facilities were established to care for the elderly when their health begins to fail and adequate long-term care cannot be provided at home. This solution is not without its problems, but given our modern lifestyles, it is often the most suitable alternative available and the elder care field is expected to continue its explosive growth.

Hell

When did the perpetual extension of human life become a common goal? When did we become so preoccupied with the preservation of physical life? Was this matter actually considered or was it just a consequence of furthering our knowledge? As the population ages, physical and mental debilitation increases. Organs fail, immunity wanes, bones weaken and break. Osteoporosis bends us over and arthritis won't let us straighten up. Our senses decline so we can no longer enjoy many of the activities that made life pleasant. 10% of people over age 65 and 50% of people over age 85 can expect to suffer Alzheimer's or other forms of dementia. [5] Onset of these diseases can be slow, leaving us acutely aware of the predicament in which we will place our loved ones. As physical pain and mental torment begin to consume us, we become dependent on anyone around us for assistance even with everyday tasks. Often only strangers are left to shoulder the burden, as family members and friends have themselves died or must take care of the business of living their own lives. Our lives can become essentially meaningless, leaving us to suffer alone the indignity of insignificance, merely lingering until the heart stops or the brain ceases to function or whatever combination of fatal symptoms is currently in vogue. But in our society, all are essentially powerless to do anything about it.

Further Transformation

As our ideas about death have changed, so have our ideas about rational suicide and voluntary euthanasia. A visit to any nursing or acute care facility is enough to convince anyone that these people are not enjoying life, are not "delighting with their friends" as the brochures promise, are not likely to experience sudden spiritual growth spurts. Many can no longer get out of bed or communicate. A surfeit of age has precluded any notion of death with dignity. Reportedly, a small but significant number of the elderly want to die but cannot because the means are not available to them. [1]

Seeing all of this, some of us are finally feeling compassionate enough to realize that it may be that allowing or helping them to die is the only morally right thing to do. [1] We question if it is any more beneficent to force them to live by natural means than it would be to force them to live by artificial means. We wonder if these people are trapped in life only because medical science closed off all the exits and society is too afraid of death to utter its name. Just as we turned away from prolonging life by artificial means, we hope that we may now turn from the extension of meaningless life. Perhaps a sea change is required here too.

Today suicide is coming to be seen as one way to assert the dignity of human life when circumstances become intolerable. [4] Some have called suicide the ultimate autonomy, an affirmation of life that restores personal sovereignty and a sense of power in the face of perceived powerlessness and acceptance of it is growing. [4] Suicide is the 13th leading cause of death among people aged 65 years or older and the rates are continuing to rise. [6] Physical pain and mental distress are not the only issues considered in the decision to end one's life, as oftentimes sufficient comfort can be provided and the desire remains. After a century of living, perhaps ordinary mortals are simply exhausted and ready to move on. They have come to terms with death and realize there is no honor in merely continuing to exist because the biological apparatus we house won't succumb in a manner appropriate to the current medical definition of death. Physical deterioration has prevailed, any human potential has been fulfilled and dignity now hangs in the balance. Lingering indefinitely serves no purpose, continued existence is more dreaded than desired and the autonomous decision that it would be better to die should not be disregarded. Given their predicament, isn't it our duty to provide them a way out if they want one? Shouldn't the final word be theirs? It's time to make up our minds to respect personal freedom and autonomy in death as in life and let individuals decide if their circumstances are tolerable. [7] But if, while still able, one expressed the desire to end their life, no one could or would help them. Suicide has long been diligently stigmatized as an act of madness, selfishness, malice, cowardice or hopelessness. Assisted suicide is against the law too, no matter how compassionate or benevolent the intention and still widely considered unethical [3], except apparently in the Netherlands. [7] Instead they must wait.

Why do we have such a difficult time letting people go? Is it our old fear of the unknown that makes us cling so tightly to life? We are afraid of death because we don't understand it? We have concocted plenty of stories to explain death, as we tend to do when we don't understand something. We need to comfort ourselves in some way to allay our fears, to protect ourselves from the unfamiliar. We trot out heaven and pearly gates, reincarnation or everlasting life in a much better place, but as soon as someone speaks of life ending, we become absolutely certain that living is better than any conceivable afterlife, let alone death. We know that dying is a natural part of the cycle of life, that life is supposed to come around and go around, so why won't we let that happen? We want instead to preserve life at all cost, to extend life indefinitely. We selfishly want loved ones to stay around, even if they're suffering. We want them to have every available test, every available treatment even if further treatment only constitutes more burden. We impose our belief systems on them, act on our own fears and prejudices born of fear. Do it for your family, we tell them, be strong, be a hero, beat this thing, hang in there. What kind of cruel and unusual people are we anyway, when all they want is to stop the pain, end the suffering. Is this how we value life? We won't accept rational suicide or voluntary euthanasia but we will let people languish indefinitely in an institution? What is our attachment to life that makes us force people to endure whether they want to or not?

Each person possesses a unique perspective, shaped by experiences and relationships. What is meaningful in our lives, how we define suffering, how we tolerate pain, are all determined on a personal basis. How we live is reflected in how we would wish to die and each individual should have the opportunity to choose how they would want their life to end. It is not for us to decide how or when other people will die, no consensus should be required and the options available should accommodate all our diversity. We say we want everyone to contemplate their own death and make advance preparation for it, but our ultimate fate remains in the hands of others.

Finally, though, the tide is beginning to turn on this issue as well. Some are starting to see that for the terminally ill at least, release from life can be an acceptable, even compassionate act. Of course, most cling closely to the very narrow segment of the population for whom they believe suicide can be considered and have specific conditions that

must be met. For instance, the dying person must be terminally ill from a painful condition that offers no realistic hope of recovery, must have undergone all available tests and treatments, must be of sound mind and of course must have consented to and be capable of ending their own life so as not to implicate anyone else. [1] But at least the dialogue has begun and the first steps are being taken toward greater acceptance of each person's right to die.

There are always those who broach the 'slippery slope' arguments to assist us in fortifying our standpoint. 'What if' people are coerced, what if people feel duty-bound or burdensome, what if unscrupulous caregivers take it too far, what if this all gets out of hand and becomes involuntary euthanasia or outright murder. There are risks associated with any action and uncertainty attends novelty; we will, as always, do the best we can to protect as many as possible from the risk of unwanted consequences. We will try to do what we know to be the right thing, spare unnecessary suffering and distress, and make compromises when necessary. There is no reason to limit the choices available and leave good people to suffer just because there are bad people. We can always find excuses not to act, to maintain our comfort zones because we are afraid. We could do ourselves and our fellow beings a world of good by just working to overcome our fear of the unknown, lessen our resistance to new ideas, and become more tolerant of different viewpoints. The lines can always be drawn differently [7], or as Proust said, "The real voyage of discovery consists not in seeing new landscapes, but in having new eyes".

At any rate, no such drastic measures as the implementation of mandatory euthanasia or withdrawing treatment at a particular age are being suggested. To be sure there are many nonagenarians and centenarians leading full lives, still mentally and physically spry, some swearing by daily regimens of a shot of bourbon and a cigar. Perhaps we have taken our duty to preserve life too far. Terminating life or failing to lengthen it as long as possible need not be viewed negatively in every situation. In many instances such acts can be viewed positively, as beneficial to the patient, which should be our first concern. Having more choices available at the end of life would ensure people the freedom to choose when and how their life would end, without having to do it themselves, alone and in secret. No one should have to resort to starving themselves or inflicting physical violence upon themselves when the means for a quiet, peaceful death can be afforded. We owe them that; we owe ourselves that.

Conclusion

For all our pride in our ability to contemplate our own death, it doesn't seem to have done us much good so far, when it comes right down to it. Compounded by the problems generated by modern medical science, it has primarily allowed us to create for ourselves a lot of ambiguity and confusion. Perhaps now, as we return to each person ultimate control over their life's end, we will be poised to realize some benefit from this expressly human trait.

It is at times disheartening to step back and look at humanity as a whole, seeing us muddling through, our potential seemingly lost in "the labyrinthine wellsprings of human motivation". [8] They say evolution has no real purpose, no direction, no motive of benefitting life so progress more or less ebbs and flows, but one might hope for better than that in the moral and spiritual evolution of man. With our acquired knowledge and experience, we could by now have more firmly taken hold of our destiny and yanked our collective selves in the direction of progress toward greater acceptance of our differences and reduced suffering for all. Selfishness and pain don't have to be part of the human condition forever and one can only hope it's true that we are still at the beginning of our evolution as a species [9,10] and, as usual, it's just taking us a long time to get started.

References

1. McGee, Glenn, editor. *Pragmatic Bioethics*, second edition. The MIT Press, 2003.
2. Aries, Philippe. *Western Attitudes toward Death*. The Johns Hopkins University Press, 1974.
3. Holland, Stephen. *Bioethics, a Philosophical Introduction.* Polity Press, 2003.
4. Moller, David Wendell. *Confronting Death, Values, Institutions and Human Mortality.* Oxford University Press, 1996.
5. Alzheimer's Association. Available at http://www.alz.org/AboutAD/statistics.asp
6. Doka, Kenneth J., editor. *Living with Grief: Loss in Later Life.* Hospice Foundation of America, 2002.
7. Singer, Peter. *Practical Ethics*, second edition. Cambridge University Press, 1993.
8. Wilson, Edward O. *Consilience - The Unity of Knowledge*. Vintage Books, 1998.
9. Thomas, Lewis. *The Lives of a Cell.* Penguin Books, 1978.
10. Lecomte du Nouy. *Human Destiny.* Longmans, Green and Co., 1947.

Humans, a species with parapatric populations (?)

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We have appreciated the paper "Biological views of the inexistence of human races." by Oliveira and Ferreira (2004), and agree with the views, expressed therein. On this aspect of human biology we have some thoughts, which are expressed in this communication.

That the modern man (*Homo sapiens*) is a single species is well proven. Before dealing with the problem of human geographic variability, let us reaffirm that the present day humans are conspecific. The concept of biological species has been clearly defined by Mayr (1940, 1942, and more recently Mayr and Ashlock, 1991). Mayr (1940) said, <Species are groups of actually or potentially interbreeding natural populations, which are reproductively separated from similar other groups.>. This modern genetic concept started taking shape much earlier. Poulton in 1904 in his address <What is a species?>, which was subsequently published in The Proceedings of the Entomological Society of London, gave a description of species almost amounting to the modern concept (Mallet, 2004). Mallet says that only one month before this address Alfred Russel Wallace, who is often recalled as the coauthor of the theory of organic evolution with Charles Darwin, presented a copy of his book on mimicry to Poulton. In the last two chapters of the book it was pointed out that highly polymorphic *Papilio* butterflies should be regarded as one species, as quite different looking individuals could be seen in copula. This part of the book appears to have influenced the species concept of Poulton.

Now let us apply the biological definition of species to humans. It is known that the so called "races" of man, living in different geographical areas, can successfully interbreed, producing healthy and fertile offspring. As Bates (1963) has pointed out, <There is ample evidence that the most different looking individuals from most remotely separated parts of the world can interbreed if given opportunity. Norwegians, Australian aborigines, Bushmen, Malays and South American Indians are all perfectly capable of interbreeding and

producing healthy and completely fertile offspring.>. Thus the human "races" are not reproductively isolated; hence they have to be regarded as conspecific.

Next let us consider the geographical variations presented by human populations. Are humans a polymorphic species? Mayr (1963) has defined polymorphism as discontinuous intrapopulation genetic variability. He has further pointed out that the morphs or variants in a case of polymorphism are strikingly different. Verma and Kalaichelvan (2004) have inferred that generally polymorphism results from initial geographic or ecological isolation followed by secondary migrations and consequent gene flow. Human "races" have had geographic origin, and people have been migrating . But before we call the human species polymorphic we should recall that man has been restlessly migratory. Large scale migrations started early in human history, much before the modern means of transport were available. Budhism, spreading eastward reached even China and Japan. Christianity from the Middle East swept Europe and later the New World. Islam extended its range southward to the northern parts of Africa, and also to the east even reaching the Far East. These human migrations have been accompanied by extensive "racial" intermixing. Because of large scale and long range migrations broad clines have resulted between the "races". (Cline, a term introduced by Huxley, refers to a character gradient.) Hence the variations among "races" cannot be called discontinuous. As has been said in the definition of polymorphism, given above, variations among morphs should be genetic. But Oliveira and Ferreira (2004) point out that through <extensive genetic studies of several human populations from different continents…..it was verified that the human diversity was higher inside the "racial" or geographic groups than among them.> Further it has been said in the definition that the morphs in polymorphism should be strikingly different. But in view of a very large range of variations in each "race", quite some of it due to environmental factors, mostly socioeconomic in nature and also resulting from a fine distribution of labour in a human society, it is very difficult to make out strikingly and consistently different features between different "races". A sailor in Britain, working generally well exposed to sun, may be as brown in his complexion as a clerk in Punjab, India, working during most day light hours in the shade of his office. Thus humans cannot be regarded as polymorphic.

Oliveira and Ferreira (2004) are very correct when they say that the racial concept is <imprecise> and <subjective>. "Race" has no taxonomic recognition. However, "race" has been generally used as an alternative term for "subspecies" specially by <taxonomists working with mammals, birds and insects> (Mayr and Ashlock, 1991). Futuyama (1998) has also pointed out frequent use of the term "race" in place of "subspecies". According to Mayr and Ashlock geographical subspecies are to be named only if they differ <taxonomically, that is, by sufficient diagnostic morphological characters>. They have also said, <The breeding ranges of two species may overlap, but the breeding ranges of two subspecies of the same species do not.>.

Geographically varying human populations cannot be regarded as subspecies, because we cannot point out taxonomically significant and consistent differences between them, and their breeding areas broadly overlap. So, if use of the term "race" is given a scientific status by regarding it as an alternative to "subspecies", it is certainly not applicable to human geographic variants.

Smith (1965) introduced a new term "parapatry", which has been an addition to the set of two older terms, often used in population studies, namely allopatry and sympatry. Sympatric populations are those which occur in the same geographic area, that is they are without geographic isolation between them. Allopatry refers to populations or taxa, living in different areas, separated by a distributional gap, and, therefore they are with geographic isolation among them. Parapatry was coined to describe two continuous populations, which are in contact. Should we refer to human geographic populations as parapatric? But then there are wide clines between such populations, extending deep on either side into the population zones. Bates (1963) points out that in Mexico 60% of population is result of marriages between American Red Indians and Europeans, and in Urals most of population is due to hybridization between Europeans and Mongoloids. He further says that half of the present world population has resulted from "racial" intermixing not far back in past. Thus human geographic populations are not merely in contact, they have, genetically speaking penetrated deep into each other's range. Hence we hesitate to call human populations parapatric. Perhaps we may call them parapatric till a better suited term has been introduced by human biologists and taxonomists to more adequately describe the relations among varying human populations.

References

Bates, M., 1963. Man in Nature (Indian reprint). Prentice-Hall of India Pvt. Ltd., New Delhi.

Futuyama, D.J., 1998. Evolutionary Biology. Sinauer Associates, Sunderland.

Mallet, J., 2004. Perspectives – Poulton, Wallace and Jordan: how discoveries in *Papilio* butterflies led to a new species concept 100 years ago. Systematics and Biodiversity, 1(4): 441 – 452.

Mayr, E., 1940. Speciation phenomenon in birds. American Naturalist, 74: 249 – 278.

Mayr, E., 1942. Systematics and Origin of Species. Columbia University, New York.

Mayr, E., 1963. Animal Species and Evolution. The Belknap Press of Harvard University Press, Cambridge, Massachusetts.

Mayr, E. and Ashlock, P.D., 1991. Principles of Systematic Zoology. McGraw-Hill Inc., New York.

Oliveira, S.F. and Ferreira, L.B., 2004. Biological views of the inexistence of human races. *EJAIB*, 14(2): 59 – 61.

Smith, H.M., 1965. More evolutionary terms. Systematic Zoology, 14: 57 – 58.

Verma, K.K. and Kalaichelvan, T., 2004. Polymorphism and microtaxonomy in

Chrysomelidae. In: New Developments in the Biology of Chrysomelidae (Editors P. Jolivet, J.A. Santiago-Blay and M. Schmitt). S.P.B. Academic Publishing bv, The Hague, The Netherlands. p. 213 – 224.

Genetic Testing and Research – Ethics and Legislations

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Abstract

Technological advances in the field of genetics have brought some major issues into limelight concerning the rights of subjects under study and outcome in the form of benefits and risks associated with the genetic research. Applications resulting in genetic testing (when and who), gene therapy and cloning will potentially do much to reduce the impact of human diseases and improve the quality of life of nearly all our community. However, many ethical issues arise from how these applications should be implemented and other perceived uses of this technology. Genetic information is being generated much more quickly than our legal and social service system can respond. Some of these issues will involve both

health and life insurance and many legal factors may also need consideration. However, these decisions will best be made when discussed by the community as a whole, encompassing the opinions of all who will be affected by the technology.

The BBC news highlighted a case of 'DNA theft', which was the hottest debate regarding the ethics of genetic testing in May 2002. Private investigators acting for the husband of a former lover stole used dental floss from the waste bin outside a millionaire's home, and tested the DNA on it. The Human Genetics commission commented that this sort of activity would be a gross intrusion into someone else's privacy. Commission calls it a criminal offence to deceitfully obtain and analyse another person's genetic information for non-medical purposes.[1]Such events are not new. There is always a negative side of the applicability of a good technological outcome and there are many other aspects related with the genetic testing also. This makes us think again about the ethics related with genetics. The misuse is not only in the applications but also at the research level.

Advances in molecular genetics and the completion of the Human Genome Project have led to the identification of hundreds of genes involved in disease causation. Along with this great technological outcome, the ethical, social and legal issues associated with these advances have also emerged and had been a major issue for public debates and government policies for the last half century. One legacy of eugenics was the establishment of an international framework of ethical guidance to protect human subjects participating in research. Since 1945, various codes for the proper and responsible conduct of human experimentation in medical research have been adapted by different organizations. The best known of these codes are the Nuremberg code of 1947, the Helsinki declaration of 1964 (revised 1975, 2000), and the 1971 guidelines (codified into the federal regulations in 1974) issued by the U.S department of Health, Education and Welfare codes for the conduct of social and behavioural research have also been adopted, the best known being that of the American Psychological association, published in 1973 (NIH report). [2] This article outlines the main principles that have been used to formulate the codes of practice and regulation to address ethical issues involved in predictive and genetic testing and how this information can be used. This article is a medium to brush up our knowledge of the underlying principles of the research proposals involving human subjects and to think twice about the legislations and ethics involved before using the genetic testing publicly.

Ethics involved in Genetic Research:

The report of National Bioethics Advisory Commission [3] addresses the concerns about protection of human research subjects. The report proposes recommendations for protecting the rights of participants and promoting ethically sound research. Other reports dealing with these fundamental questions are World Medical Association (2000), CIOMS/WHO (2002), Academy of Medical Sciences (2003). A long list of reports is available on the Internet.[4] The beauty of these principles and guidelines is that they are comprehensive and are generalized, that assists scientists, subjects, reviewers and interested citizens to understand the ethical issues. National Commission for the protection of Human subjects of Biomedical and Behavioural research [2] have emphasized on the following principles:

1. Respect for persons:

Respect for persons demands that subjects enter into the research voluntarily and with adequate information. The subjects should be given the opportunity to choose what shall or shall not happen to them. The subjects are familiarized with all the research purposes, risks and anticipated benefits, and a statement offering the subject the opportunity to ask questions and to withdraw at any time from the research.

2. Beneficence:

This involves respect of decision of subjects and protecting them from harm The pre-requisite for this outcome is the assessment of risks and benefits involved in the proposed study and these should be discussed thoroughly in documents and procedures used in the informed consent process.

3. Justice:

An injustice in ethical terms is defined as when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly. The burdens and benefits should be distributed based upon equal share, individual need, individual effort, individual's societal contribution and according to merit.

4. Confidentiality:

It means that the information disclosed by individual should not be communicated to others or used for unexplained purposes without the consent of the person.

MRC feels it essential that participants are told that their sample may be used in research which could eventually lead to the development of commercial products and that they would have no share in benefits. The MRC in principle supports the concept of commercial development of diagnostic tests based on patented information about gene sequences and mutations within such genes that result in disease or susceptibility to disease, provided cases are filed in a way where the function of the gene product is described and where a clear route to benefits for human healthcare, resulting from this information, is provided.[5] [6] Nuffield council on Bioethics recommends that those involved in the removal of tissue from donors should ensure that the explanation given to the donor is explicit about the range of intended uses of the tissue and about any risks the donor may incur either in having the tissue removed or as a consequence of its removal. Only on these conditions can the consent of the donor, and hence the procedure itself, be valid. [7]

In the developing countries the condition is worse. It arises wide range of questions and the ethics related to healthcare in developing countries are under consideration. Is it ethically acceptable to conduct research into a form of treatment in a country that may not be able to afford to provide it? The research in poorer countries is carried out on certain terms and conditions like after completion of research the pharmaceutical company will provide the treatment for free for a certain period and the people bear the risks of research in developing countries and the wealthier countries are benefited. The committees recommend that it is not ethically acceptable for research to begin without consideration having been given to what will be provided once the research is completed.[8] [9]

With the increasing number of genes being identified for complex diseases, the genetics have enabled the researchers to predict the genetic predisposition of an individual towards the disease.[10] Commercialised gene tests for adult-onset disorders such as Alzheimer's disease and some cancers are the subject of most of the debate over gene testing. These tests are targeted to healthy (presymptomatic) people who are identified as being at high risk because of a strong family medical history for the disorder. The tests give only a probability for developing the disorder. One of the most serious limitations of these susceptibility tests is the difficulty in interpreting a positive result because some people who carry a disease-associated mutation never develop the disease. Scientists believe that these mutations may work together with other, unknown mutations or with environmental factors to cause disease. But only having the mutations or susceptible genes in the DNA, does not guarantee developing a disease in the individual. The patterns like incomplete penetrance protect some individuals from developing a disease, but they pass on mutations to the next generation. Uncertainties surrounding test interpretation, the current lack of available medical options for these diseases, the tests' potential for provoking anxiety,

and risks for discrimination and social stigmatisation could outweigh the benefits of testing. Thus, the question arises that with insufficient knowledge, could these tests be implemented as genetic testing and be used to assess ability or disability of the individual for a particular job or insurance policy.

How and Where Genetic information is Used

Ethical issues are not only restricted to the unbiased selection of subject and fair collection of data with informed consent, but also the effective use of genetic information.[11] Several guidelines have been set and the legislation has been proposed to provide governance for researchers, clinicians and other health related professionals. Many of the related issues like patenting of gene-based diagnosis [12] and use of genetic information by insurers and employers have also raised many questions. [13]

Many confrontations between individuals and insurers have been reported, where insurance companies exclude vulnerable groups from obtaining insurance based upon unreliable test. This has emerged as a big concern in public interest. But the question is whether the insurers should have right to discriminate based upon certain genetic tests? Researchers have concluded based upon four surveys that only federal legislation to prevent genetic discrimination will ensure public confidence in genetics and prevent health and life insurers from using genetic test results that may be difficult to interpret. [14] This is one issue that should be given serious thought to save the public rights as well as public interest and confidence in the genetics. In this concern, The Human Genetics Commission (HGC), the Government's independent advisor on human genetics, held a joint public meeting with the Genetics and Insurance Committee (GAIC) to discuss Insurance, Genetics and Fairness. The aim was to ensure the development of a sustainable policy framework before the end of the moratorium in 2006 on the use of genetic tests for assessing insurance.[15]

Another issue that is also highlighted is the use of the genetic information in the workplace. The members of the committee on genetic information and the workplace of the National Action Plan on Breast Cancer (NAPBC) and the National Institutes of Health- Department of Energy Working Group on Ethical, Legal and Social implications of Human Genome Research (the ELSI working Group), have recommended that employers should be prohibited from using or disclosing genetic information unless it is job related and necessary. [16] Human Genetics Advisory Commission recommended that the use of genetic testing in employment should not be banned but its use should be restricted to specific circumstances like if it puts others to risk. The Commission also recommended that a common set of policy principles should be observed and that data protection principles should apply. The situation should be reviewed in five years time.[17] Individuals who have genetic susceptibility to toxic chemicals may be protected by law at their workplace. This is one benefit, which Americans may receive after completion of the Environmental Genome Project (EGP). It aims at helping people in making lifestyle changes to lower their risk. [18] People should be evaluated based upon their individual merit and abilities, and not based on predictions about their future performance or health status. In most cases genetic testing can only reveal information about probabilities, not absolute certainties.[19]

These debates led the governments to pass certain bills and set the legislation not only to restrict the insurers from using the genetic tests of the individuals, but also declared it as a criminal offence to take individuals tissue for purposes of DNA analysis. The House of Commons have also passed a bill in February 2004 regarding the use of Human tissue for research purposes and have published the regulations regarding the same. [20] A bill called 'Mental capacity Bill' has been presented in the UK parliament recently to protect the rights of the individuals who lack decision-making capacity due to any reason. [21] The questions are many but what steps governments are taking to make effective use of the genetic testing clinically. The UK department of Health [22] has set up certain plans for new investments in Genetics for National Health System (NHS). It has implemented some and supporting other specialized services to encourage and assist the clinicians throughout the NHS to incorporate genetic advances into everyday clinical practice.

Conclusions

Many ethical issues have been raised in the past decades and are matter of debate also in the present time, which led to the establishment of various legislations to protect the rights concerning consent, privacy and confidentiality of person's genetic information. But we certainly need a platform and a regulatory framework for genetics that not only protects the individuals but also encourages public interest in genetics research and implements the clinical applications for the betterment of humanity. Ethical issues are not of concern to geneticists or clinicians only, but to a common man and freedom to choose and use this potential technology for one's own betterment and of course, common good.

References

1 BBC News. DNA in the Public Domain. 2002.http://news.bbc.co.uk/2/hi/health/1998870.stm.
2 The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. 2000. World Wide Web URL: http://ohrp.osophs.dhhs.gov/humansubjects/guidance/belmont.htm
3 National Bioethics Advisory Commission: Ethical and Policy Issues in Research Involving Human Participants. 2001.
4 Committee on publication ethics (COPE). http://www.publicationethics.org.uk/cope1999/gpp/appendix.phtml.
5 Medical Research Council (UK) Ethics Series: Personal Information in Medical Research. World Wide Web URL: http://www.mrc.ac.uk/pdf-pimr.pdf
6 Medical Research Council (UK): MRC statement on Nuffield paper on DNA patenting. 2002. http://www.mrc.ac.uk/index/public-interest/public-press_office/public-press_releases_2002/public-23_july_2002b.htm
7 Nuffield Council on Bioethics: Human Tissue: Ethical and Legal issues. 2002. World Wide Web URL: http://www.nuffieldbioethics.org/publications/pp_0000000001.asp
8 Medical Research Council (UK). MRC Ethical Guidance: Research involving Human Participants in Developing Societies. 2004. http://www.mrc.ac.uk/pdf-devsoc.pdf
9 European Group on Ethics in Science and New technologies to the European Commission (EGE). Opinion Nr 17 on ethical aspects of clinical research in developing countries. Luxembourg: Office for Official Publications of the European Communities, 2003.
10 Thomas SM. Society and Ethics -The genetics of disease. Current opinion in Genetics and Development 2004; 3(14): 287-291.
11 Human Genetics Commission: Inside Information: Balancing interests in the use of personal genetic data. London: Department of Health; 2002.
12 Caulfield TA, Knoppers BM, Gold ER, Sheremeta LE, Bridge PJ. Genetic technologies, health care policy and the patent bargain. Clin Genet 2003; 63: 15–18.
13 Nowlan W.A. rational view of genetic discrimination. Science 2002; 297: 196–197.
14 Rothenburg KH, Terry SF. Before it's too late – addressing the fear of genetic discrimination. Science 2002; 297:197–198.
15 The Human Genetics Commission (HGC) and The Genetics and Insurance Committee (GAIC) meeting report: "Insurance, Genetics and Fairness - what next after the moratorium?" 2003. http://www.hgc.gov.uk/business_press23.htm
16 Rothenberg K, Fuller B, Rothstein M, Duster T, Ellis Kahn MJ, Cunningham R, Fine B, Hudson K *et al*.: Genetic information and the workplace: legislative approaches and policy challenges. Science 1997; 275:1755-1757.
17 Human Genetics Advisory Commission (HGAC): Report on Employment and Genetic Testing. The Implications of Genetic Testing for Employment. 1999.
http://www.advisorybodies.doh.gov.uk/hgac/press/press_s.htm

18 Kaiser J. Tying genetics to the risk of environmental diseases. Science 2002; 300: 563.
19 Council for Responsible Genetics. Genetic Discrimination-position paper. 2001. http://www.gene-watch.org/educational/genetic_discrimination.pdf

20 The United Kingdom Parliament — House of Commons: Human Tissue Bill. 2004. World Wide Web: http://www.parliament.the-stationery-office.co.uk/pa/cm200304/cmbills/009/2004009.htm
21 Editorial . The human tissue bill and the mental capacity bill BMJ 2004; 328:1510-1511
22 UK Department of Health White Paper: Our Inheritance, Our Future – Realising the Potential of Genetics in the National Health Service. World Wide Web URL: http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/Genetics/GeneticsGeneralInformation/GeneticsGeneralArticle/fs/en

An ethical view, from developing countries, on pharmacogenomics

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The advances on genomics studies opened a revolutionary option on therapeutics, which, if successful, may entirely change the concepts of drugs prescriptions (1). From the industrial point of view, pharmacogenomics may reduce in about 60% the costs for producing a new drug which is, actually estimated in US$880 million (2). On the hand, those enthusiastic about pharmacogenomic enhance the advantages of having the right medicine for the right person in the right dosage. Thus, a new chapter of medical practice, the "personalized medicine" is expected to cause a social revolution (3).

Despite this revolutionary perspective, pharmacogenomics, as others outstanding progress in medicine, brings various ethical concerns, mostly for developing countries.

A brief historical view of genes and drugs.

The observation that human drug metabolism depends on enzymes and proteins comes from more than half century ago. In 1946, in Japan, a physician named Takahara observed that the absence of bubbles plus a dark color shown after treating a girl's wound with hydrogen peroxide was also seen in three of her five brothers. The investigative mind of Dr. Takahara let him to the discover that the deficiency of the enzyme catalase was the cause of the unusual response to topic hydrogen peroxide, coined the word acatalasemia, suggested an autossomal recessive gene as responsible for the suggested catalase deficiency and sowed that, in Japanese, the deficient gene for catalase occurs with frequencies from 0,3% to 12% (4; 5; 6).

During the Vietnam War some American soldiers developed hemolytic episodes due to the intake of primaquine for preventing malaria infection. Later, the deficiency of glucose-6-phosphate-dehydrogenase (G6PD), in the red cells, was shown to interfering in the primaquine metabolism, causing hemolytic anemia. Not only primaquine, but many other drugs that also use the glutathione pathway for its metabolism may cause hemolytic episodes on carriers of this enzyme deficiency. The X linked recessive inheritance of G6PD deficiency facilitated its observation in males soldiers in Vietnam as well as the development of a great number of studies in various populations (7; 8; 9)

These findings plus others unusual observations on drug responses let Vogel to coin the word *pharmacogenetics* meaning the studies of genetics factors in drug metabolism. In 1971, Brewer recognized that genetics is also responsible for variations in response to environmental agents, coined the word *ecogenetics,* which concept was re-elaborated later by Omenn and Motulsky (10).

When the pharmacogenetics word was coined the science of genetics was restricted to the studies of variations in gene products (i.e. enzymes and proteins), in relation to drug metabolism. After the genome project, the pharmacogenetics studies gain one step ahead, going directly to the search of variations in the DNA and RNA molecules to be correlated to the diversity of drug responses in human (11).Thus, presently, the relationship between drug metabolism and inhered characteristic is denominated pharmacogenomic, pharmacoproteomics or even the traditional term,

pharmacogenetics (3). Sometime, the concept of these terms is not so clear, depending on special interest or terminology preference of the investigators. In the present paper, we used the word pharmacogenetics preserving its original meaning, admitting that the word "pharmacogenomic" should refer to the relationship between drug metabolism and DNA and/or RNA molecular studies explored by modern molecular biology techniques.

Social and ethical aspects of pharmacogenomics.

The social and ethics aspects of pharmacogenomics are so various and complex that allow one to select points of specific interest for developing countries.

1-The lessons from developmental biology shows that the *turning on* and *off* of genes are not well understood besides its presence from the zygote to adults (12). In addition, it already becomes clear the fundamental importance of epigenetics phenomena on the *silencing/activating* genes processes (13). Thus, the expected presence of enzymes and/or proteins on the adequate activity levels for drug personalized metabolism may not be achieved due to cultural, social and ethnics differences resulting from diverse food intake, in quality and quantity, as well as from human genetic diversity (14). Thus, mixed and undernourished Brazilians may not benefit from drugs that had been tested in well nourished Whites of the north countries and vice-versa.

2- Taking that there are so many genetic variations related to different ethnic groups, it seems impossible not to produce drugs specific for certain ethnic groups or races (15). From an ethic point of view, humanity will be less united and more challenged by pharmacogenomics, on its diversity bases. Will personalized drugs favor a more peaceful relationship among different people or the opposite?

3-A third point of concern is related to the complexity of personalized drugs prescriptions. It requires a previous DNA test which may not be absolutely conclusive but subject to probabilistic interpretation (16). Who will decide at what probability level the drug intake would be save and efficacious? Will the doctors, in general, be able to deal with DNA tests interpretations or the prescription of personalized medicine will also require the help of a geneticist or a molecular biologist? Will it be necessary to have a new type of counseling before receiving a personalized medication? Will pharmacogenomic counseling become a new practice in medicine? At what cost?

4- In developing countries as Brazil, where public health service are far from covering peoples basic health needs, who will pay for a personalized treatment having DNA tests included? Will not the personalized treatment deepener the social barriers between the poor patients and the richer ones? Will not this new type of social discrimination be more disturbing then benefic within a developing country?

5-For those that will afford and will be consumers of personalized drugs the ethics problems are also not negligible. The requirement of a DNA test previous to a treatment opens a new avenue of confidentiality risks which may be harmful to the patient and his family. The risks range from social prejudice (not treatable due to its genes), to heath insurance and employment conflicts. A new discrimination concept may arise by assigning people to the universe of the "eupharmacogenetic" patients or the opposite. Some may argue that it will be preferable to have children fathered or mothered by an eupharmacogenomic person for certain disease drugs. Will the drug industries become the designers of the genetics structure of human kind in the future?

6- What are the threshold frequencies of genetic variants that economically allow the production of a personalized drug? Similarly to the economically not welcomed production of the so called "orphan drugs", i.e. those for rare diseases, there will also be some rare genes combinations that, in spite of being good metabolizes for a certain drug, are rare in the target consumer population.

7-The overall complexity of human biology is capable of using alternative metabolic pathway in special circumstances of metabolic peculiarities. Will the DNA tests, prior to medication, be able to assess unexpected human metabolic variations either due to genetics or environmental causes? Will the promises of the right medicine, for the right person on the right dosage be really accomplished? Or shall we also expected that the "*number of reported adverse reaction for a drug increases until the middle to end of the second year of marketing*" as the traditional Weber effect (17), will also be true for those personalized medicine?

Finally, if a medical progress, as pharmacogenomics, does not, in general, changes people's life for better, can it be ethically named *progress*?

References

1- Sadée W (1999): The Human Genome Project. Pharmacogenomics. *BMJ* (319):1286-96.

2- Lipton P (2003): Pharmacogenetics: the ethical issues. *Pharmacogenomics. J* 3(1): 14-16.

Jain KK (2004): Role of pharmacogenomics in the development of Personalized medicine. *Pharmacogenomics 5*(3): 331-336.

Takahara S (1952): Progressive oral gangrene probably due to block of catalase in the blood (acatalasemia). Lancet 2:1101.

Aebi HE (1967): The investigation of inherited enzyme deficiencies with special reference to acatalasemia. *In* Proc. 3rd Internt. Cong. Hum. Genet. 189.

3- Motulsky AG (1964): Pharmacogenetics. *Prog. Med. Genet.* 3:49.

Beutler E, Yoshida A (1973): Human glucose-6-phosphate dehydrogenase variants: a supplementary tabulation. *Ann. Hum. Genet.* 37:151.

4- Motulsky,AG (1978): Multifactorial inheritance and heritability in pharmacogenetics. *Hum. Genet.* (suppl.) 1: 7.

Azevedo ES, Yoshida A (1969): Brazilian variant of glucose-6-phosphate dehydrogenase (Gd Minas Gerais). *Nature,* 222:380.

Omenn GS, Motulsky AG (1978): "Ecogenetics": genetics variation in susceptibility to environmental agents. *In* Genetic Issues in Public Health and Medicine. BH Cohen, AM. Liliersfeld, PC. Huang Ed. Charles C. Thomas.

Evans WE, Relling MV (2004): Moving towards individualized medicine with pharmacogenomics. *Nature* 429:464-468.

12 -Zingg J-M, Jones PA (1997): Genetic and epigenetic aspects of DNA methylation on genome expression, evolution, mutation and carcinogenesis. *Carcinogenesis* 18(5):869-882.

13- Kremenskoy M, Kremenska Y, Ohgane J, Hattori N, Tanaka S, Hashzume K, Shiota K. (2003): Genome-wide analysis of DNA methylation status of CpG islands embryoid bodies, teratomas, and fetuses. *Biochem Biophys Res Com* 311(4):884-890.

14 -Evans EE, McLeod HL (2003):Pharmacogenomics – Drug Disposition, Drug Targets, and Side Effects. *NEJM* 348(6):538-549.

15-Lee SS (2003): Race, distributive justice and the promise of pharmacogenomics: ethical considerations. *Am J Pharmacogenomics* 3(6):385-392.

16-Freund CL, Wilfond BS (2002):Emerging ethical issues in pharmacogenomics: from research to clinical practice. *Am J Pharmacogenomics* 2(4):273-281.

17-Harnell NR, Wilson JP, Patel NC, Crismon ML (2003): Adverse event reporting with selective serotonin-reuptake inhibitors. *Ann Pharmacother. (*37)10:1387-1391.

Biotech Patents in Australia: Recommendations of the Australian Law Reform Commission

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I. Introduction*

The patentability both of genes and gene sequences as such or as part of a technical procedure raises serious legal, economic and ethical problems. Most recently, the Australian Law Reform Commission published its elaborated report on Genes and Ingenuity: Gene Patenting and Human Health.[1] Established in 1975, the Australian Law Reform Commission is a permanent, independent federal statutory corporation, operating under the Australian Law Reform Commission Act 1996 (Commonwealth). The Commission's recommendations provide advice to government but do not automatically become law. However, nearly 80 per cent of the reports have been either substantially or partially implemented.[2] In the following, the latest report's most relevant outcomes are described in brief.

II. General Aspects of Patentability

The ALRC states that patent applications relating to genetic materials and technologies should be assessed according to the same legislative criteria for patentability that apply to patent applications relating to any other type of technology.[3] Vice versa, the Patents Act 1990 (Cth) should not be amended to exclude genetic materials and technologies from patentable subject matter.[4] The ALRC also suggests to restrain from expanding the existing circumstances in which social and ethical considerations may be taken into account in decisions about granting patents.[5] However, the ALRC calls for an amendment which includes "usefulness" as a requirement in the examination of an application for a standard patent and in the certification of an innovation patent, providing that this requirement is only satisfied if the patent application discloses a specific, substantial and credible use.[6]

This approach corresponds with the European point of view, according to which the industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.[7] In order to comply with the industrial application criterion it is considered necessary in cases where a sequence or partial sequence of a gene is used to produce a protein or part of a protein, to specify which protein or part of a protein is produced or what function it performs.[8]

III. Patent Fees

Another recommendation intended to avoid a too permissive patent practice applies to the patent fees. According to the Commission, the Government should periodically review the structure and quantum of patent fees to ensure that fees are set at levels appropriate to discourage patent holders from maintaining patents that lack real commercial value.[9]

Although a reduction of "random shots" makes sense in general, one should keep in mind that basic research often lacks the potential of immediate commercialization. Nevertheless, the results generated by basic research may be of paramount importance for the further development of products and processes which are of great commercial value. The ALRC's approach also discriminates independent researchers or start up companies which cannot afford a higher quantum of patent fees. Vice versa, higher fees won't deter international companies with a strong financial background from maintaining as much patent protection as possible. Finally, as patent law's intention is to stimulate an inventive atmosphere and to promote scientific development and economic growth, the idea of discouraging patent holders does not fit well into the patent law system. In sum, the proposed increase in charges seems to be a delicate subject.

IV. Patent Law and Healthcare

The ALRC also emphasizes the strong impact of patent protection on healthcare. The Commission comes to the conclusion, that, where particular gene patent applications, granted patents or patent licensing practices are considered to have an adverse impact on medical research or the cost-effective provision of healthcare, Commonwealth, state and territory health departments should consider whether to exercise any existing legal options (e.g. to challenge a patent application or to apply for the grant of a compulsory license) to facilitate access to the inventions. In addition, options for using government funding and purchasing power to control the cost of goods and services that are subject to gene patents and used in the provision of healthcare, should also be examined.[10] In particular, in exceptional circumstances, where the public benefit would clearly be served by broad dissemination of the results of publicly funded research, it should be considered to attach conditions to the grant of funding. These conditions might include a requirement that research results be placed in the public domain, or that a patented invention be widely licensed.[11]

The possibility of patent protection's adverse effects on public health is of paramount importance, especially for many developing and least-developed countries. On 14 November 2001, the 4th Ministerial Conference of the World Trade Organization adopted the Declaration on the TRIPS agreement[12] and public health.[13] The conference stated that the TRIPS agreement, and thereby international intellectual property law, does not and should not prevent members from taking measures to protect public health. Instead, TRIPS can and should be interpreted and implemented in a manner supportive of WTO's members' right to protect public health and, in particular, to promote access to medicines for all.[14] However, the most important question remains unanswered: What is the incentive for a pharmaceutical company to invest hundreds of millions euro or dollar for the development of new medicines if there is the risk of a (partial) *de facto* expropriation after commercialization ?

V. Stem Cell Patents

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[1] Australian Law Reform Commission (Ed.), Genes and Ingenuity: Gene Patenting and Human Health (ALRC 99, 2004).
[2] http://www.alrc.gov.au/about/index.htm [17.12.2004].
[3] List of Recommendations, No. 6-1.
[4] List of Recommendations, No. 7-1 a).
[5] List of Recommendations, No. 7-1 c).
[6] List of Recommendations, Nos. 6-3 a) and b).
[7] Art. 5 (3) Directive 98/44/EC of the European Parliament and of the Council of the European Union of July 6, 1998 on the legal protection of biotechnological inventions, OJ. L 213/13 of 30.7.98.
[8] Recital 24 of Directive 98/44/EC.
[9] List of Recommendations, No. 5-1 b).
[10] List of Recommendations, Nos. 19-3 and 19-2.
[11] List of Recommendations, No. 11-3.
[12] Agreement on Trade-Related Aspects of Intellectual Property Rights.
[13] WT/MIN(01)/DEC/2.
[14] WT/MIN(01)/DEC/2, No. 4.

The report also addresses one of the most disputed issues in patent law: The patentability of stem cells and stem cell technologies.[15] The ALRC recommends the development of examination guidelines to explain how the criteria for patentability apply to inventions involving stem cells and related technologies.[16] In developing these guidelines, the UK Patent Office's Practice Note is regarded as a worthwhile model. The distinctions drawn by the UK Patent Office between totipotent and pluripotent cells may provide a helpful way to approach the application of s 18(2) of the *Patents Act* to inventions involving embryonic stem cell technologies.[17]

In its so-called Practice Note published in April 2003, the UK Patent Office maintained the standpoint that in view of their potential to develop into an entire human body, human totipotent cells are not patentable because the human body at the various stages of its formation and development is excluded from patentability by Paragraph 3(a) of Schedule A2 to the Patents Act 1977. As Paragraph 3(d) of Schedule A2 to the Patents Act 1977 qualifies uses of human embryos for industrial or commercial purposes as unpatentable, the UK Patent Office also decided to refuse the grant of patents for processes of obtaining stem cells from human embryos. [18] However, this assessment is too undifferentiated as it disregards the fact that the potential for development inherent in stem cells is still open. Even adult stem cells[19], which are expected to be limited to the production of only some cell types, may be re-programmed to totipotent cells. Furthermore, Art. 17 of the Australian Prohibition of Human Cloning Act 2002[20] states that a person commits an offence if the person uses precursor cells taken from a human embryo or a human fetus, intending to create a human embryo, or intentionally develops an embryo so created. Vice versa, precursor cells or embryonic cells as such are not protected by law. The non-patentability of totipotent stem cells would therefore lead to a somewhat paradoxical situation that runs counter to the legislator's decision to promote stem cell research in Australia.

VI. Conclusions

On the one hand, the ALRC report presents a very elaborated overview on the manifold facets of biotech patents, providing detailed information on domestic Australian law as well as a comparative analysis. Therefore, it can be taken for granted that the report will foster the ongoing international debate regarding the patentability of genes, gene sequences and other biological materials. On the other hand, some of the report's recommendations lack differentiation to such a degree that it seems to be unlikely they will be transformed into legally binding instruments.

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[15] In-depth: Spranger, Patentability of Stem Cell Inventions with Special Emphasis to EC Law, 1 Journal of International Biotechnology Law 2004, 247 et seq.

[16] List of Recommendations, No. 15-1.

[17] No. 15.64 of the report.

[18] http://www.patent.gov.uk/patent/notices/practice/stemcells.htm.

[19] Adult stem cells are derived from an adult human being.

[20] For an analysis of the Australian Research Involving Human Embryos Act 2002 and the Prohibition of Human Cloning Act 2002: Spranger, Embryonen- und Stammzellforschung in Australien, 15 Sozialrecht und Praxis 2005, No. 1.

HIV/AIDS Epidemic, Natural Selection and Poverty

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Abstract

The global HIV/AIDS epidemic killed 3 million people in 2004 and 40 million are infected, from which more than 90% in developing countries. High prevalence of HIV in some African populations creates conditions for a strong natural selection on genetic variants that were associated with resistance to the infection by HIV-1. Care must be taken with the transmission of this important scientific knowledge to society. Despite the absolute immorality of natural selection, occasionally it has been faced as a "natural law"and even "morally adequate" for some human behaviors. The survival of the populations depending on natural selection presents important ethical repercussion and reveals not only biological differences but also profound iniquities among human beings.

Introduction

The global HIV/AIDS epidemic killed more than 3 million people in 2004, whereas about 5 million acquired the human immunodeficiency virus. Nearly 40 million people are infected, more than 90% living in developing countries. Sub-Saharan Africa remains the most affected region. In 2004, more than 25 million people in this region were living with HIV.[1]

High prevalence of human immunodeficiency virus in some African countries creates conditions for strong natural selection on genetic variants that affect resistance by HIV-1 infection. Estimates of the intensity of selection today is comparable in magnitude to that occurred in the XIV century, during Black Death.[2]

Care must be taken with the transmission of this important scientific knowledge to society. Despite the absolute immorality of natural selection, frequently it has been faced as "natural law", morally adequate for some human behaviors. Expressions like "fight for survival" and "victory of the strongest" are occasionally used to describe actions in economy, administration and even at medical sciences.

Evolutionary biology possesses repercussion in several fields of the human knowledge and it can generate controversies and misconceptions. Even in several books of biology, the concept of evolution is still not accurate.[3] Natural selection, not properly used, was argument to validate extremely prejudicial actions of social Darwinism and eugenics. These examples from the past, as well as the greater survival of million of people depending on natural selection rises not only biological questions, but also ethical ones.

Genetic Differences in Survival and Reproduction

Natural selection can be defined as any consistent difference in survival and reproduction among different biological entities.[4] Infectious diseases are recognized as an important cause of natural selection in human beings. However, only recently, cases like the HIV virus can be related.

Among people infected by HIV, disease progression and death varies substantially and part of this development can be explained by the genetic variation in individuals.

HIV virus requires a coreceptor in addition to its primary receptor CD4, to infect cells. Among the main coreceptors used are CCR2, CCR3 and mainly CCR5. Variation in gene CCR5, known as delta-32 deletion, leads to the production of a non functional coreceptor, which turns difficult the entry of the

HIV in the cell. Individuals with delta-32-delection possess greater resistance to HIV-1 infection and slower progression of the disease.[5-6] Increased survival rate of 2–4 years of people in the period of peak fertility suggests that delta-32 CCR5 deletion is submitted to considerable natural selection.[7] Variants in other genes like CCR2, CXCL12, IL10, KIR3DS1 are also associated with delay AIDS.[8]

The existence of natural selection acting in some human populations associated to AIDS is a scientific fact. Nevertheless, as stated by Lewontin[9], science is integrated and influenced by social structure, and can be utilized to support some positions and turn them natural and genuine.

When natural selection of human beings is discussed, we need to be careful to don't attribute (once again) to the genes, problems caused by a society where people don´t have minimal life conditions and access to health care. Some considerations about natural selection are necessary.

Natural selection isn´t a power with direction or purpose. Human beings are still under natural selection, even in lower intensity in some populations. Nevertheless, there are no indications that a "genetic deterioration" might happen in future generations because of a "mitigation" of natural selection.[10]

The future is unpredictable and because human beings have a great capacity to modify their environment, it becomes difficult to predict how will be the natural selection associated with AIDS. Some researches try to predict possible evolutive tendencies, as the decrease of ethnical differences and increased resistance to infections.[11] Nevertheless, as stated by the researches, there are several obstacles that keep these tendencies away from reality: the humanity has been shaped by unpredictable events; biological history of our species is trapped with our cultural, social and political history; biology and medicine possess the potential to influence actively the evolutionary process.

Characteristics that confer advantages in the present might not guarantee more adaptability in the future. Even genes considered "prejudicial" and that cause diseases may present advantages in other context, as different genetic composites, life stages or different environments.[12] Besides, more than 15,000 genetic disorders are known[13] and every moment new genetic variants that confer more sensibility to diseases are described. All of us possess some genetic variant considered "not biologically favorable".

One of the main characteristics of the human being is the great capacity of modifying the environment, decreasing the selective pressure upon him. Populations exist due to nature interference. Diseases that caused serious problems like vision disturbances are easily solved nowadays. Several pathologies like diabetes, hypertension and asthma are controlled and lots of infectious diseases have the cure. The great majority of the world population is alive because of the utilization of mechanisms "contrary to natural selection" like vaccines, antibiotics and clean water.

Finally, there is no reason for the human beings to behave in agreement with the "natural laws". Besides, to human beings it was totally natural to adopt practices for mutual benefit, which allows us to deny that the strong dominates the weak and all other abnormalities of evolutionary biology applies in human relations.[14] Natural selection can help to explain in biological terms how the world is, but does not provide ethical or moral principles to the human being.

Social Differences in Survival and Reproduction

In Africa, poverty and its adverse effects like prostitution, poor living conditions, poor education and poor health care are major contributing factors to current spread of HIV/AIDS.[15] This continent lives on 1% of the global economy and carries 70% of the world's HIV/AIDS burden.[16]

The available resources for individuals with HIV in developing and developed countries are extremely unequal. Total HIV/AIDS spending in 12 countries in Latin America in 2000 was estimated in US$ 1 billion. This expenditure is very small compared with high-income countries such as United States where total spend can be esteemed in US$ 25 billion.[17]

We can also observe great disparity in the vertical transmission of HIV. Between 1994-1997, in the United States, the percentage of mothers that received zidovudine increased from 7% to 91% and there was a reduction of 67% in the cases of perinatal AIDS.[18] In Africa, 1% of pregnant women in heavily-affected countries have access to services aimed at preventing mother-to-child HIV transmission.[19]

Where it is available, highly active antiretroviral therapy has resulted in 90% reduction in mortality and notable improvement in quality of life.[20] In high-income countries AIDS mortality continues to drop, thanks to the widespread availability of antiretroviral treatment. Despite to more funding and a recent trade agreement to allow poor countries to import copies of patented drugs, only 1% people had access to antiretroviral treatment at the end of 2002.[21]

The same differences observed in the epidemic of HIV/AIDS caused by the poverty in developing countries were related in some populations of developed countries like Canada,[22] France,[23] and United States.[24]

Final Considerations

The combat of the pandemic of HIV/AIDS needs collaboration from several fields of the human knowledge. Researches that show the existence of genetic variants responsible for the increasing resistance to HIV are extremely important for a better understanding of the physiopathology of this disease, verification of different susceptibilities and development of new and more efficient therapeutic and preventive strategies.

However, researches in developing countries must aim not only the high technology products, frequently not accessible to the individuals of these countries, but also the verification of the mechanisms that take to prevention, education, modification of risk behavior, decrease of discrimination and stigmatization of individuals. Examples of researches adequate to the problems and people of each country are the utilization of folk media for he prevention of HIV in Ghana,[25] education and distribution of condoms for specific high-risk groups in Thailand and Cambodia,[26] voluntary counseling and testing in Kenya and Tanzania.[27]

Treatment of sick people is also extremely important to better the life condition of millions people. Recognition and modification of causes that take to great global and local disparities in health service utilization is essential.

The epidemic and natural selection caused by HIV is compared in magnitude to the Black Death. Nevertheless, the HIV/AIDS affects mainly some society groups, takes years to cause death, and we know the causes and how to prevent it.[28] Natural selection that nowadays happens in developing countries, with intensity comparable to the one occurred 700 years ago, presents important ethical repercussion and reveals not only biological differences but also profound iniquities among human beings.

References

1. UNAIDS. 2004. *AIDS Epidemic Update*. Geneva, December 2004.
2. Schliekelman P et al. 2001. Natural selection and resistance to HIV. *Nature*, 411: 545-546.
3. Linhart YB. 1997. The teaching of evolution – We need to do better. *Bioscience*, 47:385-391.
4. Futuyma DJ. 1998. *Evolutionary Biology*. Sinauer Associates, Sunderland: 349.
5. Liu R et al. 1996. Homozygous defect in HIV-1 coreceptor accounts for resistance of some multiply-exposed individuals to HIV-1 infection. *Cell*, 86: 367-377.
6. McDermott DH et al. 1998. CCR5 promoter polymorphism and HIV-1 disease progression. *Lancet*, 352: 866-870.
7. Bamshad J et al. 2002. A strong signature of balancing selection in the 5' cis regulatory regiion of CCR5. *Proc Nat Acad Sci USA*, 99:10539-10544.

08. O'Brien SJ, Nelson GW. 2004. Human genes that limit AIDS. *Nat Genet*, 36:565-74.
09. Lewontin RC. 2001. *Biology as ideology: The doctrine of DNA*. Harper Collins Publishers.
10. Vogel F, Motulsky AG. 1997. *Human Genetics: Problems and Approaches*. Springer Verlag, New York.
11. Futuyma DJ. op. cit. note 5. Vogel F, Motulsky AG. op. cit. note 18.
12. Nesse RM, Williams, GC. 1997. Evolutionary biology in the medical curriculum – what every physician should know. *Bioscience*, 47:664-666.
13. McKusick VA. 2004. *Mendelian Inheritance in Man*. http://www.ncbi.nlm.nih.gov/omim/
14. Dennett D. 1995. *Darwin's dangerous idea – Evolution and the meanings of life*. Touchstone, New York.
15. van Niekerk AA. 2002. Moral and social Complexities of AIDS in Africa. *J Med Philos*, 27:143-162.
16. UNAIDS. 2003. op. cit. note 1.
17. Opuni M et al. Resources for HIV/AIDS prevention and care. *AIDS* 2002; 16:S53-S60.
18. Lindegren ML et al. 1999. Trends in perinatal transmission of HIV/AIDS in the United States. *JAMA,* 282:531-538.
19. UNAIDS. 2003. op. cit. note 1.
20. Mukherjee JS et al. 2003.Tackling HIV in resource poor countries. *BMJ*, 327: 1104-1106.
21. **Fleck F.** 2003. WHO issues global alert after grim report on HIV/AIDS. *BMJ*, 327: 698.
22. Wood E et al. 2002. Socioeconomic status, access to triple therapy, and survival from HIV-disease since 1996. *AIDS*, 16: 2065-2072.
23. Messiah A et al. 1998. HIV testing, knowledge, attitudes, beliefs, and practices among minorities: pregnant women of North-African origin in southeastern France. *J Natl Med Assoc*, 90: 87-92.
24. Smith DK et al. 2000. HIV/AIDS among African Americans: progress or progression ? *AIDS*, 14: 1237-1248.
25. Panford S et al. 2001. Using folk media in HIV/AIDS prevention in rural Ghana. *Am J Public Health,* 91: 1559-1562.
26. Cohen J. 2003. Asia - The next frontier for HIV/AIDS. Two hard-hit countries offer rare success stories: Thailand and Cambodia. *Science* 2003, 301:1658-62.
27. Sweat M et al. 2000. Cost-effectiveness of voluntary HIV-1 counselling and testing in reducing sexual transmission of HIV-1 in Kenya and Tanzania. *Lancet*, 356: 113-121.
28. van Niekerk AA. op. cit. note 24.

Obligation of Non-maleficence and Female Circumcision in Africa: A Moral Discourse

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Abstract:

The paper attempts to expose the different types of female circumcision (FC) in Africa. The reasons for and the geographical spread of FC in Africa were indicated. The physical and psychological implications of FC were also highlighted. The principle of non-maleficence was used to analyze the role of physicians who carryout FC operations on the grounds that they make the practice "safe". And due to the strong cultural implications associated with the practice of FC in Africa, symbolic form of FC was suggested in place of actual FC.

Keywords: Female circumcision, non-maleficence, initiation rites, clitoral growth, excision, infibulations, female genital surgery, real circumcision, risks/benefits

Introduction

Female circumcision (FC), often times referred to as female genital mutilation by the World Health Organization (1995:1), is the cutting off parts of a girl's genitals. The approximate number of women and girls affected is about 100-300 million with two million-increase rates annually (Toubia, 1998:6). FC may be in the form of washing the tip of the clitoris, pricking the clitoris with a pin, cleaning of the foreskin (prepuce) and sometimes the cutting and removal of sexual organs. The practice may take place at infancy or at marriageable age (Toubia, 1993:9). It is also important to note that FC may take place in the course of a woman's first pregnancy, as is the case among the Urhobo in Delta State of Nigeria. According to WHO report (1997:7), FC is prevalent in twenty-seven (27) African countries and FC is widespread in certain countries while it is limited to some ethnic groups in other countries.

One of the reasons for the practice of FC in Africa is its supposed link to Islamic religion, where FC is regarded as an old Muslim practice as indicated in the Koran. Prophet Mohammed was quoted to have said to a circumciser in Medina "do not cut severely, as that is better for a woman and more desirable for a husband". Perhaps that is the reason for the high prevalent rate of FC in Islamic African countries. However, it has been argued that the practice of FC in Africa predates Islam.

The social reasons for the practice of FC in Africa are imbedded in traditional and cultural values. It was indicated in the report by the National Plan of Action for the Elimination of FC in Kenya (1999:3), that among the Kenyans, it was believed that FC signifies; "…a rite of passage for girls from childhood to womanhood, instilling values, training and grooming to uphold family stability and preparation for the future within the community."

The report further states that, the practice of FC continues to date in Kenya because it "guarantees acceptance and respect within the community, ensures marriage ability, promotes the birth of healthy children and enhances cleanliness, prevent promiscuity and excessive clitoral growth" (Ibid).

Social reasons are intricately linked with the traditional reasons for the practice of FC in Africa. In Kenya for instance, former president Jomo Kenyatta once argued that FC was an integral part of being Kikuyu and, that to abolish FC is to destroy the tribal system (1938). Hence, the abolition of FC among African communities that carryout the practice is extremely difficult since FC is regarded as a matter of tribal identity. For instance, most Egyptian women who have been circumcised in the past, when asked if they would want their daughters circumcised? Most replies were more or less in consonance with the respondent who opined that: "Of course I shall have them circumcised exactly as their parents, grand parents and sisters were circumcised. This is our custom" (Assaad, 1980:3-16), while another replied that: "We are circumcised and insist on circumcising our daughters so that there is no mixing between male and female (Assaad: Ibid).

Another reason for the practice of FC in Africa is that of gender identity (Amnesty International, 2002:5). The practice streamlines the sexes in terms of definition of roles in life and, the removal of the clitoris is expected to promote and enhance feminity. Another indication for the practice of FC is ironically health based (Ibid:6). Amnesty International (AI) further explains that it was believed that the practice purifies the woman; hence, terms like "tahara" and "tahur" meaning purification/cleansing are used in Egypt and Sudan respectively in reference to FC. AI divulged further, that other health reasons proffered for the practice of FC was the false assumption that if girls and women were not circumcised, the female genitals would be untidy with the consequence of harming her husband and child during childbirth.

Amnesty International exposed further that FC was practiced in Africa to control a woman's sexuality and

reproductive functions (Ibid). It was also believed that FC reduces female sexual appetite and consequently reduces her tendencies for sexual infidelity. According to Katumba (1990:17), it was generally believed among the Kenyans that: "Circumcision make women clean, promotes virginity and chastity and guards young girls from sexual frustration and deadening their sexual appetite."

Types and Geographical Spread of FC in Africa

Women in most African cultures usually carry out FC operations. Where the practice of FC is prevalent, traditional birth attendants often double as circumcisers (Toubia, 1993:2). It has been discovered in recent times that midwives, nurses and physicians also engage in FC operations. Toubia (op. cit: 29) exposed that: "…medically trained midwives and nurses have taken over from the traditional practitioners and have played an important role in legitimizing the practice…doctors are also increasingly providing circumcision services, although most medical associations condemn the practice."

Toubia explains further in her work, that the vested interest of the circumcisers lay in the financial reward and the enhancement of social status; for instance in Sierra Leone, circumcisers are held in high esteem and are usually the women leaders. Besides financial reward and enhanced social status, traditional circumcisers often see their roles as that of duty and service to the community. While physicians who carryout FC operations argue that they reduce the health hazards associated with the practice by making it "safe".

Adebayo, et al (1992) categorized FC into three:

(a) Real circumcision
(b) Excision, and;
(c) Infibulations

Real circumcision involves the removal of the prepuce and clitoral hood. The clitoris and larger parts of the labia minora are not tampered with. Excision a more extensive form of FC involves the removal of the clitoral hood and clitoris. In excision, the labia minora are cut-off partially or totally without the stitching of the vulva. Infibulations, the most extensive form of FC involves the removal of part or all of the female genitals, after which the vagina is stitched. A little opening is allowed for urine and flow of monthly cycle. Reports from Amnesty International indicates that (A1, 2002):

When infibulations takes place, thorns or stitches may be used to hold the two sides of the labia majora together, and the legs may be bound together for up to 40 days. Antiseptic powder may be applied, or, more usually, pastes-containing herbs, milk, eggs, ashes or dung-which are believed to facilitate healing. The girl may be taken to a specially designated place to recover where, if the mutilation has been carried out as part of an initiation ceremony, traditional teaching is imparted.

Of all female circumcisions carried out in Africa, about fifteen percent are infibulations (Ibid). The practice of FC cuts across many countries in Africa, however the degree of practice differs. According to the statistics provided by Amnesty International and the United States government (Afrol Background, 2002:2-3), in Benin Republic the practice of FC (excision) is about fifty percent and it is predominantly in the Northern part of that country. In Burkina Faso, about seventy percent of women and girls are circumcised (excision) and it cuts across almost all ethnic groups in that country, while in Cameroon, the practice (real circumcision and excision) rate is about fifty percent and the practice involves slightly over a quarter of the female population in that country.

FC (excision and infibulations) rate in Chad is approximately sixty percent and it cuts across all ethnic groups. FC (excision) is practiced in the North, North-East and West of Cote'd Ivoire with about sixty percent prevalent rate. In the Democratic Republic of Congo, FC (excision) rate is five percent and usually among girls in the Northern equatorial part of that country. FC (excision and infibulations) rate in Djibouti is about ninety-eight percent, most women from all ethnic groups are infibulated. Egypt has about ninety-seven percent FC (real circumcision, excision and infibulations) rate. FC (real circumcision, excision and infibulations) rate in Eritrea is about ninety percent and cuts across all ethnic groups. In Ethiopia, FC (real circumcision and excision) rate is about ninety percent and cuts through all ethnic groups.

In the Gambia, FC (excision) rate is eighty-five percent average and the practice is tenable in seven out of the nine ethnic groups in that country. In Ghana, FC (excision) is more pronounced in the Northern, Upper East and Upper West of that country and the prevalent rate is from fifteen to thirty percent. Guinea has FC (real circumcision, excision and infibulations) rate of seventy to ninety percent and practiced by all ethnic groups. Guinea-Bissau and Kenya have FC (real circumcision, excision) rate of about fifty percent. FC (excision) rate in Liberia is in the neighbourhood of fifty-six percent, while Mali has FC (real circumcision and excision) rate of ninety-two percent and tenable amongst all ethnic groups. Mauritania has FC (real circumcision and excision) rate of about twenty-five percent, while Niger and Senegal have FC (excision) rate of about twenty percent. In Nigeria, FC (real circumcision and excision) has a prevalent rate of fifty percent and it cuts across all ethnic groups. Sierra Leone has FC (excision) rate of about ninety percent and prevalent amongst all ethnic extractions except the Creoles. Eight-nine percent of Sudanese girls and women are infibulated while ninety-eight percent of girls and women in Somalia like their Sudanese counterpart are infibulated. In Tanzania, FC (excision and infibulations) rate is eighteen percent while FC (excision) rate in Togo is twelve percent.

Consequences of Female Circumcision

The negative effects of FC are physical and psychological (AI, 2002:1) and, the psychological consequences of FC are difficult to investigate. The difficulty arises from the insignificant number of clinical reports related to FC (Baasher, 1979:71-105). However, accounts by those circumcised or about to be circumcised include amongst others, anxiety, depression and terror.

The physical consequences of FC seem to be better understood than the psychological. Common physical risks associated with FC include among others: scarring and keloid formation, vulval dermoid cysts and vulva abscesses, acute or chronic pelvic infection, subfertility, dysmenorrhea and recurrent urinary tract infection (Newman:1996). It has also been observed that FC was sometimes responsible for prolonged and obstructed labour, which consequently leads to tearing and haemorrhage. And during the process the child may suffer from brain damage (Azadeb: 1997).

Pain (Toubia, 1993:14) is also one of the serious consequences of FC. This is often due to the non-application of anesthesia in FC procedures. Toubia (Ibid) explains further that doctors and midwives who are involved in FC operations "…prick the clitoris with just a few drops of anesthetic, more to satisfy the relatives – and to claim a higher fee – than to relieve the child's pain" Toubia further indicates that, urine retention was also a problem associated with FC and the condition "…increases pain and discomfort and can also cause urinary infection and back pain from pressure on the kidneys".

Due to the health hazards associated with FC, efforts have been made at various levels and fora calling for the eradication of the practice. The most pronounced effort has been that of criminalizing FC. In the United States of America (Cable News Network: 3rd August 2003), FC is legally viewed as battery and violation of human rights, the law was enacted to check immigrants (mostly Africans) who carry out the practice in the United States of America. Ajabor (1998:8) of the Women's Health and Action Research Centre in Nigeria, explains that FC was "…an infringement of the physical and psycho-sexual integrity of women and thus, constitutes a form

of violence against them". And Adams (1998:9) of the Nigerian Law School, in agreement with Ajabor akined FC to victims of rape, this is because FC "…is an act of sexual invasion and a violation of a woman's privacy and physical integrity. It also reduces the ability of the sufferer to form a unified self-esteem. Unlike rape, a part or all of the female genitals is amputated or cut-off".

The United Nations (1997) now regards FC a human right issue as it violates the rights of the girl child and, that FC contravenes Articles 34, which indicates, "States parties undertake to protect the child from all forms of sexual exploitation and sexual abuse". And in line with UN, the Organization of African Unity (OAU) states in Article IV (I) that: "In all actions concerning the child undertaken by any person or authority, the best interest of the child shall be the first consideration". And it states further in Article XXI: "Protection Against Harmful Social and Cultural Practices": (1) State parties to the present charter shall take all appropriate measures to eliminate harmful social and cultural practices affecting the welfare, dignity, normal growth and development of the child and in particular: (a) those customs and practices prejudicial to the health or life of the child". Thus it is against the background of the consequences of FC and the posture of the International Community (UN and OAU) with regards FC, that it has become necessary to evaluate the activities of physicians who carry out so called "safe" FC operations or what they have renamed "female genital surgery".

Obligation of Nonmaleficence

The major reason physicians give for carrying out FC operations in Africa is that of making the practice "safe", according to them if they (physicians) do not do it, the operation would be carried out by traditional circumcisers where safety cannot be guaranteed. The scientific facts available indicate that FC can never be safe whether carried out by a physician or by anyone else. It would seem that physicians who carry out FC operations are unmindful of an aspect (obligation of nonmaleficence) of the oath they swore to uphold and which regulates the medical profession.

The contravention of the physicians' code of conduct when FC operations are carried out by physicians may be somewhat clearer, if the principle of nonmaleficence is explained further. Medical nonmaleficence (sometimes not easily distinguishable from beneficence) revolves around the idea of harm. In order not to get entangled with the various notions and definitions of harm, it would just suffice to define medical nonmaleficence as "…not imposing risks of harm as well as not inflicting actual harm (Beauchamp et al, 1989:125). However, in health care it is sometimes necessary to inflict slight harm in order to avoid or arrest a more serious harm/pain. The implication thus is, for the benefit and interest of a patient, permissible/reasonable level of pain/harm may be allowed. For instance, in order to get rid of a cancerous tumour, it may be necessary to carryout a surgical operation that could be painful and distressful. Intravenous treatments also involve the infliction of pain for a greater good. Pain, suffering and harm in medical practice must be reduced to the barest minimum while welfare and good should be maximized. FC does not maximize health; on the contrary, it is detrimental to health.

Medical nonmaleficence as derived from the code of medical ethics and as indicated by Veatch (1977:351-56), states that in accordance with the Hippocratic oath, it was the responsibility of physicians to keep patients away from harm and injustice. In the Hippocratic oath (British Medical Association Translation), it states that a physician based on his ability and judgment must follow a system of regimen which is beneficial to his patients and must not do anything or follow any procedure that would be harmful to his patients (Mason et al, 1983:257). In the Declaration of Tokyo, 1975, the physician was forbidden to participate in torture. In the preamble of that declaration, torture was defined as deliberate and systematic infliction of physical and mental suffering (Ibid). And in the first paragraph of the said declaration, it states that (Ibid):

The doctor shall not countenance, condone or participate in the practice of torture or other forms of cruel, inhuman or degrading procedures…

While in the third paragraph of the said declaration, it indicates that (Ibid):

The doctor shall not be present during any procedure during which torture or other forms of cruel, inhuman or degrading treatment is used or threatened.

It is thus very explicit that the physician must not inflict harm under any guise or pressure. And in the American Medical Association Principles of Medical Ethics in Section 3, states that physicians "should practice a method of healing founded on scientific basis…", while in the Declaration of Geneva, as amended at Sydney in 1968 (Mason et al, 1983:252), it indicates that the first consideration of a physician must be the health of his patient. Thus, physicians who engage in FC for whatever reasons, contravene the medical principle of nonmaleficence. This is because FC has no scientific basis and the practice inflicts unnecessary and non-beneficial pain and harm.

Prudent health care is usually evaluated on the basis of risks/benefits involved in any course of therapy; it implies that beneficial health care is when benefits outweigh the risks. In FC, pain and suffering are inflicted and unnecessary risks undertaken without benefits. Hence, the argument put forward by physicians who undertake FC operations, that they make it "safe" is untenable.

Conclusion

Physicians and indeed traditional circumcisers must be made to stop the practice despite cultural pressures. Physicians must be made to understand that cultural pressures are no excuse for the contravention of the code of conduct regulating medical practice.

It is also important to educate the people on the harmful effects of FC. That the practice is culturally imbedded in African traditions is no reason not to discard of it, since it is now known that FC is a harmful traditional practice. Unfortunately, legislations only push the practice underground, which is currently the case in Nigeria and most African countries that have enacted laws against the practice of FC.

In the effort to educate the (African) populace on the consequence of FC, conscious efforts must be made not to look down on the cultures and traditions of those (African countries) who practice it. This is because FC has strong cultural significance, which forms part of the initiation rites of a girl to womanhood and without which a girl may be unable to get married. And marriage (for women) in most African countries has social, legal, religious and economic implications. Hence, utmost care must be taken in condemning the practice, as sharp attacks on peoples' cultures (no matter how well intentioned) only solicit resistance and this is because criticisms by others are usually not well tolerated. What could be done, in the light of the cultural implications of FC is to replace "actual FC" with "SYMBOLIC FC". Symbolic FC would involve ***JUST*** the washing of the prepuce and the tip of the clitoris, after which a girl may take part in traditional rites of initiation, in this way, physicians should have nothing to do with FC under whatever guise[as actual FC can never be safe] as traditional circumcisers or birth attendants should be able to carryout symbolic FC which in this case is merely for the fulfillments of traditional rites without inflicting harm on girls and young women.

References

Adams, E.F. (1998): "Female Genital Mutilation: A Legal Agenda for Nigeria" Women Health Forum vol. 3, No. 2.

Adebajo, C.O., Orenuga, O and Yarnap, H. (1992): Health Effects of Female Circumcision and Other Harmful Traditional Practices, Training Courses in women's Heath. Module 6, Nigeria.
Afrol Background (2002): "Fighting Female Genital Mutilation in Africa" afrol.com/categories/women/backgr-fighting-fgm.htm.
Ajabor, H. (1998): "A Legal Framework for Action Against Female Genital Mutilation" Women's Health Forum, Vol. 3 No. 2.
Amnesty International (2002): "Female Genital Mutilation – A Human Rights Information Pack", www.amnesty.org/alibi/intcam/femgen/fgml.htm.
Assaad, M. B. (1980): "Female Circumcision in Egypt: Social Implications, Current Research Prospects for Change" Studies in Family Planning 11.1
Azadeh, H. (1997): "Female Circumcision, Genital Mutilation and Childbirth – A Mother and child Tragedy" Br. J. Theatre Nurs 7 (7).
Baasher, T.A. (1979): "Psychological Aspects of Females Circumcision" WHO-EMRO Technical Publication, Alexandria Egypt. 71-105.
Beauchamp, T and Childress, J. (1989): Principles of Biomedical Ethics, Oxford, OUP. P. 125.
Cable News Network (3rd August 2003): "Female Circumcision" Inside Africa, www.CNN/Africa.
Katumba, R. (1990): "Kenyan Elders Defend Circumcision" Development Forum.
Kenyan Ministration of Health (1999): National Plan of Action for the Elimination of Female Genital Mutilation 1999-2019, Nairobi.
Kenyatta, J. (1938): Facing Mount Kenya: The Tribal Life of the Kikuyu, London, Secker and Warburg.
Mason, J. K and Smith, M. (1983), Law and Medical Ethics, Butterworths, London. P. 252.
Newman, M. (1996): "Midwifery care for Genitally Mutilated Women" Modern Midwife 6.
Toubia, N. (1993): "Female Genital Mutilation: A Call for Global Action, New York, United Nations Plaza. Women, ink.
Toubia, N. (1998): ""Female Circumcision//Female Genital Mutilation" in African Journal of Reproductive Health. Vol. 11, No. 2.
United Nations Population Fund (1997): The State of the World Population, New York.
Veatch, R. (1977): Case Studies in Medical Ethics, Harvard University Press, pp. 351-56).
World Health Organization (WHO) (1995): Technical Working Group on Female Genital Mutilation, Switzerland. WHO/FRH/WHD/ 96.10.
WHO (1997): Regional Plan of Action to Accelerate the Elimination of Female Genital Mutilation in Africa, Brazzaville, WHO Regional Office for Africa Press.

Human Right Issues in Life Sciences

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China

Awareness of human rights has witnessed an unprecedented enhancement and extension among China's various strata ever since the clause that "the State respects and safeguards human rights" was written into the *Constitution of the People's Republic of China* in March 2004. However, as it appears, there are still some very important human right issues in certain areas yet to be noticed and realized. Such as the human right issues centering on the right to know in the field of life sciences.

A typical case at hand is the latest public concern over the proposed commercial release of genetically modified (GM) rice. In fact, long before the public began to pay attention to GM technology, which many used to regard as pure scientific matter and tend to neglect, Chinese scientists had acquired approval for the release of a number of GM crops, including cotton, tobacco and more. But to date neither China nor any country in the world has granted permit to commercialize any staple food that is genetically modified. Although the US government has approved the release of a medicinal strain of GM rice in California, the planting has not been materialized due to the opposition from the local people and government.

Genetic modification is referred to the application of modern biotechnology to "position, separate and clone the needed genes before transferring them into the target bioproducts via certain carriers."[21] Scientists expect the GM crops, such as wheat, rice, soybean and tomato, to "be able to provide more and better traits as the humankind desires," but "since the GM technology and GM products are still in the stage of research and development and are not so perfect, there might exist some elements unfavorable to human health and the environment."[22] It is because of these uncertainties that there have been controversies over GM technology in the international community, and GM products have been resisted in EU and many other parts of the world.

In contrast, the spread of GM products has encountered little resistance in China until the GM rice aroused public attention. Before we realized it, soy oil and salad oil made out of GM soybean imported from the United States had almost dominated our edible oil market.

It is certainly beyond the aim of this paper to discuss such scientific issues as whether the GM food is safe to human health and environment. What the author is concerned about is whether we have the rights to know and choose as for the matters regarding our personal interest, and whether these rights of ours are honored and guaranteed. Because China is the world's largest rice producer and consumer, because rice is the staple food for more than half of China's 1.3 billion people, and because rice, as compared with other crops, needs the least processing before it can be consumed, we naturally are more concerned with the destiny of rice and desire to choose what kinds of rice we'd like to eat. All this shall not involve the state secrecy, and we should have the right to access to the related information.

In reality, however, this seemingly simple right can hardly be guaranteed. First, the decision-making power over the approval of commercial release of GM crops belongs to some government departments. And the first step of the approval procedure is the scientific assessment made by a biosafety committee under the Ministry of Agriculture on the candidate GM crop's safety to human health and environment. If the committee decides that it's safe, the candidate crop will cross an important threshold on its way to get the safety certificate for its commercial production. This procedure, including the candidate crop's name, the background of the applicants and components of the genes transferred, are all kept confidential from the public. And more than two thirds of the members of the biosafety committee under the Ministry of Agriculture are engaged in biotechnology.[23] Some members themselves are principal investigators of the candidate GM crops to be assessed. People can hardly be sure of the assessment's justice, seriousness and impartiality in front of such an overwhelmingly one-sided organizational structure and complex relations of interests. Second, while there are regulations on identity of GM products in China, the listed varieties to be identified are limited, with many products containing GM components not listed. This leaves room for violations of consumers' right to know. Zhu Yanling, a Shanghai consumer, lost her suit vs. Nescafe over the Swiss corporation's violation of her right to know in its failure to identify the GM components in a brand of chocolate milk powder in China in 2003. Zhu lost her case just because the formula milk is not covered in the list of products to be identified in China, although it must be identified in Europe. The Nescafe is thus able to act in dual standard in GM product identification outright.[24] The closed-door approval process and

[21] Lu Yinrong: *What is GM and GM biology, World Environment*, No. 4, 2002
[22] Ibid.
[23] See *Southern Weekend*, Dec. 9, 2004: *Conflict of Interests over GM Rice and Staple Food of 1.3 Billion People*
[24] See *Southern Metropolitan News*, Dec. 18, 2003: *Nestcafe'd Dual Standard in GM Identification, No Fair to Chinese Consumeres*

imperfect regulations have determined that the public is completely passive in front of GM food as neither their right to know nor their right to choose can be guaranteed.

As a striking contrast, EU in its legislation concerning GM food has special stipulations on the public involvement: The application for authorization, "excluding confidential information, shall be made accessible to the public," the Authority "shall make its opinion public," and "the public may make comments to the Commission within 30 days from such publication" before the Commission makes a decision in three months. [25] The EU regulation specifically stipulates that information relating to the following shall not be considered confidential: "name and composition of the GMO, food or feed," "general description of the GMO and the name and address of the authorization-holder," "physico-chemical and biological characteristics of the GMO, food or feed" and their effects on human and animal health and on the environment, etc.[26]

Indeed, if the GM food is safe, an open mind and extensive public understanding will only be a plus to its spread. The problem is, in the research and development of GM crops in China, public access or public involvement is absent. This absence is mainly created by the indifference of related government departments and researchers to the public rights in this field. Some researchers even dismiss the media's objective coverage of both proponent and opponent viewpoints regarding GMO as "misleading the public." They challenge: "Is the public capable of making a judgment?" Such attitude has actually aggravated the public distrust of GMOs. On the very day when the *Southern Weekend* carried its staff reporter Liu Jianqiang's investigative report *Conflict of Interests over GM Rice and Staple Food of 1.3 Billion People* on December 9, 2003, Sina.com, a leading portal website in China, alone received nearly 2,000 comments from netizens, with the overwhelming majority opposed to the commercial release of GM rice at this stage. Many netizens expressed their distrust of GM researchers, saying that even a new drug could not be produced until after repeated animal tests and several stages of clinical trials, why is the GM rice, a staple food for millions of people, considered safe after it is fed to just mice for 90 days? Others compared people's consumption of edible oil made out of GM soybean to forcing them to become guinea pigs without their informed consent, saying, "It is not because we are willing to eat it, but it is because we have no choice!" Such antagonism between the public and researchers has been rarely seen in many years.

GMO researchers are not alone in ignoring people's rights in the field of life sciences. There have been numerous occurrences in taking away farmers' genetic samples in the name of "free physical checkup" and "free medical treatment" without seeking their advanced informed consent, and in luring some rural people living with HIV/AIDS into clinical trials of new drugs in the name of saving their lives without their knowledge. Nobody could tell exactly how many research teams from Western developed countries are conducting how many projects involving human genetic materials and clinical trials of new drugs.

These issues are known as ethical problems in the field of life sciences. But the core of these issues should be human rights. This is because life sciences target at living creatures including us human bodies, and the research is directly associated with our personal interest and our rights as human beings. However, for a long time, regardless the researchers in the field or we as the public, few of us have regarded these ethical problems as human right issues and we have tended to neglect them. The neglect or ignorance on these two parties has led to a number of misconceptions.

The first misconception is to believe that life sciences are purely academic and are a topic solely for experts. Take GMOs for example, some biotechnologists even dismiss those environmental scientists who insist in caution in the release of GM crops as "ignorant" and "not qualified to have a say," let alone discussing the issue with ordinary people. This is terribly wrong. Of course life sciences contain many academic issues, but they don't just belong to those with the expertise. Since the research has involved our rights and interests, the issue is not a matter only experts can talk about. And since the research of life sciences has involved our bodies, has expected us to provide our organs, blood, cells and genes as their research materials, it has become impossible for us to stand above it. Without our participation, they are unable to conduct the research. Yet it is unethical and immoral to let us participate without letting us know what rights we are entitled to and regard us as simply as sample presenters and subjects of trials as if we were animals without thinking. In the present world, even the animals without thinking should be protected and cannot be maltreated, let alone human beings. By all means, life sciences are a matter concerning us all and deserve attention from each of us. Unless we are willing to be abused, we must be concerned about it.

The second misconception is to assume that all research is for lofty goals and to benefit humankind. For a long period of time, the propaganda that science and technology are the primary productive force has led us to a blind admiration for science and scientists. We have tended to forget that scientists are also human beings who could be driving by selfish interests. Once science is associated with different selfish interests and money, loftiness could turn into abjection. Here we have numerous historical lessons. The most typical should be the monstrous crimes committed by German and Japanese fascist scientists during World War II, when they conducted various experiments on live persons in the name of scientific research. Today, although we have got the *Nuremberg Code*, the *Helsinki Declaration* and various principles and regulation on bioethics, they could be overshadowed by more temptations of interests. It is not rare to see researchers intentionally ignore bioethical principles and violated our human rights for their selfish benefits. When the research is not purely for the social and public interests, especially when the public is not familiar with the ethical principles and game rules of the research, it is easy for our rights to be neglected and infringed upon. As Dr. Ricarda Steinbrecher, a German biologist, said in an interview with this author, "Scientists used to be regarded as neutral and apolitical, so they were trusted by the public. But in the era of Hitler, all the scientists in Germany served for the Nazis. We cannot repeat this history. There is now a dangerous trend, that is, every one has to rely on funding for his or her research. And most funding is from big corporations. The purpose of research projects is no long for the demand for society but for getting funding. Many funded research projects are for the applied purpose, and are application-oriented or patent-oriented. There are enormous profits in biotechnology, and big corporations have drawn a lot of scientists. But the scientists should know they are easily used."

The third misconception is to regard the biosafety committee or institutional review board as an exclusive committee of experts and regard the review or assessment as a format or interlude. If we agree that life sciences are not purely academic and concern our benefits and human rights, then we should agree that the related IRB cannot be an exclusive patent of the experts from academic institutions. If we agree that scientific research is no longer innocent and lofty, then we should guard against the practice of reviewing the research projects solely within the research circles. In other words, to prevent research of life sciences from being

[25] Commission of the European Communities, Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22September 2003 on genetically modified food and feed.
[26] Ibid.

reduced to a tool of violating human rights, it is necessary for the public to perform supervision over it. As the saying goes, absolute power without supervision is bound to lead to corruption. This is also true with research without supervision. Therefore, the biosafety committee or IRB must be a watchdog for the public to monitor the research of life sciences rather than act as a rubber stamp.

The fourth misconception is to reduce informed consent to a contract signed by the participant. Even some well-known ethicists focus their attention to the fact of whether the contracts or documents are signed by the participants when a project is challenged, and deem it as OK if they are signed. Yet they don't care under how and what conditions the participants singed and whether they had really been informed. According to the principles of bioethics, informed consent is a process rather than a document. What it stresses on is the process of every participant acquiring the information rather than the acquisition of their signatures. If a researcher truly respects the participant's human rights and right to know, he or she must earnestly perform the principles. When recruiting volunteers to present blood samples or for drug trials, it is essential to adequately inform every member of the community about the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail. The participants should also be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal. The participants' freely-given informed consent should be obtained on the basis of such full information. Local administrative officials and village heads or doctors should not be involved in the recruitment lest the participants misunderstand it as an administrative mandate from above and could not make their decisions freely. No coercion should be used, and participants should not be lured into the project by such promises as "free physical checkup" and "free medical treatment."

The fifth misconception is to be content with the currently available ethical principles made by foreign experts and assume their rules are perfect. As a matter of fact, things have always developed and rules need improve constantly. The *Helsinki Declaration* went through several revisions. Nowadays, many projects are entirely new and involve many commercial benefits, which make it necessary to update the rules or our rights cannot be fully safeguarded. Many rules were made when the developing countries had little say in international affairs, so some rules may not take into full consideration of the conditions and benefits of the developing countries. The United Nations *Convention on Biological Diversity* and *Protocol of Biosafety*, which do not cover the research of human genomics, have put forward the principle of benefit sharing in the acquisition of genetic resources. Should this principle of benefit sharing be applied to the acquisition of human genetic resources? We should think about it. Then again the formulation of the rules should not be a business of the experts and authorities only. As it matters our own bodies and our personal interest, each of us should have a say in the business, and among those who formulate the rules should be representatives of the public.

The sixth misconception is to hold that as a developing country, China should not put up the equally strict demand on informed consent as the developed countries. It is just such notion that has led to many loopholes in regulations and legislation, hence some research and experiments that are forbidden in the developed countries can be conducted smoothly in China. So long as we maintain that everyone is equal in terms of human rights, our right to know should be equal, too. It is wrong to assume that the better educate enjoy greater right to know than the poorly educated, and it is even more wrong to maintain that the right to know should be better respected in the developed countries and areas than in the underdeveloped countries and areas. If there is a difference, then the researchers should make greater efforts to give full information to the local people when they conduct studies in communities where the education level is generally low. If the researcher regards the mission as impossible on the ground that the farmers are too poorly educated to get things clear, then he or she could simply leave the farmers alone, without taking anything from them. Nobody can take something away from other's house without giving a justifiable reason and letting the other know why, let alone take his or her blood.

In general, the right know concerns our human rights and our dignity as human beings as well as equality and social justice. It has become an issue the research of life sciences cannot avoid. We should and must pay due attention to this issue of human rights in this field and enhance the related legislation so as to carry out the *Constituion*'s commitment to the respect for and safeguarding of human rights.

Bringing Bioethics back to earth: Comment on Xiong Lei's Article

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In her article, Xiong Lei takes issue with the core of bioethics. How does bioethics relate to human rights? What kind of a human rights concept supports a culturally educated global bioethics? What remains from our humanitarian agenda if we deny it a perspective of humanity?

The recent 7th World Congress of Bioethics in Sydney articulated two different *cultures of bioethics*, which can be distinguished by each one's particular agenda and conceptual framework regarding "human rights and bioethics".

Ruth Macklin imagines "two *separate* approaches with an overlap between them", adding that "the two approaches can and should be mutually reinforcing". It stands to question, what would be a coherent normative frame for giving such reinforcement a purpose? George Annas, a pioneer of American bioethics, would rather situate the field of bioethics *within* a human rights framework. This debate gained substance when Angela Wasunna set bioethics amidst the context of globalization, poverty and human rights. Thus bioethics acquires a clear program, which shuns legalistic or bureaucratic distortion but invites ethical reasoning. Wasunna calls international bioethicists to address global health problems in a pragmatic way, *grounded* in ethical principles. She concludes that, "I am encouraged that bioethics as a discipline is as relevant today for a human rights practitioner in Nigeria as it is for a bioethics professor in Canada". (1)

It may seem as if the narrow and destructive scope of the apologetic question, "Whose Human Rights?" has finally become obsolete. A few fundamental insights *are* at hand in bioethics. They'd rather not be jumbled by ethical relativism if we hope to make practical sense in bioethics.

In such a situation, Xiong Lei's argument is a lesson for culturally educated and socially concerned bioethics. The journalist encourages us to de-mystify science and experts in regard of their obligations toward society, to overcome civil paternalism by capacitating lay people. She reminds us to be sincere about the interests of research and to foster IRB's as institutional safeguards ("watchdogs") for the vulnerable. She warns us not to accept formalistic excuses for law-like insincerity, e.g. in face of "informed consent forms" and by no means to tolerate double standards in ethics. Finally, Xiong prompts us to co-operate to constantly improve our codes of ethics.

Alliances are emerging, between professional "bioethics" and concerned citizens, fuelled by demand for solidarity and justice. In a recent letter to the editor of the AJoB, a group of eminent bioethicists express confidence in a bioethics that is inspired by human rights, and alert us about an abuse of bioethics if it fails to respect human rights. (2) The authors acknowledge the protracted woe of unethical research carried out on a largely illiterate rural population. They worry that research of this nature was able to escape ethical scrutiny. And they refer to the trouble of freedom of speech, which is, at times, in jeopardy, even in a bioethics community.

Xiong's paper appeals to concerned citizens in a global civil society, as stakeholders in bioethics. To me, there is no doubt that this setting leaves ample room for diversity of moral views and life stiles. In fact, it calls us to fill these spaces with life.

Notes

(1) Reflections on the 7 th World Congress of Bioethics by Paul A. Komesaroff, cf.: „http://www.bioethicsworldcongress.com/images/Congress%20Reflections.pdf"

(2) Dirceu B. Greco, Dafna Feinholz, Dirce Guilhem, Carel IJsselmuiden, Bebe Loff, Udo Schuklenk, Juan Carlos Tealdi, "Letter to the Editor Regarding the 5th Global Forum on Bioethics in Research", The American Journal of Bioethics, Volume 4 Number 4, December 2004:W38

China: Ethical Issues in the Family Planning Program

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Introduction

China is one of the greatest empires in the world. Its population reaches almost 1.3 billion people, which is almost fourth of the entire world population! But the size of population in not correlated with its settled terittory and financial, social, ecological and geographical resorces. According to analists from the human science field, China will soon not be able to support more than 1.6 billion people and this day is not so far away.

In our research we desired to examine the law of birthrate restriction or as it is officially called: " The law of Family Planning Program " and "The law of Maternal and Infant Healthcare" from Bioethical aspects and especially the principles of respect for autonomy, nonmaleficence, beneficence, justice, the meaning of life and caring.

This issue touched us deeply because of its difference from the expansive attitude in Israel: " More children- more happiness" is a common saying in Israel. This has support in the Jewish religion. As it says in our holy book, the *Tora*:" And God blessed them, and God said unto them, Be fruitful, and multiply, and replenish the earth" (*Genesis*, chapter 1, 28 and chapter 9,1) .In this sentence there are two important verbs: *blessed* and *said unto*. Having children is a good thing, and we are ethically required to do it. This means that God's saying expresses a blessing and a commandment.

This is Israel's attitude to this matter. Generally the idea of having more children is both officially and culturally encouraged. Culturally for example: poetry- "Children is happiness" by: Yehoshua Sobol, theatre:" Spanish orchard" by Yitzhak Navon, cinema: "Kadosh"(sacred) by Amos Gitai.

Mothers receive from Israeli National Insurance a generous financial grant just after childbirth. This grant requires that the mother give birth in hospital or bring the baby to hospital within 24 hours after birth. This requirement is aimed especially at improving mother and infant health in the Bedouin population.

Israeli National Insurance also gives a monthly allowance to families with children under the age of 18. The more children a family has, the larger allowance it receives from National Insurance.

In the light of our Israeli background, having one child in China at first sight seemed to us more like a "punishment" rather than a way of improving the citizens' lives.

This especially struck us because the basis of their ancient culture resembles this Jewish commandment of having many children. For example the sculpture "The laughing Buddha" .Several Chinese ideals are embodied in that figure: the fat belly symbolizes wealth; his smile and relaxation indicate his equanimity, and the children around him show his love of children, one of the principal Chinese virtues. His

eccentric actions also express the mind of Chan [Zen] Buddhism.

All of that prompted us to explore how it came about that the Chinese changed their personal philosophy, if they truly did so, and how can it be that in such a short period of time the government there suceeded in reversing the behavior of the Chinese.

The Chinese people have shared a common culture longer than any other group on Earth. The imperial dynastic system of government was established as early as 221 BC. It was overturned in 1911, and a weak republican form of government existed until 1949. In that year, after a long civil war, the People's Republic of China, with a Communist government, was proclaimed. This government and the ruling Communist party have controlled China ever since.

Believing that the revolution could not be carried on without reform of people, the communist party launched a massive campaign to change China's entire psychology, as we can see in a quote of chairman Mao Tse-Tung: "A Communist should have largeness of mind and he should be staunch and active, looking upon the interests of the revolution as his very life and subordinating his personal interests to those of the revolution; always and everywhere he should adhere to principle and wage a tireless struggle against all incorrect ideas and actions, so as to consolidate the collective life of the Party and strengthen the ties between the Party and the masses; he should be more concerned about the Party and the masses than about any individual, and more concerned about others than about himself. Only thus can he be considered a Communist." 2 The Four Olds campaign was launched to eradicate old ideas, habits, customs, and culture.

The situation in West China:

28% of the Chinese population is situated in the west of the country and composed of minorities especially Moslems, Tibetans and Mongolians. Most dwell in rural areas and live on agriculture. The need for boys is more essential for several reasons: first as a result of the need for physical strength for daily labor, and second because when a woman gets married she traditionally belongs to her husband's family and her parents loose her forever. Due to these special conditions the leaders adjusted the law there. For example if the first offspring is a female they are allowed to have a second child. In spit of that, the ratio between boys and girls has changed dramatically in the west in comparison to the rest of the country- 140/100 in the west compared with 117/100 in the entire country. Now the government declared a new project called "girl care" and their goal is to change back the ratio to normal by 2010, according to Zhao Baige, the deputy director of China's National Population Commission.**4**

The Research Tools

We sent a questionnaire by electronic mail. The questionnaire contained three main questions. We put our explanations of our reasons for the questions within italics:

1. How many children do you have? And how many would you have liked to have if there had not been a restrictive law?

The goal of this question was to learn something about the attitudes of the Chinese bioethicists themselves. Without a doubt there is a certain fear to come out against any institutional thing and particulary such a basic law. This fear may become stronger when one is open to, and reveals one's thoughts to strangers. Therefore, through this question we tried to discover the true position of the respondents. We hoped that the Chinese reserchers would understand this purpose and wouldn't see it as an invasion of privacy.

2. Do you think that the government will be successful in enforcing this law in Western China? What steps do you think might be taken to ensure the acceptance there of this and other social legislation?

The goal of this question is to find out what they think about the special situation in the West and if it can be changed and how.

3. To what extent do you think that eugenic legislation is in accord with, or departs from, ancient Chinese ethical traditions, such as Confucianism or Taoism? We are thinking in particular of restrictions on family size, abortions, autonomy.

These, in fact, are moral questions that the Chinese might have asked themselves during the legislation. Apparently there has never been a deep discussion about this issue in China.

We sent this questionnaire by email to 75 Chinese bioethicists from a list which we received from Professor Darryl Macer. We planned to analyze the results “qualitatively” on the basis of the ethical principles of respect for autonomy, non-maleficence, beneficence, justice, the meaning of life and caring. These principles were not to be used as dogma, but simply as section headings in order to facilitate an orderly and meaningful discussion. We also tried to contact Mr. Lu Ging the head of foreign relationships at the Chinese embassy but we didn’t receive any response to our e-mail.

Results

Response rate:

Unfortunately, only one bioethicist, WW, replied to our questionnaire. We wondered why...

1. Perhaps there were language obstacles

2. Perhaps there were technical problems like a wrong mail address, vacations etc.

3. Perhaps there was fear resulting from the government’s tight control of foreign relationships and what information leaves the country. This type of communication-by the Internet makes it impossible for them to be sure of the writer's identity. The government can easily know they have been in touch with Israelis.

The fact that one person, WW, did respond – and quite candidly – suggests that the "fear factor" may not be nearly as serious as we had thought.

The poor response rate may lead some to conclude that our research project has been a failure. On the other hand, the very fact that only one person answered is in itself interesting. Is may also be more interesting to learn about the views of one person in at least a little depth, than to have many summaries of answers from many unknown people who may appear in the research as nothing but faceless numbers.

W.W's responses

1." I have one child, a son. When I was young, my grandmother said to me and to my wife that we had better have two children. One child is not very good for education, the child will feel lonely. My wife and I did not consider my grandma's advice seriously. It was 20years. Now my son has grown up and become a college student, and he is preparing GRE. He wants to go abroad to finish his graduated studying. My wife feels one child is not very good for a family…. There is an example that may be our future. Our friends, an old couple, he used to be a vice president of a University. Their only child, son graduated from Beijing University (and his wife) is now in USA studying Judaism; the son is very good at Hebrew. Their parents, the old couple, over 70 years old, the father got cataract, and the mother hurt her arm in a snowing winter. So that the mother is the father's eye and the father is the mother's arm." One Couple, One Child." will soon lead the society into "aged-person society" as you know. This is the problem we faced. So that is why I think "One Couple, Two Children" maybe better than "One Couple, One Child".

The goal for this question was successfully reached. He answered us broadly and even revealed his personal story. Although we asked indirectly about one's opinion on the law, he shared with us, without any impedance, his honest opinion.

2. "In Western China and in country, things are little difference. But I don't think that the government is going to force the law, especially for the groups of "professionals" such as the "microeconomic persons", "three capital persons", farmers and "leave off post workers". I think that the decision of how many children to procreate is a couple's human right, no one can intermeddle. According to the situation of the country, government can advise young couples and give a help to them."

In his answer he confirmed our thoughts about the difference in the west, but he didn't answer the goal we were looking for in our question directly although he provided us general information.

3. " In ancient Chinese ethical traditions, "more children, more happy."There are three kinds of unworthy posterities, not having a child is the worst" .But in country, if there is no son in a family, we can't imagine how to make living. So I think in Western China and in country, the family may probably advise young couples to bear a boy, if the young couple bears a girl, the family maybe let them to bear the second child. So I think that if all the young couple have the idea: (1) If bearing a boy, then OK. (2)If bear a girl, then to bear the second child (whatever the second child is a boy or a girl); then the rate of male/female of youngsters will be badly unbalance. That will be a seriously problem for the society. Isn't it?"

In his answer he strengthens our assumptions about the old traditions that encourage proprieties. After further reading we have done we found written proves to that especially in Buddhism .Out of the main purpose here he also provided us a glimpse of his point of view, as a Chinese citizen, about what can be done.

Discussions and Conclusions

We two authors of this paper discovered that our thoughts and conclusions are quite different. Rather than writing a compromise position, which might be quite superficial and uninformative, we have decided to present our individual discussions and conclusions separately:

Discussion and conclusion of MC

In my opinion, having such a law as the Chinese family planning law is basically wrong. The main ethical problem is- Can an authority become involved in its citizens personal lives for the benefit of all? Can it rule out basic human rights such as freedom of choice and decision? What about respecting one's autonomy? Where is the limit?

Furthermore, this law results in a lot of controversial issues like: breaking the natural balance between male / female ratio in China, more abortions, more single males, more female children abandoned and even dying.The desire of having the one "perfect child" leads to an abortion rate which is one of the highest in the world and finally will result in eugenics- only perfect children will survive and there is no room for the abnormal or the crippled. Genetic counselors there are pulling the trigger on abortion easily.

I agree with the necessity of birth rate reduction but more efforts should be invested on education rather than on enforcing the law; and in the absence of other choice, the law should be changed to "one couple-two children".

Discussion and conclusion of SE

The main question we should all ask ourselves is- is there any other choice? Apparently not. We have to admit that there are ethical problems created by this law. On the other hand, without this law existential problems will come to reality. China can not contain so many people; the sources of the land will be all consumed- no food, no water.

One way or the other the amount of people in China will reach its limit- either more people will die as a result of incapacity of the land or the birthrate will decrease dramatically; for this reason, the main ethical question is- What is preferred?

Therefore my conclusion is that restricting the birthrate is a justified and an ethical way. Education only seems to be a more moral way of doing that, but until it will achieve results it might be too late…

Shared conclusions

Because we cannot imagine how can a law like this could be passed in Israel, we were wondering how come it passed through smoothly in China.

First of all, its communist regime, which it's foundation, places the benefit of the country over personal life. People there fear to speak up in public against the government. In fact, the only resistance is passive and it comes to fruition through the Taoism which is the ancient Chinese philosophy who is the opposite of Confucianism and Communism, "Tao" means "behavior, understanding and the constant change from and to". Taoism is a philosophy and a belief of simplicity and the very nature of universe. There is no absolute "stillness". Everything, including the universe, is changing all the time. The relative "stability" can be achieved when a harmony is reached between "Yin" and "Yang", which are said to be the opposite but related natural forces in the universe and it should be implemented by ways of discussion and in peaceful ways and by force and coercion. This is why the Taoism in China opposes to the "one couple – one child policy" but only passively and without means of actions, force or revolution. One of the philosophy's principles is – "If no action is taken than all live in peace." **3**

Secondly, Many Chinese hold the philosophy of Confucianism. Confucius knew but one form of government, the traditional monarchy. The king exercised an absolute authority over his subjects, as the father over his children. He ruled by right Divine. He was providentially set up by Heaven to enlighten the people by wise laws and to lead them to goodness by his example and authority. The principal is that the people cannot fail to practice virtue and to prosper when the ruler sets the high example of right conduct.

The basic assumption is that the governors want only the best for their people.

Third, it may be simple as this: the Chinese truly understand the necessity of this kind of law. Besides, since it was passed, they feel improvement in the quality of their life.

References

1. Data from the national bureau of statistics of china – www.stas.gov.cn+ BBC News, world addition – "Chinese officials held over baby death" Friday, 22 September, 2000

2. "Combat Liberalism" (September 7, 1937), Selected Works, Vol. II, p. 33.

3. The Encyclopedia of Eastern Philosophy and Religion, (Boston: Shambala, 1986), p. 199

4. BBC News, world addition- " China acts to protect baby girls" Thursday, 15 July, 2004

Preliminary Draft Declaration on Universal Norms on Bioethics

RECOMMENDED TITLE:

UNIVERSAL DECLARATION ON BIOETHICS AND HUMAN RIGHTS

This Preliminary Draft Declaration on Universal Norms on Bioethics was finalized by the International Bioethics Committee (IBC) at its Extraordinary Session on 28 January 2005 after six meetings of its Drafting Group held between April and December 2004, three sessions of IBC (April 2004, August 2004, January 2005), two written consultations (January-March 2004 and October-December 2004), numerous consultations at international, regional and national levels (including within the framework of the UN Interagency Committee on Bioethics), a session of the Intergovernmental Bioethics Committee (IGBC) and a joint session of IBC and IGBC (January 2005).
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Division of Ethics of Science and Technology, UNESCO

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The General Conference,

Reflecting on the rapid developments in science and technology, which increasingly affect our understanding of life and life itself, resulting in a strong demand for a global response to the ethical implications of such developments,

Conscious of the unique capacity of human beings to reflect upon their own existence and on their environment; to perceive injustice; to avoid danger; to assume responsibility; to seek cooperation and to exhibit the moral sense that gives expression to ethical principles,

Recognizing that ethical issues raised by the rapid advances in science and their technological applications should be examined with due respect to the inherent dignity of the human person and universal respect for, and observance of, human rights and fundamental freedoms,

Resolving that it is necessary and timely for the international community to state universal principles that will provide a foundation for humanity's response to the ever-increasing dilemmas and controversies that science and technology present for the human species and for the biosphere,

Recalling the Universal Declaration of Human Rights of 10 December 1948, the Universal Declaration on the Human Genome and Human Rights adopted by the General Conference of UNESCO on 11 November 1997 and the International Declaration on Human Genetic Data adopted by the General Conference of UNESCO on 16 October 2003,

Also recalling the two United Nations International Covenants on Economic, Social and Cultural Rights and on Civil and Political Rights of 16 December 1966, the United Nations International Convention on the Elimination of All Forms of Racial Discrimination of 21 December 1965, the United Nations Convention on the Elimination of All Forms of Discrimination against Women of 18 December 1979, the United Nations Convention on the Rights of the Child of 20 November 1989, the United Nations Convention on Biological Diversity of 5 June 1992, the Standard Rules on the Equalization of Opportunities for Persons with Disabilities adopted by the United Nations General Assembly in 1993, the ILO Convention 169 concerning Indigenous and Tribal Peoples in Independent Countries of 27 June 1989, the International Treaty on Plant Genetic Resources for Food and Agriculture adopted by the FAO Conference on 3 November 2001 and entered into force on 29 June 2004, the Recommendation of UNESCO on the Status of Scientific Researchers of 20 November 1974, the UNESCO Declaration on Race and Racial Prejudice of 27 November 1978, the UNESCO Declaration on the Responsibilities of the Present Generations Towards Future Generations of 12 November 1997, the UNESCO Universal Declaration on Cultural Diversity of 2 November 2001, the Trade Related Aspects of Intellectual Property Rights Agreements (TRIPs) annexed to the Agreement establishing the World Trade Organization, which entered into force on 1 January 1995, the Doha Declaration on the TRIPs Agreement and Public Health of 14 November 2001 and other relevant international instruments adopted by the United Nations and the specialized agencies of the United Nations system, in particular the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO),

Bearing in mind international and regional instruments in the field of bioethics, including the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine of the Council of Europe, adopted in 1997 and entered into force in 1999, as well as national legislation and regulations in the field of bioethics and the international and regional codes of conduct and guidelines and other texts in the field of bioethics, such as the Declaration of Helsinki of the World Medical Association on Ethical Principles for Medical Research Involving Human Subjects, adopted in 1964 and amended in 1975, 1989, 1993, 1996, 2000 and 2002 and the International Ethical Guidelines for Biomedical Research Involving Human Subjects of the Council for International Organizations of Medical Sciences adopted in 1982 and amended in 1993 and 2002,

Considering that, by virtue of its Constitution, it is incumbent upon UNESCO to promote the democratic principles of the dignity, equality and respect of human beings and to reject any doctrine of inequality, and that this constitutes a duty which all nations must fulfil in a spirit of mutual assistance,

Considering also UNESCO's role in developing universal principles based on shared ethical values to guide scientific and technological development and social transformation, in order to identify emerging challenges in science and technology taking into account the responsibility of the present generation towards future generations, and that questions of bioethics, which necessarily have an international dimension, should be treated as a whole, drawing on the principles already stated in the Universal Declaration on the Human Genome and Human Rights and the International Declaration on Human Genetic Data, and taking account not only of the current scientific context but also of future developments,

Aware that human beings are an integral part of the biosphere and that they have responsibilities and duties towards each other and towards other forms of life,

Recognizing that scientific and technological developments have been, and can be, of great benefit to humankind in increasing *inter alia* life expectancy and improving quality of life and emphasizing that such developments should always promote the welfare of individuals, families, groups or communities and humankind as a whole in the recognition of the inherent dignity of the human person and the universal respect for, and observance of, human rights and fundamental freedoms,

Recognizing that bioethical issues may have an impact on individuals, families, groups or communities and humankind as a whole,

Bearing in mind that cultural diversity, as a source of exchange, innovation and creativity, is necessary for humankind and, in this sense, is the common heritage of humanity, but

emphasizing that it may not be invoked to contravene fundamental human rights and freedoms,

Convinced that ethical reflection should be an integral part of the process of scientific and technological developments and that bioethics should play today a predominant role in the choices that need to be made concerning issues arising from such developments,

Considering the need for a new approach to social responsibility to ensure, whenever possible, that progress in science and technology contributes to justice, equity and to the interest of humanity,

Stressing the need to reinforce international cooperation in the field of bioethics, taking into account in particular the special needs of developing countries,

Proclaims the principles that follow and adopts the present Declaration.

General Provisions

Article 1 – Use of Terms

For the purpose of this Declaration:

(i) the term "bioethics" refers to the systematic, pluralistic and interdisciplinary study and resolution of ethical issues raised by medicine, life and social sciences as applied to human beings and their relationship with the biosphere, including issues related to the availability and accessibility of scientific and technological developments and their applications;

(ii) the term "bioethical issues" refers to the issues mentioned in Article 1(i); and

(iii) the term "decision or practice" refers to a decision or practice arising within the scope of this Declaration and involving bioethical issues.

Article 2 – Scope

The principles set out in this Declaration apply as appropriate and relevant:

(i) to decisions or practices made or carried out in the application of medicine, life and social sciences to individuals, families, groups and communities; and

(ii) to those who make such decisions or carry out such practices, whether they are individuals, professional groups, public or private institutions, corporations or States.

Article 3 – Aims

The aims of this Declaration are:

(i) to provide a universal framework of fundamental principles and procedures to guide States in the formulation of their legislation and policies in the field of bioethics, and to form the basis for guidelines concerning bioethical issues for the individuals, groups and institutions concerned;

(ii) to promote respect for human dignity and the protection and promotion of human rights and fundamental freedoms in any decision or practice involving bioethical issues, in accordance with international human rights law;

(iii) to recognize the importance of freedom of scientific research and the benefits derived from scientific and technological developments, whilst ensuring that such developments occur within the framework of ethical principles that respect human dignity and protect human rights and fundamental freedoms;

(iv) to foster multidisciplinary and pluralistic dialogue about bioethical issues between scientists, health professionals, lawyers, philosophers, ethicists, theologians and all the other intellectual, religious and professional groups concerned, policy makers, non-governmental organizations, representatives of civil society, the persons concerned and society as a whole;

(v) to promote equitable access to medical, scientific and technological developments as well as the greatest possible flow and the rapid sharing of knowledge concerning those developments and the sharing of benefits, with particular attention to the needs of developing countries;

(vi) to recognize the importance of biodiversity and the responsibilities of human beings towards other forms of life in the biosphere; and

(vii) to safeguard and promote the interests of the present and future generations.

PRINCIPLES

Article 4 **–** Human Dignity and Human Rights

a) Any decision or practice shall be made or carried out with full respect for the inherent dignity of the human person, human rights and fundamental freedoms;

b) Any decision or practice shall respect the principle that the interests and welfare of the human person prevail over the sole interest of science or society.

Article 5 – Equality, Justice and Equity

Any decision or practice shall respect the fundamental equality of all human beings in dignity and rights and ensure that they are treated justly and equitably.

Article 6 **–** Benefit and Harm

Any decision or practice shall seek to benefit the person concerned and to minimize the possible harm resulting from that decision or practice.

Article 7 **–** Respect for Cultural Diversity and Pluralism

Any decision or practice shall take into account the cultural backgrounds, schools of thought, value systems, traditions, religious and spiritual beliefs and other relevant features of society. However, such considerations shall not be invoked to infringe upon human dignity, human rights and fundamental freedoms nor upon the principles set out in this Declaration, nor to limit their scope.

Article 8 **–** Non-Discrimination and Non-Stigmatization

In any decision or practice, no one shall be subjected to discrimination based on any grounds intended to infringe, or having the effect of infringing, the human dignity, human rights or fundamental freedoms of an individual, nor shall such grounds be used to stigmatize an individual, a family, a group or a community.

Article 9 **–** Autonomy and Individual Responsibility

Any decision or practice shall respect the autonomy of persons to make decisions and to take responsibility for those decisions while respecting the autonomy of others.

Article 10 – Informed Consent

a) Any decision or practice in the field of scientific research shall only be made or carried out with the prior, free, informed and express consent of the persons concerned. Such consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage or penalty.

b) Any decision or practice regarding the medical diagnosis and treatment of a person shall only be made or carried out with the consent of the person concerned, based on information appropriate to the decision, and with the ongoing participation of such person.

c) In any decision or practice involving persons who do not have the capacity to consent, special protection shall be given to such persons. Such protection shall be based on ethical and legal standards adopted by States, consistent with the principles set out in this Declaration.

Article 11 – Privacy and Confidentiality

Any decision or practice shall be made or carried out with respect for the privacy of the persons concerned and the confidentiality of their personal information. Unless irretrievably unlinked to an identifiable person, such information shall not be used or disclosed for purposes other than those for which it was collected.

Article 12 **–** Solidarity and Cooperation

Any decision or practice shall pay due regard to solidarity among human beings and encourage international cooperation to that end.

Article 13 **–** Social Responsibility

Any decision or practice shall ensure that progress in science and technology contributes, wherever possible, to the common good, including in the achievement of goals such as:

(i) access to quality health care and essential medicines, including for reproductive health and the health of children;
(ii) access to adequate nutrition and water;
(iii) improvement of living conditions and the environment;
(iv) elimination of the marginalization and the exclusion of persons on the basis of any grounds; and
(v) reduction of poverty and illiteracy.

Article 14 – Sharing of Benefits

a) Benefits resulting from scientific research and its applications shall be shared with society as a whole and within the international community, in particular with developing countries. In giving effect to this principle, benefits may take any of the following forms:

(i) special and sustainable assistance to the persons and groups that have taken part in the research;
(ii) access to quality health care;
(iii) provision of new diagnostics, facilities for new treatments or medical products stemming from the research;
(iv) support for health services;
(v) access to scientific and technological knowledge;
(vi) capacity-building facilities for research purposes; and
(vii) any other form consistent with the principles set out in this Declaration.

b) This provision may be implemented through legislation, international agreements or by other appropriate means, which shall be consistent in every case with international human rights law.

Article 15 **–** Responsibility towards the Biosphere

Any decision or practice shall have regard to its impact on all forms of life and their interconnections and to the special responsibility of human beings for the protection of the environment, biodiversity and the biosphere.

CONDITIONS FOR IMPLEMENTATION

Article 16 **–** Decision-Making

Any decision or practice should:

(i) be made or carried out following full and free discussion and in accordance with fair procedures;
(ii) be made or carried out on the best available scientific evidence and methodology;
(iii) pay due regard to any different information on the subject reasonably available to the decision-maker;
(iv) be considered rigorously and based on the principles set out in this Declaration;
(v) observe, when appropriate, proper procedures of risk assessment, management and prevention; and
(vi) be considered individually, having regard to the circumstances of the persons, groups and communities concerned.

Article 17 **–** Honesty and Integrity

Any decision or practice should be made or carried out with:

(i) professionalism, honesty and integrity;
(ii) declaration of all conflicts of interest; and
(iii) due regard to the need to share knowledge about such decisions and practices with the persons affected, the scientific community, relevant bodies and civil society.

Article 18 **–** Transparency

Any decision or practice should, subject to the provisions on privacy and confidentiality in Article 11:

(i) be made or carried out transparently and openly;
(ii) be available for appropriate scrutiny by the persons concerned and by civil society; and
(iii) be susceptible to informed, wide and pluralistic public debate.

Article 19 – Periodic Review
Any decision or practice, including those depending upon specialized scientific or other knowledge, should take into account the need to reconsider periodically the state of such knowledge and different opinions about it and the need to engage in a regular dialogue with:
(i) persons affected by any such decision or practice;
(ii) members of relevant disciplines;
(iii) appropriate bodies; and
(iv) civil society.

Article 20 **–** Ethics Committees
Independent, multidisciplinary and pluralist ethics committees should be established, promoted and supported at the appropriate level in order to:
(i) assess the ethical, legal and social issues related to scientific research projects involving human beings;
(ii) formulate recommendations and contribute to the preparation of guidelines on issues within the scope of this Declaration, in accordance with the principles set out herein; and
(iii) foster debate and education in bioethics.

Article 21 **–** Promoting Public Debate
States should promote opportunities for informed, pluralistic public debate, ensuring the participation of all persons and bodies concerned, including relevant ethics committees and non-governmental organizations, and the expression of various socio-cultural, religious, philosophical and other relevant opinions.

Article 22 **–** Risk Assessment, Management and Prevention
a) When evidence of serious or irreversible damage to public health or human welfare becomes available, appropriate measures should be taken in a timely manner.
b) When there are threats of serious or irreversible damage to public health or human welfare, and there is not yet scientific certainty about such threats, provisional, adequate and proportionate measures should be taken in a timely manner. Such measures should be based on the best scientific knowledge available and on procedures that are specially designed for evaluating the ethical issues at stake. These measures should be carried out in accordance with the principles set out in this Declaration and with respect for human dignity, human rights and fundamental freedoms.

Article 23 – Transnational Practices
a) States should take appropriate measures to ensure that any activity with bioethical implications, which is undertaken in whole or in part in different States, complies with the principles of this Declaration. Public and private institutions and professionals associated with a transnational activity should also take all appropriate measures to achieve the same end.
b) When research is carried out in one country and funded partially or wholly by sources from one or more other countries, such research should be subjected to ethical review in all of the countries involved. This review should be based on ethical and legal standards, consistent with the principles set out in this Declaration, adopted by the States concerned.

IMPLEMENTATION AND PROMOTION OF THE DECLARATION

Article 24 – Role of States
a) States should take all appropriate measures, whether of a legislative, administrative or other character, to give effect to the principles set out in this Declaration, in accordance with international human rights law. Such measures should be supported by action in the spheres of education, training and public information. States should also take appropriate measures to involve young people in these activities.
b) States should encourage the establishment of independent, multidisciplinary and pluralist ethics committees, in accordance with Article 20.
c) States should establish processes for the assessment, management and prevention of risks. Such processes should include the identification of the issues, the characterization of risks and benefits, the development of options, the implementation of the decisions and the monitoring of the results.

Article 25 – Bioethics Education, Training and Information
a) In order to implement and promote the principles set out in this Declaration and to achieve a better understanding of the ethical implications of scientific and technological developments, States should endeavour to foster all forms of bioethics education and training at all levels as well as to encourage information and knowledge dissemination programmes about bioethics.
b) States should encourage the participation of international and regional intergovernmental organizations and international, regional and national non-governmental organizations in this endeavour.

Article 26 – International Cooperation
a) States should foster international dissemination of scientific information and encourage the free flow and sharing of scientific and technological knowledge.
b) Within the framework of international cooperation, States should promote cultural and scientific cooperation and enter into bilateral and multilateral agreements enabling developing countries to build up their capacity to participate in generating and sharing scientific knowledge, the related know-how and the benefits thereof.
c) States should respect and promote solidarity between and among States, as well as individuals, families, groups and communities, with special regard for those rendered vulnerable by disease or disability or other personal, societal or environmental conditions and those with the most limited resources.

Article 27 **–** Roles of the International Bioethics Committee (IBC) and the Intergovernmental Bioethics Committee (IGBC)
a) The International Bioethics Committee (IBC) and the Intergovernmental Bioethics Committee (IGBC) shall contribute to the implementation of this Declaration and the dissemination of the principles set out herein. On a collaborative basis, the two Committees should be responsible for its monitoring and for the evaluation of its implementation, in particular on the basis of reports provided by States. The two Committees should be responsible in particular for the formulation of any opinion or proposal likely to further the effectiveness of this Declaration. They should make recommendations in accordance with UNESCO's statutory procedures, addressed to the General Conference.
b)Reports provided by States, on the steps they have taken, whether of a legislative, administrative or other character, to give effect to this Declaration, should be addressed every five years to the Director-General of UNESCO.

Article 28 **–** Follow-up action by UNESCO

a) UNESCO shall take appropriate action to follow up this Declaration by evaluating new developments in science and technology and their applications according to the principles set out herein.

b) UNESCO shall reaffirm its commitment to dealing with the ethical aspects of the biosphere and, if necessary, shall endeavour to elaborate guidelines and international instruments, as appropriate, on ethical principles related to the environment and other living organisms.

c) Five years after its adoption and thereafter on a periodical basis, UNESCO shall take appropriate measures to examine this Declaration in the light of scientific and technological development and, if necessary, to ensure its revision, in accordance with UNESCO's statutory procedures.

d) With respect to the principles set forth herein, this Declaration may be further developed through international instruments adopted by the General Conference of UNESCO, in accordance with UNESCO's statutory procedures.

OPERATION OF THE PRINCIPLES AND DECLARATION

Article 29 **–** Interrelation and Complementarity of the Principles
In their interpretation and application, the principles set out in this Declaration are complementary and interrelated and each principle should be construed in the context of the other principles. Where there is conflict between the principles this should be resolved by balancing all those principles that are appropriate and relevant in the circumstances.

Article 30 **–** Restrictions on the Principles

No restrictions shall be placed on the principles set out in this Declaration other than those prescribed by law, and which are consistent with international human rights law and necessary in a democratic society in the interest of public safety, for the prevention of crime**,** for the protection of public health or for the protection of the rights and freedoms of others.

Article 31 – Denial of acts contrary to human rights, fundamental freedoms and human dignity

Nothing in this Declaration may be interpreted as implying for any State, group or person any claim to engage in any activity or to perform any act contrary to human rights, fundamental freedoms and human dignity.

Ethical issues about human reproductive cloning

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Abstract

The first scientific hypotheses about of a possible human cloning were made almost 40 years ago. However, it was only with the announcement of the first mammal cloning through somatic cells that the debate about this technique was intensified and broadly discussed. The first human cloned embryo announced in March 2004, intensifies the discussion regarded to the ethical aspects related to this technique in human beings.This work intend to summarize the main questions that rising about human reproductive cloning.

Introduction

The first scientific hypotheses about of a possible human cloning were made in 1966, by the geneticist Joshua Lederberg, when he hypothesized the advantages of human cloning and other forms of genetic engineering.[1] By the 1980s, cloning controversy had died, with most scientists and philosophers agreeing that it was a fantasy beyond the world of serious science.[2] It was only with the announcement of the first mammal cloning through somatic cells that the debate about the human reproductive cloning was intensified and broadly discussed.

The debate about cloning has repeatedly been driven by these extra-scientific announcements and the public have been poorly served by the quality of this bioethical discussion.[3] In some cases, the media passed the impression of science isolation, where scientists appear as people of great power, but also as a remote from the public at large.[4] Usually, cloning in the popular and media imagination was portrayed of armies of drones, carbon-copy, masses of identical babies produced, clone farms to produce spare parts and Mary Shelley's Frankenstein.[5]

It is important to remember that intense repulse reaction ("yuck factor") has a crucial role in the idea of morality being dangerous. It is difficult to know when one's sense of outrage is an evidence of something morally disturbing and when is an expression of prejudice, like in recent past, when some moral feelings were used to discriminate Jews, black people and women.[6] Moreover, this yuck factor by the great part of public, media and scientists against human reproductive cloning was seen at other moments when new technologies appeared and later were broadly accepted and used, like fertilization *in vitro*, organs transplantation and recombinant DNA technology.

The first human cloned embryo using nuclear transfer was announced in March 2004. South Korean scientists at the Seoul University derived a pluripotent embryo stem cell line from a cloned human blastocyst, created by somatic cell nuclear transfer.[7] This experiment, as well as the others performed years ago in animals intensifies the discussion regarded to the ethical aspects related to this technique in human beings.

Cloning

The term cloning, from Greek (*klón*), which means vegetal bud, is used routinely to the process of creating a precise genetic copy of a molecule, cell, tissue, plant or animal. Human cloning technology can be applied to produce a genetically identical individual of an existing human (reproductive cloning) and to produce particular cells and

tissues for therapeutic purposes (therapeutic cloning). It is obtained by embryo splitting or nuclear transfer. The first method refers to the separation of an early human embryo, which will give origin to two or more individuals. This type of cloning can produce a limited number of individuals and isn't not able to produce a "clone" of an adult that already exists. Nuclear transfer consists in remove the nucleus of an egg cell and replacing it with the material from the nucleus of another cell. This technical can produce a genetically identical individual adult that already exist.

Cloning and reproduction

Frequently there are statements that twins are clones, and there would be no immorality on this. Twinning is a random, unpredictable event, which happens with no human intervention and originates a very reduced number of contemporaneous idividuals, through sexuate reproduction. Cloning may, in theory, produce an unlimited number of subjects with separated births through years or decades, occur with genetic material from one progenitor with previous intention of creating a genome identical to a preexisting one.[8]

Other arguments favoring cloning are the right of reproduction autonomy, the possibility of offering to infertile couples that suffer from intractable infertility a chance to have their children and the option for same sex couples to have a child genetically related to one of them. However, it is very difficult to define what is a person's right. In countries where demands and desires are frequently framed in terms of rights, cloning was defined as a "right" and the defenders of this technique insisted that it is a reproductive right of human beings.[9] Nevertheless, although reproduction is a private matter, development and implementation of a genetic technology in which reproductive decisions will be based are matters of public interest.[10] Besides, is important to remember that in an over medicalized society almost any product, procedure or technology can find a condition to demonstrate its "therapeutic" benefit, doing the medical value a weak criteria to decide which are the acceptable ways of human cloning.[11]

Sexually transmitted diseases, inadequate nutrition, poor health, limited access to health care also contribute to reproductive problems. If our concern is with solving infertility, there are other more effective ways to diminish the problem. Besides, other relevant aspects must be considered before accepting the cloning as a new manner of reproduction and an infertility treatment: there have been significative advances in reproductive medicine, which took several infertile couples to have their children; the number of people that cannot have children may diminish even more before we have cloning as a safe technique; it can be more interesting make efforts to diminish the pathologies that can lead to infertility, before spending time and resources to develop a technique that will benefit a reduced number of people[12].

Genetic and social disturbings

Some argue that a consequence of cloning in great scale would be a restriction in the diversity of the human gene pool. Even if human cloning became safety, there are no reasons to believe that this technique can be used in great scale and the number of individuals produced by cloning will be small compared to the human gene pool[13].

Confusion in family relationships and in the child's identity are being pointed as a consequence of cloning. However, familiar patterns vary in accordance to habits, religion and society morality. Besides, people can adapt socially to new technologies, as it happened with the *in vitro* fertilization. Nevertheless, there is no denial that the cloning will have moral, religious, and cultural effects in the values of society and could change our self-understanding of family.[14]

Human dignity

Many people argue that reproductive cloning is an attack to human dignity. However, there are vague references to "human dignity", with little or no attempt to explain how these might apply to cloning.[15] One way of viewing cloning as a contradiction to human dignity is often linked to kantian ethics, particularly related to an instrumentalization of human beings.

Kantian principle states that the respect to human dignity requires that an individual should never be used as an instrument. Use individuals as an instrument to the purpose of others is called "instrumentalization". Regarded to the reproduction, in some cases, the progenitors of a child think not only of the happiness of the child but also on their own. Among the possible reasons that people wish have genetic children are: wants to love and belong to others while at the same time one enjoys others belonging to and loving oneself; importance people give to their name family; saving a relationship; be accapted and admired by society and the community.[16] If cloning is a form of instrumentalization and violates the Kantian ethics, many other procreations probably be the same.

Nevertheless, cloning may diminish the human dignity through other factors. Cloning would transform human procriation into human manufacture and would give the creators unjustifiable powers over clones produced deliberately to resemble an existing individual (or even a dead person) just to satisfy the desires of third persons.[17]

Autonomy and individuality

A real problem that would help diminishing the individuality of clones is the removal of genetic identity.[18] The lost of subject autonomy, besides its genetic identity, is related with the concept that the subjects have the "right to ignorance" and an "open future". Right to ignorance is a conception that the ignorance about its own genetic constitution is needed for free construction of a life and for being autonomous. Open future can be understood as the need of people to have future possibility to build their own lives. In accordance to proponents, reproductive cloning takes away the freedom of the human being to have his own history, to be born and grow with the freedom of being himself. The clone would live in the shadow of the subject that was cloned ("life in a shadow argument"), being always compared his donator.

The belief that the parents will have more control on their cloned children are not based on the false premise that we can make an inference from genotype to phenotype, but only on the true premise that there is a public tendency to make such an inference.[19] In attempting to cull out from the resulting child the favored traits of the cloned one, the social parents will probably limit the environmental stimuli, experiences and opportunities.[20]

Obviously, genes are not completely responsible for our autonomy and individuality. However, a person who wishes to be cloned, wants to obtain some preselected characeristics in the clone, thus children born by cloning probably will have a limitation or redirectioning of stimuli and several expectations not ever seen. Cloning would be a new order of power for parental domination, representing a power abuse that no one should have over a child.[21] This way, even it is a mistake to belive in genetic determinism, reproductive cloning would undermines individuality and autonomy of a cloned child.

Psychological and physical harms

Many claim that cloning is associated with serious psychological harms for the cloned child. Some argue that the cloned child will never be perceived as our descendant, but only our pre-selected "genetic replicant" or a "copy" of another person. Besides, socially and psychologically, cloning will produce an entirely new individual, whose biological features just happen to be quite similar to somebody else's.[22]

Cloning would not produce copies, but other person with the same genome one already existing. Thus, there is no sense to believe in some "applications" of cloning as create soldiers' armies or dictators, getting back a lost person, have a second life chance or to obtain immortality. If or when a human being will be cloned, he/she will never be considered a "replica" or "copy" and will have all the rights and all the moral attributes of any human being.

The technique of cloning is still a dangerous scientific experiment. The immense majority of the attempts to produce mammalian animal clones resulted in death during gestation and many survivors suffered severe abnormalities.[23] Alterations in cloned animals during the development and after birth[24-27] show that attemps at cloning humans for reproduction are unsafe at present.[28] Safety is a fundamental ethical consideration and not merely a scientific consideration, even though it requires obviously scientific evidence.[29]

Final Considerations

Reproductive cloning still needs considerable improvement in efficiency before it wildely used for different propouses. Although, still there are many questions with regard to the reproductive and therapeutic cloning, the techninique of nuclear transplantatiion created many new opportunities in research, medicine and agriculture. It should be valuable for the study of human genetic diseases, cancer, control of gene expression, cell differentiation and aging, developing transgenic farm animals and contribute to production pharmaceuticals, tissues or cells for transplantation and xenotransplantation.[30-32]

Althought in many cases the distinction between reserch and uses of research is by no means easy to draw, control should not be over the research, but over of its uses.[33] The serious technical and ethical problems that nowadays exist in cloning turn the utilization of this thecnique for human beings' reproduction a procedure morally unacceptable. However, the good or evil is not intrinsic to this thecnique, but in it's purposes, utilization and consequences. It is necessary to establish, even locally and provisionally, if or what utilizations of this technique can be considered morally acceptable.

References

1- Kass LR (2001) The wisdom of repugnance. *In:* Brannigan MC (ed) Ethical issues in human cloning. Seven Bridges Press, New York, pp 43–66.
02- Bowring F (2004) Therapeutic and reproductive cloning: a critique. Soc Sci Med 58:401-409.
03- Hall SS (2003) Eve redux: the public confusion over cloning. Hastings Cent Rep 33:11-15.
04- Wilkie T and Graham E (1998) Power without responsability: Media portrayals of Dolly and science. Camb Q Healthc Ethics 7:150-159.
05- Hopkins PD (1998) Bad copies: How popular media represent cloning as an ethical problem. Hastings Cent Rep 28:06-13.
06- Harris J (1998) Cloning and human dignity. Camb Q Healthc Ethics 7:163-167.
07- Hwang WS, Ryu YJ, Park JH, et al (2004) Evidence of a pluripotent human embryonic stem cell line derived from a cloned blastocyst. Science, 303:1669-1674.
08- Bruce DM (2002) Stem cells, embryos and cloning - Unravelling the ethics of a knotty debate. J Mol Biol 319:917-925.
09- Nelkin D and Lindee S (1998) Cloning in the popular imagination. Camb Q Healthc Ethics 7:145-149.
10- Cheshire WP, Pellegrino ED, Bevington LK et al (2003) Stem cell research: Why medicine should reject human cloning. Mayo Clin Proc 78:1010-1018.
11- Bowring F (2004) op. cit. note 02
12- Melo-Martín I (2002) On cloning human beings. Bioethics 16:246-265.
13- Harris J (2000) Clones, genes, and reproductive autonomy: The ethics of human cloning. Ann N Y Acad Sci 913:209-217.
14- Mittelstrass J (2002) The impact of the new biology on ethics. J Mol Biol 319:901-905.
15- Harris J (1998) op. cit. note 06
16- MacKellar C (1996) The biological child. Ethics & Medicine 12:65-69.
17- Andorno R (2002) Biomedicine and international human rights law: in search of a global consensus. Bull World Health Organ 12:959-963.
18- Williamson R (1999) Human reproductive cloning is unethical because it undermines autonomy. J Med Ethics 25:96-97.
19- Holm S (1998) A life in the shadow: One reason why we should not clone humans. Camb Q Healthc Ethics 7:160-162.
20- Andrews LB (1998) Mom, dad, clone: Implications fo reproductive privacy. Camb Q Healthc Ethics 7:176-186.
21- Annas G (1998) Why we should ban human cloning. New Engl J Med 399:122-125.
22- Häyry M. (2003) Philosophical arguments for and against human reproductive cloning. Bioethics 5-6:447-460.
23- Di Berardino MA (2002) Ban Human Cloning. Differentiation 69:147-149.
24- Heyman Y, Chavatte-Palmer P, LeBourhis et al (2002) Frequency and occurrence of late-gestation losses from cattle cloned embryos. Biol Reprod 66:6-13.
25- Rhind SM, King TJ, Harkness LM et al (2002) Cloned lambs – lessons from patology. Nat Biotechnol 21:744-745.
26- Hill JR, Roussel AJ, Cibelli JB et al (1999) Clinical and pathologic features of cloned transgenic calves and fetuses. Theriogenology 51:1451-1465.
27- Tamashiro KL, Wakayama T, Yamazaki Y et al (2003) Phenotype of cloned mice: development, behavior, and physiology. Exp Biol Med 228:1193-1200.
28- Rhind SM., Taylor JE, DeSouza PA et al (2003) Human cloning: Can it be made safe ? Nat Rev Genet 4:855-864.
29- Childress JF (1997) The challenges of public ethics: Reflections on NBAC's report. Hastings Cent Rep 27:9-11.
30- McKinnell RG and Di Bernardino MA (1999) The biology of Cloning: History and Rationale. BioScience 49:875-885.
31- Di Berardino MA (2001) Animal Cloning - The route to new genomics in agriculture and medicine. Differentiation 68:67-83.
32- Paterson L, DeSousa P, Ritchie W et al (2003) Application of reproductive biotechnology in animals: implications and potentials. Applications of reproductive cloning. Anim Reprod Sci 79:137-143.
33- Warnock M (1998) The regulation of technology. Camb Q Healthc Ethics 7:173-175.

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http://www.biol.tsukuba.ac.jp/~macer/NBB.html
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