EXPERT MEETING ON ETHICAL AND LEGAL ISSUES OF HUMAN EMBRYO RESEARCH

12-14 February 2008
Cairo, Egypt

Final Report of the Meeting
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EXECUTIVE SUMMARY

The Expert Meeting on Ethical and Legal Issues of Human Embryo Research was held in Cairo, Egypt, 12–14 February 2008. The meeting was organized by UNESCO Cairo office (UCO), WHO Eastern Mediterranean Region Office (WHO/EMRO), and the Islamic Education, Scientific and Cultural Organization (ISESCO). Experts from countries in the Region attended, from UNESCO Arab Region, WHO Eastern Mediterranean Region, and ISESCO Islamic Region. The participants consisted of international and regional experts on bioethics, science, medicine and law. Senior technical staff from UCO, WHO/EMRO and ISESCO also took part.

The Expert Meeting was preceded by a meeting of the Drafting Committee on 11 February, which was established to facilitate the discussion on recommendations to be adopted at the closure of the Expert Meeting.

The meeting was inaugurated by Dr Abdul Rahman Al-Awadi, President, Islamic Organization for Medical Sciences (IOMS); Dr Faiq Billal, Director of Science, ISESCO; Dr Hussein A. Gezairy, WHO Regional Director for the Eastern Mediterranean Region, and Awad Elhassan, Director UNESCO Cairo office. The four speakers emphasized the importance of reaching consensus on ethical and legal issues concerning human embryo research in the Arab region in light of new technology. One of the most important issues is the question of when an embryo can be considered a human being, and so worthy of respect, dignity and legal protection. The speakers also expressed their appreciation of the cooperation between the four organizations, UNESCO, WHO, ISESCO and IOMS, and reiterated their hope that the meeting would produce a comprehensive set of recommendations covering these issues in the region.

The objectives of the meeting were outlined by Dr Gamal Serour, Director, International Islamic Center for Population Studies and Research, and Dr Ahmed Regai El-Gendy, Secretary-General Assistant, IOMS, gave a report of the International Seminar on Stem Cell Research, held 3–5 November 2007, which laid down recommendations concerning stem cell research, including the moral status of human embryos from the Islamic perspective.

Several international experts gave presentations on medical treatment and scientific research involving human embryos, and the legal, ethical and religious status of human embryos. An important presentation dealt with the preliminary results of a survey on bioethical regulations in the Arab states conducted by UNESCO, September 2007–January 2008.
The second day of the meeting consisted of discussions on the draft recommendations prepared by the Drafting Committee. The recommendations were revised according to the legal and ethical aspects of embryo research deliberated on by the participants. Discussions continued on the third day, when the revised recommendations were reviewed and finalized. In the last session, the recommendations towards regional guidelines on legal and ethical aspects of embryo research were adopted. The recommendations will be circulated by UNESCO to the relevant government ministries, policy makers, physicians, lawyers and religious experts in the region in preparation for a further meeting to be held in 2009, when it is hoped that guidelines on embryo research in the Arab Region will be formulated and adopted.

1. INTRODUCTION

The Expert Meeting on Ethical and Legal Issues of Human Embryo Research was held in Cairo, Egypt, 12–14 February 2008. The meeting was organized jointly by UNESCO Cairo office (UCO), WHO Eastern Mediterranean Region Office (WHO/EMRO), and the Islamic Education, Scientific and Cultural Organization (ISEESCO).

The objectives of the meeting were:

- To start a regional dialogue on the scientific, medical, philosophical and religious aspects of human embryo research with possibility of networking.
- To identify the regulatory system and current regulations on human embryo research in each country of the region.
- To identify the areas of need for further promotion of bioethical discussion, and establishment of regulations concerning human embryo research.
- To explore the possibility to harmonize regulations at the regional level.
- To prepare for a larger conference on the issue, where the participants will come from governments, parliaments, legal, medical, religious experts, and other specialists from related fields, aiming at increasing awareness among decision makers, and facilitating the establishment of regulatory guidelines for research on human embryos.

The meeting commenced with technical presentations from a number of international experts dealing with human embryo research in fertility treatment,
preimplantation genetic diagnosis for medical and non-medical purposes, challenges of human embryo stem cell research and so-called therapeutic cloning, international and regional legislations and guidelines on human embryo research, the moral status of human embryos for research and policy making, and the Islamic view on human embryos. Discussions were conducted after each session of presentations.

Draft recommendations compiled by the Drafting Committee were presented to the participants, and the second and third days of the meeting consisted of lengthy discussions on the feasibility of setting guidelines on human embryo research in the Arab region, elaboration and revision of the content and text of the recommendations, and adoption of the recommendations in the final session.

The meeting was inaugurated by Dr Abdul Rahman Al-Awadi, President, Islamic Organization for Medical Sciences (IOMS), followed by addresses by Dr Faiq Billal, Director of Science, Islamic Educational, Scientific and Cultural Organization (ISESCO); Dr Hussein A. Gezairy, WHO Regional Director for the Eastern Mediterranean Region, and Awad Elhassan, Director UNESCO Cairo office.

Dr El-Awadi began by stressing the importance of the meeting and the complex challenge of dealing with ethical issues regarding cloning and stem cell research. He referred to the IOMS meeting held four months ago in cooperation with WHO, UCO, ISESCO. This was an international conference on stem cells and future research, attitudes and challenges from an Islamic point of view, which was held in Cairo, Egypt, 3-5 November 2007. Heading the agenda at this meeting was the subject of the human embryo from different points of view. The embryo is considered the main source of cells for different reasons, one of which, that it is the richest and purest source of cells.

Another consideration is regarding the anticipated hopes from preliminary results of stem cell research, that they will conquer the sufferings of most severely ill people, and those with conditions such as diabetes, Parkinson’s disease, spinal problems, and heart muscle deficiency, as well as many other life-threatening conditions, and diseases identified through research carried out in different parts of the world. It was, therefore, necessary for the IOMS to arrange for such a meeting to discuss the human aspects when dealing with the embryo, and other subjects related to stem cells. The successful results of the research, and the hopes of the sick, place a heavy burden on governments, and those concerned with ethics from the moral and psychological points of view, to make decisions regarding these issues.

The important question is whether the embryo in its early stage has the same rights as a fully developed human being, and whether using the embryo and killing it can be considered as killing a human being. This is why the decision is not an easy one for religious and ethical experts, because the problem is complex, between deciding to allow
research and the use of the results in treating illness, or utter refusal, putting in mind that the research involves killing a human being, and subsequently trading in human products.

Dr El-Awadi remarked that the argument is not within one particular state, or certain group, religion, or specific organization, but the argument is between all people. In Islam, for example, there are those who agree to the use of the embryo as a source of stem cells, while other Islamic scientists are totally against it. The same applies to Christianity. Some consider the moment the embryo is fertilized as the moment when the soul is formed, so there is no difference between when the embryo is fully developed and when it is just cells. Others look at it differently and do not object to medical research on embryos, which leads to another important question: What is a human being and how can it be defined?

If every fertilized cell which goes into the uterus is considered a human being, keeping in mind that between 70%-80% of the embryos do not continue to develop in the uterus, but are dead, the question arises whether this should be considered killing, or the natural cycle and God’s will. Another issue is the fate of the remainder of the embryos from IVF after the owner has made use of some of them. When these extra embryos are left to die, should this be regarded as a criminal act, or must they be made use of to improve the life of someone with a serious illness? Some argue that the use of these embryos in research or treatment is an insult to human dignity. It would seem preferable, however, to provide treatment to someone who is an invalid because of illness. Such treatment can be a way to lessen his suffering and pain, and bring him back to health, to play a part in society, which can be considered as defending his dignity.

We are confronting differences in understanding and double standards about the use of embryos in research, but if we manage to define clearly the human being, only then can we decide what path to take. In the Quran, in Sura XV ‘The Rock’, the creation of human life is described, making it clear that only when God provides the human form with a spirit can it be called a human being.

However, some Islamic scientists regard this as happening within 40 days, and others within 120 days, which is the limit for abortion. This does not mean that the fertilized eggs are not to be respected, but respect increases over time, until the embryo reaches the limit and no abortion can be conducted, unless the life of the mother is threatened.

Islam is not only concerned with the embryo after fertilization, but also with precautions to ensure the health of members of Muslim society. In Islamic sharia extreme care and full protection is advocated, not only for the unborn child, but also for the pregnant mother. The protection of the baby is the duty of all the family, and Islam has
several clauses in the law to protect it, any breach of which is punishable from the early stages of pregnancy, and increases as the pregnancy goes on.

The subject of research on the human embryo is an important issue, which will dominate life in future. It is to be hoped that some decisions can be taken at this meeting in accordance with Islamic sharia, as Islam is the major religion in the Region, and guidelines for research need to be laid down, including the question of punishment for those who violate the regulations. IOMS spares no effort to study the rights of the embryo from test tube babies to abortion, inheritance, and genetic engineering, in order to light the way for researchers in this field, and the topic of the meeting is included in the agenda of IOMS at a future stage.

Dr Faiq Billal, Director of Science. ISESCO, began his address by commenting that it was a source of great satisfaction for ISESCO to have joined hands with UCO and WHO/EMRO in organizing this meeting, which provided an important forum to exchange ideas and experiences pertaining to the vital issues of regulations of human embryo research. Within the implementation of Action Plans activities and other specialized projects, ISESCO has debated bioethics issues from various scientific and ethical angles, but the current meeting was a different event, as now we are observing regulations existing at the regional level, as well as finding ways of developing consensus to harmonize these regulations.

In 2005, the United Nations General Assembly approved the declaration calling on all UN Member States to adopt measures to prohibit all forms of human cloning, as it was incompatible with human dignity and protection of life. It did not prohibit the development of cells and tissue based therapies based on research involving cloning technologies to produce DNA molecules, organs, tissues and cells other than human. Further, this declaration was non-binding and there was no consensus on the use of the human embryo for research purposes. Although a number of countries were in favour of banning human cloning, they did not vote in favour, as it was debated that the declaration did not incorporate moral, ethical, and religious aspects of many countries. It is, therefore, of the utmost necessity to debate further, and involve more on such issues to explore general consensus.

Research on human embryos and stem cells has the potential to produce many major medical discoveries. Cures may be found for previously untreatable diseases and disorders; new and improved treatments may be developed. However, this research raises many ethical, moral, legal, religious, social and cultural considerations concerning the pursuit of medical research involving embryos and stem cells. Medical ethicists and religious groups are divided on the morality of pursuing these lines of research.

Safeguarding the features and distinct characteristics of our societies, and protecting them from various threats and distortion factors is one of the prime objectives of
ISESCO. Since its inception, therefore, ISESCO has focused its attention on analyzing and evaluating the ethical dimensions of the latest developments in science and technology in the light of Islamic thought and values. In February 1993, the International Seminar on Ethical Implications of Genetic Engineering discussed all aspects related to genetic research from scientific, religious, medical, social and ethical points of view. The general consensus was adopted that different stages of human life have their own respect and rights, specifically after 120 days when the embryo is fully formed.

The principal strategic objective of the Islamic Body on Ethics of Science and Technology is to observe and analyse new scientific developments from ethical and moral points of view, and to provide guidance to the Member States to establish consensus, strengthen standard setting, and encourage respect of the ethical dimensions. It is of prime importance that we foster debate on sensitive ethical issues arising from recent developments of science and technology and their applications, in order to enhance general consensus, knowledge and understanding among the Islamic countries for the benefit of common people as well as Muslim researchers. Today’s expert meeting is part of this action and we believe that working together with international organizations under common objectives, through active participation in each other’s programmes will develop consensus, aiding the evolution of the best regulations accepted by all.

From the Islamic point of view, however, there is no consensus on stem-cell research so far, but the teaching of Islam shed lights on various important issues, which may help to clarify certain aspects attached to it. According to Islamic teaching, saving lives and curing diseases is a high priority, so stem cell research, including therapeutic cloning, is favoured by some scholars. However, the way the research is performed, and the purpose for which it is performed, are of great importance. According to the Islamic point of view, each stage of development of human life has a different status. The Holy Quran also mentions these gradual stages of physical development in Chapter 23, verse 12–14: “We created man of an extraction of clay, then we sent him, a drop in a safe lodging, then We created of the drop a clot, then we created of the clot a tissue, then We created of the tissue bones, then We covered the bones in flesh; thereafter We produced it as another creature. “ At the stage when the soul is given, and the embryo fetus has breath to live, it is regarded as another creature. The punishment for someone who assaults a pregnant woman, killing her unborn child, increases with the length of the pregnancy, which indicates the difference of status in the various stages of human development.

There are a number of issues at mega and micro levels, which have already been discussed and general opinion has already been evolved, but it is necessary to examine all these sensitive issues with great care to protect the ethical and human values, as well as the unique characteristics of our societies. Uniformity of opinion on ethical standards of important and sensitive technologies from social, cultural, religious, ethical, moral and scientific perspectives, is of prime importance. Religion in general, and faith in particular,
play a greater role in our societies, and ignoring these arguments asserts that what we
decide among ourselves may not be accepted by the public at large. The voices from
various faiths will provide broader understanding, and help in the development of
genuine consensus accepted by the majority.

Dr Hussein A. Gezairy, Director WHO Eastern Mediterranean Region opened his
address by observing that some researchers regard stem cells as offering the greatest
potential for the alleviation of human suffering since the development of antibiotics.
Unfortunately, however, the benefits are not without risks. The use of stem cells in
research has raised many ethical and legal concerns around the world. In general, there
are no major ethical concerns about the extraction of stem cells from umbilical cords,
skin, bone marrow, etc., to be used directly in research as long as the donor gives
permission. But in present day scenario, the only way to obtain the most potentially
useful stem cells is from human embryos. However, the harvesting of stem cells from
embryos has become a serious political, religious, and ethical issue. The pro-life and pro-
choice movements take opposing positions about the ethics of embryo stem cells
research, the key difference being the point when they believe human life becomes a
human person and is thus worthy of legal protection.

The big question is, can we deny the promising role of stem cells research, and
check the outbreak of a forthcoming disruptive technology? If not then shall we have to
compromise with the ethical implications?

Adult stem cells can be obtained from sources other than embryos, and have a
major advantage because there are few ethical concerns over their collection and use. On
the other hand, harvesting embryonic stem cells kills the pre-embryo. Since many pro-life
supporters believe that a pre-embryo is a full human person, they believe that this is the
equivalent of murdering a human being. One of the points of your able deliberations is
this transitional period of stem cells research, where active researchers have to choose
between embryonic and adult stem cells. The former source at present seems to well
guaranteed but full of ethical skirmishes, while the latter is a potential emerging source
but with far less ethical concerns.

The Regional Office, in partnership with the Standing Committee for Science and
Technology of the Organization of Islamic Countries (COMSTECH), has established a
special grant for Research in Applied Biotechnology and Genomics. The overall aim of
the grant is to promote research, encourage networking, generate new knowledge, and
stimulate the application of biotechnology and genomic driven interventions in health
care. Stem cells research and related ethical aspects are included in the priority areas of
the grant. In response to two calls, 35 proposals have been funded through this Grant and
the third call is due by the end of this month.
In addition, WHO/EMRO has been actively engaged in supporting activities aimed at developing ethical considerations, in both health research and care at national and regional levels. The Regional Office has carried out short-term training programmes, within Member States as well for countries in the region. Currently, WHO/EMRO, in partnership with the University of Toronto, Canada, is funding a programme to train health care professionals from the Eastern Mediterranean Member States for a Masters degree in Bioethics.

The Regional Office has translated into Arabic two WHO publications on ethical issues for dissemination in the Region, and has also made them available on the Internet. EMRO engages with international organizations, such as the Council for International Organization of Medical Sciences (CIOMS), IOMS, ISESCO, UNESCO and others, to organize international meetings and seminars on key issues related to bioethics. For the current biennium (2008-2009), EMRO has several programmes for strengthening national capacity in ethical review of research for health, including a short-term training course in ethics of research for health in collaboration with the University of Maryland; mapping infrastructure for ethical review of research in the Region in collaboration with UNESCO; and providing technical assistance to Member States to establish national ethics review committees. The first meeting of the forum on bioethics and the second Regional meeting for national bioethics committees for the WHO Eastern Mediterranean Region and UNESCO Arab Region are foreseen.

In October 2007, WHO/EMRO established an EMRO Research Ethics Review Committee (EMERC), and in future, all health research proposals involving human subjects, that will be conducted or supported by the Regional Office, will be reviewed by EMERC. We hope this policy will further strengthen ethical practices in health research being conducted in the Region.

In his address, Mr Awad Elhassan, Director of UNESCO Regional Offices for Sciences, emphasized that UNESCO has a huge mandate in education, both natural and social sciences, culture, communication, and information. The organization prides itself on elaborating, and acting as a standard setter for international agreements, as well as arranging forums where experts can exchange views, and dealing with technical assistance to Member States. Mr Elhassan noted that the purpose of the Expert Meeting was to tackle one of the most controversial ethical issues in our time, the ethical implication of research on human embryos. Rapid progress in science and technology, especially genetics and embryology, opened up a way to better understand the mechanism of life, and brought us hope to develop treatments for incurable diseases. However, numerous ethical concerns have been raised in relation to such research, and some argue that manipulation of genetic components of human embryos, and destruction of embryos for research purposes may lead to instrumentalization of human life. On the contrary, some argue that a human embryo does not enjoy the same rights as a born baby, thus it could be employed in research under certain circumstances.
Accordingly, different policies and regulations have been established in different countries and regions. Nevertheless, whatever policy option is taken by the government, regulations on scientific and medical research that touches the fundamental concept of life and death should be established with full respect to human rights and human dignity, as it is stated in Article 10 of the Universal Declaration on the Human Genome and Human Rights (1997), that “No research or research applications concerning the human genome, in particular in the fields of biology, genetics and medicine, should prevail over respect for the human rights, fundamental freedoms and human dignity of individuals or, where applicable, of groups of people.”

Mr Elhassan also referred to the International Declaration on Human Genetic Data (2003), and the Universal Declaration on Bioethics and Human Rights (2005), both of which reaffirm the ultimate values of human rights and human dignity, as the basis to promote scientific research and its application for the well being of humanity.

The issue of research on human embryos is still new to some of the countries in the Arab Region, and the scientific community and policy makers have been slow to anticipate the establishment of an ethical framework for research on human embryos. However, scientific findings and research easily transcend national borders, and may seriously affect the well being of the people in the world. Thus international and regional dialogue and bioethical discussion should be promoted, and accurate information on scientific findings and their ethical implications should be widely disseminated to the public, so that each society will be vigilant in safeguarding the value of human rights and human dignity.

UNESCO is strongly committed to working on the promotion of bioethical discussion through organizing expert meetings on issues of priorities in the Region, the dissemination of ethical principles stipulated in the Universal Declarations, and the establishment of bioethical regulations and ethics education systems in the Region.

Mr Elhassan expressed his conviction that interdisciplinarity is the essence of bioethical discussion, and the participation in the meeting of distinguished experts from different disciplines, such as medicine, science, religion, philosophy and law from the whole Region, as well as from Europe and North America, would enrich the discussion, and bring about an important step forward to the establishment of harmonized regulations concerning human embryo research at the regional level. Commenting that the meeting had been realized by the joint efforts of UCO, WHO/EMRO, and ISESCO, he also stated that various joint projects promoting ethical principles in the field of science and medicine are foreseen in the next few years. Establishing partnership with these organizations, and working together with other international organizations with high competence, such as IOMS, will bring great benefit to the Region.
Following the opening addresses, Dr Ahmed Rajai El-Gendy, Assistant Secretary-General, IOMS, briefed the meeting on the International Seminar on Stem Cell Research, held in Cairo at WHO/EMRO, 3–5 November 2007. The seminar was organized by IOMS in cooperation with WHO/EMRO, UCO, ISESCO and the Islamic Fiqh Academy, Jeddah, Saudi Arabia.

Dr El-Gendy began by outlining the aims of the Seminar, and the issues which had to be addressed. These included whether the human embryo should be considered as a human being, and so should be treated in the same way as a full human being; whether human dignity is granted or guaranteed; the benefits of using stem cells, and their affect on society and human ethics; and the search for other sources of stem cells. With regard to policy-making, topics included the importance of lessening suffering, freedom of scientific research, and the ethical status of the embryo. One of the principle objectives of the seminar was discussing the ethics of human stem cell research, and other allied subjects covered in the meeting, from the Islamic point of view.

On the subject of relieving human suffering, the question arises whether this is more important than the ethical value, or not. One opinion holds that the embryo should be protected as soon as it is fertilized, and it should not be used for research, as the general rules of research forbid any experiments on a human being, if this will cause danger to human life, or disrespect human dignity. However, a contrary opinion holds that the difference here is not the kind of research or its importance, but is because it is carried out on a human being in its early stage of life, and this has to be protected and respected. Regarding research, some consider that researchers should have complete freedom, regardless of ethical issues, while others are opposed to this view.

The protection of the embryo depends on whether the embryo in its early stages is considered to be a human being with full rights, in the belief that the spirit starts to function from the moment of fertilization, and an individual human being is produced. God endows the soul in a miraculous moment, when a new human life begins, and each individual is given ethical value as a member of humanity, deserving the dignity granted to him by God. The opposing view does not consider that the embryo should be treated as a full human being, arguing that the first opinion gives protection to something, the fate of which is only known to God. Statistics show that 50%–80% of embryos do not survive. Does that mean that God gives them all a soul, and then takes it away? Similar arguments can be applied to twins. The human being is a combination of body, breath and soul, and these three elements are not present in the fertilized embryo. However, the early embryo should be respected, but not protected at the same level as the embryo at later stages.

It is known that each human being has special genetic components for his personality and human nature, but recently scientists have begun to contemplate interfering with the genes for repair or improvement, to produce human beings with
certain qualities. Scientists of ethics consider that this sensitive issue should not be approached under any circumstances, because of concerns over creating a human being with a horrific disorder, and starting a process, which it would be impossible to stop in the future. The value of human life and health could be lost, as the presence of unhealthy people in society promotes compassion and cooperation between people, and an appreciation of the benefits God has given to those who are healthy. Opposed to this view are those who consider that there should be complete freedom of research, as one of the worthwhile targets of modern science is to produce people who are healthy and strong. From the Islamic viewpoint, the possibility of interfering medically is permissible, if it will be of benefit to individuals and society. However, genetic engineering should not be allowed to interfere with human values, to be used for evil purposes, or to bypass the genetic barrier between species. It is not permissible to use genetic engineering as a policy to replace the genetic basis, in what is called eugenics, 'the improvement of the human race.'

On the issue of medical benefits, an important basic principle in scientific research is the focus on benefiting humanity. There are two main opinions. Those working on stem cell research are trying to find the best therapies for overcoming many incurable diseases, such as Alzheimer’s, and Parkinson’s, reducing pain and giving hope to sufferers. They respect the wish of millions of sufferers by enabling them to play a role in society. The second opinion considers that stem cell research kills millions of embryos, which have a human personality, and God’s will regarding health and disease must be accepted.

The three major world religions have differing views on stem cell research. Christians are not all of one mind. Roman Catholics are the most rigid, refusing to sanction stem cell research, because they believe that the moment of fertilization is a miracle, when God imbues the soul, and produces an individual with its own genetic components. It is our duty to protect humanity from any human interference, and the principle of benefit is a selfish one, which will lead to degradation. Judaism, on the other hand, agrees to stem cell research, depending on the belief that the embryo is only a drop of water, and does not reach the full human form during the first 40 days, so research before the fortieth day is permissible. Muslim scholars do not consider that the fertilized embryo has equal rights with fully formed human beings, but they differ as to when the soul is bestowed, whether it is after 40 or 120 days. The embryo goes through various stages of development in the mother’s uterus, which are all referred to in the Quran and in hadith. Islamic opinion takes account of these stages, and the religion specifies different rules according to the various stages, which become tougher as the age of the embryo increases. According to sharia law, the pregnant mother has rights which she did not have before she became pregnant; for example, she can pray in any position, she does not have to fast, or go on the pilgrimage. The unborn child inside its mother also has rights, such as welfare and inheritance. Islam, therefore, does not consider the embryo as a full human being with the same rights, as referred to in the Quran, but it needs to be
respected, although not necessarily protected. Research is permitted on the fetus from miscarriage, provided the miscarriage is unintentional.

On the subject of ART, Roman Catholics do not agree to IVF under any circumstances, as they consider it unnatural, and therefore, unethical. Jews agree to fertilization outside the uterus, as they consider that the soul is not given until after 40 days, and what exists before that is just water, so there is little consideration for it. In Judaism, having a child through IVF is accepted, as long as the couple are married, but no third party should be involved, i.e. no sperm, egg, or womb. As for surplus embryos, they cannot be called human beings, and do not have the same dignity, but they should be respected and not treated trivially. The Islamic view is that it is permissible to make use of surplus embryos from IVF, and donate them for research with the couple’s consent, and the husband and wife should be informed of all research carried out on their embryos. It is not permissible to implant surplus embryos in another woman’s uterus. Islamic experts encourage Muslims to donate embryos for research, although there is concern regarding errors or problems if an embryo is implanted in another mother’s womb, because of mixed lineage and inheritance. Donors must be protected and personal details obtained through DNA kept secret.

Another important issue is whether research on stem cells can be considered as abortion. There are varying opinions on this. The fertilized embryo used in research is controlled at the stage before implantation, before the time that it is capable of living at the uterus wall, and leading to pregnancy. The argument surrounding abortion explained it as the separation between mother and baby. Such a relationship does not exist when it comes to the embryo used in stem cell research, as this is carried out on the gamete before implantation, so it is not considered abortion.

Dr El-Gendy concluded by listing the principle recommendations of the International Seminar on Stem cell Research held in Cairo, 3–5 November 2007. A complete copy of the recommendations was distributed to each participant in the Expert Meeting, and these formed the basis of the recommendations endorsed on the last day of the meeting.

The agenda, programme and list of participants of the meeting are given in Annexes 1, 2 and 3 respectively.
2. MEDICAL TREATMENT AND SCIENTIFIC RESEARCH INVOLVING HUMAN EMBRYOS

2.1 Human embryo research in fertility treatment

*Jacques Milliez, Chair, FIGO Ethics Committee, Paris, France*

Dr Milliez began by explaining why embryos are so valuable, as they can be used for research, therapy and experimental therapy. Research includes the cell differentiation process, gene control of embryogenesis, gene expression, and toxicology. With regard to treatments, embryos are a means for stem cell therapy, and numerous treatments are possible, some experimental and some in medical practice. Examples of treatments include blood marrow grafting for leukaemia, spinal cord injury repair, pancreatic islet in juvenile diabetes, and skin grafts after burns.

Although how stem cells function has not been fully established, embryonic stem cells are preferable to adult stem cells, which have less plasticity, and the differentiation, fusion and chemotropism of which are still unknown. The principal sources of human embryos are fresh embryos from IVF or PGD, which are improper for transfer; and supernumerary, cryopreserved embryos left over after ART. The question arises as to whether human embryos can be created or cloned for research. The British have produced chimera or cybrids, such as rabbit/bovine/human hybrids, but cloning has never been achieved in humans, so this is out of the range.

The nature of the human embryo is the reason why embryo research is a sensitive and controversial issue. According to some religious beliefs, the embryo is sacred as soon as it is conceived, in others it is unprotected until fetal, neonatal, or even self conscience age, while a further concept is that it is neither a person, nor a thing, but is granted a specific status worthy of dignity and consideration as a potential person. On the question of whether using human embryos for research is ethical, answers have been provided by UNESCO, the International Federation of Gynaecology and Obstetrics (FIGO), the American college of Obstetricians and Gynecologists (ACOG), and the European Union. The ethical debate on embryo research appeals to scientific arguments, cultural considerations, philosophy, moral stances and religious beliefs.

On the status of the human embryo, according to the International Bioethics Committee (IBC) of UNESCO, if the embryo is a person, no embryo research is permitted, and even if it is not a person, it nevertheless demands respect as the source of human life. Personal individuality (not personhood) can be attributed after the day when division into normal twins is no longer possible, up to 14 days after fertilization. Since any potentiality for personhood requires implantation, non-implantable embryos are deemed ethically suitable for embryo research/therapy, in view of the fact that the only other alternative is their destruction. Regarding the sources of human embryos, the IBC
stated that these could be IVF embryos not suitable for implantation, supernumerary IVF left over embryos, and abnormal embryos at PGD. On the issue of creating embryos for research, the IBC decided that embryos may be created for research, provided that they will not be used for a pregnancy. On the subject of cloned embryos (SCNT), the IBC considered that it may be ethically acceptable to create embryos by cloning, nuclear transfer, in order to produce embryonic stem cells (ESC) for therapeutic purposes.

The FIGO Committee formulated recommendations on embryo research in Luxor, Egypt, November 2005. Regarding the possibility of research on the creation, or use of embryos, this was considered acceptable, but specific consent must be sought when gametes are collected. In IVF programmes, the recipient of resulting embryos shall be asked for consent to the use of their supernumerary embryos for research. Embryos should not be created for research unless there is a demonstrable need for the planned studies, which must be submitted for ethics committee appraisal and peer review. Research into alternative treatments should also continue. The creation of, and research on, pre-implantation embryos specifically created for the purpose of research, is appropriate only if the information cannot be obtained by research on existing supernumerary embryos. On the issue of whether cloning human embryos for research is ethical, the FIGO Ethics Committee considered that cloning (SCNT) to reproduce a human individual is unacceptable on the grounds of safety. Such research in animals may be ethically justified because it has the potential of human benefit. Research on a human embryo produced by cloning/somatic cell nuclear transfer (SCNT) to produce various cell lines for therapeutic purposes, is encouraged to alleviate human suffering, but subject to tight ethical guidelines.

In the USA, the ACOG Committee on Ethics laid down guidelines for using pre-implantation embryos for research in November 2006. The Committee takes the position that human embryo research can be justified under certain circumstances. This position is based on an interpretation of the moral status of the embryo as a living entity with a human genetic code, deserving of some form of respect in itself, and not solely for its usefulness in research. However, this position also recognizes the value of the embryo as relative, in the sense that it does not require the degree of protection and absolute respect that is accorded to human persons. In other words, the embryo is human, not simply like other human tissue, but because it is genetically unique and has a human potential, although it is not a human person. The information sought should offer scientific and clinical benefit, such as embryonic development, and for embryonic stem cell lines, potential disease therapies. The research will not exceed 14 days after evidence of fertilization in any case. The ACOG Committee on Ethics opposes reproductive cloning.

In the European Union, the European Group on Ethics in Science and New Technologies (EGE) to the European Commission provided recommendations on the ethical review of human embryo stem cells only for EU funding of Framework Programme 7 embryo research projects 2007–2013. At present, there is no EU consensus
on the moral status of the embryo and its products, reflecting the wide diversity of moral cultures. European Commission Guidelines and Regulations applied to FP7 must be in conformity with the Nuremberg Code (1947), the Declaration of Helsinki (1964), the Belmont Report (1979), the Convention for the Protection of Human Rights and Medicine (Oviedo Convention 1997), and the additional protocols to the Convention, the UNESCO Universal Declaration on the Human Genome and Human Rights of (1997), the International Declaration on Human Genetic Data (2003), the International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS 2002), and the UNESCO Universal Declaration on Bioethics and Human Rights (2005).

On the important issue of protection for embryo research, protection of the privacy of the donors of embryos for the creation of stem cell lines should be provided, no financial inducement should be offered, save reimbursement of costs incurred (gametes), or reduction of IVF costs (Article 12, Directive 2004/23), no pressure should be put on the donors at any stage, and the donor’s health should be protected, i.e. no ovarian hyperstimulation (OHSS).

With regard to information and consent for embryo research, the European Commission stated that there should be informed consent to the donation of an embryo originally planned for reproduction, and consent may be withdrawn up to the stage of the creation of stem cells. Concerning the source of embryos for research, this can be ART supernumerary embryos which have not been transferred, or PGD (genetic defect) embryos. Embryos can be created solely for research purposes via IVF, but outside the ART context, and not by cloning.

The European Commission supports funding of research involving the use of human non-implanted embryos and human embryonic stem cells, except research modifying the genetic heritage of human beings, germ line gene therapy, or at PGD gene therapy for sick embryos, (although there is the question whether the latter should be destroyed, or treated to ‘rescue’ them). The Commission will not fund projects that involve research activities which destroy human embryos, including for the procurement of stem cells, (but cell biopsy from the inner cell mass of blastocysts may destroy the embryo); SCNT, above all reproductive cloning, (in the EU, therapeutic cloning is allowed in only four countries, Belgium, Spain, Sweden, UK); embryos created with donated gametes; or human /animal hybrids for ‘humanized stem cells’ (accepted in the UK, 5 Sept 2007). The EU (EGE) emphasises its view that the use of embryos for research or to generate stem cells should be minimized as much as possible. It calls on the European Union to develop appropriate systems to limit the use of human embryos to cases for which no alternative exists.

In conclusion, Dr Milliez reiterated that embryo research is an irreplaceable contributor to human medicine, but it also presents enormous challenges. It is hoped that ethics will set the limits.
2.2 Pre-implantation genetic diagnosis for medical and non-medical purposes

Inge Liebaers, Centre for Medical Genetics, Free University, Brussels

Professor Liebaers began by defining pre-implantation genetic diagnosis (PGD), and explaining the procedure. Genetic diagnosis is performed on embryos made in vitro on Day 4 after fertilization, and by Day 5 it will be known whether any embryos have developed a defect, and is to be hoped that an unaffected embryo can be implanted. Approximately 20–25% of patients will then become pregnant. A pregnancy test is carried out on Day 12, and if the woman is pregnant, there will be follow-up. If she is not pregnant, the situation will be discussed with the patients to decide if PGD should be repeated.

PGD is indicated for inherited conditions (the most common practice), to improve IVF, for a saviour baby, and for social sexing. The procedure is undertaken for monogenic (early lethal or late onset), for chromosomal inherited conditions, and for high miscarriage recurrence risk (25%–30%), to avoid disease transmission where couples know of a disease in the family, sometimes associated with infertility, and to aid reproduction. The first PGD was carried out in the UK in 1989 for couples at risk of transmitting an X-linked condition to their sons. PGD is an early form of prenatal diagnosis (PND) offered to couples at risk, within the framework of genetic counselling.

Preimplantation genetic screening (PGS) is used in PGD to improve the IVF outcome by finding non-inherited gene defects in the embryo in infertile patients over 36 years of age, in couples with recurrent miscarriages, and in couples with repeated IVF failure. PGS also aims to improve the IVF outcome by lowering the miscarriage rate post IVF, and avoiding liveborns with aneuploidy. With the PGS approach, chromosome content is also looked for. In a patient needing IVF, an embryo for transfer is selected on the basis of morphology and chromosome content, and the chance of pregnancy is increased. However, there is much controversy over this form of screening, which has not yet been fully proven.

PGD can be used to create a saviour baby, in order to treat an existing ill child, who is suffering from a genetic defect, or a disease such as leukaemia. Candidates for PGD and human leukocyte antigen (HLA) typing are parents of a sick child who needs stem cell implantation from a sibling, not a donor bank, and no compatible sibling is available. Regarding PGD for social sexing, either for family balance or on demand, although the procedure is technically easy, the issue is ethically difficult.

On the subject of follow-up, patients are asked to participate in follow-up studies before treatment, and questionnaires for the couple and their obstetrician are given to them at the moment of embryo transfer. Questionnaires for parents and their paediatrician are sent to them around delivery, and it is requested that children are brought to the clinic
at 2 months, one year and two years. Data from follow-up has been collected from the EU and abroad, and is stored in a database. Results show a surprisingly high percentage of stillborns and neonatal death (4.9%), but the misdiagnosis rate in PGD is acceptable at 1%, and the malformation rate of 2–3% has not increased. Gestational age and birth weight are satisfactory, and PGD and PGS children seem healthy, although the numbers are still small. Multiple pregnancies are to be avoided.

Informed consent is an important factor in PGD. The risks should be fully explained to a couple, including the fact that this is a new procedure, and only a limited number of mostly healthy children have been born (+/- 5000, although the exact number worldwide is unknown). Control PND is recommended, and pregnancy, baby and child follow-up is to be conducted. It should also be made clear that affected and non-biopsied embryos will never be replaced, but used for research, mainly to derive stem cells; surplus unaffected embryos are frozen if possible for later use, but the pregnancy rate is low after frozen embryos transfer.

Professor Liebaers concluded by saying that PGD is now an option, alongside PND, for couples at risk of transmitting a genetic condition. It avoids termination of pregnancy, but requires IVF with a relatively low take-home baby rate. Whole genome amplification (WGA) will most probably facilitate the availability of PGD in the future. However, the ethical debate is still ongoing regarding PGD for late onset conditions, such as a disease developing at 30 years of age, breast cancer for example. This type of diagnosis is being carried out in Brussels, but there is not general agreement.

2.3 Challenges of human embryonic stem cell research and therapeutic cloning

Guido Pennings, Bioethics Institute Ghent, Ghent University, Belgium

Professor Pennings outlined the main challenges of human embryonic stem cell (hESC) research, dividing them into embryo issues and non-embryo issues. The embryo issues comprise the definition of an embryo, categories of embryos, and justification of use of embryos, while the non-embryo issues are oocyte donation for SCNT, guidelines for clinical trials and clinical application, and distributive justice.

Regarding the definition of an embryo, the question can be subdivided into whether the entity is an embryo, and whether it is a human embryo. The answer will depend on the definition. In Belgian law, for example, a cell or coherent whole of cells that has the potential to grow into a human is considered to be a human embryo. There are, however, different ways of defining an embryo, depending on the method of creation, whether by fertilization, SCNT, or parthenogenesis, or on the presence of certain characteristics or capacities, such as potentiality, or totipotency. If the entity is not an embryo, there is no ethical problem. Examples are entities created by altered nuclear transfer (ANT), parthenotes or clonotes. Similarly, a defective embryo will not grow into a complete
organ, so the main problem is how to distinguish an embryo-like entity from a defective embryo, such as an aneuploidic embryo.

The question of whether the entity is a human embryo has to be addressed in this generation of animal-human mixtures (hybrids, chimera). The principal issue concerns the percentage of animal or human genetic material which identifies the embryo as animal or human, and a further question concerns whether the presence of cross-species DNA changes the moral status of the embryo or entity. With technical interventions and modifications, there is the problem of how much technical intervention is included in the definition of an embryo. If no intervention is allowed, then a normal embryo in vitro would not be an embryo. If all interventions are allowed, then every somatic cell would be an embryo.

An ethical balance has to be reached, but at present, any method which does not use, destroy and/or create embryos is considered morally superior, regardless of the possible other disadvantages. Other relevant criteria to decide about the necessity of using embryos include whether it is the fastest path to therapy, the safest way, the most cost-effective method, or the most widely applicable method. All these criteria are morally relevant and should be taken into account in deciding which cells to use in research and therapy. For example, clinical research should be performed first on animals, adult stem cells should be used prior to embryonic stem cells, and research embryos can only be created if, and only if, the same results cannot be obtained by using supernumerary embryos. However, more research is needed to determine which type of stem cell (adult or embryonic) is most promising to develop therapies.

Concerning induced pluripotent stem (iPS) cells, the dedifferentiation or reprogramming of somatic cells to the level of a pluripotent stem cell, the preliminary question is whether these cells are pluripotent or totipotent. There are some serious disadvantages with regard to these cells; the insertion of genes by means of viral vectors, some transcription factors may act as an oncogene, and very little is known about the characteristics of these cells. However, there are also advantages; the procedure avoids the creation and destruction of embryos, (although it is only possible because of knowledge obtained from embryonic stem cell research), it may be technically easier, and a more efficient and practical way to produce large banks of pluripotent cells.

Different categories of embryos are distinguished based on two criteria, 1) viability or potentiality, and 2) the quality of life of the future person. These categories, which have implications for the moral status of the embryo, include affected embryos, carrier embryos, low quality embryos, at risk embryos, SCNT embryos (clonotes), supernumerary embryos, and research embryos. There are two major justifications for creating and discarding embryos, namely reproduction, and research and therapy. The embryo in ART is mainly instrumentally valued, either to have a child, or to increase
knowledge and/or develop therapies. With regard to discarding of supernumerary embryos, its intrinsic value is very low.

On non-embryo issues, oocyte donors are required for infertility treatment, and as research subjects in clinical trials. Oocytes are needed to develop stem cell lines by somatic cell nuclear transfer (SCNT). The extent of the demand for oocytes is unclear, but will depend largely on new technical developments, such as in vitro maturation of oocytes, new methods to obtain stem cells without SCNT (like dedifferentiation), and other ways to induce transplant tolerance.

Clinical trials should be seen as the ethical framework to evaluate oocyte donation for stem cell research. This implies that the ethical principles applied in research should be transferred to oocyte donation. The risk/benefit ratio can be improved by minimizing the risks for the donors, and maximizing the benefits of the research. The principle of autonomy encompasses free informed consent without undue inducement. Regarding payment and compensation, research subjects should be compensated for their time, effort and discomfort, but risk should be excluded. On the subject of guidelines for clinical trials, there is enormous pressure to move rapidly from basic research to clinical application. However, there is also the danger of rash transfer of technology from laboratory to patient, with major concerns about safety (cancerogenic cells, xeno-free media and feeder cells), and quality (genetic stability, immunological status, purity). A detailed analysis of all aspects of the technology is needed, in order to determine whether stem cell therapy is different in morally relevant aspects from drug manufacturing, tissue transplantation etc.

Distributive justice should be applied to a number of issues. For example, there is very limited access to high-tech medical interventions by poor people in countries, which do not guarantee equal access to health care (economic or financial access). People of non-Caucasian origin should be included in stem cell banks, to make sure that they also might benefit from eventual therapies based on these lines. Large sums of money are directed at this research, while other diseases could benefit from these funds, possibly with larger numbers of beneficiaries.

In conclusion, the developments in the field of stem cell research are unpredictable, and as there is no certainty about the best way to go, all lines of research should be developed simultaneously. A small minority of religious people, who attribute a high moral value to the embryo, have managed to dominate the whole political and ethical discussion. There is no reason why the others should give in; freedom of research and development of therapies to increase human well-being, and decrease human suffering are more important values.
Discussion

Clarification was provided regarding the EU position on hESC research. The EU allows embryos for research purposes, but in 2000 the European Group on Ethics stated that the creation of embryos by somatic cell nuclear transfer for research on stem cell therapy would be premature.

On PGD, the question was raised about fears that the procedure would be used for sex selection, as the research seems to indicate approval of this. However, whether the PGD should be available on demand, or for family balancing, or only for very specific cases, such as avoiding sex-linked diseases, are still issues for debate. It was also queried whether PGD avoids termination. This is the aim of the procedure, but there is some risk of misdiagnosis because of the composition of the embryos. This risk, which is now less than 1%, is explained to those seeking to undergo the procedure.

A further subject discussed was the imbalance in research between developed and developing countries, and the solution regarding hESC research. The question is linked to the economic situation, and just as with the development of drugs, an attempt should be made to make the bias as small as possible. This could be done by focusing on specific diseases in developing countries. It may be a problem of global justice, and perhaps international funding could be streamlined for certain diseases. The same applies to stem cell banking, and steps should be taken now to ensure that, as well as the West, more people from developing countries, and especially from poor countries, are included. The process is justified by referring to the hundreds of millions who will benefit.

3. LEGAL, ETHICAL AND RELIGIOUS STATUS

3.1 International and regional legislation and guidelines on human embryo research

_Bernard Dickens, Faculty of Law, Toronto University, Canada_

Dr Dickens stated that with regard to international and regional legislation on reproductive research, the international focus is principally from Western Europe, North America (USA, Canada and Mexico), and Asia (China, Japan, India and South Korea). From the information obtained from these countries, it is possible to distinguish three models, mainstream, progressive and prohibitive. The mainstream model followed in western countries allows research on existing stem cell lines and surplus IVF embryos. The progressive model as well as allowing research on existing stem cell lines, and surplus IVF embryos, also permits the creation of embryos for research, and therapeutic cloning. The prohibitive model forbids all scientific embryo research, but permits some research to address problems of infertility in a couple, such as chronic spontaneous abortion.
Referring to legislation in other regions around the world, Dr Dickens mentioned that the situation in the Arab States would be covered later in the meeting in the presentation on the UNESCO survey to be presented by Dr Magdi Shehata and Orio Ikebe. In Central and South America there is no real legislation, except in Brazil, which follows the European mainstream model. In sub-Saharan Africa, only South Africa has legislation, which follows the UK in the more progressive model. In Central Asia, Russian territories follow the progressive model, while Ukraine follows the mainstream model of most European countries.

Legislative analysis shows that there is almost universal agreement on the prohibition of reproductive cloning of human beings, for a variety of moral, ethical and religious reasons, including the scientific basis that larger cloned animals do not survive long, but die early of age-related disorders, thus making the procedure unacceptable at human level, as it is unsafe. Countries following the mainstream model, that research is allowed on existing stem cell lines and surplus IVF embryos, are in wide agreement. These include about twenty European countries, many US States, Canada, Russia, China, Japan, India, South Korea, Singapore, and Australia. Prohibitions are, as expected, due to a strong Roman Catholic influence in countries such as Ireland, Italy, Poland, Slovakia, and five US States, but the issue is under national review in Norway. Cloning of embryos for non-reproductive uses, therapeutic cloning and human/animal chimera research, are spearheaded by Britain, with a number of other countries across the world in some agreement on these techniques.

Regarding international guidelines specific to hESC research, there are several steps, including the World Medical Association Declaration of Helsinki (1964), the Council for International Organizations of Medical Sciences (CIOMS) International Guidelines for Biomedical Research involving Human Subjects (2002), and the IOMS recommendations (2007). Guidelines commonly require an independent medical assessment of research proposals. Some national guidelines on hESC research are very influential internationally. A pioneering example is the Code of Practice of the UK Human Fertilization and Embryology Authority, the legislation regarding which is currently being revised. In the USA, the National Academy of Sciences issued Guidelines for Human Embryonic Stem Cell Research in 2005, with amendment in 2007. Drawing on these sources among others, a distinguished multidisciplinary Task Force of the International Society for Stem Cell Research (ISSCR) published Guidelines for the Conduct of Human Embryonic Stem Cell Research in December 2006.

The ISSCR Guidelines aim not to cover general areas of ethics review of research already addressed by such documents as the Declaration of Helsinki and the CIOMS Guidelines, but to focus on hESC research, and identify activities that require additional oversight by a Stem Cell Research Oversight (SCRO) committee. To save researchers having to appear before several ethics review committees, the ISSCR Guidelines allow a single suitably composed comprehensive committee to combine both the general ethics
review function under principles set out, for instance, in the Declaration of Helsinki and the CIOMS Guidelines, and the SCRO function under the ISSCR Guidelines.

Among the key topics addressed by the ISSCR Guidelines that amplify more general issues in research ethics are free consent of donors of sperm, ova, embryos and somatic cells; disclosures to ensure that such consent is adequately informed; privacy and confidentiality of donors; payments, if any, to donors, and undue inducements; adherence to local law, for instance on capacity to consent; and conflict of interest by information-providers.

Some of the topics more particularly related to hES cell research include prohibition of human reproductive cloning, on safety grounds; international collaboration and management of issues concerning ownership and custodianship of intellectual property; preservation of non-commercial research community access to materials in agreements with commercial entities; submission of any derived stem cell lines to national or international depositories that allow open distribution; ensuring embryos are not developed beyond 14 days’ growth or primitive streak formation, whichever is first; disclosure to donors of researchers’ and/or their institutions’ commercial interests, actual and/or potential; covering costs of medical care required as a result of donation of materials for research; payments to infertility clinics or others obtaining consent or collecting materials for research; and demonstration of appropriate expertise or training before attempting to derive new human stem cell lines. With regard to training, the question arises as to whether it is permissible for investigators to go to other countries to undertake research, which is forbidden in their own country.

Examples of research particularly requiring SCRO review include research involving the derivation of new human pluripotent cell lines; clinical research in which cells of totipotent or pluripotent human origin are transplanted in living human subjects; research that generates chimeric animals using human cells, and research involving payments to donors of research materials.

The ISSCR encourages establishment of national and international repositories of stem cell lines. Among other activities, the Guidelines have provisions on reviewing and accepting deposit applications; characterizing cell lines; quality assurance and quality control of procedures; website maintenance with data on and availability of hES cell lines; and distributing and tracking distribution of cell lines.

Dr Dickens noted in conclusion that the ISSCR Guidelines do not cover development of types of fetal stem cells, which raises special issues of procurement. Future revisions of the Guidelines may address this area. In August 2007 the ISSCR Ethics Committee proposed Ethical Standards for Human-to-Animal Chimera Experiments in Stem Cell Research (Cell Stem Cell (2007) 1: 159-163).
3.2 The ethics and policy of stem cell research

Bonnie Steinbock, University at Albany, New York State, USA

Professor Steinbock opened her presentation by commenting that there are two related questions with regard to stem cell research, which are familiar from the abortion debate, defining the moral status of the embryo, and deciding at what point in development the human organism begins to exist. The motivation for doing hESC research is the potential for reducing human suffering, and prolonging human lives, but at the same time, at present, the process of deriving stem cells kills the embryo. There have been a number of attempts to sidestep the moral issue, for example, by using adult stem cells, not embryonic ones. However, most scientists believe that embryonic stem cells are more effective, so it is imperative to continue doing hESC research. Another possibility is to find a way to derive human pluripotent cells without killing human embryos, and a number of proposals have been made, but all of them have both technical and ethical difficulties.

Three views are held on the moral status of the human embryo. Firstly, that it has full moral status, and is entitled to all the rights and protection of any other human subject. This gives rise to the further question of the point at which there is a human organism. The most conservative view, held particularly by the Roman Catholic Church, is at conception, which has serious implications for stem cell research, as it rules out anything that kills or harms an embryo, even in its earliest stages. Others put the beginning of a unique organism at implantation, which would, therefore, allow for embryo research.

The second view holds that an embryo has no moral status, but is morally like any other cell in the human body. Professor Steinbock considers, however, along with a number of other philosophers, that a baseline condition for having moral status is sentience, defined narrowly as the capacity to feel pain and pleasure, or more broadly, as the ability to feel or experience anything. This view makes some kind of awareness necessary for moral status. Blastocysts are no more sentient than a sperm or an ovum, as they have no nervous system at all. The precursor to the nervous system, the primitive streak, does not develop until about 14 days after fertilization, long after the blastocyst stage.

The third view is a compromise between the first two. It acknowledges that the developing human embryo is not a person, yet it does have moral importance, so is entitled to special respect, which should be explained.

One possible basis is respect for people’s moral and religious beliefs, although this does not commit others to go along with their views. Another basis for respect for embryos is that they are potential human beings. However, the issue of potentiality raises
several questions. For example, the embryo created by IVF requires active intervention to reach what could be considered potential life, as if left untouched, it will die. However, if potentiality is a necessary condition of respect, then only viable embryos that could develop into human beings would be entitled to respect. Another possibility is the symbolic value of the embryo as a form of human life, as this represents concern for life generally, and human life in particular. This is a universally held view, but it is necessary to distinguish between respect for humans and respect for embryos.

Kantian respect, respect for persons, is inapplicable to embryos as they are non-sentient. On the other hand, Kantian respect is not the only kind of respect, and non-persons can be respect-worthy. For example, morality requires that the dead are disposed of respectfully, with the proper rituals, but at the same time, respect for the dead does not rule out autopsies, or the use of cadavers in medical school. Dead bodies are owed respect because they are the remains of a once-living human organism, and symbolize the human person who is no more. Human embryos deserve respect for similar reasons. Some of them have the potential to develop into persons, but even those that do not have that potential can be seen as a symbol of human life, which is worthy of respect in all its stages.

With regard to what respect for embryos entails, if they were persons and entitled to Kantian respect, they could not be used, even in research proven to save and improve lives. Non-Kantian respect, however, does not rule out embryo research, but it does exclude frivolous or trivial uses, such as for cosmetics, or in a high school biology class. Respect for human life in general does not rule out significant research that could cure devastating diseases, or save lives, quite the contrary.

In conclusion, Dr Steinbock mentioned two remaining ethical issues, whether egg donors should be paid, and whether there should be differentiation between surplus embryos and those created specially for research purposes. With regard to the first question, some are of the opinion that donors should be paid if the eggs are for reproductive purposes, but should not be paid if they are for research. It is hard to see the rationale for this opinion, as women go through some pain, inconvenience and risk, whether the eggs are for reproductive purposes or research. On the question of surplus or created embryos, the same logic should apply. There are surplus embryos from IVF, because more are created to give the couple another chance at pregnancy if the first round does not work. Therefore, the morally valuable goal of helping infertile people to have children, justifies destroying embryos in IVF. If the destruction of embryos is justified in one case, it is justified in the other, so there is no moral distinction between surplus and created embryos. Stem cell research is vital for creating and saving future life, and both reproduction and research are valuable projects. Neither is a trivial or frivolous enterprise that contravenes the principle of respect for embryos as a form of human life.
3.3 Islamic views on the human embryo

Dr Mohamed Ra’afat Othman, Ex-Dean, Faculty of Sharia and Law, Ain Shams University, Cairo

Dr Othman began his presentation with the scientific definition of stem cells, stressing that these, and the x and y-chromosomes that determine the sex of an embryo, are all created by the will of God. Human beings are dignified by God, and as it states in the Quran, they are superior to all other creatures (Sura ‘El-Esraa’, verse 70). Muslim scholars explained this as meaning that God organized the whole world and everything in it for the service and benefit of humanity (Sura ‘The Cow’ verse 29). Some consider that this is because of the human mind and knowledge, or because of human beings’ mission on earth. Dr Othman quoted several Islamic scholars on human dignity, commenting that it is not easy to completely define it. The Universal Declaration of Human Rights (10 December 1948) stated in Clause 1, “All individuals are born free, and equal in dignity and rights,” but the Declaration did not define the word ‘dignity’. The term is also not clear in constitutions laid down by different states in the last few decades. There was no Islamic definition in the past, but any explanation was only related to showing how God made man superior, but with no clarification. He also referred to the German philosopher, Kant, who proposed that as the embryo has no duties or rights to itself or others, the question of dignity does not apply. This issue and other relevant questions were discussed in the IOMS Seminar on Stem Cell Research, held in Cairo, 3-5 November 2007.

Dr Othman himself defines dignity as a characteristic, which indicates that a person should be treated with respect. The Arabic word for ‘dignity’ (karama) can also mean something precious or rare, and the term can, for example, be used with regard to precious stones. To apply this concept to embryos, they have to be given dignity, so should not be treated in a humiliating way. However, the question arises whether research conflicts with the dignity given by God. Some Christian scholars, particularly Roman Catholics, hold this view, believing that the fertilized cell has human characteristics, and is therefore an individual. They consider that when human characteristics are present, the soul will be also, so the entity must be treated with dignity. Dr Othman is of the opinion that this concept is very extreme, and he compared the embryo with a date stone or olive pip, which cannot be treated as a full plant. The same applies to the embryo, which cannot be treated as a fully developed human being with senses, but is more like plant life, or preliminary life. Therefore, a balance should be struck between research on embryos, which can help millions suffering from serious diseases, and cells which have no feeling.

It is believed that human life does not enter the embryo until after 120 days from conception, as is clear in one of the hadith of Prophet Mohamed, which was narrated by Moslem, one of the disciples of the Prophet, in the ‘Book of Fate’, (Kitab el-Kadir), so the life of stem cells and people’s suffering must be taken into consideration. Stem cells
must be treated as an embryo, but only in the metaphorical sense. The laboratory should be considered like the mother’s uterus, so that this concept can support one of the Islamic opinions regarding abortion. An embryo can be aborted at different periods of time during early pregnancy, although Muslim scholars do not all agree about this. When scientists agreed to ban abortion when the embryo is 120 days old because it will then have human life, it is well known that science cannot discover this life, which is different from the soul, and no branch of science can show when this is given. Prophet Mohamed stated that the embryo is an individual once it is ensouled. Some Hanafi and Shafei scholars ban abortion, while others allow it if there is a good reason, for example, if a woman can only give birth by caesarean section, and further such births would endanger her life (‘The Footnotes (hasheya) of Ibn Abdeen’, vol. 2, p.380; ‘The Footnotes of El-Gamel’, vol. 5, p. 390). Although abortion is forbidden, if a woman aborts herself, this is not considered a sin. One very prominent opinion states that abortion is not allowed after 120 days, but before this it is permitted, if it happens before 40 days from fertilization.

On the question of whether an ovum can be fertilized from the husband’s sperm for the purpose of stem cell research, this is allowed under certain conditions. The experiments should be conducted by at least two well-respected and honest scientists, in order to minimise mistakes because of Islamic rules on lineage; the embryo should not live more than 14 days, as after that the primitive streak and then the nervous system is formed; the embryo should not be implanted in another woman. These conditions can also apply to surplus embryos from IVF.

Discussion

Professor Haitham Khayat, Senior Policy Adviser to the Regional Director, WHO/EMRO, began the discussion by commenting on Dr Othman’s presentation, referring to passages in the Quran, hadith, and opinions of Islamic scholars. These examples of Islamic thought reinforced the opinion that the embryo does not have the dignity of a human being for the first 40 days of existence, before the soul is given. This concept is defined as when the embryo is in the womb of the mother, so when it is outside the womb, it is not a conceptus. Therefore, such embryos formed outside the womb can be made for research, and to create stem cells for treatments, on condition that they will not be put into the womb. Almighty God knows better than us.

Further comments on the stand of Islamic sharia regarding medically assisted conception were made by Sheikh Ali Hashim Alsarag, Director, Sarag Organization, Khartoum, Sudan. He began by stressing that Islamic sharia and fiqh support all issues that benefit the human being, but scientific progress must adhere to ethical and religious values. According to sharia, procreation must occur within the bonds of matrimony, where marriage is a contract between a man and a woman. If a third party is involved in procreation, then the procreation is vitiated. Therefore, the tolerant Hanafi school, for
example, authorizes IVF to treat infertility under the following conditions; the artificial fertilization and implantation are performed with the bonds of matrimony, and spouses are not separated by divorce or death; the sperm is that of the husband, and the ovum to be fertilized is that of the wife; the zygote in the wife's uterus is fertilized by her husband. These conditions are to ensure the continuation of a harmonious family environment, free of the complications that usually disturb those who are denied progeny, the adornment of life.

The subject of hESC research in the USA was discussed, with regard to the difference in research conducted by the public and the private sector. On August 9, 2001, the US administration issued its policy statement on embryonic stem cell research, stating that federal funding could be used only for research on existing embryonic stem cell lines under certain guidelines. First the stem cells had to be derived from an embryo that was created for reproductive purposes, and was no longer needed; second, informed consent was required for the donation of those excess embryos; third, the donation of any embryos could not involve financial considerations; and fourth, the process to derive all cell lines utilized in research had to have begun before August 9, 2001. The reason for this has to do with abortion policy in the USA; paying for eggs in the USA, as well as donation for reproductive purposes, take place although there is no legislation for that.

The issue of payment to egg providers was also raised, and the fear that this may lead to commercial transactions in human products, which is against international agreements. The argument is that if everyone is getting paid, the physicians, nurses, the hospitals, the egg provider should not be denied her right to be paid like the others, at least for the risk she may be exposed to. The real problem is that the egg provider is not told the whole story, is not told the potential risks she might face.

4. UPDATES ON THE SITUATION OF GUIDELINES IN THE REGION

4.1 Ethics of human embryo research and work of UNESCO

Orio Ikebe, Programme Specialist, Social and Human Sciences, UNESCO Cairo Office

Orio Ikebe provided material for discussion on the legal and ethical issues of human embryo research, by referring to a number of international declarations and reports related to the subject. The Universal Declaration on the Human Genome and Human Rights, issued by UNESCO in 1997, was the first international document to forbid research into reproductive cloning. Article 11 of the Declaration states: “Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted.” Article 24 of the same Declaration refers to the International Bioethics Committee (IBC): “It (IBC) should make recommendations, … in particular regarding
the identification of practices that could be contrary to human dignity, such as germ-line intervention.”

In the United Nations Declaration on Human Cloning 2005, “Member States are called upon to prohibit all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life.” The Declaration was adopted in March 2005, but there is some ambiguity with regard to the definition of ‘human life’, and whether an embryo constitutes ‘human life’. The United Kingdom, Netherlands and Belgium, may claim that it does not, while Costa Rica, Germany and Ireland, may hold that it does. Ms Ikebe gave the record of the vote on the Declaration on 8 March 2005. Many of the Arab States were in favour of the Declaration, although some abstained, including Algeria, Egypt, the Syrian Arab Republic, and Yemen.

The IBC report on ‘The Use of Embryonic Stem Cells in Therapeutic Research” (2001) examined the philosophical and religious points of view, “… in the case of Islam, the use of embryos for therapeutic or research purposes may be acceptable, provided that it takes place before the point at which the embryo is ensouled, i.e. from the 40th day after fertilization.” In exploring the different types of embryo, an issue for consideration was whether the intention or means of creation change the moral status of embryos. The report concluded with the recognition that hESC research should be debated at national level, and all new technologies using hESC should be considered. “In all aspects of research involving human embryos, particular importance should be given to respect of human dignity and the principles set out in the Universal Declaration of Human Rights (1948) and the Universal Declaration on the Human Genome and Human Rights (1997).”

The IBC Report on Pre-implantation Genetic Diagnosis and Germ-line Intervention (2003) stated with regard to germ-line intervention, “Because of the many technical problems and uncertainties about possible harmful effects on future generations, germ-line intervention has been strongly discouraged or legally banned.” On the subject of PGD for non-medical purposes (sex selection), the same report concluded, “It is recommended that PGD be limited to medical indications. Therefore, sex gender selection for non-medical reasons is considered to be unethical.” There were differing responses on this issue in Arab States. On the issue of PGD for HLA typing, the conclusion of the Report was: “Embryonic HLA typing for fitness as a donor of stem cells after birth to save the life of a sibling with a genetic blood disease or leukaemia, is considered ethically acceptable.”

Ms Ikebe explained that in order to review the situation in the Arab States, a survey of human embryo research regulations in the Region, was conducted by UNESCO Cairo Office from September 2007 to January 2008. Sixteen Arab countries were selected, based on contacts with experts, some of whom attended the Expert Meeting. The survey covered not only human embryo research, but research in general. Regulations were sought in relation to human reproductive and therapeutic cloning, embryonic stem cell
research, genetic testing, human genome and gene analysis, research involving human subjects, organ transplants, assisted reproductive technologies, pharmaceutical research, medical practice, and abortion. The sixteen Arab countries selected were Algeria, Bahrain, Egypt, Jordan, Kuwait, Lebanon, Morocco, Oman, Palestine, Qatar, Saudi Arabia, Sudan, Syria, Tunisia, United Arab Emirates, and Yemen. The results observed so far are only preliminary results, and some need more clarification.

4.2 Overview of the human embryo research regulations in the Region: Report of the UNESCO survey on bioethical regulations in the Arab States

Dr Magdi Shehata, Member, Egyptian Scientific Council Committee for Bioethics of Research

Dr Shehata gave details of the preliminary results obtained from the recent UNESCO survey of regulations concerning human embryo research in the Arab States. The survey was conducted in order to report the status of various types of regulations in relation to biomedical ethics, to compare the guidelines existing in different countries, to identify the potential needs to develop specific regulations, and to update existing ones in accordance with ethical, legal and social issues.

The types of regulations surveyed included national constitutions, national laws, national guidelines and codes, professional association regulations, institutional regulations, opinions of scholars and specialists, religious figures, scientists, and policy makers. Sources of information for the survey were data collected by assigned country representatives, official documents, published books and articles, parliamentary and academic libraries, media and the Internet, institutional regulation documents, and personal interviews.

Four of the ten topics in the survey involve research on human embryos; human reproductive and therapeutic cloning, embryonic stem cells, genetic testing, and assisted reproductive technologies (ART). The UNESCO designed format was filled for each topic.

For human cloning issues, some countries have issued legal and professional guidelines to regulate such practices and its applications. Of these countries, some need to update their regulations to address specific cases or practices, and need the legal framework to organize such practices and set up the sanctions to violations of these regulations, in order to protect human life and dignity from misuse of technology and information. However, other countries neither have the practices nor regulations concerning these issues.

Some of the countries surveyed prohibit any manipulations of human embryos (tissues and cells as well) for research purposes. In some countries, creation of human
embryos for therapeutic purposes, such as fertility treatment in married couples, is allowed under strict conditions, as long as they conform to the cultural, religious and social norms of each country. None of surveyed countries has established a law or official guidelines to allow therapeutic cloning. However, some scholars point out that an exception should be made for therapeutic cloning practices aimed at cloning certain body parts, but not the entire human being.

I A. Regulations by country: constitution, laws and guidelines

Algeria

Cloning an embryo or cells for any study or research purpose, or creation of a human being, is explicitly prohibited. Exception for therapeutic purposes for the embryos is only accepted with the written consent of the parents. ART are only allowed for married couples, and it is prohibited to use preserved embryos or gametes after the dissolution of marriage (by death or divorce). It is proposed by a Ministry of Health (MOH) Instruction No. 300 of May 12, 2001, that donation of sperms and gametes should be prohibited, surrogate mothers should be prohibited, IVF and ART should not be proposed to women who are less than 35 years and less than two years of infertility. The IVF and ART should be proposed only to women in age of reproduction, less than 50 years old.

Egypt

Human reproductive cloning, use of human organs, tissues and cells, and human embryos for commercial purposes, is prohibited. Conducting researches and practices that involve the suspicion of mixing lineages, or participating in them in any way, are also prohibited. ART has been conducted in Egypt since 1980, following the Recommendations and Proposals that originated from the 1980 Fatwa of the Fiqh Academy of Mecca; the 1986-1990 Fatwas of the Fiqh Academy attached to the Organization of the Islamic Conference; the 1991 Fatwa published in the guidebook of the National Islamic Centre for Population Studies and Research of Al-Azhar University; the Fatwa of ISESCO and the World Islamic Da’wa Association Seminar, held in Qatar, on the moral repercussions of the researches submitted in genetics; and the 1994 Fatwa of the Jordanian Islamic Fiqh Association for Medical Sciences. These recommendations were concerned with licensing of the institute, conditions for staff members; personnel conditions governing work; and the supervising body, or responsible authority. They are now applied by the Medical Syndicate, and the Ministry of Health and Population (MOHP) in Egypt, as essential guidelines for giving licenses to IVF clinics and centres.

Based on the Egyptian Islamic Fatwa Council, Research Issues in Human Organ Transplantation, (Dar el-Eftaa el-Masria, 2007), Chapter 4, recommendations on stem
cells transfer have been issued to regulate hESC researches, where it is stated that “It is permitted to obtain stem cells from legitimate sources for scientific and therapeutic researches, as long as no harm will affect the donor, and with written consent. Stem cells could be taken from surplus IVF embryos, umbilical cord, or legally aborted fetuses after acquiring the parental written consent”. “It is not permitted to obtain stem cells through illegal conduct, such as induced abortion without a legitimate reason, or by conducting IVF between a woman’s ovum and a sperm from a foreign donor (not her husband), or from a child, even by taking the permission of the child’s guardian, because the guardian in this case does not have to act with regard to who is under his mandate, only when the action will strictly benefit him ”.

**Lebanon**

Reproductive and therapeutic cloning; performing or undertaking tests that are inconsistent with the dignity of the human being; carrying out any genetic manipulations that can affect the human beings dignity, freedom and fundamental rights, are all prohibited by law. Performing IVF, or the use of ART, unless between spouses, and with their written consent, is also prohibited by law (Code of Medical Ethics).

A draft law concerning ART practice submitted to the MOH in 2002, updated in 2003 and 2007, proposes that it should be prohibited to use embryos for commercial or research purposes, or to carry out experiments to introduce genetic changes to the embryo; donation of sperm, eggs, preserved embryos, use of surrogate mothers, and sex selection of embryos, shall be prohibited; prenatal diagnosis and selective abortion shall only be allowed for therapeutic and preventive purposes; embryos and gametes should be preserved for 5 years after fertilization with the parents informed consent”.

**Morocco**

Donation, removal, and transplantation of organs and human tissues is allowed by law except for reproductive cells. Therefore donation of oocytes, spermatozoids, or supernumerary embryos for any research purpose cannot be carried out. A draft document on ART-based practices developed by professional societies, which was submitted to the MOH in 1999 and updated in 2007, proposes prohibition of any embryo donation for fertility treatment, and prohibition of reproductive cloning. The draft proposal calls also for an open discussion about a national regulation concerning the use of supernumerary embryos in research.

**Tunisia**
Researches on human embryos, and reproductive cloning in general are prohibited by law, and are only allowed for the therapeutic purpose of embryos. Preservation of embryos is allowed for reproductive purposes only. Creation of human embryos for research is prohibited by law, so creation of hESC for research is not allowed. PGD is permitted by law for medical purposes only in order to prevent a severe affection for the expected child. Preservation of embryos and gametes is allowed for five years, renewable once if the couple wishes it, based on written informed consent. In the case of dissolution of marriage by divorce, or death of one spouse, supernumerary embryos should be automatically destroyed under the responsibility of the ART centre.

**Saudi Arabia**

Guidelines established by the national REC, prohibit human reproductive cloning or any of its consequent applications, as the risks outweigh the benefits. Storage of embryos and gametes for reproductive purposes are allowed after approval of the married couple.

**I B. Regulations by Country: Draft laws, guidelines, and opinions**

**Jordan**

There are no practices of human cloning or embryo research due to technical obstacles and lack of resources, cultural and religious barriers. There are also no ART regulations and no legal framework. Draft guidelines for ART practices submitted by professional societies and the private sector to MOH are still under review. This draft law permits preservation of embryos for fertility treatment within married couples. A second draft proposal for a blood stem cells bank submitted to MOH in 2007, and still under review includes: it shall be allowed to obtain and preserve stem cells from legitimate sources for scientific research and treatment with the parents’ written consent, for example, aborted fetuses (based on abortion laws), surplus embryos from IVF within married couples; using and studying stem cells should be prohibited in the case of fetuses of enforced abortion (illegal abortion), creation of embryos for research using donated gametes, and therapeutic cloning.

**Qatar**

There are no laws controlling the issues of ART practices. However, the State of Qatar adopts the UN Declaration on Human Cloning issued by vote in 2005, as it was one of the 84 countries that voted in favour of it, so it can be understood that human cloning is prohibited. The institutional guidelines on ART-based practice issued by the Hamad Medical Corporation are in effect, in which creation of embryos by IVF for fertility treatment within married couples is allowed. Embryos fertilized by IVF are either
transferred directly into the mother’s uterus, or frozen for transfer into her uterus in the next therapeutic cycle according to the couples' written consent. Therefore, creation of embryos, or the use of surplus (and defected) IVF embryos to obtain ESC is not allowed. There is no mention of the position on PGD tests for sex selection, or HLA typing and genetic diseases.

**Palestine**

There are no specific regulations or laws concerning human cloning. A draft law on human organ transplant in 2003 proposed that human cloning should be prohibited; creation of embryos should be allowed only for reproductive purposes, such as fertility treatment problems for married couples with consent of the patients.

**Sudan**

There are no national guidelines or rules to regulate the issues of human cloning or embryo research. However, many centres are practising ART according to the international guideline, so there is an urgent need to have a national regulation.

**Bahrain**

There are no national regulations on human cloning and embryo research at present. ART are conducted in Bahrain, based on rules and regulations of Islamic laws and fatwas in which ART is allowed only for married couples during marital life; donation of gametes and embryos is prohibited; embryo sex selection is allowed in cases with clinical indications; surrogate motherhood is not allowed; cryo-preservation of human gametes and embryos is allowed for couples only and not for donation. No time limit is mentioned. Draft guidelines for the establishment of ART centres were submitted to the MOH in Bahrain, which suggest requirements for the establishment of ART centres (building, clinics, laboratories, operation room, equipment, and application of infection control programme); accreditation of embryo laboratories and specialists at a practical level, through implementation of quality control and assurance systems; reporting the results of every centre regarding cases, techniques, and other information to MOH; a monitoring system for updating facilities, presenting data, and solving patient’s complains. It is also suggested that a review of research protocols should be carried out by the relevant university or MOH committee.

**Kuwait, Oman, Syria, UAE and Yemen**

There are no national regulations on human cloning and embryo research, so national legal regulation is urgently needed.
II.  Sanctions to Violations

Sanctions to violations of the existing rules, which range from imprisonment to fining, are present in these countries. The penalty may lead to the withdrawal of the physician’s license, closure of the clinic or hospital for a specific period of time, or the case may be transferred to the criminal authority.

III.  General Consensus

Reproductive cloning is implicitly/explicitly prohibited in laws and national regulations, and by MOH. Creation of human embryos for fertility treatment is only allowed in married couples under strict conditions; no donation of embryos or gametes to other couples; no surrogate mothers, no commercial exploitation, no research. None of the surveyed countries has established a law or official guidelines to allow therapeutic cloning. Scholars pointed out that an exception should be given to therapeutic cloning practices aimed at developing certain body tissues, but not entire human beings. Some countries in the region refer to Islamic fatwa as the only reference to regulate certain medical practices and research. Although, Islamic Sharia is the source of basic regulations in the region, the question remains to be answered whether the Islamic Fatwa in this situation could be considered as the guidelines for ART practices, or it is a free reference according to individual preference.

IV.  The Way Forward

The way forward requires standardization with regard to procedures such as sample collection, storage, and processing; trained personnel, including practitioners, and regulators. Certification is also necessary for accreditation of laboratories, for example ISO. There should be governmental management, and a unified glossary should be developed to define specific terms and processes based on reliable scientific sources. Consent forms should have unified types of questions.

A mechanism should be developed for data exchange between centres in the country, and in other countries of the Region. There should also be periodical meetings and discussion panels, as well as a database for genetic disorders, and related information for decision-making, national, regional, and consortia. There should be an increase in public awareness for informed opinions, such as those of scholars and scientists, and there should be more community engagement.
Discussion

On the subject of cloning, there is now in Kuwait a law under discussion about cloning, and Egypt already has a law for this procedure. In Lebanon, in 2002 the Cabinet requested the opinion of the ethics committee on cloning. The committee was against both reproductive and therapeutic cloning. There are no practices of human cloning in Sudan at the moment, because ART are only according to fatwa.

With regard to sex-selection, it was considered that there should be a religious fatwa to be complied with, and the matter should not be left as a personal choice. In Iran, sex selection is allowed for therapeutic reasons, or for having the other sex in the family, but only for the third child according to fatwa. In Syria, there is no legislative framework according to which sex selection could be practiced, and there are also no regulations for genetic tests, promoting fears that the lack of such might lead to social problems.

The topic of ART in countries participating in the survey was also discussed. In Jordan there is a law which requires a licence to be obtained from the MOH in order to establish a centre. In Iran, there are now about 40 IVF centres, and a licence from the MOH is necessary for establishing a centre. There is no prohibition of ART. As for having a third party or surrogacy, it is allowed only by a special fatwa. In Egypt, surrogacy became allowed in 1985, if the surrogate is the second wife of the same husband, but only a year later in 1986, the Islamic Council for Mecca rescinded that decree. The same situation occurred with the Church of Alexandria in Egypt, which allowed surrogacy for a friend of the family, but then later rescinded the approval. In Sudan, a fatwa regarding ART was issued about 8 years ago before ART started, as there had to be a fatwa to permit the technologies. Sudan is keeping to the general guidelines, including only between couples, no donating, etc., but there is no law regulating ART.

Details of regulations in some countries were given, such as the ministerial decree in Egypt (No.238/2003, Article 51), according to which it is prohibited for physicians and researchers to conduct any research on human cloning, the violation of which exposes the violators to penalties, which range from imprisonment to fining, from withdrawal of the physician's licence, to disclosure of the clinic or hospital, and possible referral to the Criminal Investigation Authority. In Libya, there are laws under the heading of Medical Responsibility of Practice, issued in 1978, that regulate all medical practices, including abortion, and IVF. Accordingly, cloning, and surrogacy are prohibited, but research on surplus embryos is permitted, and freezing embryos is allowed. In Jordan there are two draft laws for ART practices submitted to the MOH, the first one proposes to permit preservation of embryos for fertility treatment within married couples, and the second one, submitted in 2007, on blood stem cells bank, includes legitimate sources from aborted fetus and IVF excess embryos. In Iran, stem cell research, and research on embryos in general is allowed based on fatwa, but no law exists that regulates embryo research. Therapeutic abortion has recently been allowed in the
event of problems for the mother or the fetus. The reason why Syria is sorted among the countries that have no legislation, is that Syria adopts international law but does not have its own national law.

5. Adoption of the Recommendations

The second day of the meeting consisted of discussions on the draft recommendations prepared by the Drafting Committee. The recommendations were revised according to the legal and ethical aspects of embryo research deliberated on by the participants. Discussions continued on the third day, when the revised recommendations were reviewed and finalized. In the last session, the recommendations towards regional guidelines on legal and ethical aspects of embryo research were adopted. The recommendations will be circulated by UNESCO to the relevant government ministries, policy makers, physicians, lawyers and religious experts in the region in preparation for a further meeting to be held in 2009, when it is hoped that guidelines on embryo research in the Arab Region will be formulated and adopted.
Recommendations of the Expert Meeting on Ethical and Legal Issues in Human Embryo Research
12 – 14 February, 2008, Cairo, Egypt

Introduction
An Expert Meeting on Ethical and Legal Issues in Human Embryo Research was held in Cairo from 12 to 14 February 2008 organized by United Nations Educational Scientific and Cultural Organization (UNESCO) Office in Cairo, World Health Organization Regional Office for the Eastern Mediterranean (WHO/EMRO) and the Islamic Educational, Scientific and Cultural Organization (ISESCO). The Meeting was attended by 25 experts from the region as well as 5 international experts. At the closure of the Meeting, the following Recommendations were adopted by the participants.

The Recommendations below are designed to prepare participants to contribute to a future consultation, to develop national and regional policies on human embryo stem cell research. They build upon the foundation laid in Recommendations of the Stem Cells Seminar held by the Islamic Organization of Medical Sciences (IOMS), in cooperation with WHO/EMRO, UNESCO and ISESCO, Council for International Organizations of Medical Sciences (CIOMS), and the Islamic Fiqh Academy, between 23-25 of Shawwal 1428/3-5 November 2007, in Cairo.

The Recommendations are based on UNESCO declarations in the field of bioethics, such as the Universal Declaration on the Human Genome and Human Rights (1997), the International Declaration on Human Genetic Data (2003) and the Universal Declaration on Bioethics and Human Rights (2005), and evolving international guidelines on research with human subjects and animals in general, and in particular on guidelines specific to human embryonic stem cell (hES cell) research developed by some national and international agencies including the International Society for Stem Cell Research (ISSCR).

The Recommendations are intended to fit within the distinctive religious and social cultures and values of the Eastern Mediterranean and the Arab region. They reflect issues raised by a survey of laws, national guidelines, professional guidelines and religious rulings including Islamic fatwas in the regional Arab States conducted by the UNESCO Cairo office in coordination with experts in the region, and presentations and discussions held at the February 2008 Meeting.

The survey found a uniform prohibition of human reproductive cloning, expressed in legislation, national regulation and/or, for instance, Ministry of Health policy rulings. It also found that while there were few barriers to research on existing stem cell lines, provisions differed on research using embryos that proved surplus to patients’ needs in IVF programmes. Admission to such programmes was generally limited to legally married couples, and did not allow transfer of sperm, ova or embryos to another couple, or surrogate motherhood. Some barred the use of surplus embryos for research, even including reproductive research. Another common theme of regional provisions was a
prohibition of commercial exploitation of IVF patients and others to provide surplus embryos for research. However, on the basis of influential religious rulings, the IOMS Seminar in November 2007 agreed that use of surplus IVF embryos within 14 days after fertilization “for the purposes of treatment and scientific research is better than wasting them.”

Similarly, none of the surveyed countries had established law or official guidelines to allow research cloning, but it was not always clear that this was explicitly prohibited. That is, provisions prohibiting reproductive cloning did not necessarily also ban research cloning. However, some scholarly commentators found that therapeutic cloning to produce certain bodily tissues might be permitted to create tissues suitable for placing in those whose cells were cloned. This is an issue that may be resolved through an interpretation of legislation, Islamic sharia, which are the basic rules of the region, fatwas, and comparable sources of guidance, although an absence of interpreted prohibition may be understood to allow individual choice and conscience.

Since the purpose of this Expert Meeting is to promote harmonization of regional regulations on hES cell research, on an ethical basis, the Meeting recommends that each country in the region should consider, and try to be in harmony with its neighbors, on the following matters. The Recommendations are addressed not only to national policymakers and scientific investigators, but also public and private research institutions, patients and wider communities. That is, they invite the responses of stakeholders both directly and indirectly involved in the science and social values that hES cell research may promote, and endanger.

**Recommendations**

1. Provisions on hES cell research (derived from fresh or cryopreserved embryos) in the region should respect and reflect religious and cultural values. For instance, where research and/or biological materials are allowed to be imported from other countries, care should be taken, by appropriate oversight if necessary, to ensure that their procurement and creation do not contradict ethical or religious values or traditions. Research should be respectful of human dignity, but may be motivated to relieve the indignity of limitations and suffering due to preventable or treatable illness or disability.

2. Terms applied in hES cell research should be defined and where possible agreed, to ensure that laws and comparable provisions achieve their purposes and do not unduly affect related matters with which they are not designed to deal. Terms to be defined, when employed, include:
   - informed consent
   - genetic engineering
   - *in vitro* fertilization (IVF)
• human embryo (addressing, for instance, products of chimeric studies)
• embryonic stem cells (in contrast to non-embryonic stem cells)
• research (in contrast to reproductive) cloning
• cloning
• embryo twining, or splitting
• parthenotes
• mitochondrial injection in fertilized ovum
• cytoplasmic donation
• supernumerary embryos
• altered nuclear transplantation (ANT)
• induced pluripotent cells (iPCs)
• PGD
• germ cell transplantation

3. The purposes of ethically appropriate, cost-beneficial research should be defined, considering purposes such as;
   • study of human genetics such as;
     ➢ genome stability and imprinting phenomena
     ➢ research on the origins of genetic diseases in general
     ➢ treatment to overcome transmission of genetic diseases in natural reproduction
     ➢ research on the origins of potentially harmful genetic predispositions to disease in general
   • infertility treatment

4. Research that a country may consider unacceptable should be defined, such as;
   • reproductive cloning
   • germ-line genetic therapy
   • germ-line genetic manipulation (enhancement)

5. Countries without provisions should consider whether to create them, and those with provisions should review them, on such issues as;
   • the use of surplus embryos from IVF for research
   • research cloning (cloning cells for the purpose of deriving embryonic stem cells for research or possibly treatment)
   • HLA typing of embryonic, fetal or other cells for treatment of a couple’s born child (“saviour sibling” cells)

6. Countries should consider the acceptability/unacceptability of topics such as:
   • donation of gametes for research use
   • creating embryos from donated gametes for research (e.g. into fatal
childhood diseases)

• promotion of, or collaboration in, commercially-inspired research (e.g. by pharmaceutical or biological manufacturers)
• human/animal chimera research (see IOMS 10th and 19th Recommendations)
• specific funding for capacity building to undertake hES cell research and development
• research on human embryos beyond 14 days after fertilization

7. Countries should consider whether the standard requirements for ethical review of research with humans requires additional oversight for hES cell research on such matters as:

• consent of gamete or embryo donors
• consent for use of fetal sources of materials (e.g. from induced abortion)
• withdrawal of consent to use of gametes and/or ova in research
• confidentiality/privacy (e.g. involving DNA identification)
• coercion of and payment (in money or kind) to, donors of material
• respect for protection of intellectual property interests
• conflict of interest (e.g. rewards to researchers and/or research institutions)
• reinforced or additional ethics committee review
• investigator, research and/or donor participation in commercial profits from licensing agreements
• commercial use of gametes and/or embryos

8. Countries should consider

• forms of hES cell research that require special oversight
• by what agency (for instance governmental) any such oversight should be conducted
• to what body any such agency should be accountable

9. Countries should consider governing principles for the operation of hES cell banks, such as:

• acceptance of materials submitted for banking (e.g. their derivation)
• distribution of banked cells/cell lines
• quality control (e.g. pathogen and genetic testing of cells, and their preservation in storage)
• tracking distributed cells
• cost-control to prevent exploitation and profiteering by banks
• respecting ethnic balances in populations in banked materials

10. Countries should consider licensing and/or comparable requirements for:

• undertaking hES cell research
• undertaking hES cell therapy
• operating hES cell research facilities

11. Countries should consider systems and implications of regional and/or wider international collaboration, including:
• information exchange on research data
• toleration of deviations from national provisions to accommodate other countries’ different provisions
• entitlement of researchers and (postgraduate) students to undertake research in other countries that is prohibited in their own (e.g. on embryos created for research purposes)
• entitlement of nationals to receive in other countries hES cell research treatments that are prohibited in their own
• entitlement of nationals from other countries to receive research treatment that is unlawful to receive in their own countries

12. Countries should monitor and exchange information that would reduce or eliminate the need for hES cell research, such as development of induced pluripotent stem cells (iPS cells) and cell lines that are safe for use in humans.

In conclusion, the Meeting recommends that UNESCO, WHO, ISESCO, IOMS and other partners convene a future meeting of all stakeholders in the region, in 2009, to consider and give effect to the Recommendations above, to produce suitable regional policy.

14 February 2008, Cairo