FIRST REGIONAL MEETING OF NATIONAL BIOETHICS COMMITTEES
Cairo 5–7 May 2007

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EXECUTIVE SUMMARY

The First Regional Meeting of National Bioethics Committees (NBC) was held in Cairo, Egypt, at WHO Eastern Mediterranean Regional Office (EMRO) 5–7 May 2007. The meeting was organized jointly by UNESCO Cairo office and EMRO, and was the first time the two international organizations had collaborated in holding such a meeting. Experts from 15 countries in the Region took part, representing Member States from both UNESCO Arab Region and WHO Eastern Mediterranean Region. Senior technical staff from the Arab League Educational, Cultural and Scientific Organization (ALECSO), the Gulf Cooperation Council (GCC), the Islamic Organization for Medical Sciences (IOMS), UNESCO and WHO also participated.

The meeting was inaugurated by Dr Hussein A. Gezairy, WHO Regional Director for the Eastern Mediterranean Region, Awad Elhassan, Director a.i. of UNESCO Cairo office, and Dr Ibrahim Badran, Chairman of the Egyptian National Bioethics Committee, who was representing the Egyptian Ministry of Health. All three stressed the significance of this first regional meeting of NBC and the collaboration between UNESCO and WHO. This would be an opportunity for Member States in the Region to share their experiences in establishing national bioethics committees, to consult the two international organizations, and discuss the best ways to encourage other countries in the Region to set up NBC, how to improve capacity building of existing bioethics committees, problems of sustaining such committees, to promote cooperation and networking among NBCs, recommendations for the future.

The technical presentations covered the present status of WHO and UNESCO with regard to bioethics and the international community; activities of international bodies in the Region concerned with ethics; updates on the priority issues in the field of bioethics, and international networks and NEC in the Region.

Presentations on challenges and successes were given by representatives of the participating Member States, including Afghanistan, Egypt, Islamic Republic of Iran, Jordan, Lebanon, Libyan Arab Jamahiriya, Morocco, Pakistan, Qatar, Saudi Arabia, Sudan, Syrian Arab Republic, Tunisia and Yemen.

Following the technical and country presentations, participants were divided into two working groups: the first group discussed a strategy for setting up new, or strengthening existing NBC, and the second group debated how to establish cooperation between NBC in the Region, including the possibility of virtual networking.

Discussions were held on a variety of topics arising from the presentations during the Meeting, including the respective roles of UNESCO and WHO Member States regarding bioethics in the Region; legislation in Member States on human cloning, stem cell research and organ transplantation; the Islamic sharia viewpoint on ethics; the status of existing NBC in the political sphere, and ways of reaching and possibly influencing
policy makers; the relationship between Institutional Review Bodies (IRB) and NBC. Further subjects debated covered the need for common guidelines and ethical codes for countries in the Region; the necessity for bioethics committees to be multidisciplinary and independent, but also to have some legislative power; the reviewing of medical and scientific research programmes. An important issue raised by the participants was the need to raise awareness of bioethics in schools and universities as well as institutions and research centres.

The group session suggested as a strategy for new NBC, that initiatives should be started, but each country should decide when and how to establish a bioethics committee. The NBC should be under a high authority, and could be the umbrella for other committees in different ministerial institutions. Experiences of other countries should also be reviewed. For capacity building, much distance learning is available, but there is a need for monitoring and evaluation. The future role of UNESCO and WHO, as well as ALECSO and ISESCO, was discussed, and it was agreed that there is a need for common initiatives and harmonies in different agencies. With regard to dissemination of the culture of bioethics, there is a need for materials in educational institutions, and also an Arabic dictionary of bioethics terminology from the scientific standpoint. How to establish communication and cooperation between NBC in the Region was keenly debated, particularly concerning the most practical method to be adopted, a website, networking, or an association. The question of public awareness of bioethics was also raised, as people should know their rights regarding public health, medical and scientific research, as well as plant and animal research.

The final session was a discussion on the future cooperation and activities in the Region and international and regional organizations. A number of points of agreement were reached, including the setting up of a network to ensure that the meeting was followed by concrete activities. The next regional meeting in two years time could be a deadline to access progress. The importance of Islamic and Arab culture was also stressed, and the need to acknowledge that this culture is different from that in Western countries. It was agreed that there should be more regional control. There is an urgent need for more NBC to be established in the Region, and these committees can keep in touch through the proposed network. The task of WHO and UNESCO is to assist, but setting up the committee must be undertaken by the country concerned.

For the first time the two international organizations have collaborated together on a regional level. The hope of all participants was that this meeting would be a springboard for the future of bioethics in the Region.
1. INTRODUCTION

Recent advances in science and technology have great potential to ameliorate the wellbeing of humanity, but at the same time serious ethical concerns have been raised throughout the world in this regard. UNESCO, as an international agency mandated to ethics, established in 1993 the International Bioethics Committee (IBC), represented by 36 experts from the Member States of UNESCO, and in 1998 the World Commission on the Ethics of Scientific Knowledge and Technology, represented by 18 experts from the Member States of UNESCO, in order to address these important issues.

WHO/EMRO identified the importance of ethics, especially in the biomedical field. Since the 1980s, EMRO has led development of the “Islamic Code of Ethics of Medicine and Health.” In addition, capacity building in bioethics has always been an integral part of WHO/EMRO planned activities to strengthen health research capacity in the Region.

In the field of bioethics, the General Conference of UNESCO has adopted three international instruments drafted by the IBC, namely the Universal Declaration on the Human Genome and Human Rights”, the “International Declaration on Human Genetic Data (2003)”, and the “Universal Declaration on Bioethics and Human Rights (2005).” It is clearly mentioned in these instruments that the Member States should encourage the establishment of independent, multidisciplinary and pluralist ethics committees.

The role of national ethics committees is of great significance, especially in addressing legal, ethical and social issues of science, advising the government on formulating guidelines, and fostering ethical debates involving policy makers, scientists, religious leaders, philosophers and the general public. Therefore, UNESCO Cairo Office and WHO/EMRO decided to combine their efforts in the field of bioethics and organize a regional meeting of national bioethics and other ethics committees.

The First Regional Meeting of National Bioethics Committees (NBC) was held in Cairo, Egypt, at WHO Eastern Mediterranean Regional Office (EMRO) 5–7 May 2007. The meeting was organized by UNESCO Cairo office in collaboration with EMRO, and was the first time the two international organizations had cooperated to hold such a meeting.

The objectives of the meeting were:

• To exchange information among existing national bioethics and other ethics committees in the Region.

• To promote networking and cooperation among committees.

• To support countries of the Region in establishing national ethics committees in the Region.
The meeting consisted of technical presentations by experts from various international and regional organizations, including the Islamic Organization for Medical Sciences (IOMS), the Arab League Educational, Cultural and Scientific Organization (ALECSO), the European Group for Ethics in Science and New Technologies (EGE), the Middle East Research Ethics Training Initiative (MERETI), the International Federation for Gynaecology and Obstetrics (IFGO), the Central European University, the Gulf Cooperation Council (GCC), UNESCO and WHO. Participants gave presentations on experiences with ethics committees in their respective countries, and group sessions discussed strategy for establishing new, or strengthening existing bioethics committees, and how to initiate communication and cooperation between different ethics committees in the Region.

Discussions were held at different stages during the meeting and covered the technical and country presentations, and suggestions arising from the group sessions. A number of recommendations were reached in the final discussion, which dealt with future activities and cooperation in bioethics in the Region.

The meeting was inaugurated by Dr Hussein A. Gezairy, WHO Regional Director for the Eastern Mediterranean. In his address Dr Gezairy expressed the hope that the combined experiences of WHO and UNESCO in the field of bioethics will help strengthen bioethics programmes in the Region. He observed that with increasing globalization and digitization, medical sciences are undergoing revolutionary changes, population health is broadening its scope to include genetic factors, and nanotechnology, stem cell research and genomics are presenting new ethics challenges. He noted, however, that unfortunately, the recent growth in biomedical and health-related research activities has not been accompanied by a corresponding enhancement of the bioethics infrastructure in many resource-poor countries, including the countries in our region.

Dr Gezairy emphasized that bioethics is interdisciplinary, being concerned with the ethical questions that arise in the relationships between life sciences, biotechnology, medicine, politics, law, philosophy, environment and theology, and including human health and life, as well as animal and plant life. He stressed that each country needs to implement bioethical standards in different aspects of life to protect people, their life, dignity and wellbeing. The gap between developed and developing countries regarding application of biotechnology is huge, and is widening further. Developing countries need to incorporate bioethical standards in development activities to ensure better life for their people, but bioethics standards and applications need to be developed and shaped according to the culture and norms of each community.

Dr Gezairy referred to WHO’s launch of its Ethics and Health Initiative in October 2002, and the establishment of the Eastern Mediterranean Region Research Ethics Committee (EMRREC) in March 2006. To help in capacity building, training courses in bioethics have begun in the University of Toronto, Canada, and the University of Maryland, USA. Candidates for these courses are supported by the Regional office. Dr
Gezairy emphasized the necessity for much to be done to strengthen the field of bioethics in the Region and said that the Regional Office plans to increase its activities in this regard.

Awad Elhassan, Director, UNESCO Cairo office, expressed his pleasure at the subject of the meeting and the cooperation between UNESCO and WHO/EMRO. He commented that there is a need for a wider selection of participants to be involved in the discussion of bioethics, which includes many sensitive issues, such as the use of human embryonic stem cells, cloning and genetic engineering and reproductive techniques. Ethical issues involve experts and specialists from several disciplines, theologians, economical, medical and scientific experts, and therefore should not be left only to technical experts.

There is pressure on society to allow freedom of scientific and medical research because of the potential of solving human problems, but the risks are great and some kinds of research may be tampering with the delicate balance of nature. The long term effects of new developments in research in the life sciences should be borne in mind, and ethics could even affect human existence. Elhassan raised the question of the role of UNESCO in promoting bioethics in the 1997 Universal Declaration on the Human Genome and Human Rights, and the establishment of committees at national level. He said that it is the ambition of UNESCO that all countries in the Region will have national ethics committees, observing that scientists are not always qualified, or aware of ethics, or the legal dimensions of what they do, so it is important to have discussions at national level for all stakeholders. He also noted that legislation must be tailored to the needs and culture of the countries in the Region.

Dr Ibrahim Badran, Chairman, National Ethics Committee, Egypt, addressed the meeting on behalf of the Egyptian Ministry of Health and Population, commenting that in the past ten years the world has seen an outburst of scientific research, but this has not been accompanied by parallel development of ethics. Egyptian collaboration in the field of bioethics began in 1993, and the Egyptian Bioethics Committee was established in 1995.

Dr Badran observed that ethics is an innate human quality, combining science, law, religion, social sciences and other disciplines. Today, he continued, there are serious ethical concerns on the world stage, but the developing world is plagued with poverty, unrest and other negative factors. A range of problems confronts developing countries, including the new world economic order, globalization concepts, the World Trade Organization and property rights, the supremacy of capitalism, the Declaration of Human Rights (compulsive democracy), the blurring of identity and faith, the influence of giant multinational companies (fostering corruption), invasive influences of frontier sciences, the changing world epidemiology, and new criminal events affecting health status (substance abuse, manmade destructive weapons, child abuse and drug trafficking). Dr
Badran concluded with the hope that the cooperation displayed in this meeting will start a new chapter in the field of ethics.

The agenda, programme, list of participants of the meeting and list of countries, are given in Annexes 1, 2, 3 and 4 respectively.

2. BIOETHICS AND THE INTERNATIONAL COMMUNITY

2.1 The status of ethics in WHO/HQ

Dr Marie-Charlotte Bouesseau, Technical Officer, WHO/HQ

Dr Bouesseau gave an overview of the status of ethics in WHO/HQ, referring first to the Ethics and Health Initiative launched by the WHO in October 2002. The aim of the Initiative was to provide a focal point for ethics issues raised by the three levels of the organization, focusing on regional and country levels; to develop activities regarding a wide range of global bioethics topics, such as research with human beings, fair access to health services, and pandemic influenza planning. Previously, several HQ departments had been active in research ethics.

The main objectives of the Initiative are to develop WHO policies and strategic approaches, to strengthen capacity in the Member States, to collect and disseminate information, and to contribute to international debate. WHO provides support at the different levels of the Organization for analysing the ethical aspects of health, and also assists Member States through tools and guidelines to incorporate an ethical analysis into health services delivery, health research, and public health activities.

Ongoing work continues in close collaboration with other HQ departments regarding equitable access to care and treatment, pandemic preparedness, human organ and tissue transplantation, and research ethics. The WHO website contains information on various aspects of bioethics and the involvement of WHO in this field. Dr Bouesseau gave examples of research ethics projects in which WHO is taking part, including Networking for Ethics on Biomedical Research in Africa (NEBRA), a project consisting of a consortium of European and African institutions working with WHO in 15 West African countries, to carry out a survey of ethical review of health research in the 15 countries, and construct a strategic plan to improve ethics of research for health in those countries. Other projects included training activities in Ibadan (February 2007) with the European and Developing Countries Clinical Trials Partnership (EDCTP); Tunis (March 2007) in collaboration with the Department for Reproductive Health and Research (RHR); Ouagadougou (July 107) with the Program for Applied Technology in Health (PATH) and RHR; and Gabon (2007) with EDCTP.

The project Training and Resources in Research Ethic Evaluation (TRREE) for Africa, which is funded by EDCTP, is a web-based training and capacity building
initiative on the ethics of research involving humans conducted in African countries, and "
aims to facilitate distance learning for ethics bodies in Africa. The Global Forum on "
Bioethics in Research is a venue for delegates from developing and developed countries "
to debate the ethical issues surrounding international collaborative research. The next "
forum will take place in Vilnius, Lithuania, in June 2007, and will focus on fostering the "
research ethics infrastructure in the developing world/transition societies, with special "
emphasis on the ethical aspects of mental health. Another event in 2007 is a satellite "
meeting, which is to be organized by the Initiative for Vaccine Research (IVR) and the "
Ethics and Health team, to address issues related to vaccine research.

Regarding the characteristics of collaboration on ethics and health, Dr Bouesseau "
stressed that there is a need to concentrate more on synergies between WHO and other "
international organizations, regional and national initiative bodies, as well as to "
contribute to strengthening local capacity and avoid duplication of initiatives, which "
requires active partners. She added that collaboration requires active partnerships, which "
include all relevant stakeholders.

In the 42nd session of the Regional Committee for the Eastern Mediterranean "
(1995), the EMRO technical paper on ethics of medicine and health was discussed, and "
the Committee recognized that there was a need for a detailed code for health ethics to "
guide the countries of the Region, that there should be more collaboration on ethics "
between organizations concerned, and that a compulsory course on ethics and health "
should be included in undergraduate curricula. Much has been done in the past decade, "
but more collaboration is required, not only because of the mandate of the WHO, but also "
to promote health in Member States.

2.2 WHO/EMRO and ethics

Dr Alaa Abou-Zeid, Technical Officer, Research Policy and Cooperation, "
WHO/EMRO

Dr Abou-Zeid opened his presentation on the current state of ethics in the Eastern "
Mediterranean Region with a reminder that interest in ethics in the region as an integral "
part of health started a long time ago. In the 1980s, for example, EMRO played a role in "
developing the Islamic Code of Medical Ethics. The concern of EMRO is with all types "
of ethics related directly or indirectly to health, which include ethics of health research, "
medical practice, environmental and other ethics.

With regard to the status of health research in the Region, two surveys were "
conducted to explore the awareness of researchers regarding ethical considerations in "
health research. The first survey covered ethical practices for health research in genomics "
and biotechnology, and the second, investigators' determination of the need for informed "
consent, and the adequacy of informed consent documents. Data was obtained from a "
questionnaire, and results showed that 43% of researchers obtained ethical clearance before "
they start their researches; 62% stated that informed consent is needed as part of subject
policy makers; the relationship between Institutional Review Bodies (IRB) and NBC. Further subjects debated covered the need for common guidelines and ethical codes for countries in the Region; the necessity for bioethics committees to be multidisciplinary and independent, but also to have some legislative power; the reviewing of medical and scientific research programmes. An important issue raised by the participants was the need to raise awareness of bioethics in schools and universities as well as institutions and research centres.

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The project Training and Resources in Research Ethic Evaluation (TRREE) for Africa, which is funded by EDCTP, is a web-based training and capacity building
initiative on the ethics of research involving humans conducted in African countries, and aims to facilitate distance learning for ethics bodies in Africa. The Global Forum on Bioethics in Research is a venue for delegates from developing and developed countries to debate the ethical issues surrounding international collaborative research. The next forum will take place in Vilnius, Lithuania, in June 2007, and will focus on fostering the research ethics infrastructure in the developing world/transition societies, with special emphasis on the ethical aspects of mental health. Another event in 2007 is a satellite meeting, which is to be organized by the Initiative for Vaccine Research (IVR) and the Ethics and Health team, to address issues related to vaccine research.

Regarding the characteristics of collaboration on ethics and health, Dr Bouesseau stressed that there is a need to concentrate more on synergies between WHO and other international organizations, regional and national initiative bodies, as well as to contribute to strengthening local capacity and avoid duplication of initiatives, which requires active partner. She added that collaboration requires active partnerships, which include all relevant stakeholders.

In the 42nd session of the Regional Committee for the Eastern Mediterranean (1995), the EMRO technical paper on ethics of medicine and health was discussed, and the Committee recognized that there was a need for a detailed code for health ethics to guide the countries of the Region, that there should be more collaboration on ethics between organizations concerned, and that a compulsory course on ethics and health should be included in undergraduate curricula. Much has been done in the past decade, but more collaboration is required, not only because of the mandate of the WHO, but also to promote health in Member States.

2.2 WHO/EMRO and ethics

Dr Alaa Abou-Zeid, Technical Officer, Research Policy and Cooperation, WHO/EMRO

Dr Abou-Zeid opened his presentation on the current state of ethics in the Eastern Mediterranean Region with a reminder that interest in ethics in the region as an integral part of health started a long time ago. In the 1980s, for example, EMRO played a role in developing the Islamic Code of Medical Ethics. The concern of EMRO is with all types of ethics related directly or indirectly to health, which include ethics of health research, medical practice, environmental and other ethics.

With regard to the status of health research in the Region, two surveys were conducted to explore the awareness of researchers regarding ethical considerations in health research. The first survey covered ethical practices for health research in genomics and biotechnology, and the second, investigators’ determination of the need for informed consent, and the adequacy of informed consent documents. Data was obtained from a questionnaire, and results showed that 43% of researchers obtain ethical clearance before they start their researches; 62% stated that informed consent is needed as part of subject
recruitment for the research; on the informed consent, 53% stated that risk was not mentioned, and 31% recorded that assurance of confidentiality was not mentioned.

For information on the status of national bioethics committees in the Region, a joint research was carried out with the University of Maryland. The aim of the research was to identify function, resources, services and needs within national bioethics committees. Up till the present 13 responses have been received, and it is hoped that more responses and final results will be communicated at a later date. The objectives of EMRO’s current activities in bioethics are:

- to increase awareness of bioethics in Member States
- to help in capacity building by training in the field of bioethics
- to provide technical advice to help Member States to comply with international standards in bioethics.

Increasing awareness of EMRO Member States in bioethics can be achieved by research on bioethics and the publication of results; meetings and workshops, both regional and international; and training in bioethics. Training may consist of short training courses on health research ethics and the establishment of institutional research ethics committees (REC). Two workshops were conducted in Sudan and Jordan in 2007, when 56 researchers and REC members were trained. A similar workshop is planned to take place in Oman in late 2007. Certificate training is available at the University of Maryland, USA, and the University of Toronto, Canada, and EMRO supports candidates attending these courses. Participation in international conferences is also supported.

EMRO provides technical advice and expertise in bioethics to Member States at the request of countries or institutions for training researchers (Oman and Saudi Arabia), conducting situation analysis at national or institutional level (Egypt and Oman), and providing technical guidance for establishing national and/or institutional ethics committees (Egypt and Oman). EMRO also guides the process of developing standard operating procedures for ethics committees (Egypt), and helps outline the process of developing national codes of ethics (Oman).

EMRO’s perspectives in bioethics include:

- continuing the evaluation process of the status of bioethics in the Region
- expanding EMRO’s current activities to include more Member States
- introducing new activities to cover the gaps in bioethics in the Region, such as the lack of national ethics codes in almost all Member States
- Strengthening collaboration and coordination with partners.

2.3 UNESCO HQ’s ethics programme
Dr. Henk ten Have, Director, Division of Ethics of Science and Technology,
UNESCO/HQ

Henk ten Have stated that UNESCO and the WHO have many activities in common but there are also many differences. In 1970 Member States of UNESCO already recognized the importance of discussing the ethics of life sciences. In 1993 the bioethics programme started with the establishment of the International Bioethics Committee (IBC), which consists of 36 independent experts appointed by the Director General. It is the only global ethics committee. Four experts on the present IBC committee were attending the Cairo meeting. In 1998 the Intergovernmental Bioethics Committee (IGBC) was set up, and consists of 36 Member States of UNESCO elected by the General Conference. In the same year, the programme was expanded to include ethics of scientific knowledge and technology, when the World Commission on the Ethics of Scientific Knowledge and Technology (COMEST) was established, and in 2002 the Interagency Committee on Bioethics came into being.

In the field of ethics of science and technology, UNESCO can mediate between scientific expertise and policy making through standard-setting actions, capacity building and awareness raising. In an intergovernmental setting, shared values and principles can be explored, and global standards laid down, capacities in Member States to deal with ethical issues can be enhanced, public awareness increased, and public debate promoted.

The principal standard-setting actions taken by UNESCO are 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). The Universal Declaration on Bioethics and Human Rights, which was unanimously adopted by the 191 Member States in October 2005, laid down a new agenda for bioethics. UNESCO was asked to promote the application of the Declaration. The Organization’s follow-up action after the adoption of the Declaration includes dissemination by providing information and publications, with translations in several languages; promotion through rotating conferences and giving presentations in various conferences; application and elaboration consisting of input activity through three projects, the Global Ethics Observatory (GEObs) system of databases, the Ethics Education Programme (EEP) which has 109 teaching programmes registered in the database to date, and assisting bioethics committees (ABC) project.

The EEP consists of fact-finding, identifying experts and those who have teaching programmes. A draft proposal for a core curriculum in bioethics based on the principles of the Universal Declaration on Bioethics and Human Rights has been completed. This will be followed by a consultation meeting with ethics teaching experts in July 2007, resulting in finalization and the development of supporting multimedia resources. The next stage is to introduce a course on bioethics in universities. An ethics teacher training course took place in Bucharest last year, and a similar course will be held in Riyadh, Saudi Arabia, in November 2007. There is also a plan to establish a UNESCO chair in
bioethics in Saudi Arabia. The EEP also plans to set up a documentation centre in the Region, amongst its interconnected activities. In addition, there is a need to involve the public in debate.

2.4 UNESCO Cairo Office’s ethics programme

Orio Ikebe, Programme Specialist, UNESCO Cairo Office

Orio Ikebe described the role of UNESCO Cairo Office, which is the Regional Office for Science and Technology, and the focal point on bioethics and ethics science and technology for the Arab region, so has many contacts which help with bioethics committees. Bioethics is a priority project for UNESCO in social and human sciences, and the Cairo Office is working with field offices and Member States in the region, as well as regional organizations and UN agencies. One of the roles of the office is a clearing house, providing information on experts, institutions, legislation, guidelines and teaching programmes in the Region for databases, such as the Global Ethics Observatory (GEObs). There is also a project to establish a documentation centre in the Region.

Standard setting is embodied in the three UNESCO declarations relating to bioethics adopted in 1997, 2003 and 2005, and reinforced at the regional level through workshops and support for national bioethics committees (NBC) to implement principles into national legislation and guidelines. Capacity building is being implemented by supporting the establishment of NBC, and the activities of existing NBC, through this First Regional Meeting on National Bioethics Committees, and by promoting ethics education through the first Experts Meeting on Ethics Education, which was held in Oman, 26–27 November 2006. With regard to regulations on bioethical issues, there are two aspects; each country should deal with regulations according to its culture and norms, but there is also a need to harmonize and seek a common approach. Ikebe raised the question of the contribution of this region to the international community, giving the example of the contribution of the Arab States to the UN discussion on human cloning between 2002 and 2005.

The promotion of networking is essential for the publication and dissemination of meeting reports, as well as the exchange of information from organizations involved in bioethics, and from national bioethics committees. UNESCO can host a website of ‘Bioethics in the Region’, which can provide links to NBC in the Region, and to regional and international organizations, in addition to information on experts and institutions, announcements of forthcoming events, newsletters and reports of meetings.

2.5 The International Bioethics Committee of UNESCO (IBC)
Dr Nouzha Guessouss-Idrissi, Chairperson, International Bioethics Committee

Dr Guessous-Idrissi spoke about the International Bioethics Committee (IBC), of which she has been chairman for two years. The IBC was established in 1993, and is the first global intellectual forum for in-depth bioethical reflection. The tasks of the IBC are to promote reflection on the ethical and legal issues raised by research in the life sciences and their applications; to encourage action to heighten awareness among the actors concerned; to cooperate with other institutions concerned by the issues raised in the field of bioethics; and to contribute to the implementation of the Universal Declaration on the Human Genome and Human Rights, and the International Declaration on Human Genetic Data, and the dissemination of the principles set out therein.

The 36 members of the IBC are appointed by the Director-General of UNESCO for a four-year term, with a maximum of two terms. The members are independent experts acting in their personal capacity as specialists in the life sciences, in the social and human sciences, including law, human rights, philosophy, education and communication. Criteria for membership include cultural diversity, balanced geographical representation and pluridisciplinarity. IBC works through plenary sessions and working groups, which send recommendations and reports to the Director-General, along with the IGBC. Information is then disseminated to Member States through the General Conference and Executive Board, and to other institutions and the general public.

Dr Guessous-Idrissi listed the reports and advices of the IBC from 1994 to 2003, and referred to the importance of the three Declarations for ethics in the Region. Article 25 of the Universal Declaration on Bioethics and Human Rights (UDBHR) states that UNESCO shall promote and disseminate the principles set out in this Declaration. In doing so, UNESCO should seek the help and assistance of the IGBC and the IBC. Continuing implementation of the Declaration, at its twelfth session (Japan, December 2005), IBC reaffirmed its commitment, and the readiness of each of its members to help and assist UNESCO in carrying out activities for the promotion and dissemination of its principles at international, regional and national levels. The IBC programme for 2006–2007 includes working groups on consent, and on social responsibility and health, reports of which will be presented to the fourteenth IBC session in Nairobi, 15–18 May 2007. Other ongoing activities include the publication of a book on the UDBHR with contributions from IBC members, and contributing to the promotion of establishing NBC and supporting existing ones.

3. ACTIVITIES OF INTERNATIONAL BODIES IN THE REGION CONCERNED WITH ETHICS

3.1 The Islamic Organization for Medical Sciences (IOMS)

Dr Abdul Rahman Al-Awadi, President, Islamic Organization for Medical Sciences
Dr Al-Awadi gave an account of the IOMS, commenting that four important events in 1978 highlighted the necessity to form the IOMS. These events were the Islamic celebrations to mark the beginning of the 15th century hajira, the birth of the first test tube baby, the 10th Meeting of the Organization for Science and Technology in Paris, and the provision of medical care for those in need. The first meeting of the IOMS was held in 1980, with the title “Giving birth in the light of Islam,” and topics of discussion included test tube babies, surrogate mothers, and artificial insemination with donors, as well as other related subjects. From the outset the IOMS adopted a new policy, inviting both medical and technological experts to give their opinions, and consulting them on a variety of problems. Decisions were sent to theologians and scholars of jurisprudence, and then recommendations were given for each case. In order to make the Organization international, the IOMS conferred with regional and international Islamic communities in the Islamic world, and invited their representatives. IOMS committee members also became members of several international organizations, such as the Regional Office of WHO.

Referring to the recommendations of the Helsinki Declaration from 1975 to 2000, and other recommendations from the WHO and the Council for International Organizations of Medical Sciences (CIOMS) from 1995 to 2000, Dr Al-Wadi raised the question of ethics and its origin in Islam. He pointed out that one can find passages in the Quran which illustrate this. The basic Islam precepts which were adopted by the IOMS are the respect of people for each other, achieving benefits according to Muslim sharia, and justice between people. These precepts resulted in the Islamic Code of Medical Ethics, which was published in 1980. The Code was guided by Islamic sharia, most of its clauses focussing on professional ethics, and the relationship between the doctor and God, the doctor and himself, his patient and society. The reaction of the rest of the world to the publication of the Code was encouraging.

However, Dr Al-Awadi noted that since 1980, there have been new developments, so medical practice today does not only concentrate on the doctor and patient, but there are other parties involved because of the introduction of technology. He gave as an example doctor/patient confidentiality, and the current use of computers for storing data about the patient, both nationally and internationally, which raises the issue of who has the right to this information, and to what extent. He also mentioned abuses and unethical practices, such as the trade in organs, and the impact of the discovery of the genome, as a result of which the insurance company has become a party in the debate, leading to the question whether an insurance company has the right to request genome analysis from the client, so as to be aware of his medical problems, especially if this information is acquired without the client’s consent.

Dr Al-Awadi said that the IOMS organized a conference at the end of 2004 to issue a new code, which would take into account new developments since 1980 and be more relevant to the 21st century. The International Islamic Code for Medical and Health Ethics has three parts, covering professional ethics, rules of ethics to be observed in all
medical research, and new medical issues from the Islamic perspective. Further subjects have been addressed by the IOMS since 2004, such as individual health problems, family and society, which was studied with the support of the WHO, and resulted in the Amman Declaration on Health Promotion in 1989. Another subject was the patenting and manufacture of medicine, and its price in developing countries. Several recommendations were issued on this topic, and a report was sent to the World Trade Organization. Organ transplantation from living to living persons, and from dead to living persons has also been discussed in a conference held by the IOMS, with experts from medical and other sciences, religious scholars and legal representative. The religious position on this issue is very positive, without sacrificing any Muslim beliefs. Further activities are planned, such as the forthcoming international conference on stem cell research and future challenges, to be held in Cairo in November 2007.

Dr Al-Awadi said that the IOMS is planning a project on teaching health ethics, and aims to spread knowledge and the ethics culture, not only among Islamic people and physicians, but also among the general public in the Islamic and Arab worlds. In addition, the IOMS is formulating controls for medical research, and is preparing a new programme for the ethics of practitioners in all medical specializations. Other international conferences organized by the IOMS have discussed HIV/AIDS, and the rights of the disabled.

Dr Al-Awadi concluded his account of the IOMS by saying that the Organization has also issued a number of recommendations regarding the use of herbal medicines, how they should be planted, harvested, dried and stored, in order to be hygienic, and free of contamination.

3.2 The Arab Committee for Science and Biotechnology Ethics of ALECSO

Dr Salwa Baassiri, Vice President, Arab Committee of Ethics of Science and Technology

Dr Baassiri began by commenting that the meeting was significant in view of the concern as to whether the field of bioethics is compatible with Islam, or not. She emphasized that the Arab region has a strong position on science and technology, not as an outside observer, and this touches on the values of Arab communities all over the world. She observed that it is necessary to encourage the impact of technological advancement, and to crystallize the vision of ethics issues, not to limit research, but to recognize the dangers to human dignity, as well as moral costs.

Dr Baassiri explained that the Arab League Educational, Cultural and Scientific Organization (ALECSO) coordinated with many international bodies to develop an institutional framework, and these efforts culminated in the formation of the Arab Committee for Science and Biotechnology Ethics in Beirut in 2003. The eight members of the Committee were selected on personal merit by the Director General of ALECSO from recommendations by Member States. In the first meeting the members adopted the
internal policy of the Committee in twelve articles defining its role and objectives, including conditions for, and duration of membership, funding and financial regulations. The Committee operates under the supervision of the Secretary General of ALECSO.

Dr Baassiri confirmed that from the outset the Arab Committee for Science and Biotechnology Ethics succeeded in holding annual meetings, which covered new developments and issues, and discussions of the Committee’s future activities. In order to reach intended goals, annual workshops were held to debate ethics issues, in addition to the regular annual meetings. Each of the workshops was concerned with one of the important ethics issues in national communities and human society worldwide.

Dr Baassiri listed the conferences and meetings organized by the Arab Committee over the past four years in different ALECSO Member States, giving details of the main topics of the conferences, and the number of papers presented at each. She stressed that such meetings are an effective way to monitor scientific and technological advances; to learn the opinions on these new developments discussed in scientific meetings held in Arab states; to participate in international debate; to raise public awareness of moral and ethical values among a large portion of Arab society; and to communicate with experts in bioethics from national, regional and international institutions, so as to synergise efforts.

Dr Baassiri concluded by enumerating the future aims of ALECSO as follows:

- to activate collaboration at all levels;
- to intensify collaboration between ALECSO and other Arab organizations, which have not yet established ethics committees;
- to accelerate channels for discussion of ethics issues in the Arab region;
- to invite Arab bioethics committees at national level to play a bigger role with more activities;
- to call on national committees to advise and give support;
- to be guided by conferences and workshops to implement recommendations.

Recommendations should be documented and made available to all concerned, and the Arab Committee seeks to make documents more easily obtainable, and understood by different sections of Arab society, particularly the youth.

3.3 Activities of GCC in relation to bioethics, ethics of science and technology

Dr Tawfiq A.M.Khoja, Director-General, Health Ministers’ Council for Gulf Cooperation Council States

Dr Khoja stated that the Executive Board of the Health Ministers’ Council for Gulf Cooperation Council (GCC) States has been very interested in promoting health research in the Region since the 1990s, and he referred to Resolution #3 issued by the 37th Ministerial meeting in 1994, which emphasized the importance of having a system for
organization of the medical profession and its practice. He also gave examples of resolutions and recommendations issued by Ministerial meetings and meetings of the Executive Body in 2003 and 2005, which rejected human cloning and all experiments on human embryos; emphasized the need to develop a unified Gulf system model about human cloning, and establish a special task force to issue unified Gulf guidelines on this subject; stressed the importance of establishing national committees for medical ethics in the GCC states, and the need to raise general awareness about medical ethics among healthcare workers and the community, urging Member States to include medical profession ethics in their educational and training curricula.

Dr Khoja described the involvement of the Executive Board in capacity building in the Member States in the field of health research, mentioning that there have been many workshops, such as that held in Saudi Arabia in December 2004 on constraints of scientific research in health, in which the need to clarify research ethics, the lack of national ethical guidelines, and the aims and conduct of research were discussed. The Executive Board has also collaborated with related bodies, such as the Council on Health Research for Development (COHRED), WHO/EMRO, the Global Forum for Health Research (GFHR), Child Health Nutrition Research Initiatives (CHNRI), and the Islamic Organization for Medical Sciences (IOMS). He referred to the joint meeting held with COHRED and EMRO in November 2005, in which 10 countries from WHO Eastern Mediterranean Region and GCC participated. At the meeting it was agreed that a situation analysis should be carried out in the participating countries using a tool developed by COHRED, with a view to strengthening the national systems of health research in the countries concerned. At a workshop on the same subject held in May 2006, it was decided that a phased action-oriented approach should be taken, the first phase being mapping of national systems of health research, to help decide priorities for system strengthening.

Dr Khoja said that collaboration with the IOMS had been particularly fruitful in clarifying the mechanism of preparing and implementing the draft Islamic document on ethics for the medical profession. The IOMS undertook coordination with all bodies, institutions and organizations interested in the issue of medical ethics, including the Executive Body of the Health Ministers’ Council. This collaboration was crowned by the International Islamic Code for Health and Medical Ethics, which was issued at the 8th World Conference of the IOMS in December 2004.

Exchange of information among the GCC countries in the field of medical ethics is ongoing, through dissemination of various related publications, conference reports, books and articles dealing with bioethical issues, such as cloning, use of stem cells, genetic engineering and human reproduction, organ transplantation, forensic medicine, and excessive promotion of drugs. Dr Khoja gave examples of several publications, including the two volume *Scientific Medical Research and its Legal Controls*, edited by Dr Tawfik A.M. Khoja, which is the first book published in Arabic on this subject.
In conclusion, Dr Khoja outlined future objectives:

- Increasing coordination with all related and concerned organizations to include medical ethics in the educational and training curricula in health institutions, colleges and academic institutions.
- Continuously updating the bioethics guidelines available, in order to cope with recent issues evolving in the community, such as biotechnology, and genomics.
- Developing guidelines for the pharmaceutical profession, and other health-related professions, including nursing.
- Strengthening coordination with international organizations, notably the IOMS.

Supporting effectively research in the field of biomedical ethics.

3.4 The European Group for Ethics in Science and New Technologies (EGE)

Dr Inez de Beaufort, European Group of Ethics in Science and New Technology (EGE)

Dr de Beaufort began her overview of the European Group for Ethics in Science and New Technology (EGE) by stating that the group is an independent, pluralist and multidisciplinary body, which advises the European Commission on ethical aspects of science and new technologies. The regulation of ethical issues is the responsibility of the Member States, but there is a common set of basic shared values in the Charter of Fundamental Rights. The group currently has 15 members, experts in such disciplines as law, medicine, food sciences and bioethics, who are appointed solely for their expertise and personal qualities.

From 1991–1997 ethical issues in the EU were discussed by the Group of Advisers on the Ethical Implications of Biotechnology, and the first mandate for the EGE covered the period from 1998 to 2000. The mandate was renewed for the years 2001–2004, and further redefined for 2005–2009. Members of the EGE are appointed by the President of the Commission for a term of four years, and the Group elects its own President and Vice President.

The opinion of the Group on a particular issue is provided at the request of the Commission on the Group’s initiative. The Parliament and the Council may also draw the Commission’s attention to specific issues. An opinion is arrived at through working meetings, consulting experts, studies and public round table discussions. With regard to the adoption of an opinion, the Group always endeavours to reach a consensus opinion, but if disagreement remains regarding specific points in the full opinion, then this is recorded in the opinion as a “minority opinion.” Certain problems can arise during the formation of an opinion, where a delicate balance has to be reached between consensus and compromise, the field to which the ethics concerned apply, as well as depth and timing. Once an opinion is adopted, an official meeting is held with the President of the
Dr de Beaufort listed the opinions published by GAEIB between 1991–1997, and the opinions published by the EGE from 1998 to 2007, giving details of the last two opinions, ‘Ethical aspects of information and communication technologies (ICT) implants in the human body’ (No.20, 16/03/2005), and ‘Ethical aspects of nanomedicine’ (No. 21, 2007).

4. PRIORITY ISSUES IN THE FIELD OF BIOETHICS

4.1 Ethics of research involving human embryos

**Dr Gamal Serour, Chairman, International Federation for Gynaecology and Obstetrics/Committee for Ethical Aspects of Human Reproduction and Women’s Health**

Dr Serour opened his presentation with the observation that ethics of research involving human embryos is a very controversial topic, and he was approaching the subject from the physician’s point of view. He described the different types and sources of stem cells used in this kind of research, referring also to cloning. The objectives of human embryonic stem cell research are to treat injuries and degenerative diseases, to understand early human development, to provide disease modelling, and to aid in drug discovery.

Dr Serour gave examples of a number of international ethical perspectives regarding human reproductive cloning, such as a person’s identity, respect for human dignity, as well as cooperation between states and international organizations in identifying such practices, and he referred to the relevant Articles in the International Declaration on Human Genetic Data (UNESCO 2003), and the Universal Declaration on the Human Genome and Human Rights (UNESCO 1997). He also pointed out that the WHO and other international organizations condemned human reproductive cloning. Dr Serour quoted parts of the Report of the IBC on the Ethical Aspects of Human Embryonic Stem Cell Research (UNESCO 2001), as well as the reports on ‘Embryo research’ and ‘Human cloning’ of the Committee for the Ethical Aspects of Human Reproduction and Women’s Health of the International Federation of Gynecology and Obstetrics (FIGO), which were published in the Federation’s journal in 2006.

Regarding the Islamic perspectives of ethics, Dr Serour outlined the primary and secondary sources of *sharia*, and the broad principles of Islamic jurisprudence, pointing out that while the primary sources encouraged marriage, family formation and procreation, the secondary sources and Islamic jurisprudence encouraged the use of assisted reproductive technology and research, if it is necessary, for infertility treatment and benefit of human kind. For example, embryo research for therapeutic purposes, such as prevention of genetic diseases and non-reproductive cloning, is permitted and
encouraged, but embryo research for non-therapeutic purposes, such as to produce designers babies or reproductive cloning, is prohibited.

In conclusion, Dr Serour gave further extracts from the 2001 Report of the IBC on the Ethical Aspects of Human Embryonic Stem Cell Research, and the Universal Declaration on Bioethics and Human Rights (UNESCO 2005).

4.2 Ethics and law of biobanks

Dr Judith Sandor, Director, Centre for Ethics and Law in Biomedicine, Central European University

Dr Sandor observed that changes in medical research from the mid-20th century onwards raise the question whether it requires a new ethical or legal paradigm. Before the mid-20th century research was performed on the body, but current medical research, although it is about the body, is carried out in test tubes in a laboratory. The frontiers of the human body, therefore, need to be defined. The legal concept of the body can be taken as a starting point, a problem which goes back centuries, as can be seen in Roman law and philosophy. Legal concepts of the human body and body parts cover personal rights, privacy, property, property-like interest, transferability, medical waste and abandoned property.

A number of issues need to be addressed, such as how to protect the information related to stored tissues, and the status of the living human body, body parts and the dead body. Decisions on such issues should be made by ethics committees. Dr Sandor gave examples of legal cases involving non-consensual testing of stored samples. Information is also available through different types of databases, such as publicly accessible databases and national DNA databases, as well as commercial, clinical research, academic, study-specific and non-study-specific genetic databases.

Dr Sandor commented that international norms were laid down in the three UNESCO Declarations, and quoted several Articles concerning transnational practices, the special status of human genetic data, the need to promote independent, multidisciplinary and pluralist ethics committees. She also referred to the Council of Europe, set up in 1949, which is an intergovernmental organization fostering political, legal and cultural cooperation between its 46 Member States. Articles in the Council of Europe Convention on Human Rights and Biomedicine (Oviedo Convention 1997), deal with primacy of the human being, informed consent, private life, non-discrimination, prohibition of financial gain, and disposal of a removed part of the human body.

The Recommendation on Research on Biological Materials of Human Origin, which was drafted by the Steering Committee on Bioethics (CDBI), and adopted by the Committee of Ministers in 2006, states as its object that ‘Member States should protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity, right to private life and other rights and
fundamental freedoms with regard to any research governed by this recommendation.’ The Recommendation defined a population biobank as a collection of biological materials that has the following characteristics:

- the collection has a population basis;
- it is established, or has been converted, to supply biological materials or data derived therefrom for multiple future research projects;
- it contains biological materials and associated personal data, which may include, or be linked to genealogical, medical and lifestyle data, and which may be regularly updated;
- it receives and supplies materials in an organized manner.

A proposal to establish, or to convert a collection to a population biobank should be subject to an independent examination of its compliance with the provisions of this recommendation.

Dr Sandor also enumerated the European Union directives concerning human tissues and cells, the legal protection of biotechnological inventions, and the processing of personal data. She observed that with the possibility of storing tissues and using them for further research, such as genetic studies, not only ethical and legal perspectives are affected, but individual expectations and even personal rights may emerge or change, and she cited examples of biobank projects in Iceland, Estonia and the United Kingdom, as well as the HapMap project, which involves scientists and funding agencies from Canada, China, Japan, Nigeria, the United Kingdom and the United States.

Dr Sandor concluded by describing how the collection of tissue and blood samples has been practised since the beginning of the 20th century. However, society is now demanding more control for several reasons: because of historical experiences (eugenic health policies), more extensive expectations for the protection of our bodies and body parts, the greater expansion of genetic research, and the fear of cross-linking and identification. Regarding policy consequences, biobanks are the subject of regulation, and data protection rules are being developed and extended to this field. Biobanks have been considered predominantly as a challenge to data protection laws. Security and legality have also been concerns for legal policy, but commercialization and its consequences have not yet been adequately assessed.

4.3 Ethical issues in pandemic influenza planning and response

Dr Andreas Reis, Technical Officer, WHO/HQ

Providing an epidemiological background to pandemic influenza, Dr Reis commented that many Member States of WHO have had outbreaks of avian flu since 2003, and up till the present there have been almost 200 human deaths from the H5N1 virus. So far no human to human transmission has occurred, but there is concern that the normal flu virus and avian flu might combine and start a pandemic. Examining the
The likelihood of this happening, statistics of flu pandemics in 1918, 1957 and 1968, show that a pandemic has occurred almost every 40 years, so another may be due.

Ethical issues in pandemic preparedness and response include equitable access to health care in a pandemic; non-pharmaceutical measures such as isolation, quarantine, social-distancing, and border controls; obligations of and to health care workers; and international cooperation. No country will have enough resources to deal with a pandemic. Some countries have started stock-piling, but this is still not enough. Before there is a confirmed outbreak, a vaccine cannot be developed. Many intensive care beds may be needed and will be in short supply. Animal issues, such as culling, also have to be considered. With regard to isolation, if someone is put into quarantine, there may be infringements of human rights, so the benefits for public health should outweigh affects on the individual. The question also arises as to who has the power to impose and control this process.

Dr Reis stressed the importance of planning and preparedness, saying that countries should prepare and discuss various issues ahead of time, and make sure that the public has been engaged in the decision-making process. He gave examples of activities conducted by various countries, including Canada, Finland, France, New Zealand and Switzerland. He also described the WHO project, which consists of the formulation of guidance for Member States on how to address the ethical issues that arise in the preparation, and response to a potential influenza pandemic. In the process for developing guidance to equitable access, public health measures, health care workers’ obligations and international responsibilities, each topic is being addressed by a working group chaired by an expert. There are 35 working group members in public health, science, medicine, ethics, human rights and law from inside and outside WHO, including other intergovernmental organizations. A technical meeting of all working groups, with WHO Regional Office participation, took place in May 2006 in Geneva, as a result of which, four issues papers have been written. A Global Consultation was also held in October 2006 in Geneva.

Dr Reis mentioned several capacity-building activities in Cambodia, France, Indonesia, Kazakhstan, Japan, the Eastern Mediterranean Region, and Pakistan. The way forward includes the publication of the Report of the Global Consultation, and the Document on Ethical Considerations for Pandemic Influenza Planning (May/June 2007), as well as dissemination through various channels such as WHO, MOH, NGOs, the UN Interagency Committee on Bioethics, the Global Summit of National Bioethics Advisory Bodies, conferences and workshops. The WHO/HQ functional areas related to pandemic planning and response were outlined: influenza preparedness, standards, and scientific coordination; alert and response operations; WHO contingency planning; and communications.

Dr Reis said that new infectious disease threats will continue to emerge, and this project is setting standards for pandemics in general, not just pandemic influenza. The
main issue is how to develop the sustainable national and global capacity to detect and respond effectively, in a way that respects ethics and human rights standards. Ethical issues need to be addressed in preparedness and planning ahead of a pandemic in order to respond effectively. WHO is giving support and guidance to Member States in order to address technical and ethical issues.

4.4 Discussion

The issue of public health ethics was raised in the discussion, including topics such as access and transparency, as it was pointed out that this aspect of bioethics is not dealt with so much in depth. The same also applies to environmental issues, pandemics and clinical research. This is in spite of the fact that the UNESCO declaration on bioethics applies not just to research, but to all relevant groups.

The collaboration between WHO and UNESCO regarding ethics was also discussed, with comments made on the difference in the regional states covered by the two organizations. UNESCO, for example, includes Afghanistan, Iran and Pakistan, although they are not Arab countries. Participants agreed, however, that it is necessary to be pragmatic if collaboration is to continue. There are also ethics programmes in FAO and ILO, and UNESCO has established an interagency committee on bioethics to bring together all bodies in this field, to avoid overlap and better impact activities. There is the need for synergy, and since there is no contradiction between UNESCO and WHO, there is no problem. Specialists from both organizations can contribute their expertise, as collaboration is vitally necessary for the future of bioethics.

Drawing the attention of the media to bioethics was stressed, and the possibility of providing training in the subject for media personnel. Another point commented upon, was the need for international bodies to undertake more discussions on the problems of stem cell research, both animal and human. Legislation on the ethics of this type of research, including abortion and cloning, needs to be enacted in countries in the Region.

5. INTERNATIONAL NETWORKS AND NATIONAL ETHICS COMMITTEES IN THE REGION

5.1 The UNESCO Global Ethics Observatory and ABC Project

Dr. Henk ten Have, Division of Ethics of Science and Technology, UNESCO/HQ

Henk ten Have gave an overview of the UNESCO Global Ethics Observatory (GEObs), the Ethics Education Programme (EEP) and the project for Assisting Bioethics Committees (ABC), which represent the ethics infrastructure in the application of the Universal Declaration on Bioethics and Human Rights. The GEObs consists of five databases, which are freely accessible in six languages (Arabic, Chinese, English, French, Russian and Spanish), on the UNESCO website:
Ten Have described the development of Database 4 on ethics-related legislation and guidelines, which was launched in March 2007, and showed examples of web pages on selecting a region, a country, topics and Declaration articles, as well as country details. On legislation, the GEObs tries to make the relevant texts of legal documents available, and it is hoped that data from Egypt, Jordan and Saudi Arabia will be available in the near future.

Outlining the project Assisting Bioethics Committees, ten Have referred to the problems in recording data, which is dependent on the return of questionnaires which have been sent out. Practical information on how to establish, activate, and educate bioethics committees is provided in the form of guidebooks in different languages. How ethics committees are defined depends on the countries concerned. The principal types are policy-making and/or advisory bioethics committees (PMA), health-professional associations bioethics committees (HPA), health care/hospital ethics committees (HEC) and research ethics committees (REC). There are different ways to constitute an ethics committee; sometimes it is a sub-committee, sometimes it is part of a government department, and it is up to Member States to decide on their approach to a bioethics committee, which should be multidisciplinary, and maintain a cultural balance.

Ten Have said that countries have been approached to ask if they need advice, and five African countries and one in Latin America are currently in the process of establishing bioethics committees. Technical support is being provided by two teams of experts from the Democratic Republic of Congo, France, India, Mexico, the Netherlands, Saudi Arabia and the United Kingdom, who are advising on methodology and a plan of action. Togo established a National Ethics Committee in March 2007, and Ghana will do so in the next few months. A three-year project of assistance from UNESCO will provide training in various aspects of sustaining a bioethics committee. It is hoped that new committees can be included in a network of ethics committees worldwide.

5.2 The Global Summit of National Bioethics Advisory Bodies

Dr Marie-Charlotte Bouesseau, Technical Officer, WHO/HQ

Dr Bouesseau put the Global Summit of National Bioethics Advisory Bodies (GSNEC) in context, commenting that in the past decade many countries have formed their own NBC, with Egypt as a good example. Members of the NBC are appointed by Chief Executives, Ministers of Health and legislatures, and their function is to analyse and offer recommendations regarding the ethical issues that arise in healthcare. Their mandate and functions differ. In some countries the topics dealt with cover a very wide
range, while in others the focus tends to be the ethical review of research protocols. Providing historical background, Dr Bouesseau mentioned the six Global Summits which have taken place so far, highlighting the London Summit in 2000, which saw strong participation of committees newly established in Europe; the 2002 Brasilia Summit, when a new model of work was introduced with plenary discussions as a way of sharing experiences; and the last Summit in Beijing in 2006, when several pertinent issues were openly discussed.

Dr Bouesseau stated that the main outcomes of the first decade of the Global Summit were the provision of a unique platform for exchange of information about the work of NECs; the opportunity for open debate, focusing on specific issues; facilitating access to working documents prepared and circulated prior to the meeting; contributing to the updating of information regarding the status and functions of national bodies. She mentioned that the next Global Summit of National Bioethics Advisory Bodies will be held in France, and the 9th World Congress of Bioethics in Croatia, in September 2008. She concluded by reiterating the progress towards a global network, with increasing participation from low and middle income countries, and the need to identify mechanisms of solidarity between NBC; the benefits derived from cultural diversity, in the exchange of information and experiences, and participation in open debate; as well as ensuring continuity with WHO serving as secretariat, and the role of international organizations in the field of bioethics.

### 5.3 Bioethics capacity mapping in EMRO countries

*Dr Henry Silverman, Director, Middle East Research Ethics Training Initiative (MERETI), University of Maryland*

Dr Silverman reported on the survey of the bioethics capacity in EMRO countries, stating that the survey was developed to identify the existence of NEC, functional aspects, resources, challenges and needs. The survey was sent to the EMRO office in 33 countries, and delivered to individuals involved with NEC, or involved with ethics with the MOH. The results show a response rate of 12/22 responses received, 11 with NEC and one without the existence of NEC. The general information reveals that 10/11 NEC meet regularly, twice a month (1), once a month (2), every two months (4), although one NEC has never had a meeting, and three others did not answer this question.

In a series of bar graphs, Dr Silverman illustrated activities of the 12 NEC, covering types of involvement, the roles of the Committee, types of research review, capacity to perform duties, training topics for more training, use of ethics guidelines and challenges to their use, laws regulating research, and financial support. With regard to training topics, some were rated as “very/quite” important by eight Committees. These topics included provision of appropriate risk reduction measures, assessment of understanding of informed consent, privacy and confidentiality, monitoring and oversight. The least important topic was incentives for participation.
Summing up, Dr Silverman emphasized that the NEC that submitted responses are active, meeting regularly, and reviewing research; they are involved with training, have produced publications in ethics, and have developed national guidelines. They grade themselves as having good capacity, but less than half of them have financial support. Challenges to be met include lack of training of members in medical ethics, lack of ongoing training for members, inadequate ability to monitor approved protocols, and the need to regulate the conduct of Research Ethics Committees (REC). Challenges to the use of guidelines include the development of appropriate national guidelines, the variable use of guidelines across committees, and the development of appropriate laws. Areas for discussion are training programmes, the development of appropriate national guidelines, the drafting of laws regarding research ethics, and the establishment of a network.

6. COUNTRY PRESENTATIONS

6.1 Afghanistan

Dr Mir Lais Mustafa, Secretary, Institutional Review Board, Afghanistan

Dr Mustafa stated that after the fall of the Taliban in Afghanistan, the country attracted the attention of the world community to assist financially and technically. There was, however, a need for baseline information because of reports of extensive research studies in Afghanistan without approval, and violations. The Ministry of Public Health considered it necessary to set up a review board, and in October 2004 the Afghanistan Institutional Review Board (IRB) was established. Dr Mustafa gave the terms of reference of the IRB which include examining and reviewing proposals, meeting on a monthly basis, setting conditions for approval of a proposal, laying down guidelines in accordance with Afghan socio-cultural aspects, and other terms concerning IRB membership, decision making and programme evaluation.

Dr Mustafa mentioned the successes achieved by the Afghan IRB, first of all in establishing for the first time an IRB, which is functional and meets regularly, ensuring that no research on human beings can be conducted without review. Seventy-six proposals have been reviewed so far, six of which have been rejected. The IRB has also held an ethics workshop for local government and NGOs, and included medical ethics in the curricula of the medical faculty. Challenges for the IRB in the future include female representation, appointing as a committee member a lay person with religious knowledge, legal expertise, monitoring of projects, lack of resources, (at present projects far from Kabul cannot be monitored), guidelines and codes of conduct, updating members’ knowledge of research ethics, and lack of interaction with international bodies. It is also hoped that in future all members of the IRB will be Afghan nationals. The present committee has ten members, six of whom are foreigners.
6.2 Egypt

Dr Ibrahim Badran, Chairman, National Bioethics Committee, Egypt

Dr Badran provided an overview of the National Bioethics Committee (NBC) in Egypt, which was established in 1996, and has 30 members from various disciplines, including physicians, scientists, agriculturalists, sociologists, religious specialists, pharmacists, and experts in jurisprudence, communications and genetics. The objectives of the Committee comprise undertaking studies and offering advice that relate to the ethical principles in carrying out biological research applications; harmonization of national activities undertaken by concerned Egyptian institutions in the field of ethics in biological sciences; raising public awareness; developing educational curricula on bioethics; and instituting a national focal point fostering communication with other organizations, regional and international agencies, all of which have contributed to the extension of ethics worldwide. These include, UNESCO, WHO, the World Medical Association (WMA), CIOMS, ISESCO, ALECSO and IOMS.

Dr Badran summarized the activities of the NBC in Egypt over the past ten years, which consist of regular monthly meetings of the Committee, with twice weekly meetings for sub-committees studying specific subjects; the organization of seminars and workshops on particular issues of biosciences; representation of the Committee in the Islamic High Institute, School of Medicine in Al Azhar University, and Supreme Islamic Council in the Ministry of el-Waqt; consultation with the Coptic Patriarchate Authorities for representation in all seminars and workshops; boosting NBC activities with special multi-faceted working groups, for example on food safety and bioethics, the relation of bioethics to international laws, genetically modified food, bioethics in dealing with natural disasters, bioethics in human medical research, animal research, genetic research, and in nuclear research.

Other activities were the development of a number of scientific documents on various topics, participation in conferences, seminars and workshops organized at local, regional and international levels; the formulation of research ethics councils, such as the bioethics research groups set up in 13 universities with advice from the NBC.

Dr Badran stated the challenges facing the Egyptian NBC, which include poor harmonization between regional bioethics committees, the lack of funding to support research and publications at national and regional levels, poor response and participation in world activities on the subject, the weak dissemination of published material produced in each region, the need to foster scientific visits, periodical meetings, scholarships, and so on, as well as obstacles to institutionalizing the regular supply of information and research to media concerned with medical and university education. Dr. Badran mentioned a number of conferences on aspects of bioethics, which have taken place in Egypt over the past few years, and also expressed the need for more meetings like this first Regional Meeting of National Bioethics Committees.
6.3 Islamic Republic of Iran

Dr Hussein Malek Afzali, Deputy Minister for Research and Technology, Ministry of Health and Medical Education, Islamic Republic of Iran, Head, National Bioethics Committee

Dr Afzali began by tracing the development of bioethics in Iran, pointing out that as early as the 9th century Iranian Muslim scholars laid great emphasis on teaching and practising medical ethics. In Iran, ethical issues are discussed among physicians, legal experts and religious scholars, so the principles of bioethics and solutions to ethical problems are derived from the Islamic legal rulings.

Dr Afzali outlined the progress of medical ethics activities in Iran, from the establishment of the Medical Ethics Research Centre by the Ministry of Health and Medical Education (MOHME) in 1993, through the formation of Medical Ethics Research Committees at different levels, to the development of the National Committee of Medical Research Ethics in 1997, which paved the way for establishment of Medical Research Ethics Committees nationwide. He stated that there are now 42 universities and 130 research centres in the country, all with medical ethics committees. The National Code of Ethics for Biomedical Research (2000) was prepared by MOHME, and includes 26 ethical guidelines. The MOHME also compiled a strategic plan for medical ethics activities, which started in 2002, and is very broad, covering major areas of management, regulations, communications, research, education, training, public announcement, monitoring and assessment of medical ethics activities at national level. Dr Afzali gave examples of some of the important activities, including a nationwide bioethics network, and the establishment of the National Medical Ethics Information Centre and Library.

Dr Afzali said that the Specific National Ethical Guidelines for Biomedical Research were compiled in 2005, with the collaboration of the Medical Ethics and Medical History Research Centre in Tehran University of Medical Sciences. The Guidelines were developed to observe ethical codes in various types of research, and to protect research participants’ rights. With regard to medical ethics education, undergraduate and postgraduate courses in medical ethics have been initiated at Tehran University of Medical Sciences, and books and guidelines have been printed and are part of the curriculum. One of the future plans of MOHME is the institution of a doctoral course in bioethics.

On the subject of legislation, Dr Afzali described how experts have expressed positive viewpoints about bioethical issues, such as organ transplantation, abortion, genetics, and stem cell research in Iran, and some of these have been implemented into law by parliament in recent years. He gave examples of some of the legislation on brain death and organ transplantation, abortion, assisted reproduction, stem cell research, and cloning. Reproductive cloning is prohibited in Iran, although embryonic stem cell research has been approved by the religious authorities.
Dr Afzali mentioned a number of Iranian publications on medical ethics, including the attempt to publish a professional journal in the field of medical ethics and medical history, and the establishment of a medical ethics website. He noted that the First International Congress on Medical Ethics in Iran was held in Tehran in 1993, and the second will be held in Tehran in November 2007.

6.4 Jordan

Dr Suheil Shaheen, Rapporteur, National Ethics Committee for Science

Dr Shaheen stated that the Jordanian NEC was formed in 1998, headed by the then President of the Supreme Council for Science and Technology. However, there were problems in activating the committee, and no meeting was held for four years because of other commitments of members of the committee. Four years ago the committee was renamed as the National Committee for Science and Technology. Members of the Committee are from the Ministries of Waqf, Health, Education and Mass Communications. The aims of the Committee are to enhance discussions on ethics and legal issues, to take measures to increase public awareness, to hold workshops and seminars, to cooperate with national and international bodies in bioethics, to contribute to an Arab consensus on bioethics, to familiarize people with the Arab viewpoint and underline values for better cooperation in the Arab region.

Dr Shaheen admitted that the main achievements of the Jordanian Committee are modest compared to Tunisia or Egypt. No laws have been enacted in line with the principles of the 1997 Universal Declaration on the Human Genome and Human Rights, but a questionnaire on the principles was distributed, and some scholars expressed opinions on various aspects. There was much convergence in the opinions of Muslim and Christian specialists. It was agreed that the Committee should support projects in medical research centres in technology, for example stem cell research and genetic data, and should also support training and dissemination of information on bioethics in schools and universities in cooperation with the Ministry of Education, in order to acquaint students with the most appropriate methods of research.

Dr Shaheen commented that sustaining the Jordanian Ethics Committee has not been easy, due to some administrative and financial problems, and there is a need for an active host institution, for incentives and support from other institutions. One project will be assisted by UNESCO, but more are required. It is hoped that ALECSO will be like the European Group for Ethics in Science and New Technologies (EGE), and give advice to the Arab League, as there is a need for harmony on regional and international levels.
6.5 Lebanon

H.E. Dr Marwan Hamade, Minister of Telecommunications, Chairman, National Bioethics Committee, Lebanon

Dr Hamade began by remarking that Lebanon’s experience in the ethics of life sciences and health is both pioneering and complex, because the country is rich in diversity but also suffers from this, particularly at the political level. The NBC in Lebanon was one of the first in the Arab world. It was established by cabinet decree in 2001 to involve jurisprudence, physicians, experts in Islam and Christianity, but there were limitations due to different spiritual contents and sectarian concepts. Because of the diverse groups in Lebanese society, it was easier to find agreement on issues of medical ethics than social and political understanding.

Dr Hamade stated that although the NBC was formed by cabinet decree, the members were chosen independently. The members mainly work voluntarily, except for the secretary who is paid by the government. In order to free the Committee from political involvement, it receives advice from all ministries and laws go through the national committee. Publications are contributed by NBC members. Taking as an example the IBC, where committee members are not members of government, the attempt was made to do the same with the NBC in Lebanon, although there were some problems because of conflicts or differences of focus, but the government continued to support the NBC.

The mandate of the NBC is to give opinions, conduct studies and give advice on legal, social and medical issues. Meetings are held in camera, and only recommendations are disclosed. Some recommendations are the concern of scientific and academic groups, such as the establishment of an ethics committee to discuss biological issues, for example assisted reproductive technology, and to advise on formulating a law on exaggerated treatment. The NBC is trying to revise the law on medical ethics, which is now before parliament. The Committee publishes reports annually, and articles by members are published in the Lebanese press.

Dr Hamade emphasized that the NBC has shown its readiness to expand work in Lebanon, and parliament hopes to support other countries who wish to establish NBC. The diversity of Lebanese members, who speak French, English and Arabic, as well as their expertise, means that the Committee has the capacity to help and advise policy makers with recommendations. He concluded by expressing the wish that an inventory could be compiled of what is lacking in the Region to establish ethics committees, and which countries in Asia and Africa also need the support of the Lebanese NBC.

6.6 Libyan Arab Jamahiriya

Dr Abdul Qader El Maleh, Member, Arab Committee of Ethics of Science and Technology
Dr El Maleh began his presentation by citing quotations from the Quran relevant to bioethics, commenting that it is necessary to return to the origin of our religious faith to find ethical roots common to all humanity. He then gave an account of the Libyan National Committee for Biotechnological Ethics and Bio-safety, listing the tasks of the Committee, to control scientific research and equipment used in biotechnology, direct them to peaceful use and keep records of them; to classify relevant national research and verify it; to report on the research in bioethics of cloning, proposing regulations and setting principles for control; to define the Libyan viewpoint with regard to the bioethics of cloning before national and international communities; to promote rules on research ethics of cloning, and to prepare appropriate programmes for their implementation; to make note of the international treaties and agreements to verify their implementation, and to advise on whether or not they should be ratified.

Further tasks include preparing the necessary documents and forms relevant to disease outbreaks, and asking for assistance in case of biological disasters; training and qualifying Libyan cadres to acquire knowledge to deal with related international laws and agreements; discussing and considering subjects raised by relevant government agreement agencies, and any other urgent matter.

Dr El Maleh gave examples of meetings concerning bioethics held in Libya, and participation by the National Committee for Biotechnological Ethics and Bio-safety in meetings abroad, mentioning the meeting on stem cells in Syria in October 2003, and conferences held in Libya in 2001 and 2004 on the human genome, the gene bank and cloning.

6.7 Morocco

Dr Nouzha Guesouss-Idrissi, Chairperson, International Bioethics Committee

Dr Guesouss-Idrissi began with some data on health and research statistics in Morocco, and noted that the day-to-day ethical issues are lack of quality and appropriate health care, inequity in access to health services, and lack of patient information, respect of autonomy, and request of consent. With regard to new medical technologies, there is also still a marked lack of national bioethical standards and institutions, absence or inadequacy of national jurisdiction regulating their practice, and no national bioethics committee, or hospital ethics committee.

Dr Guesouss-Idrissi stated that the only law to date is that passed in 1999 relating to organ and tissue donation, removal and transplantation, under which organ donation from the deceased is permitted, but campaigning for consent if family members object, is not allowed. All ethical decisions are entirely left up to the medical team. Concerning ethics of research in life sciences, there is still no national law for the protection of participants in biomedical research, although a draft law is under discussion. Individual initiatives have been taken by health and research health professionals; local Research Ethics
Committees have been set up independently in the Medical Schools of Casablanca and Rabat, and the Moroccan Association for Bioethics (AMB) was established in 2005.

The Ethics Biomedical Research Committee of Casablanca (CERBC) set up in 1989 at the Medical School of Casablanca, undertakes to protect human participants in research, clinical trials or studies, and to review the ethical and scientific aspects of research proposals and protocols. Submission to the Committee is optional, not required by law, and the Committee’s opinion is advisory. The Committee is also committed to raising awareness of bioethics through seminars, conferences and publications. Dr Guesouss-Idrissi gave an assessment of the activities of the CERBC from 1989 to 2005, stating that 158 proposals from different sources and in various areas of research had been examined, ten of which had been refused. She also described the objectives of the Moroccan Association for Bioethics, and referred to a joint Workshop on Research Ethics held by WHO and AMB in Morocco in 2005.

Needs and challenges facing ethics committees in Morocco include the necessity to be multidisciplinary and pluralist, as at present there are no lawyers, humanists or lay people on the ethics committees; training, monitoring and evaluation; status and terms of reference; open debates for public awareness; and the promotion of ethics teaching in universities, as well as the publication of relevant materials. Dr Guesouss-Idrissi defined a number of future prospects, including the initiation of public information and debates on ethical issues to promote national regulations on bioethics, taking into account the historical and socio-cultural characteristics of Morocco; the creation of new research ethics committees, and the establishment of a National Bioethics Committee. These factors are dependent on a political decision, available national expertise and the support of international and regional organizations.

6.8 Pakistan

Dr Huma Qureshi, Secretary, National Bioethics Committee, Pakistan Medical Research Centre, Pakistan

Dr Qureshi began by saying that when the National Bioethics Committee was established in Pakistan in 2004, bioethics was a new concept, so a national workshop on the subject was organized. The NBC is linked with ethics review committees in various organizations, such as the Pakistan Medical and Dental Council (PMDC), medical colleges, universities, and the Ministry of Health. The NBC is an independent functioning committee, and has two major sub-committees, the Research Ethics Committee (REC) to address ethics in health research, and the Medical Ethics Committee (MEC) to address ethics in medical practice and education.

Dr Qureshi reviewed the progress of the Committee, which included developing standing operative procedures for the NBC, and guidelines for the REC, (those for the MEC are in preparation); developing just a month ago guidelines for stem cell research/therapeutic use and regulations in Pakistan; establishing prioritization of ethical
issues in Pakistan; and formulating the Bioethic Act for ethical issues in medical research, so that those who do not comply can be penalized.

Dr Qureshi added that another function of the NBC is to set up institutional ethics review committees (IERC), and last year the Committee held a 3-day training workshop with the help of WHO/EMRO. There were 33 participants from 10 public sector hospitals, and since the workshop these 10 participating institutions have formed their own IERC. The second round of training of IERC has started; training in one province out of the four provinces in the country has been completed, and it is planned to cover the other three in the next two to three months.

Dr Qureshi concluded by explaining that as the NBC is only three years old and still in its infancy, projects are reviewed by IERC, and only the controversial proposals by the REC of the NBC. So far the Committee has reviewed 10 projects, of which 7 have been cleared. There is a need to have more funding for meetings, workshops and training, to increase awareness of the NBC, and make its status more important.

6.9 Qatar

Dr Khalid Alali, Member, World Commission on the Ethics of Scientific Knowledge and Technology (COMEST)

Dr Alali gave an overview of the situation in Qatar, where there are is no NEC at present, mentioning the many recent changes in society, education and investment in many universities, private universities, and sport development, as well as new health reforms and the move towards privatization, commenting that reforms are easier in Qatar because the population is small. He said that 3.7% of national income is now going to research, and a Science Park is being developed in collaboration with big companies, such as Shell, for large research projects.

Dr Alali described the current practice for handling ethical issues in Qatar, in which the Hamad Medical Corporation reviews ethical issues in committees, based on need and occasional requirements. Hospitals or universities have ethics committees for approval, national issues are dealt with by ad hoc temporary committees, and research and education by research ethics committees. He said that the Qatar Foundation is an umbrella for several foreign universities, Cornell, Virginia, and so on, which are branches of home universities and come with their own ethics standards, which need to be revised to conform with Qatari society.

Dr Alali noted that the draft proposal for a National Ethics Committee will be based on various factors; a review of regional and international experiences, what should be common and what should be specific, an integrated governmental and non-governmental body to ensure political accountability and productivity, and the impact and status in the political system. As questions to be answered, he gave committee size, which varies in other countries; recruitment of members; funding and whether members
should be compensated; the mechanism for implementation and follow up. He stressed that the Committee must have authority to supervise work at international, as well as national level, as many international companies are working in Qatar. He added that he understood that UNESCO would help set up an NEC and provide support for three years, and expressed the hope that Qatar will establish an NEC this year.

6.10 Saudi Arabia

Dr Faisel Mohamed Abu-Duheir, National Bioethics Committee, Saudi Arabia

Dr Abu-Duheir provided an overview of the Saudi Arabian NBC, which was established by decree in 1422 Hajira (2001), to define criteria for bio and medical ethics according to Islamic sharia, human dignity and human rights. The NBC represents several bodies, as well as King Abdul Aziz City for Science and Technology. Many cities in the country have research centres, but there is a need to set standards for ethics, so that bio and medical research will be conducted observing ethics from the viewpoint of Islam and security. It is hoped that a law to this effect will soon be passed in Saudi Arabia.

Dr Abu-Duheir stressed that the NBC aimed to set rules and standards to be recognized by laboratories working in the biomedical field, so that research would be carried out in an ethical manner according to international standards. Although this is one of the goals of the NBC, there is not a mandate as yet, because the ethics system has not been widely adopted in Saudi Arabia so far. The religious viewpoint has to be taken into consideration along with technological advances. He noted that patient confidentiality is observed in collaboration with UNESCO, ALECSO, ISES CO, and other organizations in the field. The scope of the NBC’s work comprises procedural controls, and there is a call for local committees in institutions, hospitals, and research centres involved in medicine and bioethics.

Dr Abu-Duheir said that the head and members of the NBC are chosen by decree by the President of King Abdul Aziz City, and the Committee meets monthly to discuss developments and achievements. Sub-committees examine specific issues, for example, use of genetic substances and animal research. Dr Abu-Duheir emphasized that practitioners and the public should be aware of plant and animal research ethics. There is also collaboration with partner committees in hospitals and research centres, such as legal and regulatory committees. Another committee has been proposed for human research, but this has not yet been adopted by the Shura Council. Meetings were held twice last year between the NBC and local committees, encouraging them to discuss important issues, to open channels of discussion between the NBC and local committees, and to involve institutions in their localities. Seminars and workshops are held to discuss clinical research and ethical aspects, field visits are conducted for better communication with local committees, and the NBC also takes part in internet conferences to familiarize these committees with the NBC and new developments.
Dr Abu-Duheir pointed out that the field of bioethics is facing challenges in different countries, including lack of cooperation of some agents or researchers. Issues concerning medicine and bioethics are a new concept, and some feel they would restrict research. The existence of unethical practices motivated Saudi Arabia to create bioethics committees, but some local committees suffer from lack of understanding, and lack of financial support. In some local research centres, the head of the centre is also the chairperson of the ethics committee, which creates a conflict of interest.

Dr Abu-Duheir concluded by recommending that more workshops and seminars should be held, education programmes and collaboration with the mass media developed, in order to promote awareness of bioethics. He added that it is necessary to communicate and interact with researchers, and to convey the ethics message at local and national levels.

6.11 Sudan

*Dr Iman Abdalla Mustafa, Reporter, National Ethics Review Committee, Sudan*

Dr Mustafa opened her presentation by stating that the research ethics committee in Sudan is the National Ethics Review Committee (NERC). Medical practice in Sudan is overseen by the Sudan Medical Council. The NERC was established by a resolution of the Federal Ministry of Health (FMOH) in November 2002, and represents universities which have potential for medical and health research, and research institutes and centres, especially of the MOH. The decree included sub-committees and technical sub-committees. The NERC has nine members, most of whom are university professors, and the function of the Committee is to review proposals for research from the scientific perspective. The NERC represents the University of Khartoum and a number of other universities which have potential for research. Legal advisors, members of the veterinary council, Islamic and Christian representatives are also consulted.

Dr Mustafa stated that the NERC promotes consideration of human dignity, guidelines for health research and ethical approval of health research. She noted that each state in the country has the right to its own IRB, provided it is accepted by the NERC. The regulations of the NERC were laid down in 2006 by several experts from different disciplines. Guidelines were set out for approving health research, and these were approved in 2007 in a workshop sponsored by the MOH. Mapping of health research institutes and centres was recently completed, and will be a reference for all research centres. Dr Mustafa announced that a framework of ethics was established at a workshop held in March 2007 which was attended by UNESCO.

Winding up her presentation, Dr Mustafa stressed that much still needs to be done, as the NERC is still in its early stage as a federal and central directory. No specific laws regarding NEC have been enacted in Sudan to date, and there is only one law on medical research, which was passed in 2001. There is, therefore, a need to establish laws and regulations for monitoring health research. Developments on the global scene should also
be borne in mind, but at present the most important objective is to train bioethics committees, and it is expected that large hospitals will form committees for training.

6.12 Syrian Arab Republic

*Dr Fawaz El Saleh, Secretary General, National Bioethics Committee, Syria*

Dr El Saleh opened by saying that the NEC in Syria was established in 2003 through an initiative of UNESCO. The function of the Committee is to give opinions and organize symposia. There are seven members, comprising physicians, religious scholars, lawyers and natural scientists. Another committee was proposed by the MOH in the same year, but was not activated. In 2005 Damascus University established an ethics committee, and in 2006 an independent body for scientific research was set up.

With regard to NEC activities, Dr El Saleh gave an account of meetings and workshops which have been held, including conferences on bioethics and on stem cell research with UNESCO and the IOMS. At the end of 2003 there was the first Syrian/French Conference on Bioethics, which discussed the ethics of death with medical assistance. In 2005 the NEC in collaboration with the Ministry of Education, held a conference on bioethics in the Arab World. Publications have been produced independently by members of the committee, not as part of an NEC publication. The NEC has not so far been asked to give an opinion on research, except where the research project is funded by an international body, which requires the approval of an ethics committee.

Dr El Saleh stated that there is legislation in Syria for some specific ethical issues, such as the 2007 law on eyes and corneal grafts, and there are increasing requests to enact a comprehensive law on bioethics in Syria. He noted that four years ago bioethics were included in undergraduate curricula in Damascus University, and the subject is being studied from the ethical, legal and religious perspectives, with fruitful results. The government has requested the publication of a book on the subject.

6.13 Tunisia

*Dr Majed Zemni, Member, Arab Committee of Ethics of Science and Technology, Tunisia*

Dr Zemni gave an overview of the Tunisian National Committee of Medical Ethics (CNEM), which was established in 1994, and is made up of 29 members from various disciplines, who are nominated by decree of the Minister of Public Health (MOPH) for a renewable period of three years. The composition of the CNEM consists of the presidents of the national councils of the association of doctors, dentists, veterinarians and pharmacists, or their representatives; the deans of the faculties of medicine, dentistry, and pharmacy, or their representatives; six persons from the domain of health; one person from the social sector, Ministry of Social Affairs, and one from the information sector, Primary Ministry. A technical section of seven members was created within the
Committee from the existing members, to study the recorded files on the agenda of the works of the Committee before circulation. The president of the section is designated by decision of the MOPH from among its members.

Dr Zemni stated that the MOPH is kept informed of all opinions given out by the CNEM, and a yearly report on all the CNEM work and activities is drawn up, and transmitted to the MOPH before the end of the following year. The CNEM is assigned to organize a yearly conference during which important medical ethics issues are debated publicly. It can also organize symposia and seminars on subjects relating to medical ethics. Ten yearly conferences open to the public have been organized, as well as an Internation Meeting on Bioethics, and a ‘Maghrab’ Meeting on Bioethics. Documentation on bioethics has been made available to students. The CNEM has participated in international meetings held by national authorities of ethics and UNESCO, and has taken part in televised debates and interviews. Seven national and regional commissions have been created for the survey of different themes.

Dr Zemni outlined the opinions expressed by the CNEM on medically assisted procreation (MAP), local ethical committees, cloning, striking the balance between medical and technological progress and costs, and organ transplantation. Commenting on the impact of the CNEM, he said that the opinion on MAP has largely inspired the Tunisian legislature in the development of the law on the medicine of reproduction (2001). At the local level the CNEM does monitoring work and provides recommendations to local committees. Currently all hospitals have established Local Ethics Committees.

Since its creation the CNEM has sought to encourage the establishment of ethics committees in other Arab countries. At the Meeting of the Arab Ministers of Public Health held in Beirut in 2000, the Tunisian MOPH presented the example of the CNEM. During the meeting it was decided to create an Arab Committee of Medical Ethics composed of the country members of the Arab League, and to recommend teaching ethics in medical institutions.

6.14 Yemen

Dr Abdullah Hattab, Arab Committee of Ethics of Science and Technology, Yemen

Dr Hattab emphasized the importance of going back to basics in order to establish effective bioethics committees, saying that capacity building is important, and there is a need for courses on bioethics in secondary schools as well as universities. This approach is a priority in Yemen. An undergraduate course on medical ethics for one semester (72 hours) was introduced in 1978, and has been modified in the last 10 years to address advances in research, treatment and bioethics worldwide. The course covers theoretical principles of medical ethics, the social responsibility of the doctor, the doctor-patient relationship, relations among doctors and with other professions, medical error and
negligence, professional confidentiality, ethics and research, environmental ethics, and ethics and public health.

Dr Hattab continued that there is also a postgraduate course on ‘Ethical issues in medical research’ as a module in an MA programme. The main topics of the course are the historical links between medical care and scientific research, the International Codes of Ethics of Research, ethical issues in different types of health research, the informed consent in research, the IRB or REC.

With regard to the Bioethics Committee in Yemen, the National Committee for Health and Medical Research, headed by the Ministry of Health, was established by ministerial decree in 2002. Several meeting were held to lay down rules and regulations, and a working mechanism, but these were stopped because of political changes. One of the challenges is the need to reactivate and structure the Committee.

6.15 Discussion

The country presentations were discussed by all the participants, and some queries regarding specific points in certain countries were clarified.

On the question of whether there is a legal framework for medical trials in Egypt, the NBC makes a framework for medical research, but the medical reviews are carried out by the IRB, of which there are now 14 in Egypt in different sectors. No research is permitted without the approval of the NBC or IRB, and in universities, no publications can be made without the Committee’s approval.

Regarding organ transplantation in Iran, organs are donated free, both for brain death and live donations.

It was clarified that there are two NEC in Jordan, one for Science and Technology and one for Medical Research.

Concerning membership of the NBC in Saudi Arabia, and research review, the members of the NBC are selected on the basis of the nomination of institutions, ministries and other bodies represented in the committee; the NBC surveys all local committees, and all researchers are supposed to comply with the Committee, but as the resolution of the Committee has not yet been adopted there is not full compliance. However, researchers should register, and research projects should be reviewed by local committees. The NBC does not review all research, but sometimes new subjects, such as biobanks.

Participants discussed the definition of bioethics and the apparent confusion between the terms medical ethics and bioethics, commenting that most committees formulated are specialized in medical ethics, whereas their scope should be wider.
Medical ethics are essentially a part of bioethics, so perhaps the more accurate term would be ethics of the biological sciences, which would include clinical, and medical research ethics. The definition of medicine is also different today, as social science, basic science and technology also contribute to medicine. This discussion highlighted the need for agreement on terminology in Arabic.

A further topic debated was the way in which ethics committees in the Region are working. Formation of an ethics committee depends much on the multidisciplinary aspect, and the questions of independence, nomination of members, and the committee’s mandate, are important issues. As a central body, the NBC should have the power to set an ethical framework for any research work or body.

On the subject of legislation, it was pointed out that established committees are consultative, but their recommendations are not binding until laws are enacted. In some countries, laws are adopted after the problem has arisen, and some research takes advantage of the lack of laws. Developing countries should be aware of this dilemma. It is also important to have medical practice law, to handle issues such as organ transplantation, HIV/AIDS, and cloning.

Raising ethics awareness was also stressed, so that institutions and research centres know of ethics and the importance of its application. The problem of leadership in the Region was mentioned, with the necessity to emphasize capacity building, and ethics in both medical and scientific research, and the question was raised as to what part UNESCO and other organizations could play in this regard. The need for monitoring and evaluation of all aspects of bioethics was also expressed, because of the impact on human rights and social conditions, which are closely linked to health and wellbeing.

7. WORKING GROUPS

Participants were divided into two working groups to discuss mechanisms for strengthening the NEC in the Region, and a strategy to support the establishment of new bioethics committees, and establishing cooperation among NBC in the Region, including the possibility of virtual networking.

7.1 Group 1

This group was formed by merging Groups 1 and 2 originally proposed, and three topics were discussed:

- Strategy for establishing new, or strengthening existing NEC
- Terms of reference.
- Capacity building.

Regarding strategy, initiatives should be started in each country, and individuals, groups of professionals, institutions, NGOs, and existing committees at a subnational
level can promote the establishment of ethics committees. International organizations can assist in a number of ways; UNESCO already has a book of guidelines, and the Organization could also contact national commissions, and ministries in charge of UNESCO, WHO could address Ministries of Health, ALECSO, ISESCO, and other organizations could contribute help and advice. There may be conflicts between the several ministries concerned or contacted, MOH, MOE, MoSc and MOFA, but ideally the NEC should be under the highest authority.

The type of committee needs to be determined, and the NEC could be the umbrella for other committees in different ministerial institutions. There may be need for an advisory board, as a law or decree might be required to establish an NEC. In some countries other committees already exist, even if there is no NEC, such as Health-Professional Association Communities, Health Care/Hospital Ethics Communities (HEC), and Research Ethics Communities. These could be used by the NEC at other levels. Experiences of other countries in the Region should be reviewed, and collaboration, coordination and interaction between NEC should be promoted.

Concerning terms of reference, examples of ethics committees in countries in the Region can be contacted; on forming NEC, Egypt, Lebanon and Tunisia, for instance; IRB in Afghanistan and Egypt for university IRB, or other kinds; REC regarding reviewing of research proposals, in Egypt, Morocco and Sudan; HEC for clinical ethics, in Lebanon, Iran, and so on. Terms of reference can potentially be amended and enlarged later, and coordination of different kinds of committees is very import.

For capacity building, some material is already available, but more is needed. International organizations could provide examples of guidelines, models and existing rules of procedure and statutes. With regard to training of committee members on the national and regional level, UNESCO,WHO and MERETI provide various types of training, but there is a need for pooling of information on available training possibilities in the Region, such as courses and distance learning, as well as a need for evaluation and accreditation of courses. The group recommended that UNESCO and WHO should take the lead in this.

The group also suggested that UNESCO and WHO could provide criteria indicators for evaluation and quality improvement of NEC. Potential criteria could include regular reports, frequency of meetings, composition, and funding. Evaluation can be internal and external, covering peer review, exchange of experience, networking on a regional and global scale, such as at the Global Summit of National Bioethics Advisory Bodies.

7.2 Discussion

One of the basic difficulties affecting the impact of NBC in countries in the Region, is the situation regarding UNESCO, WHO and the relevant government ministries. In Kuwait, for example, the contact ministry for WHO is the MOH, while for UNESCO it is
the Ministry of Planning. As it is difficult to coordinate between different ministries, it is a good idea to focus on the function of each committee. Sub-committees or review boards should be appointed by the NBC for specific points, different issues and activities, which would assist the NBC in acquiring information. Research centres should be aware that the Committee exists.

It is up to each country to define the kind of ethics committee it wants, and decide to which ministry it should be related. The NBC should be at high ministerial level, as it then has contacts at the decision-making level. Within the country there can be any number of sub-committees, and at the level of institutions specific issues can be dealt with, such as tissue and organ ethics. All can then join at a higher level for coordination, as there is need for a supervisory body. It has been stated that it is the responsibility of UNESCO Member States to establish NBC, as they agreed to the Declaration, so should implement it. UNESCO should provide support and assistance along with other international organizations, but the ultimate decision is that of the country concerned. As bioethics is a new subject, both UNESCO and WHO should approach and encourage policy makers. It is also important to establish how to make institutions in a country work together.

There is a need for a monitoring process, possibly a joint division between UNESCO and WHO, to monitor and evaluate the situation of ethics committees in Member States every 3–5 years, and there is also a need for a committee to set indicators for ethics committees. There was consensus on the need for joint activity, and the creation of the United Nations interagency committee on bioethics in order to bring together all organizations dealing with ethics and human rights issues was welcomed.

7.2 Group 3

Group 3 discussed establishing cooperation between NBC in the Region, including the possibility of virtual networking. Several issues on how to enhance regional national committees were debated, including how to participate in the NBC, and the necessity of creating mechanisms of cooperation between different ethics committees in the Region. One of the most important needs is to disseminate the culture of bioethics in school and university curricula, and the need for relevant materials. It is hoped that all programmes would be covered in the educational sphere. It is also necessary for ethics to be well understood, and with the continuous emergence of new branches of science, a unified Arabic dictionary with terminology of bioethics from the scientific standpoint is required for use in Arabic-speaking countries.

The group emphasized that the committee could be the focal point between WHO and UNESCO, and suggestions for Committee activities included holding an annual conference to discuss contemporary issues of ethics; incorporating bioethics in educational curricula, and encouraging a sense of responsibility in students, as there is a
close link between ethics, safety and security; publishing a periodical on awareness covering different professional practices, such as physics, for example.

The group also suggested forming an association made up of members of committees and NGOs, which would hold an annual meeting with a chairman elected for one year, create a website to link all member organizations and participants, establish a secretariat, and publish information in hard copy or electronically. The values of the association would be those of WHO and UNESCO.

7.4 Discussion

The participants discussed networking, or setting up an association of NECs to coordinate with networking, meetings, publications and so on, and possibly a joint secretariat from UNESCO and WHO. It was agreed that a network would be more practical in the first instance, and a step towards harmonizing ethics in the Region, with the objective of setting up an association to help solve ethics problems mainly related to culture in the Region. The association would help countries deal with scientific advances in line with the regional culture, and decide on curricula for education, for example. As the present number of NEC is small, and there are ethics committees in organizations like ALECSO, they should also be included in an association. There are ethical problems in many research centres, for example either political, or lab-based, so a joint programme could be evolved to try and find a way to address these problems, and to look for quotes in the Quran to cover ethical issues.

Although there was general consensus that establishing a network for ethics in the Region would be beneficial, it was pointed out that there is already a website which could contain information on mapping, national guidelines, document sharing, participants in this meeting, and other topics. The website could also include a discussion forum, and links to other bioethics websites.

Public demand and debate on ethics is very important, as people should know their rights. This activity needs a push from the community, and the participation of many stakeholders, such as the mass media, NGOs involved in people’s rights, patients’ associations, and so on. An advantage of this Region is that the language in most countries is Arabic, unlike the European Region, for example. All agreed that the idea of an Arabic dictionary of bioethics terminology is a good one, as English terminology is not always accurate in another language.

8. DISCUSSION ON THE FUTURE COOPERATION AND ACTIVITIES IN THE REGION AND INTERNATIONAL AND REGIONAL ORGANIZATIONS

The discussion addressed a number of points of agreement reached in previous discussions, including setting up a network to ensure that this First Meeting of National
Bioethics Committees would be followed by concrete activities. The next regional meeting in two years could be the deadline for collaboration and sharing of information, with the view to establishing a larger body in future. Networking is only a means of communication; an association can contain several sections within it, but has to have legal status. It was agreed that WHO and UNESCO could circulate a questionnaire to obtain more information through a virtual network. There is a need to keep in touch and receive the input of the meeting participants; local and regional concepts should be shared.

The participants agreed that some kind of forum or association will ultimately be necessary, but what is more urgent now is to establish more NBCs for more discussion and sharing of information and experiences. There is a need to identify the reasons why some countries have NBC, and some do not. Initiatives to form NBC should come from both inside countries, and from international organizations, UNESCO, WHO, ALECSO and ISESCO. As the culture and perception of government in countries in the Region are very different from Western countries, it is essential to take these factors into consideration when discussing the formation of NBC, and to use word and expressions which are readily understood.

It was also suggested that as health and system research is one of the policies of the WHO, special ethics codes should be formulated for this field, and also for public health. Community participation and consultation with policy making departments are important for this subject, and this could be done at regional level, or by networking.

Through the General Conference of UNESCO, it has become clear that most countries want more decentralization and more regional control. Member States the Region should work closely with regional offices of WHO and UNESCO to plan for their own region, as they are aware of the cultural, social and religious aspects.

9. RECOMMENDATIONS

- The establishment of NBC in countries which do not yet have one should be encouraged, with help and support from UNESCO and WHO.

- A process for monitoring and evaluation of bioethics and ethics committees should be devised.

- A network should be set up for communication between existing NBCs, with the objective of forming an association in future.

- An Arabic dictionary of bioethics terminology should be compiled.

- Medical and science students from all branches of these disciplines should be educated in bioethics.
• Public awareness of ethics should be increased, so that people know their rights.

• More consideration should be given to public health ethics.
Annex 4

LIST OF MEMBER STATES

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