



National Bioethics Committee (NBC) Pakistan

Shahrah-e-Jamhuriat, Off Constitution Avenue, Sector G-5/2, Islamabad

Tel: 92-51-9207386, 9216793, Fax: 92-51-9216774. E-mail: pmrc@isb.comsats.net.pk, www.pmrc.gov.pk



MINUTES OF THE MEETING OF NATIONAL BIOETHICS COMMITTEE HELD ON April 20 2007, AT PMRC HEAD OFFICE, ISLAMABAD.

A meeting of the **National Bioethics Committee (NBC)** was held on April 20, 2007 at PMRC Head Office, Islamabad under the Chairmanship of Maj. Gen (R) Masood Anwar in the absence of Chairperson NBC, Maj. Gen. Shahida Malik (R), Director General Health, Ministry of Health, Government of Pakistan who was on official tour abroad.

The following members attended the meeting:

1. Prof. M. Zafarullah Chaudhri, President, College of Physicians & Surgeons of Pakistan
2. Prof. Mohammed M. Amin, Dean, Shifa College of Medicine, Islamabad
3. Prof. Dr. Zulfiqar A Bhutta, Aga Khan University, Chairman, Research Ethics Committee of NBC.
4. Dr Maqbool H Jafary, Consultant Physician/Cardiologist, Aga Khan University Hospital, Karachi.
5. Mr. Shaukat Ali Jawaid, Chief Editor, Pakistan Journal of Medical Sciences and Pulse International, Karachi.
6. Dr. Aasim Ahmad, Associate Professor/Chief Nephrologist, the Kidney Centre, Karachi.
7. Dr. Asmatullah, Professor, Islamic Research University, Islamabad.
8. Prof. Baqi Durrani, Department of Medicine, Bolan Medical College, Quetta.
9. Dr. Muhammad Zaheen , Department of Health, NWFP, Peshawar.
10. Mr. Ansar Mansoor, nominee Justice (Retd) Muhammad Qayyum Malik, President, Supreme Court Bar Association
11. Dr Huma Qureshi, Executive Director, PMRC, Member/Secretary NBC.

The following members could not attend the meeting:

1. Dr. Khalif Bile Mohamud, WHO representative in Pakistan.
2. Prof. Anis Ahmad, Vice Chancellor, Riphah International University, Islamabad.
3. Dr. Anwar Nasim, Adviser Science, COMSTECH Secretariat, Islamabad.
4. Dr. S. Qasim Mehdi, Director General, Biomedical & Genetic Engineering Division, Dr. A.Q. Khan Research Laboratories, Islamabad.
5. Prof. Syed Sibtul Hasnain, President, Pakistan Medical and Dental Council, Islamabad.
6. Mrs. Faiz Alam Zaib (R), Postgraduate College of Nursing, Peshawar
7. Dr. Sharriatullah Siddiqui, President, College of Family Medicine, Karachi
8. Dr. Farid Khan, Managing Director, Novartis Pharma Pakistan, Karachi.
9. Prof. S. Haroon Ahmed, Director, Psycho Social Centre, Karachi. .

The meeting started with the recitation from the Holy Quran.

Dr Huma Qureshi, Executive Director, PMRC/ Member Secretary NBC, welcomed all members specially Prof M. Zafarullah Chaudhri, President, College of Physicians & Surgeons of Pakistan (CPSP) for the first ever participation of CPSP in NBC meeting. After introduction of NBC members she briefed the participants about the activities performed so far. She also stressed

the importance of this meeting for reviewing the guidelines developed for conducting Stem Cells Research in Pakistan, Draft Bioethics Act and Organ transplant Ordinance recently announced by the Government (yet to be approved by the Cabinet).

Maj. Gen (R) Masood Anwar, acting Chairman of NBC expressed his views about the importance of bioethics in medical research, especially the stem cells research involving human subjects and agreed for the development of ethical guidelines for stem cells research in particular and other medical research in general. He said that there is a need of prioritization of ethical issues in medical research. He affirmed that Stem cells Research (SCR) being carried out in Pakistan should be monitored by NBC.

All members showed deep concern over the lack of finances and support staff for the NBC and its Secretariat and for support of Research Ethics Committee. They were of the view that without finances this Committee can not make progress and the potential impact that It could make as the National Bioethics Committee. Members stressed that as promised in prior meetings in 2005 and 2006, the Chairman NBC, Director General Health, Ministry of Health, Islamabad must use its good offices to procure finances for functioning of this Committee. In this regard one member suggested that a PC-I may be prepared and get approved by the Ministry of Health. Dr. Zaheen gave the example of Non Annual Development Budget which is in the jurisdiction of Secretary Health and can be used for meeting the financial requirements of NBC.

Dr. Zulfiqar Bhutta suggested that NBC should also have freedom to raise funds for NBC from donors, WHO and other sources. In fact this source was the mainstay of the work undertaken by the NBC to-date in education and capacity development. He also opined that joint working with Higher Education Commission (HEC), and Ministry of Science and Technology after widening the scope of NBC can bring more funds for its functioning. He also suggested that Provincial Ethical Committees be established to share the functioning of NBC and lessen the need for travel etc.

The Chairman then asked Member/Secretary NBC Dr. Huma Qureshi to discuss the agenda.

Agenda Item 1: Progress of the National Bioethics Committee (NBC)

Members were appraised about the activities carried out after the Gazette notification of NBC. The important documents developed by the members of NBC includes Standard Operating Procedures (SOPs) for Research Ethics Committee of NBC, Guidelines for Stem Cell Research/Regulations in Pakistan, Draft Bioethics Act, and review of research projects submitted to NBC for ethical clearance. Members were informed that NBC in collaboration with WHO EMRO conducted National Training for Establishing Institutional Ethical Review Committee (IERC) in Pakistan. Following this all 10 participating institutions established their IERCs. Priority Ethical Issues in Pakistan are also identified by the members of NBC and will be finalized in this meeting.

The Committee appreciated the efforts of NBC members who developed these guidelines and approved in principles for its Gazette notification after minor corrections.

The NBC also constituted National Regulatory Committee (NRC) for cell based Research & Therapy.

The members of this Regulatory Committee are:

- Maj. Gen (R) Masood Anwar, Executive Director, NIH
- Dr Zulfiqar Bhutta, Chairman, Research Ethics Committee of NBC and Chairman Paediatrics Department, Aga Khan University, Karachi
- Dr Maqbool Jafary, Consultant Cardiologist, Aga Khan University, Karachi
- Dr Huma Qureshi, Member/Secretary NBC, Executive Director PMRC
- Dr Aasim Ahmed, Associate Professor/Chief Nephrologist, The Kidney Centre, Karachi
- Mr. Shaukat Ali Jawaid, Medical Journalist/Chief Editor, Pakistan Journal of Medical Sciences and Pulse International
- Dr. Baqi Durrani, Professor of Medicine, Bolan Medical College, Quetta
- Prof. Raheel Qamar, Institute of Biosciences, COMSATS, Islamabad
- Prof. Anis Ahmad, Vice Chancellor, Riphah International University, Islamabad
- Dr. Yasmeen Rashid, Gynecologist, King Edward Medical College, Lahore

While discussing the activities of NBC, Mr. Shaukat Ali Jawaid pointed out that the Standard Operating Procedures (SOPs) for Medical Ethics Committee (MEC) have not been formulated by PMDC, so far, although a preliminary draft was forwarded to PMDC by him. The Secretariat appraised the members that efforts have been made by the Secretariat through personal meetings and official correspondence with PMDC on this matter but no success has been achieved so.

The Committee decided that the stem cell guidelines be disseminated by making a booklet, putting it on website and sending it to provincial health departments. The committee advised that the draft MEC prepared by Mr. Jawaid be forwarded to NBC Secretariat for circulation to all members for their input and then sent to PMDC for finalization.

Decisions:

- 1. The Chairman NBC, Director General Health, Ministry of Health shall look for avenues to get funds for NBC**
- 2. NBC may be allowed to raise funds from various donors.**
- 3. National Regulatory Committee (NRC) for cell based Research & Therapy has been constituted and this shall be gazette notified.**
- 4. Dr. Shaukat Ali Jawaid will forward draft SOPs for MEC to NBC Secretariat for circulation to all NBC members**
- 5. PMDC will be approached for finalization of SOPs of MEC.**

Agenda Item 2: Organ Transplantation Ordinance – Ethical Issue

The NBC discussed the said ordinance in detail and is of opinion that there are some aspects which need clarification; some need deletion and other need modification.

Dr. Aasim Ahmad, member NBC volunteered to make necessary amendments in the light of discussion made in the meeting and agreed to submit the revised version to NBC Secretariat for onward submission to Ministry of Health for further action by intimating the Cabinet for necessary amendments before its approval by the Cabinet.

While Dr. Aasim is working on the Ordinance document a letter will be sent to Ministry of Health indicating that there are some clinical and ethical issues in the Ordinance which need to be dealt before it is approved. Dr. Zulfiqar Bhutta shall draft this letter on behalf of NBC. The letter shall be signed by the DG health and then sent to Ministry of Health.

Decisions:

- 1. Dr. Aasim Ahmad will make/prepare necessary amendments/comments on the ordinance and submit to NBC Secretariat for circulation by the end of April 2007**
- 2. Dr. Bhutta will draft a letter on ethical issues of the Organ transplant Ordinance. on behalf of NBC which shall be signed by the DG Health and then sent to Ministry of Health**
- 3. NBC Secretariat will submit comments to Ministry of Health for onward submission to Cabinet for necessary amendments.**

Agenda Item 3: Draft Bioethics ACT 2007

The Legislation Drafting Committee under the Chairmanship of Mr. Justice (Retd) Muhammad Qayyum Malik Mr. Justice (Retd) Muhammad Qayyum Malik formulated a Draft Bioethics Act which was discussed, however, in depth discussion could not be made due to shortage of time, therefore, it was decided that all member will go through this Act and will send their comments to NBC Secretariat to be forwarded to Draft Legislation Committee for necessary amendments.

Members were of the opinion that this draft act deals with aspects only about stem cells, embryos and genetic manipulation, however, it needs to be expanded to cover other ethical issues related to social aspects.

It was suggested that Draft Legislation Committee may also consult PMDC's old document on clinical ethics in research and use that document to clear things which are already approved. To broaden the base of this bioethics act it was suggested that Dr Baqi shall prepare guidelines on genetics, genomics research and take help of fellow members and the Ministry of Science and Technology (MOST). For developing guidelines on reproductive health and reproductive technology/research it was suggested that Mr Mubashir may seek help from Prof Tayyab the gynaecologist of Rawalpindi Medical College and Prof Yasmin Rashid from Lahore. Mr. Ansar Mansoor, nominee of Mr. Justice Abdul Qayyum was advised to consult NBC Secretariat for definition of Medical terminology used in the Act.

Decisions:

- 1. All members will give their input to NBC Secretariat by mid of May 2007**
- 2. The NBC Secretariat will forward these comments to Mr. Ansar Mansoor drafting the Act**
- 3. Mr. Ansar Mansoor will consult NBC Secretariat for medical terminology used in the Act.**
- 4. Draft Act will also be modified covering ethical aspects related to reproductive health and genomics/genetics and other social issues**
- 5. The Draft legislation Committee will also consult old PMDC documents to avoid any overlap/duplication on issues already addressed.**

Agenda Item 4: Clarification Regarding Selection of NBC Members

NBC has discussed the selection of new members either on the retirement of some members or in case of their death.

The Committee agreed that selection may be made in the said category/discipline from among the professionals of that particular discipline. For the discipline nominee of Surgeon Gen /DGMS, Pak Army and for Nurse it was decided that its selection be made Ex-officio and for nursing the Head of Nursing Council be taken on the Committee. Though the tenure for each member is 3 years which shall end by August this year but it was decided that members who are actively contributing to the NBC may be retained while those who are not attending may be replaced.

Decision:

1. The selection of new member will be made in same discipline from which person a person retired or passed away.
2. **The discipline of Surgeon Gen of Army and Nurse was declared Ex-Officio. For nursing the Head of Nursing Council will be selected as member.**
3. **Nomination from Surgeon Gen./DGMS, Pakistan Army may also be requested.**
4. **Membership of office bearers end on August 2007 but members who are actively contributing to the NBC may be retained while those who are not attending may be replaced.**

Agenda Item 5: Decisions about members not attending meetings of NBC

It was brought into the knowledge of all NBC members that some members have not attended a single NBC meeting held so far. This is affecting the collective vision and way forward on the various issues of Bioethics in general and medical research in particular.

Dr Qasim Mehdi from University, Dr Sharriatullah Siddiqui, from General Practice, Dr Asmatullah from Religious Scholar, Prof Haroon Ahmed from Human rights commission and Mr Farid Khan from Industry,

The NBC has decided that new names in these disciplines may be invited for further selection as per rules..

Decision:

1. **The NBC decided to replace members who did not attend any NBC meeting so far and select new members by asking for nominations from among the professionals of same discipline.**

In the end Dr. Huma Qureshi, ED PMRC and Member/Secretary NBC thanked the Chairman and all members of NBC for sparing their valuable time for this very important meeting