

DRAFT MINUTES OF THE NATIONAL BIOETHICS COMMITTEE MEETING KARACHI, FEBRUARY 20, 2012

A meeting of the National Bioethics Committee was held on 20th February 2012, at Aga Khan University. Professor Dr Bhutta, Chaired the meeting. Following Members attended in the Meeting:

1. Prof. Dr. Zulfiqar Ahmed Bhutta, Prof. of Paediatrics & Child Health, The Aga Khan University, Stadium Road, Karachi -74800.
2. Dr. Huma Qureshi, Executive Director, Member/ Secretary NBC, Pakistan Medical Research Council (PMRC) Shahrah-e-Jamhuriat, Sector G-5/2, Islamabad.
3. Prof. Dr. Farhat Moazam, Professor & Chairperson, Centre of Biomedical Ethics and Culture Sindh Institute of Urology and transplantation, Karachi.
4. Prof. Dr. Anis Ahmed, Vice-Chancellor, Riphah International University, Sector I-14, Near Hajj Complex, Islamabad
5. Prof. Dr. Aasim Ahmad, Associate Professor / Chief Nephrologist, The Kidney Centre 197/9 Rafiqi Shaheed Road, Karachi-75530.
6. Dr. Maqbool H. Jafary, 65/1C Block 6, P.E.C.H.S. Karachi.
7. Mr. Shaukat Ali Jawaid, Editor In chief, Pakistan Journal of Medical Sciences & Pulse International, Room No.522, 5th Floor, Panorama Centre, Building No.2, Raja Ghuzanffar Ali Road, Saddar, Karachi.
8. Dr. Asmatullah, Assistant Professor, Islamic Research Institute, Islamic University, Faisal Masque Campus, Islamabad.
9. Dr Anwar Aziz, Principal, State School of Nursing, Mirpur, Govt. of Azad Jammu and Kashmir, Mirpur AJK.
10. Prof. Rizwan Azmi, Nominee, President CPSP
11. Dr. Jawaid Akhtar Sheikh, Nominee WHO Representative, World Health Organization, Islamabad.

The following members could not attend the meeting due to their prior commitment or being abroad:

1. Mr Muhammad Yasin Azad, President Supreme Court Bar Association, Islamabad
2. Prof. Muhammad M. Amin, Dean, Shifa College of Medicine, Islamabad.
3. Dr Saeed-ul-Majeed, President, College of Family Medicine, Peshawar
4. Dr. S. Haroon Ahmed, Director, Psycho Social Centre, Clifton, Karachi.
5. Dr. Nadeem Akbar, Nominee PMDC, Islamabad
6. Dr. Anwar Nasim. Adviser Science, COMSTECH
7. Dr. Farid Khan, Pharmaceutical Industry
8. Dr. Baqi Durrani, Professor of Medicine, Bolan Medical College Quetta.
9. Dr. Muhammad Zaheen, Deputy Director Monitoring Research & Evaluation (MRE) Provincial Health Services Academy (PHSA), Peshawar
10. Maj. Gen. Abdul Khaliq Naveed, Dean Faculty of Medicine, National University of Science & Technology

The meeting started with recitation of Holy Quran. The Chair welcomed the participants of the meeting. After the introduction of the members, the Chair asked the Member/Secretary NBC to start the proceedings of the meeting.

Agenda Item No. 1: Confirmation of the Minutes of the Meeting held on 29th December 2010

The last meeting of National Bioethics Committee (NBC) was held on 29-12-2010, at PMRC Head office, Islamabad under the Chairmanship of the Secretary Health, Mr Kushnood Akhtar Lashari

The Minutes of meeting were circulated to all members and no comments were received from any member.

Decision: Minutes of the NBC meeting held on 29-05-2010 were approved.

Agenda Item No. 2: Briefing of the NBC Activities

The Chair and the members expressed at the long intervals between NBC meetings (the last meeting. and for lack of communication with them in the intervening periods regarding follow up of actions/decisions agreed upon during the previous meeting. It was pointed out that the latter could easily be done through emails.

The Chair and Members were also categorical in expressing their concern on sub-optimal functioning of the NBC following the devolution of Ministry of Health. They re-enforced that more strict follow-up is required to get the things moving. The Members also stressed that the Cabinet Secretary who by default is now the Patron NBC should be requested to Chair NBC meetings for better functioning of NBC.

Dr Huma Qureshi, Member Secretary, NBC, briefed the members that things have been changed due to devolution and frequent change in our administrative ministry from IPC to Cabinet. She further briefed the members on the activities related to national bioethics committee and its progress, which is as below:

1. **Progress on NBC Budget:** *In the last meeting Secretary Health had asked the DG and NBC Secretariat to work out budget for the next year. The budget was calculated and sent to the Ministry of Health but no further action took place. Dr Huma however, told the house that approximately Rupees 1.0 million is required to meet the expenditures for the NBC and REC meetings which can be arranged by the PMRC from their own budget (there is no specific budget ear marked for NBC) and also from the project's ethical review fee received by the PMRC which is also the NBC Secretariat. The members were of the opinion that a detailed, specific NBC budget (even if within the ambit of PMRC) involving all activities should be carried out, including all trainings of IRCs and provincial NBCs, publication of News Letter, Maintenance of NBC Website etc.*

Decision: Substantial budget is required to meet the activities of NBC. The PMRC to forecast budget for NBC for next 5 years and share it with the members for finalization

2. **Progress on NBC News Letter:** *It was decided in the last NBC meeting that in view of the financial constraints, the newsletter will have to wait. The member*

Secretary said that in view of the importance of News letter, PMRC would arrange funds for printing and dissemination. Mr Shaukat Ali Jawaaid may proceed with the design and development of the letter. There was a unanimous consensus among all NBC members on this suggestion.

Decision: Mr Shaukat Ali Jawaaid to proceed with the designing and development of News letter and once developed a draft should be shared by all NBC members. The approved version should be sent to PMRC/NBC Secretariat for printing and dissemination.

3. **Progress on NBC Website.** *It was volunteered in the last meeting by Professor Anis Ahmed that he will help PMRC in developing a Website for NBC Pakistan. He deputed his IT specialist from RIPHA University to work on this. First meeting with the IT specialist was held on 14th Feb 2012. Details were discussed. Two things related to website i.e. the domain ID and the “acknowledgment to the RIPHA” were also presented to the committee for their guidance. Two domains for NBC Website were suggested by the members and they asked PMRC to see the availability of any one of these two domains:*

**nationalbioethicscommitteepakistan.org.pk
bioethicscommitteepakistan.org.pk**

Dr. Moazam pointed out that the current NBC website appears to have not been updated for at least 2 years as demonstrated by the outdated list of members it contains. She suggested that somebody in PMRC should be designated to at least update the website information regularly. (This is not true)

Decision: PMRC to go ahead with the development of Website with technical support from RIPHA International. Necessary payments on account of two yearly fees for the domain and for other expenses may be made. It was also agreed that RIPHA may be acknowledge in the foot note. NBC Logo will also be developed by RIPHA International University.

4. **Progress on the establishment and notification of Provincial Bioethics Committees (PBCs):** *It was decided in the last NBC meeting that DG Health will write letters to all provinces for the establishment of provincial bioethics committees. Dr Huma told the Committee that letters were written by the DG Health to all provincial secretaries and later reminders were also sent to them by PMRC, but so far none of the provinces have established these committees.*
5. **Decision:** Dr Huma will request Secretary Cabinet Division to write a letter to the provincial Health Secretaries to expedite the case. It was also agreed that the Provincial Bioethics Committees would include both research and clinical ethics components.
6. **Progress on the nomination of Provincial Directors General of Health as Members NBC:** *It was decided in the last meeting that provincial Secretaries will be asked to nominate Provincial DGs of Health as members of NBC. Dr Huma informed the House that letters have been written to all provincial Secretaries but so far only two provinces i.e. AJK and Baluchistan have notified their DGs of*

Health as members NBC Pakistan. The members asked the Member Secretary NBC to follow-up with the provincial secretaries on this issue for expediting the nominations.

Decision: Dr Huma Qureshi will request the Secretary Cabinet Division to write letters to the provincial Secretaries for the nominations of provincial DGs as Members NBC Pakistan. It was also decided that as soon as the letter goes from the Secretary Cabinet, an NBC meeting should be called immediately.

7. Progress on the Activation of Medical Ethics Sub-committee of NBC: In the last NBC meeting, *the Nominee of PMDC Dr Nadim informed that all the decisions taken by NBC on medical and research issues shall be owned by PMDC and in this regard a draft has already been sent to the DG (Health) for approval. This will also include the establishment of the medical ethics sub-committee by February 2011.* Dr Huma told the Members that PMDC has implemented all recommendations regarding interaction of doctors with pharmaceutical industries in its gazetted code of ethics which are binding on the institutions/individuals of Pakistan. A copy of the letter and its enclosures were also shown to the members. A point was raised that merely issuance of a gazetted letter cannot be construed as “implementation” by PMDC without wide dissemination of the code to those who are supposed to act on the guidelines. It was suggested that PMDC should be asked to do so.

The members were also told that the approved Physician Pharma guidelines developed by the NBC were also shared by the PMDC. The Committee expressed their dissatisfaction on the fact that the PMDC has not yet established a medical ethics sub-committee and recommended that it should be brought to the notice of the Cabinet Secretary that “it has been several years that NBC is trying to activate clinical ethics committee, but due to unknown reasons this has not yet been done by the PMDC.

Decision: Secretary Cabinet may be informed that PMDC despite NBC requests has not yet been able to activate the Clinical Ethics Sub Committee and that PMDC may be asked to expedite the process. It was decided that Prof. Dr Bhutta will speak with President PMDC in this regard.

It was also decided that all Medical institution should be informed about this gazette notified code of conduct. PMDC should be asked to circulate these guidelines to the principals of all medical colleges and pharmaceutical industry for compliance.

8. **Progress on the Approval of National Stem cell guidelines developed by NBC:** *In the last NBC meeting members were informed by Prof Bhutta that stem cell guidelines were made by NBC’s subcommittee almost 2 years back and approved by all members.* These were shared by the secretariat with a subcommittee formed by Human Organ Transplant Authority (HOTA) to develop guidelines for stem cell transplant. HOTA has reproduced these guidelines therefore, it is suggested that they should specify that these have been adopted from NBC guidelines. It was decided in the last meeting that the DG (Health) will write a letter to the

administrator HOTA to make corrections on the HOTA stem cell guidelines and state that these have been adopted from the guidelines developed by NBC. Dr Huma informed the members that a letter was written to HOTA by the DG but so far no action has been taken by HOTA on this.

Decision: A follow-up is required to get this done by the HOTA. Dr Huma will write a letter to HOTA for the implementation of NBC decision.

9. **Progress on Contract Research Organizations (CROs):** In the last NBC meeting two things were decided regarding CROs functioning in Pakistan. Firstly all trials brought by CROs and Pharma industry which are of national importance or are supported by donor organizations will undergo ethical clearance by the NBC (or its provincial counterparts in due course) and secondly the MoH will define registration criteria for CROs and code of conduct for operations in Pakistan. Dr Huma informed the house that no guidelines have been received from the then MoH regarding registration of CROs. However, PMRC has drafted the guidelines by consulting the UK and Indian laws. This draft would be shared with the NBC Members for their inputs and further guidance.

Decision: A sub committee comprising of the following members was formed by the Members NBC:

1. Prof. Dr. Aasim Ahmed Member NBC
2. Professor Dr Zulfiqar A Bhutta, Member NBC
3. Dr Maqbool Jeffery, Member NBC
4. Dr Muhammad Zaheen, Member NBC

It was also decided that Dr. Huma will share the early draft guidelines with all the NBC members.

9. **NBC Meetings:** Members were asked about the frequency of NBC Meetings annually. It was decided that quarterly NBC meeting should be held and efforts be made to hold these meetings in turn in different provinces.

Decision: Quarterly NBC meetings will be held. The next meeting should be in May 2012 preferably at Lahore. PMRC will circulate possible dates in May to members with a request that they email back the most convenient one for them, following which the day of the meeting can be confirmed.

10. **Issue of Projects being conducted by a pharmaceutical company without NBC approval**

Dr Huma brought to the notice of the NBC that as per letter received from the Sheikh Zayed Hospital, Lahore following two projects are being run by the Roche in various sites in Pakistan, without ethical approval of the NBC:

- Project No 1: Use of Peg interferon plus ribavirin in chronic HCV cases. The project is funded by the Multinational Company

- Project 2 :Study on IL 28B marker (a blood marker used to predict the responders Vs non responders to interferon therapy) in HCV patients receiving interferon

She asked the members for their guidance as to what should be done in this case. The members appreciated Sheikh Zayed hospital, for bringing it to the notice of NBC and said that as per DGs letter and decision of the last NBC meeting Chaired by the then secretary Health; all such projects must have the approval of NBC before execution. Dr Zulfiqar A Bhutta commented that any external funded projects with national profile have to be approved by the NBC.

Decision: A letter along with the earlier circular sent by the then DG Health should be sent to PPA for notifying all medical institutions for compliance. A letter should also be written to all pharmaceuticals to re-circulate the DGs letter for compliance. Dr Huma will write a letter to the Roche Company asking them about this violation of conducting the project without being approved by the NBC. A letter of appreciation to be sent to SZH Lahore for bringing this issue in the notice of NBC

11. **Issue of Stored blood and tissue Samples and genetic material:** Dr Zulfiqar A Bhutta, pointed out there should be some process for regulating blood samples and genetic material out of the country. Professor Dr. Aasim and Professor Dr. Farhat Moazam said that there is a need for a clear policy and guidelines for research on stored blood and tissue sampling. Dr Moazam said that increasing number of instances are coming to light in which such samples are being transferred out of Pakistan, including for genetic studies. In the US, following perceived misuse of stored samples, it is being suggested that a “tiered” consent be used and participants’ permission obtained as to which form of research on their stored samples is acceptable to them. She said that if tissues need to be used for the purpose other than for which these were collected, then ethically there is a need for getting consent of the participant from whom the tissue or blood sample was obtained. The Chair suggested using local guidelines which can be later modified and used for our own purpose. He also mentioned tissue banking as another important area to be considered.

Decision: It was decided to establish a sub-group with Prof. Dr Aasim Ahmed as the lead person to look at the whole issue of tissue banking and blood sampling and their transportation especially outside Pakistan. Following Group was formulated having provincial representation also, for developing guidelines for the storage of blood and tissue guidelines:

1. Prof. Dr Aasim Ahmed, Member NBC (Lead person)
2. Dr Maqbool Jaffrey, Member NBC
3. Dr. Laliani who wrote tissue banking guidelines
4. Dr. Baqi Durrani from Baluchistan, Member NBC
5. Dr Muhammad Zaheen from KPK, Member NBC
6. Some one to be identified from Punjab
7. PMRC coordination/logistics

The meeting ended with a vote of thanks to the Patron and Chair