

NATIONAL BIOETHICS COMMITTEE

DRAFT MINUTES OF THE MEETING OF THE NATIONAL BIOETHICS COMMITTEE (NBC)

02 March 2015

A meeting of the National Bioethics Committee (NBC) was held on 02 March 2015 at Azad Jammu & Kashmir Medical College, Muzaffarabad. Due to non-availability of the Secretary Health, Dr Farhat Moazam, Chairperson, Health Care Ethics Committee (HCEC) and Member NBC, chaired the meeting.

Following Members attended the meeting:

Members

1. Prof. Dr. Farhat Moazam, Professor & Chairperson, Centre of Biomedical Ethics and Culture, Sindh Institute of Urology and transplant, Karachi.
2. Prof. Dr. Aasim Ahmad, Dean and Chief Nephrologists, Kidney Centre, Karachi
3. Dr. Aamir Mustafa Jafarey, Associate Professor Centre of Biomedical Ethics and Culture, Sindh Institute of Urology and Transplantation, Karachi.
4. Prof. Dr Munir Akhtar Saleemi, Professor of Social and Preventive Pediatrics, University of Health Sciences, Lahore
5. Dr. Mahjabeen Khan, Assistant Professor, Research and Development, Dow University of Health Sciences, Karachi

Ex-Officio Members

1. Dr Huma Qureshi, Executive Director PMRC and Member Secretary NBC
2. Dr. Farooq Azam Jan, Director General Health Services, Health Department, Government of Baluchistan, Quetta.
3. Dr. Sardar Mehmood Ahmed Khan, Director General Health Services, Health Department, Government of AJ&K, Muzaffarabad.
4. Prof. Dr. Mukhtar Focal Person Bioethics Committee AJK, Muzaffarabad.
5. Dr. Ghulam Nabi Qazi, World Health Organization, Islamabad.

6. Dr. Abdul Majeed Akhtar, Representative Nominee, Director General Health, Health Department, Government of Punjab, DG Office, 6 Cooper Road, Lahore.
7. Dr Saleem Memon (Representative) Director General Health Services, Health Department, Government of Sindh, Hyderabad.
8. Dr Khawaja Tahir Aziz (Representative) President CPSP), Muzaffarabad, AJ&K.
9. Representative Registrar, Nursing Council, Islamabad.
10. Dr. Muhammad Arif Munir Focal point NBC Secretariat, Pakistan Medical Research Council, off Constitution Avenue, Sector G-5/2, Islamabad.

Following members could not attend the meeting due to their prior commitments:

Members

1. Prof. Dr. Abdul Razzaq Sabir, Vice Chancellor, University of Turbat (Baluchistan), Makran Division, Baluchistan.
2. Dr. Farid Khan, 68/1 Khyban-e-Mahafiz, Phase 6, DHA, Karachi
3. Prof. Dr. Asmatullah, Associate Professor (IRI), International Islamic University, Shah Faisal Mosque, Islamabad. P.O Box 1035, GPO, Islamabad.
4. Prof. Dr Zafar Hayat, Khyber University Head of Department Medicine. Khyber Teaching Hospital, Peshawar
5. Dr. Farah Qadar, Head of Department Behavioral Sciences, Fatima Jinnah Women University, Rawalpindi

Ex-officio Members

6. President, Supreme Court Bar Association, Supreme Court Building, Islamabad
7. Director General Health Services, Health Department, Government of Khyber Pakhtun Khwa.
8. Director Health Services, Federally Administered Tribal Areas (FATA)
9. Director Health Services, Health Department, Government of Gilgit Baltistan

10. Prof. Dr Hafizullah, Vice Chancellor, Khyber Medical University, Peshawar (Representative PM&DC).
11. Dr Tariq Mehmood Mian, President, Pakistan Association of Family Physicians
12. Maj. Gen Abdul Khaliq Naveed (Representative) DGMS (IS)/Surgeon General, Pakistan Army. Medical Directorate, General Head Quarters, Rawalpindi.

The meeting started with recitation from the Holy Quran. Dr. Huma Qureshi welcomed the participants of the meeting. In the absence of the Secretary, Ministry of NHSRC, Dr. Farhat Moazam was asked to chair the meeting.

Dr Farhat Moazam thanked NBC members who had traveled to Muzaffarabad for the meeting and expressed her disappointment at the absence of members/ provincial representatives from KPK, FATA, and Gilgit-Baltistan. She also noted that once again there was no representative of PM&DC present in the meeting. On behalf of NBC she expressed her appreciation to the Director General Health AJK, Dr Sardar Mehmood Khan (present in the meeting), and Dr Mukhtar Ahmed, focal person for Regional Bioethics Committee, AJK for the hospitality and support they had extended for the NBC meeting being held in Muzaffarabad.

After the introduction of the members, the Chair asked the Member/Secretary NBC to start the proceedings of the meeting.

Agenda item 1: Approval of minutes of the last NBC meeting held on 07 August 2014.

Dr Huma Qureshi informed the house that minutes were circulated to all members and all corrections that were suggested have been incorporated. The members were requested to approve the minutes.

Decision: Minutes were approved.

Agenda item 2: Briefing on NBC activities

Dr. Huma Qureshi updated the members on the decisions of the last NBC meeting held in Quetta on 13 November 2014 and the actions taken. She informed the house that as per decision of the last NBC meeting all Provincial DGs or their nominees were asked to present their progress

regarding establishment of Provincial Bioethics Committee in their Provinces. They will share with the house the progress made so far in this connection.

Dr Huma then gave a report of the expenditure incurred by NBC in 2014 and the current balance in the NBC account. In addition to the government funding for activities, a major NBC source of funds remains the fees charged by the REC of research projects submitted to it for ethical approval. The Chair advised, and members approved, that project processing fee must be received up front and NBC clearance letter should not be issued until the principal investigators has cleared their dues.

In response to a question, Dr. Huma said that NBC funds also support all “Bioethics workshops” and expenditure for all other activities undertaken by NBC and its subcommittees. The Chair requested that every attempt should be made to hold NBC meetings not in 5 star hotels but in more economical venues such as academic institutions. She also advised that at some stage NBC should consider review standards of institutional bioethics committees and help in building and improving their capacity.

Agenda item 3: Progress in establishing PBCs

3.1. Progress on PBC Baluchistan: Dr Farooq Azam Jan, Director General Health, Baluchistan informed the members that Baluchistan has constituted the Provincial Bioethics Committee whose composition has been forwarded to the Secretary Health, Balochistan for approval and notification. The delay in notification is mainly due to change in the management of the Health Department and he affirmed that he will follow the case with the Secretary Health and hoped to get the notification issued in 2-3 weeks. Regarding composition of PBC Balochistan, the members advised that individuals from outside Quetta should also be included, to which the DG agreed and said he will do so once new medical colleges are established (2-3 are in pipeline). The secretary NBC suggested that all DGs or their representatives of the PBC can make formal requests to NBC secretariat for training workshops so that all activity is noted and officially catered for.

Decision:

- Dr Farooq Azam Jan will follow with Secretary Health regarding notification of the provincial PBC and inform the NBC Secretariat once PBC is “notified”

3.2. Progress on PBC Sindh: The representative of Director General Health Services, Sindh, Dr. Saleem Memon, informed the house that they have constituted the PBC Sindh but it has not yet been notified by the Secretary. He requested the Chair for holding “Bioethics Workshop” for the members of the Provincial Bioethics Committee, similar to ones conducted for Quetta and AJK. Dr Moazam stated that NBC will organize an ethics workshop concomitant with NBC meeting scheduled to be held in Sindh in June 2015. It was emphasized that PBC should also include members from outside Karachi to which Dr Saleem Memon agreed.

Decision:

- The Provincial Bioethics Committee Sindh should also include Members from outside Karachi and Dr Memon will share the revised composition with the NBC Secretariat.
- Dr Saleem Memon will follow with Secretary Health, Sindh, regarding notification of the provincial PBC and inform the NBC Secretariat once PBC is “notified”.

3.3. Progress on PBC AJK: The representative of Director General Health, AJK, Dr. Muhammad Mukhtar gave a presentation on the formulation of Regional Bioethics Committee for AJK and the three Institutional Bioethics Committees that have been constituted in the three public medical colleges in AJK. He however, mentioned that these committees are still to be notified by the Secretary Health AJK. He then shared the ToRs of the Regional Bioethics Committee as well as the list of members of each committee. NBC members appreciated the diversity of members chosen for the committees and Dr Mukhtar’s efficiency and promptness in getting this task done.

Dr Mukhtar informed NBC members that he will soon be retiring and traveling abroad for a few months. The Chair expressed her concern that as he has been the focal person for ethics in AJK, this may result in a halt in further progress with the AJK bioethics committees. She stated that it was Dr. Mukhtar’s responsibility to ensure that this did not happen and that an appropriate person is identified to take the process further. Dr. Mukhtar stated that he will make sure that the progress made so far does not stagnate.

Decision:

- Dr Mukhtar will follow up the process of notification of Regional and Institutional Bioethics Committees and share the progress with the NBC secretariat

- He will soon call a meeting of the regional committee and share the minutes with the NBC Secretariat.

3.4. **Progress on PBC Punjab:** Dr Abdul Majid Akhtar from Punjab informed that they established PBC in March 2014 and notified its members. He stated that training of the PBC members was done by the NBC in collaboration with the Directorate General Health Services in Lahore on 17th March 2014. Dr Akhtar informed the house that they have also constituted two sub-committees of the PBC i.e. Research Ethics Committee (REC) and Health Care Ethics Committee (HCEC).

Dr Aasim Ahmad suggested that members with some training in bioethics should also be included in the PBC, Punjab. The Chair noted that Punjab has several professionals with formal education in bioethics including from CBEC, Karachi. Dr Abdul Majeed Akhtar agreed to expand the PBC and requested Dr Aasim and Dr Amir Jafarey to provide him suitable names, which they agreed to do.

Dr. Majeed stated that although they had constituted the ToRs of the PBC Punjab and its sub-committees he would like to modify these and use the NBC TORs instead (those developed by Dr Farhat Moazam and Dr Aasim Ahmad). The members present were informed that such NBC material is available to and can be used by all provincial and regional committees.

Dr Abdul Majeed Akhtar requested for more Bioethics Workshops in Punjab so as to enhance the capacity of the Members of PBC. The Chair pointed out that education of PBC members is an ongoing process and that they are welcome to organize more bioethics workshops with NBC help. He was advised to send a written request to NBC Secretariat mentioning possible time and venue for a bioethics workshop in Punjab.

Decision:

- NBC ToRs are considered a resource for all PBCs and can be used as needed by them.
- Dr Abdul Majeed Akhtar will send a written request to the NBC Secretariat to organize another Bioethics Workshop in Punjab.
- The Member /Secretary PBC, Punjab will share the minutes of all PBC meetings with the NBC secretariat.

- Dr Aasim and Dr Amir Jafarey will provide names of candidates who have been trained in ethics to Dr Abdul Majeed Akhtar for inclusion in the PBC Punjab.

3.5. Due to the absence of Khyber Puktoonkhwa and FATA representatives there was no PBC progress report from that province.

Agenda Item 4: Briefing on Research Ethics Committee.

Dr. Aasim Ahmad gave detailed briefing on the progress of Research Ethics Committee (REC). He presented the revised ToRs of the Research Ethics Committee to the NBC for discussion and approval. He discussed in detail the process of research projects evaluation and review. Dr Aasim further informed that project review form (REC Application Form) and guidance document have also been revised and updated. He also pointed out that previously we had two categories of review; routine review (12 weeks) and expedited review (6 weeks), but in the revised ToRs there is only one type of review for all projects. The review time line is now 08 weeks. The Chair and the NBC Members appreciated the efforts put in by Dr Aasim in developing the revised ToRs. The Chair with the consensus of the house approved the revised ToRs of the Research Ethics Committee.

Dr Aasim also shared the names of the REC members and informed that currently there are 07 regular Members of REC and 02 Co-opted members and this number need to increase. The Chair agreed and advised Dr Aasim Ahmad to get more REC members on board. She also suggested that REC should arrange trainings for the REC members on document review to which Dr Aasim agreed.

Dr Huma, Member Secretary NBC, invited the attention of the house to the fact that NBC has not yet developed guidelines on transportation of biological material within and outside the country. She informed the house that PMRC was approached by the Foreign Office in Islamabad who requested that as transportation of human tissues and material comes under NBC therefore NBC give certificate for transportation of material and tissues. The foreign office requested NBC for the development of guidelines for the transportation of biological material. Dr Aasim Ahmad said that has already collected enough material on this issue and that guidelines can be developed. He however, invited more members to be part of guidelines development. Dr Huma suggested she can give names of PMRC researchers to help Dr Aasim.

Decision:

- Revised ToRs of Research Ethics Committee were approved.
- Dr Aasim Ahmad with 1-2 more members and PMRC researchers will develop guidelines on the storage and transportation of biological material within the country and abroad and share it with NBC.

Agenda Item 4: Report on HCEC progress. Dr Moazam, Chair Health Care Ethics Committee (HCEC), presented progress report on HCEC activities. The committee focuses on ethics education – through ethics workshops for PBCs and national institutions and development (currently underway) of a comprehensive set of guidelines with a resource Handbook to help introduce ethics to undergraduate dental and medical students. The aim of the latter exercise is that these guidelines will be used by PMDC to enforce ethics education in colleges in Pakistan. She reminded the group that a draft of the guidelines was presented to NBC in the last meeting (in Quetta) and suggestions offered by members have subsequently been incorporated into the document.

The last HCEC meeting (8th since the constitution of the committee in December 2012) was held in January 2015. This was the first time that a designated representative of PMDC, Dr. Hafizullah (KMU, Peshawar) was present. The ethics guidelines document was discussed at length and he provided useful input and support for introduction of bioethics into the undergraduate curriculum. He stated that PMDC is currently reviewing the curricula and hope to convert it into a modular system in a year. He would discuss the HCEC recommendations with relevant people as well as the PMDC committee reviewing the curriculum.

HCEC recommendations to Dr. Hafizullah included that the current PMDC Code of Ethics statement that medical ethics “may’ be taught to the medical and dental students should be replaced with “should” and PMDC should enforce this in all colleges. Moreover, PMDC should move to formal recognition of those who have education in bioethics and teach this topic to students. PMDC should also institute at least 50 hours be spent on teaching ethics spread over the years in college. Dr Hafizullah assured HCEC that these recommendations will be taken up by PM&DC.

During the meeting Dr Hafizullah suggested that HCEC should also develop guidelines for postgraduate trainee education in collaboration with CPSP. He was informed that this is beyond the current mandate of HCEC and that postgraduate ethics education is entirely different from the undergraduate. During the ensuing discussion on this point by NBC members, Dr Khawaja Tahir Aziz, representative CPSP present in the meeting, offered to take up the importance of postgraduate ethics education with CPSP and will inform the NBC in their next meeting.

At the end of the January HCEC meeting, Dr Hafizullah had assured members that the recommendations will be taken up in the next meeting of the PM&DC and he would inform Dr. Moazam of the progress.

Decisions:

1. Dr Hafizullah will take up the HCEC recommendations at the next meeting of PM&DC and shall inform HCEC of progress.
2. Dr Khawaja Tahir Aziz will discuss the matter of developing guidelines on medical ethics for the postgraduate medical/dental students and inform the NBC members in the next NBC meeting.

Agenda Item 5: Presentation of revised NBC ToRs by Dr Aasim Ahmad.

Dr Aasim Ahmad, Member NBC and Chair REC, presented the revised ToRs of NBC which were revised by himself, Dr Moazam and Dr Aamir Jafarey. He explained that the process involved both email exchanges as well as a meeting of the three members. The revision of the TOR was undertaken as the current document, developed over 10 years ago, is fragmented and unclear, and does not serve as a good guide for constituting PBCs. The decision to review and modify these had been discussed and approved by NBC members in the Quetta meeting. The modifications are also based on the experience of the functioning of NBC so far and an attempt to make this more efficient and fruitful.

The major modifications suggested include the following -

1. The regular, voting members in NBC (excluding ex-officios) be increased from 15 to 20; quorum for meetings be 30% of regular members
2. Regular members be sought not only via notifications to universities/institutions (as done currently) but also through placing of advertisements and names suggested by current members; those with relevant education/experience in bioethics be preferred over institutional affiliations

3. Provincial Bioethics Committees including AJ&K will identify one member each who will also serve as member of NBC

In the discussion that followed, Dr Moazam noted the importance of increasing the number of appropriate NBC members as this would also benefit the two sub-committees which do not have sufficient members to work efficiently.

Following a discussion, the modifications were approved unanimously by NBC members.

Decision:

1. Revised NBC ToRs were approved.
2. Increase in non-ex-officio members to 20 including one permanent focal person from each provincial and Regional Bioethics committee were approved.
3. Each Provincial Bioethics Committee and Regional Bioethics Committee of Azad Jammu & Kashmir will nominate one permanent member and inform the NBC Secretariat accordingly.
4. Since Dr Mukhtar Ahmed is now retiring, he will take up the matter with the DG Health, AJ&K for nomination of a permanent focal person for RBC and a representative or NBC, before proceeding on leave.
5. NBC Secretariat will provide the current number of regular NBC members and institute the selection and election process to bring this number up to 20
6. The current TOR and SOP will be replaced with the modified approved version on the NBC website; the previous TOR can be maintained as archives on the website

Agenda Item 6: Next NBC Meeting

It was decided that the next NBC meeting will be held in Sindh Province in the first week of June. Dr Saleem Memon will propose the venue of the meeting.

Decisions:

1. The next NBC meeting along with 02 days Bioethics will be held in between 1-5 June 2015 workshops in Sindh.
2. Dr Saleem Memon, will inform the NBC Secretariat regarding the venue of the meeting and the Bioethics workshop.

In the end the Director General Health Services, Government of Azad Jammu & Kashmir gave his concluding remarks. He thanked Dr Farhat Moazam, Dr Huma Qureshi and other members of NBC who came all the way to attend this important meeting. He said that very useful discussions

had taken place in today's meeting. He stated that the Health Department of AJ&K is fully on board and assured his full ownership and support for this very important initiative.

The meeting ended with vote of thanks by Dr. Moazam.

Dr Farhat Moazam
Chairperson HCEC
03 April 2014

Secretary
Ministry of NHR&C