

MINUTES OF THE NATIONAL BIOETHICS COMMITTEE (NBC) MEETING

August 17, 2017 at Quetta

A meeting of the National Bioethics Committee (NBC) was held on Aug 17, 2017, in Gardinia Hotel and Resort Quetta at 2:00 pm. The meeting was chaired by Prof. Dr. Aasim Ahmad, Chair REC, NBC as the Secretary MoNHSR&C could not attend the meeting due to last moment cancellation of flight to Quetta.

Following Members attended the meeting:

1. Dr. Masood Akhtar Nausherwani, Director General Health, Baluchistan
2. Prof. Dr. Aasim Ahmad, Dean and Chief Nephrologist, The Kidney Centre, Karachi
3. Dr. Huma Qureshi, Executive Director, Pakistan Health Research Council/Member Secretary NBC.
4. Prof. Dr. Aamir Mustafa Jafarey, Centre for Biomedical Ethics and Culture, Karachi
5. Prof. Dr. Jamshed Akhtar, Professor and Head of the Department of Pediatric Surgery, National Institute of Child Health, Karachi
6. Dr. Ambreen Munir, LUMHS, Jamshoro
7. Dr. Babar Akram, Representative WHO, Islamabad
8. Dr. Sahibzada Muhammad Khalid, Representative, Director Health Services, FATA.
9. Dr. Farkhanda Ghafoor , Ex-Principal Research Officer, PHRC
10. Dr. Salman Ahmed Tipu, Vice Dean, Isra University, Islamabad
11. Brig ® Razia Ishfaq, Registrar, Pakistan Nursing Council, Islamabad
12. Mr. Abdul Ghani Sasoli, IPH, Quetta
13. Dr. Muhammad Hayat, Focal Person DGHS Baluchistan
14. Dr. Waqar uddin Ahmed, Deputy Director (HSR), PHRC Head Office, Islamabad
15. Dr. Faiza Bashir, Focal Person, NBC Secretariat, PHRC, Islamabad.

Members who were absent

1. Director General Health Services, Punjab
2. President, Supreme Court Bar Association, Islamabad
3. Director General Health Services, KPK
4. Secretary, Health and Population Welfare, Gilgit Baltistan
5. Director General Health Services, AJK

Members who sent their regrets to the NBC Secretariat prior to meeting

1. Prof. Dr. Farhat Moazam, Centre for Biomedical Ethics and Culture, Karachi
2. Maj.Gen ® Salman Ali, Representative CPSP
3. Maj. Gen. Sohail Aziz, Advisor in Cardiology AFIC Rep of Surgeon General/ DG (MS-IS), Pakistan Army.
4. Prof. Dr. Abid Farooqui, Focal Person President PMDC
5. Director General Health Services, Sindh
6. Prof. Dr. Munir A. Saleemi, Lahore University, Lahore
7. Dr. Inayatullah Memon, In charge Department of Bioethics and Medical Education, Indus Medical College, Hyderabad
8. Dr. Saima Pervez Iqbal, Associate Professor, Shifa College of Medicine, Islamabad
9. Dr. Manzar Anwar Khan, Khyber College of Dentistry Peshawar
10. Chief Executive Officer, DRAP, Islamabad
11. Dr. Tariq Mehmood Mian President, Pakistan Association of Family Physicians

The meeting started with recitation from the Holy Quran. Dr Huma Qureshi Member/Secretary welcomed the participants and this was followed by the introduction of the members. Director General Health, Baluchistan, Dr. Masood Akhtar Nausherwani, greeted the members and thanked all for arranging the NBC and bioethics training workshop in Baluchistan.

Agenda Item-1: Approval of the minutes of the last NBC meeting

The member Secretary informed that the minutes of the meeting held in Islamabad on April 25, 2017 were circulated to all attending members and after incorporating their comments the minutes were circulated to all members and no further comments have been received. The members unanimously approved the minutes.

Decision: Minutes were approved.

Agenda Item-2 Briefing on the actions taken on the decisions of the last NBC Meeting.

The members were briefed about the NBC activities along with the status of the actions taken in the last NBC meeting held in AJK on December 22nd 2016.

Agenda Item-2.1: Ex officio members to nominate permanent focal persons:

In response to the letters written by the Ministry to all Ex officio members to nominate one permanent focal person, member secretary informed that all Ex Officio members have nominated their representative except DG KPK and President Supreme Court Bar Association. For KPK nomination, the ministry shall intervene again.

Decision: Secretariat to send a DO letter for KPK secretary to Chair

Agenda Item-2.2: compliance by AKU and Shifa Hospital regarding submission of research projects to NBC:

In response to the letters written by Ministry to Institutions/Organizations/Medical Colleges/Universities that a certain type of projects need to be submitted to NBC, Shifa University and AKU had sent their reservations to which NBC had sent its clarification. It was decided that Dr Aasim Ahmed and Dr Saima Perwaiz who represent these institutions should get a letter of agreement from these institutions.

Responding to this, Dr Aasim informed that this matter had been resolved and now all research projects are submitted to NBC by AKU, however he will see if he can get it in writing as well. Dr Saima was not present so the secretariat will ask her again to get the letter from the institution.

Decision: Dr Aasim will get a written acknowledgement from AKUH while for Shifa, the secretariat will request Dr Saima to get the letter from Shifa.

Agenda Item-2.3: Subcommittee meeting regarding endorsement of “Handbook for Introducing Bioethics to Medical and Dental Students”

Member Secretary informed that for the endorsement of the Handbook for Introducing Bioethics to Medical and Dental Students, the Secretariat contacted Dr Abid Farooqui Vice President PMDC twice. On first occasion he was out of country but on the second time he informed that this matter had been referred to PMDC’s Curriculum Committee. He shall inform PMDC once their decision comes.

Decision: Secretariat to find out the decision from Dr Abid

Agenda Item-2.4: Subcommittee Meeting regarding “Guidelines for ethical interactions between Physicians and Pharma Industry/ Trade”:

NBC has developed above guidelines which need to be implemented through Pharma Bureau (PB) and Pakistan Pharmaceutical Manufacturers Association (PPMA). NBC members therefore met the representatives from PB and PPMA on June 16, 2017 at Kidney Centre Karachi to develop short and long term action points for implementing the above guidelines. The issues highlighted in PPI guidelines like gifts, sponsorships, CMEs and conflict of interest were discussed. PPMA and PB agreed to discuss these issues in their board meeting and give a feedback to NBC in 4-6 weeks.

PPMA and PB also pledged to organize a workshop of heads of different medical associations and institutions to highlight these issues and find a way forward. Moreover it was desired that mapping of institutional committees should also be undertaken by NBC.

Upon contacting at 6 weeks, Dr Naveed from PB informed that they could not have board meeting, therefore they need more time.

Decision: Secretariat should keep contacting them to find out the progress and also workout with the NBC members for holding a workshop of heads of different medical associations and institutions to highlight these issues.

Agenda Item-2.5: Subcommittee meeting with DRAP regarding Clinical Trials:

Member Secretary informed that a meeting of subcommittee of NBC members and DRAP was held on July 5, 2017 at PHRC Head Office. DRAP informed that NBC clearance is mandatory for all drug trials before they are undertaken by the pharmaceutical industry. However DRAP requested that a copy of NBC decision given to any drug trial may be forwarded to DRAP as well, to which NBC Secretariat has agreed.

Regarding the Clinical Trials Registry and disclosure of sponsoring events as stated in PPI Guidelines, DRAP informed that their new Policy is already addressing all the concerns of NBC and policy board decisions will be communicated to NBC soon.

Decision: NBC should send drug trial decision to DRAP too.

DRAP policy board's decision may be inquired by NBC secretariat

Agenda item No 2.6: Progress on Provincial and Regional Bioethics Committees (PBC)

Agenda item No 2.6.1: Progress on PBC Punjab.

Dr Haroon Jehangir Khan has been nominated as the permanent representative of PBC Punjab. Meeting of PBC Punjab was held on July 25, 2017. Minutes of the 1st PBC meeting were shared and circulated.

Decision: Secretariat should ask for the minutes of the meeting of July.

Agenda item No 2.6.2: Progress on PBC Sindh:

Dr Saleem Memon shared the minutes of the meeting held in April 2017 which were circulated to NBC members. Dr Memon has retired from his service and Dr Ali Akbar Dahri has been nominated as new representative of DG Health Sindh. Bioethics Workshop will be held in Jamshoro in Oct/ Nov 2017.

Decision: Secretariat should work with Dr Ali Akbar for organizing the workshop

Agenda item No 2.6.3 Progress on PBC Khyber Pakhtunkhwa (KPK):

The Member Secretary informed that there has been no representation from PBC Khyber Pakhtunkhwa (KPK) and neither permanent representative for NBC has been identified despite two more reminders from Ministry.

Decision: Secretariat to send a DO letter to Chair NBC to write to Secretary Health KPK for nomination of focal person.

Agenda item No 2.6.4: Progress on RBC GB:

Nomination of permanent focal person is awaited. No representative attended the last NBC meeting.

Decision: Secretariat to send a DO letter to Chair NBC to write to Secretary Health GB for nomination of focal person

Agenda item No 2.6.5: Progress on PBC Baluchistan:

Dr. Muhammad Hayat has been notified as permanent representative of DG Health Baluchistan. Their request for Bioethics workshop was entertained with this meeting.

Agenda item No 2.6.6: Progress on FATA:

Secretariat has received multiple requests for training workshop for FATA Regional Bioethics Committee members which shall be decided in this meeting

Decision: secretariat to decide the dates after consultation with members

Agenda item No 2.6.7: Progress on RBC Azad Jammu & Kashmir:

Regional Bioethics Committee of AJK will continue its regular meetings and send minutes to NBC however, despite reminders Secretariat did not receive any progress.

Agenda item 2.7: Bank account of NBC:

In the last NBC meeting it was decided that ministry shall take up this matter with Finance division on how to retain this account and NBC members shall come up with the suggestions on how to utilize this fund and share it with the secretariat.

Matter taken up with up Ministry and Finance division. Some queries were received which are being addressed. Suggestions from members for effectively utilizing the funds were also communicated to Ministry.

However Member Secretary informed that an audit para had been published by Auditor General on this account which was communicated to the Chair NBC.

Agenda item 2.8: NBC Meeting in Islamabad:

Consequent upon the decision of last meeting regarding the rotation of meetings in the Provinces, this time the meeting was held in Quetta.

Agenda item 2.9: NBC Meeting with Foreign Office:

A meeting of the NBC members with Foreign Office representatives was held on July 5, 2017 at PHRC Head office to discuss the amendments suggested in HBM Guidelines by Foreign Office. It was decided that a draft document will be prepared by NBC by incorporating all the amendments and this will be shared with Foreign office. The representative of foreign office will

add certain links to this draft document. The first draft has been shared with foreign office and based on their incorporating links; a final HBM document will be prepared by NBC.

Members were also informed that as the Secretariat has received requests from different bodies like laboratories and institutions/ hospitals for clearance/ approval of export of **non-research** samples. Non research samples do not fall in the domain of NBC, therefore it was decided that NBC will take this issue with Ministry of NHR&C. A letter in this regard has been sent to the Chair NBC the Secretary MoNHR&C to identify the institution that should be tasked to do this work.

Decision: Secretariat should check with foreign office about the position of the HBM document and addition of links.

Secretariat should track the letter written to Chair for identifying institution for giving ethical clearance of non research samples.

Agenda Item-2.10: Review of process and fee structure of amended and extended projects:

It was decided in REC Meeting that fee for amended project will be half of the total fee. Whereas only extension will not be charged any fee. If there is amendment and extension at the same time it will be charged as amendment.

Moreover amendments and extensions will continue with their 1st given NBC serial number with Extensions/ Amendments mentioned in them as giving them a new number creates confusion.

Agenda item 2.11 Election of new members:

Consequent upon decision in last NBC meeting it was informed that the invitations from different institutions from all over the country were invited for two vacant seats and upon calling nominations from NBC members for suitable candidates, the members suggested to defer the process till the next NBC meeting for finalizing the process of election.

NEW AGENDA

Agenda Item-1: Progress of REC:

Prof Dr Aasim Ahmed briefed the members on REC composition and working and explained that in last 8 months 35 new projects were received by REC, of which 22 were approved and 11 are in process. He said that out of 9 REC members; only few are regularly sending their reviews and therefore requested that non responding members to at least respond to the emails or withdraw their memberships.

Agenda Item-2: Progress of HCEC:

As Prof Dr Farhat Moazam was unable to attend this meeting therefore Prof Dr Aamir Mustafa Jafarey presented the progress of HCEC, stating that the "Handbook for Introducing Bioethics to Medical and Dental Students," developed by the HCEC is now available on the net and requested members to endorse this as a teaching tool in their institutions. He mentioned that endorsement from PMDC is still awaited.

Agenda Item-3: Election of new members

As decided in the last meeting the Secretariat compiled a list of vacancies for the elected members and called for nominations from Institutions. However the process was stopped as recommended by the members. Currently there are two vacant seats for which elections shall be held and the weightage to lesser developed provinces and regions and election process shall be same as before. Secretariat will invite the NBC members to send nominations too.

Decision:

Election on the 2 vacant seats shall be held as done last time and mentioned in TORs. Secretariat will email all NBC members to send nominations too.

Agenda Item-4: Progress on Provincial and Regional Bioethics Committees:

4.1 PBC Punjab:

No representative from PBC Punjab could attend the meeting however, Dr Haroon Jehangir Khan from PBC Punjab had sent an information to NBC Secretariat. As per information a meeting of PBC was held on July 25, 2017 and two meetings of REC were held. PBC REC also reviewed a project that was sent to them. Moreover the process of opening a separate bank account is also in process.

Secretariat has also received a request for workshop for PBC Punjab

Decision:

PBC Punjab will share the minutes of the meeting with Secretariat and workshop may be held in consultation with NBC members in the next few months.

4.2 PBC Sindh:

No representative attended the meeting. Regarding raining of PBC members, Dr Ambreen Munir said she is willing to arrange the training if she is kept in the loop of communication

Decision:

Secretariat will contact Dr Dahri the new focal person for holding the next meeting and workshop at Jamshoro and shall keep Dr Ambreen Munir in the loop of communication.

4.3 RBC FATA:

Dr Sahibzada Muhammad Khalid who is also the nominated permanent focal person of RBC FATA, again requested for a workshop for proper functioning of their RBC

Decision:

A workshop will be held specifically for the FATA in September. Secretariat to float the proposed dates the members to enter their availability and decide dates.

4.4: PBC Baluchistan:

Dr Nowsherwani DG Health and Dr Muhammad Hayat thanked NBC for holding the workshop and meeting at Quetta, and hoped that after getting this training PBC Baluchistan will be more active. They expressed their willingness for reviewing projects that come to REC.

Dr Aamir Jafaery raised the concern of training of REC of PBC for foreign funded projects. Dr Aasim suggested that we may send the REC of PBC to review a research proposal in 2-3 weeks while NBC REC will also continue to review it in 6 weeks. Comments from both RECs will be collated as combined comments and communicated to the PI and the provincial REC. This will help in orienting them to this process till they are trained enough to review their own proposals.

Decision:

All the projects that are either foreign funded or are spanning to multiple districts of same province shall be reviewed by REC of that province also. Initially it will be reviewed by NBC REC as well as provincial REC. Once the members of PBC REC are trained enough in reviewing their own projects PBC REC will independently review their proposals.

4.5: PBC KPK and Gilgit Baltistan:

There was no representative from KPK and GB in the meeting.

Agenda Item-5: Dates for the next NBC Meeting:

It was decided that the next NBC meeting will be held in Jamshoro Sindh in last week of Oct/ 1st week of Nov 2017.

Decision:

Secretariat will share the proposed dates and venue of next NBC meeting after consultation with the Chair NBC i.e. Secretary Health.

The meeting ended with vote of thanks from the Chair.



Prof Dr Aasim Ahmed

Chair Research Ethics Committee