

**MINUTES OF 29th QUARTELY NATIONAL BIOETHICS COMMITTEE (NBC)
MEETING
Feb 16, 2018, PC Hotel Peshawar**

The 29th Quarterly National Bioethics Committee (NBC) meeting was held on Feb 16, 2018; in Pearl Continental Hotel Peshawar at 10:00 am. The meeting was chaired by Prof. Dr Aasim Ahmad, Chair Research Ethics Committee as the Secretary MoNHSR&C could not attend the meeting.

Following members attended the meeting:

1. Mr. Muhammad Ali Shahzada, Member Secretary/Executive Director, Pakistan Health Research Council/Member Secretary NBC.
2. Prof. Dr. Farhat Moazam, Centre for Biomedical Ethics and Culture, Karachi
3. Prof. Dr. Aasim Ahmad, Dean and Chief Nephrologist, The Kidney Centre, Karachi
4. Prof. Dr. Aamir Mustafa Jafarey, Centre for Biomedical Ethics and Culture, Karachi
5. (Retd) Maj. Gen Salman Ali, Representative CPSP
6. Maj. Gen. Imran Fazal, Representative Surgeon General Pak Army
7. Prof. Dr. Jamshed Akhtar, Professor and Head of the Department of Pediatric Surgery, National Institute of Child Health, Karachi
8. Dr. Tayyaba Ijaz, Representative Director General Health Services, Punjab
9. Dr. Inayatullah Memon, In charge Department of Bioethics and Medical Education, Indus Medical College, Tando Jam
10. Dr. Saima Pervez Iqbal, Associate Professor, Shifa College of Medicine, Islamabad
11. Dr. Ghulam Murtaza, Focal Person, DGH Services Sindh
12. Dr. Muhammad Hayat Ronjho, Representative Director General Health, Baluchistan
13. Dr. Lamia Mahmoud, Representative, WR, WHO, Islamabad
14. Dr. Muhammad Saleem, Representative Director General Health Services, KP
15. Prof. Dr. Munir A. Saleemi, Lahore University, Lahore
16. Dr. Ambreen Munir, LUMHS, Jamshoro
17. Dr. Salman Ahmed Tipu, Vice Dean, Isra University, Islamabad
18. Mr. Shaikh Ansar Ahmed, Representative DRAP
19. Mr. M. Arif Chaudhary. Deputy Direrctor DRAP, Peshawar
20. Dr. Ghulam Sarwar, Representative HEC
21. Mr. Abdul Ghani Sasoli, Institute of Public Health (IPH), Quetta
22. Dr. Manzoor Ahmed, Representative President Pakistan Association of Family Physicians

23. Dr. Muhammad Ayaz Mustufa, Focal Person NBC, Pakistan Health Research Council, Islamabad
24. Dr. Faiza Bashir, Coordinator NBC, Pakistan Health Research Council, Islamabad.

Members who were absent

1. Representative President, Supreme Court Bar Association, Islamabad
2. President PM&DC
3. Director General Health Services, AJK
4. Dr. Farkhanda Ghafoor , Ex-Principal Research Officer, PHRC
5. Director Health Services, FATA
6. Registrar, Pakistan Nursing Council, Islamabad
7. Secretary Health, Population and Social Welfare, GB
8. Dr. Manzar Anwar Khan, Khyber College of Dentistry Peshawar

The meeting started with recitation from the Holy Quran. Mr Muhammad Ali Shahzada, Member Secretary NBC; welcomed the Members, followed by the introduction of the Members.

Approval of the minutes of 3rd Quarterly NBC Meeting held on Nov 1, 2017:

The Member Secretary informed that the minutes of the last NBC meeting held in Karachi were circulated to all attending members and after incorporating their comments, the draft minutes were finalized and approved by the Chair, Prof. Dr. Farhat Moazam, and circulated to all NBC members.

Decision: The house unanimously approved the minutes of last NBC meeting.

Agenda Item-1: Briefing on the actions taken on the decisions of the last NBC Meeting.

The members were briefed about the NBC activities during the last quarter along with the status of the actions taken on decisions of last NBC meeting.

Agenda Item-1.1: Subcommittee meeting regarding endorsement of “Handbook for Introducing Bioethics to Medical and Dental Students”

Member Secretary informed the committee that regarding the endorsement of the Handbook for introducing Bioethics to Medical and Dental students, Prof Dr. Abid Farooqui, Vice President PMDC/ Focal Person for NBC, was contacted wherein he informed that endorsement of the document is only possible when PM&DC Curriculum Committee will meet under stable legal environment. Once the committee meets, PMDC will inform NBC over the progress on the issue.

Agenda Item-1.2: Subcommittee meeting regarding implementation of “Guidelines for ethical interactions between Physicians and Pharma Industry/ Trade”:

Subsequent to the meeting of NBC members (Dr. Aasim and Dr. Moazam) with stakeholders from Pharma Bureau and PPMA on the subject matter in June 16, 2017 at Karachi, it was agreed upon that, an orientation session is needed for the stakeholders from Trade and Industry to sensitize them on guidelines developed by NBC. In this regard, the liaison with Pharma Bureau was established. However due to the change in the leadership of PPMA the process got stuck at their end. Focal person NBC; met the new chairperson PPMA on Feb 14, 2018; wherein new Chairman PPMA agreed to coordinate with Pharma Bureau regarding the session. Once finalized NBC members will be intimated.

Agenda Item-1.3: Subcommittee meeting with DRAP regarding Clinical Trials:

Consequent upon the decision of 27th and 28th quarterly NBC meeting; Secretariat inquired the DRAP policy board's decision regarding the Establishment of clinical trials registry as well as obtaining the ethical clearance for all the drug trials from NBC. It was communicated to the Secretariat by Mr Sheikh Ansar, Director Pharmacy Services DRAP, that the issue has been addressed in the form of "Revised Bio-Study Rules 2017" which are being presented in Cabinet for approval. Once approved, Rules will be shared with NBC for information.

Agenda Item-1.4: PBC Punjab:

Pending request for training workshop for PBC Punjab will be entertained with upcoming NBC meeting in Punjab in the next quarter.

Agenda Item-1.5 Sever based domains:

It was informed that the process for server-based domains and linking of PBCs with NBC has been initiated for NBC and its subcommittees initially; it will be extended for PBCs in next phase.

Agenda Item-1.6: PBC Sindh:

The proposed dates received from the DG Sindh office for the pending training workshop are between March 19-23, 2018. To this, the members of NBC including facilitators after having discussion, proposed the training in 1st week of April 2018. Secretariat will coordinate with DG office and HCEC for the details.

Decision:

1. The training workshop will be held in 1st week of April. Secretariat will circulate the dates and coordinate with Dr Ghulam Murtaza the focal person for NBC.

Agenda Item-1.7: PBC Baluchistan:

Consequent upon the decision of the NBC meeting Dr. Muhammad Hayat Rhujio, Focal person NBC, forwarded the proposed curricula/policy draft doc to NBC which was circulated to all NBC members. Some of the members submitted their concern over the document and its content. To resolve this, a meeting with Curriculum Development Core Committee was proposed by

Member Secretary which was held in Center of Biomedical Ethics and Culture (CBEC), Karachi on Feb 10, 2018.

Agenda Item-1.8: Amendments in Human Biological Material Transport Guidelines proposed by Foreign Office:

Member Secretary informed that the final draft containing the proposed amendments is with REC for its consideration and finalization.

Agenda Item-1.9: Export of Non-Research Human Biological Materials:

Regarding the issue of identifying institutions for giving ethical clearance for the export of non-research human biological material the Secretariat had communicated the concern of NBC that the matter does not fall under the ambit of NBC as it is advisory body only therefore, it may be dealt with by Ministry of Foreign Affairs and Provincial Governments. Member Secretary stated that the Secretary agreed to the proposal from NBC and the matter is referred to the Ministry of Foreign Affairs.

Agenda Item-1.10: Secretarial Structure:

Consequent upon the decision of last NBC meeting where in it was proposed that a proper secretarial structure will be put in place, the Member Secretary informed the house that it has been reorganized and shall soon be notified and communicated to members.

Agenda Item-1.11: Election of new NBC Members:

It was decided in the last meeting that for holding elections against two vacant seats in NBC, the Secretariat had to compile a one-page summary from the CVs of nominations, but as a result of retirement of ED PHRC/ Member Secretary and induction of new Focal Person, Chairs of the Subcommittees of NBC suggested that this issue may be discussed afresh in the Peshawar meeting. Therefore, this process was deferred for discussion in this meeting.

Agenda Item-1.12: Regional EMRO Summit on Bioethics:

Member Secretary informed that the Secretariat is working on the financial implications of the summit and proposal will soon be submitted for approval to Ministry.

Agenda Item-2: Update on HCEC:

Dr. Farhat Moazam; Chairperson HCEC, briefed the members on the activities of the committee in 1st quarter of 2018.

1) She stated that a long-requested workshop for FATA along with KP was conducted on 13-14 Feb just ahead of the NBC meeting. It was interactive with good participation from KP and FATA both physically and intellectually, and a useful experience for both participants and facilitators. However, she made a point that from PBC KP, only 11 out of 19 members participated in the workshop. She also expressed her concern over the multiple changes in PBC membership due to frequent changes in DGs of provinces. This meant that in effect, with every ethics workshop HCEC runs facilitators are engaging with completely new groups of participants

from a province (as was the case for the KPK PBC). In her opinion, this remains the primary reason why NBC has not been able to make an impact on the ground in the provinces so far, and neither have the ever changing PBCs been able to accomplish much. For efficient working of PBCs at least some continuity in terms of trained members should be maintained even with the change of a DG.

2) She then updated the house on the meeting, held in CBEC on Feb. 10, of NBC-HCEC members (Dr. Aamir and herself) and NBC focal person (Dr. Ayaz) with Baluchistan PBC members who are serving as the Curriculum Committee of Baluchistan. The Baluchistan delegates included Drs. Hayat (NBC focal person), Ghulam Rasool, Saeedullah, and Mr. Fahim (Director Nursing, Baluchistan). The objective of the meeting was to discuss the draft document Baluchistan PBC had submitted to NBC, “Professional Ethics and Morality Curriculum,” and provide help in improving it. The draft was discussed in detail and following suggestions made, and agreed on, for revision of the document. The curriculum should focus on medical and dental students, its content should be relevant to Pakistan, material from other sources should be clearly referenced/acknowledged (to avoid charges of plagiarism), and well referenced. Mr. Fahim expressed an interest in developing a curriculum for nurses and paramedics and was encouraged to do so.

Dr. Moazam expressed her surprise that none in the Baluchistan delegation seemed aware of the document developed by HCEC for national use - “Guidelines and Teachers Handbook for Introducing Bioethics to Medical and Dental Students.” She was concerned over the ignorance of PBC members about a document prepared and endorsed by NBC over a year ago and emphasized that the Secretariat must take appropriate steps to remedy this problem. Baluchistan team was provided hard copies of the doc and advised to use it as a template for what they were developing, and which they agreed to do. They were also advised to review ERC guidelines on the NBC website as they are also in the process of developing this aspect for Baluchistan. It was also suggested to Dr. Hayat that he consider sending nominations for CBEC’s Certificate Courses to be held in 2018; he said he would like to do so as this would help build capacity in Baluchistan.

Overall, HCEC members were impressed with the commitment and seriousness of the Baluchistan PBC members and their efforts to advance bioethics in their province. They were reassured that NBC was willing to help them achieve this.

3) Regarding the issue of holding the once cancelled ethics workshop for PBC Sindh, it was decided that will be re-scheduled for the first week of April 2018, in Jamshoro.

Agenda Item-3: Update on activity of REC:

Prof Dr. Aasim Ahmed, Chairperson REC, briefed the members on REC, its composition working and status since January 2018. REC has received 07 new projects for review and all of them were in process. He also informed that Dr Salman Ahmad Tipu, has rejoined as a member of REC. Again, expressing his concern regarding the increasing load of projects for review with

fewer number of reviewers available, he again extended a call to NBC members to join REC as reviewers.

Agenda Item-4: Update from the representatives of Provincial and Regional Bioethics Committees (PBC)

a. PBC Punjab:

Dr. Tayyaba Ijaz briefed the house that since its establishment the PBC has met twice. Advocacy has been initiated for the establishment of IBCs in Punjab. PBC Punjab has a functional REC which has reviewed one research project. It is planning to have a bank account for its activities especially the fee for project review. PBC Punjab is also planning to write to all medical institutions to consolidate information on existing IBCs/IRBs but its Performa is yet to be designed. She further mentioned that upon demise and retirement of certain members, new members have been inducted for which a training workshop is needed.

To the issue of having a fee for review at a stage where RECs of PBCs are not fully mature; house was split in opinion whether to charge fee or not. After quite long deliberations on pros and cons, the Chair suggested that it's the internal matter of every province/ region to fix any charges or not. Therefore, they shall decide the way forward for themselves at their own.

Decision:

1. Next NBC meeting is in Punjab which will be followed by training for their PBC members.
2. Every region/ province shall decide about having the fee structure for reviewing research proposals.

b. PBC Sindh:

Dr Ghulam Murtaza, Focal Person from Sindh informed that PBC Sindh met on 9th Feb, 2018. In that meeting it was requested that NBC be requested again to hold the training workshop for PBC Sindh and suggested that for sensitizing the DG Health over the mechanism of operation of this committee especially the financial matters a representative from NBC Secretariat may be nominated for a meeting. To this Member Secretary and Chairperson suggested that the best advocate is the focal person himself; however, NBC representative can meet if requested formally by PBC.

Budget allocation for the upcoming workshop was also requested by focal person to which it was made clear that all the training workshops till now are sponsored by NBC.

Dr Jamshed member NBC and also a member of PBC Sindh, stated that till now PBC Sindh has no allocated budget to organize its activities and members are to bear their own expenses which is not practically possible if PBC has to be fully functional and has to meet repeatedly.

Decision:

1. NBC representative will meet with the DG Health Sindh for sensitizing him over allocation of funds for PBC and making it a regular activity of the health department.
2. Training workshop for PBC Sindh will be held in the first week of April 2018.

c. PBC Khyber Pakhtunkhwa (KP):

Dr Muhammad Saleem focal person for KP briefed the house that their PBC is yet to meet for the first time. However, he hoped that the day's training conducted before NBC meeting will prove to be useful in terms of revitalizing the PBC.

d. PBC Baluchistan:

Dr Muhammad Hayat Rujhio focal person for NBC from Baluchistan briefed on the activities of PBC Baluchistan that included, the establishment of Institutional ERCs at various institutes in the Province. Further he informed that the curriculum committee was briefed by NBC members in a meeting at CBEC SIUT in Karachi and is now working on restructuring of the curriculum. Baluchistan PBC will reorganize Curriculum for Nursing and paramedics in accordance to the guidelines of NBC.

Member Secretary raised a concern over the reporting system of the PBCs in NBC meetings. He suggested that a certain criterion shall be laid down for them to report their activities in NBC meetings with specified targets and timelines to monitor their progress. This suggestion was appreciated and agreed upon by the house.

Agenda Item- 5: Code of Ethics for interaction on social media

Dr Saima Perwaiz Iqbal Member NBC, briefed the committee on need for Social Media Guidelines for Health Care Professionals in Pakistan; the need of which arose after a doctor was fired for making an attempt to interact with his patient on the social media. She informed the house that internationally many guidelines/ codes of conduct deliberate on this issue in terms of benefits and risks of social media, professionalism, code of ethics and code of conduct, patient privacy and confidentiality, informed and mutual consent. As Social media has gained much popularity in Pakistan, this is high time that we should think and make efforts if we require any such codes. The house unanimously agreed to developing certain code of ethics for guiding or healthcare practitioners regarding interaction on social media. For this the Chair suggested tasking a subcommittee of NBC members for which call was extended to help Dr Saima take the issue forward. The subcommittee was constituted by voluntary participation from Dr Saima, Dr Salman Tipu, Dr Lamia, Dr Inayat and Dr Aamir Jafaery. It was further agreed that member/ members can be coopted at any stage of developing the code of conduct.

Decision:

1. The subcommittee will present its progress in next NBC meeting.

Agenda item- 6: Revamping the election process for new members:

Member Secretary briefed the house that the current election process requires its structural mechanism and proper formalization to enhance the scope.

He reiterated that Ministry is very receptive towards the issues of NBC and now efforts shall be first directed towards formalizing NBC to have a legal framework.

As a way forward, he proposed a two-pronged approach; as a short-term plan NBC shall continue with the currently laid down mechanism for electing its new members, while on other hand efforts shall be directed towards formalization of the process. Chairperson appreciated the strategy and suggested that for the current election a one-page summary containing the information of nominees with clear directions regarding voting process shall be circulated to the members soon.

Decision:

1. Secretariat will prepare and circulate a one-page summary of all the nominations received for the information of members with clear directions regarding voting till March 14, 2018.
2. Secretariat will work towards formalizing the NBC and its various processes.

Agenda Item-7: EMRO Regional Summit of National Ethics / Bioethics; Pakistan 2019:

Prof. Dr. Aasim Ahmad briefed the house on the intend of Pakistan to host the 2nd Regional EMRO Summit; wherein he mentioned that Pakistan has the opportunity to bid for 2019. For this the formal approval from Prime Minister's office needs to be sought on which Secretariat is working already. Members will be intimated once Secretariat gets any response from PM office. To this Dr Moazam stated that WHO Office needs to be intimated after this NBC meeting. Member Secretary informed the chair that at least 4-6 weeks' time is expected for the response. Dr Lamia made a request that WHO Country office (WR WHO) may be kept in correspondence on the subject matter and its progress which was agreed upon.

Agenda Item-8: Ethical Criteria for Pharmaceutical Regulations; 2017 and Revised Bio-Study Rules 2017 by DRAP:

Sheikh Ansar the Director Pharmacy Services DRAP; briefed the committee that the new proposed legislation under consideration addresses and facilitate ethical interaction by companies having marketing authorization. These regulations bind the pharmaceutical industry to conform with the high standards of product, provide scientifically valid data, respect confidentiality of patient information and abstain from exaggeration of product information.

These regulations aim at making sure that decision making is in the patients' best interest, public confidence in medical device and diagnostic industry is increased, access to safe and effective use of medical technologies is ensured and a culture of transparent business environment is

promoted. He further informed the house that revised Biostudy rules addressing the concerns of NBC over clinical trials and their registration are addressed. The same is in cabinet for approval and once approved the rules will be made public.

The Chairperson appreciated the efforts of DRAP towards regularization of pharma trade and industry. He raised his concern, which was supported by other members that there is no mention of any limit in these regulations on the allocated budget for Research and Education. These regulations also do not set the limits of budget for “Corporate Social Responsibility”. There exist certain loop holes in these regulations whereby pharma companies take the advantage and have unethical interactions with physicians. He further stated that despite the Secretariat shared the Pharmaceutical Regulations the members have not reviewed these regulations; and Revised Biostudy Rules 2017 also need to be shared. He suggested that these documents may be shared with NBC members for review and comments. The coalited response from NBC may then be communicated to DRAP for addressing in draft of regulations.

Decision:

1. Secretariat will recirculate the Ethical Criteria for Pharmaceutical Regulations; 2017 to all NBC members for their review and comments.
2. DRAP will share the Revised Biostudy Rules 2017 with NBC once approved from Cabinet.

Agenda Item-9: Formalization of NBC:

Member Secretary stated that since its inception NBC has performed its advisory role in its true spirit which is evident by the development of many essential sets of guidelines on issues pertaining to Bioethics.

For its working though, the TORs and SOPs are developed but they are not Gazette notified. Members list is also not updated in notification. For induction of new members, it conducts the election process which also has no legal standing. NBC charges fee for its review and that is helpful in self sustainability of the Committee but being only a gazette notified body does not give a legal cover for all NBC’s activity. As the body is gaining prominence with each passing day it is very important to formalize it in proper legal framework.

The suggestion of Member Secretary was much appreciated for its importance and relevance by all the members and the Chairperson; and it was agreed upon that Secretariat will contact law division for formalizing the status of NBC.

Decision:

1. Secretariat will draft a summary for consulting the Law division regarding the formalization of NBC and its processes.

Agenda Item-10: Dates for the next NBC Meeting:

The next NBC meeting and the training workshop for PBC will be held in Punjab in last week of April/ 1st week of May 2018.

Decision:

1. Secretariat will suggest a couple of dates of next NBC meeting after consultation with Secretary Health. Members expressed a preference for the last week of April 2018.

Agenda Item- 11: Any Other Business:

1. Focal Person Ministry:

Member Secretary appreciated that NBC is making all out efforts to develop appropriate linkages with other state organs to play its effective role in implementation of bioethical codes. We believe this purpose can be served in a better and effective way with the involvement of Ministry in this process.

Therefore, Secretariat has a plan to propose nomination of a Focal Person within the Ministry for enhanced collaboration to oversee the activities of NBC; and be a direct link between NBC and other stakeholders. The Chairperson appreciated this suggestion and all members unanimously agreed to the suggestion.

Decision:

1. Secretariat will write to Ministry for nominating a permanent focal person

2. Annual report:

Member Secretary also made it a point that as NBC is a viable body with quarterly meetings trainings and developments in the form of advisories; it is the time to consolidate the yearly activities in the form of an annual report for presentation to Ministry and other stakeholders.

Decision:

1. The Chairperson appreciated this suggestion and it was agreed that the Secretariat will draft an annual report for the year 2017 and share it with members for review.

The meeting ended with a vote of thanks.



Prof. Dr. Aasim Ahmad

Chairperson HCEC

Member NBC