

MINUTES OF 2nd QUARTELY NATIONAL BIOETHICS COMMITTEE (NBC) MEETING

**May 11, 2018; Faletti's Hotel
Lahore**

The 2nd Quarterly National Bioethics Committee (NBC) meeting was held on May 11, 2018; in Faletti's Hotel Lahore at 10:00 am. The meeting was chaired by Prof. Dr Farhat Moazam; Chairperson Healthcare Ethics Committee as the Secretary MoNHSR&C could not attend the meeting.

Following members attended the meeting:

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1. Mr. Muhammad Ali Shahzada, Member Secretary/Executive Director, Pakistan Health Research Council/Member Secretary NBC.
2. Mr. Shahzad Nawaz Cheema, Joint Secretary, M/o NHSR&C, Islamabad.
3. Prof. Farhat Moazam, Center of Biomedical Ethics and Culture, Karachi.
4. Prof. Dr. Aasim Ahmad, Dean and Chief Nephrologist, The Kidney Centre, Karachi.
5. Prof. Dr. Muhammad Tayyab, Representative CPSP.
6. Prof. Dr. Jamshed Akhtar, professor and Head of the Department of pediatric Surgery, National Institute of Child Health, Karachi.
7. Dr. Abdul Majeed Akhtar, Chairperson REC, Punjab.
8. Dr. Inayatullah Memon, Incharge Department of Bioethics and Medical Education, Indus Medical Colleg, Tando Jam.
9. Dr. Saima Perwaiz Iqbal, Associate Professor, Shifa College of Medicine, Islamabad.
10. Dr. Abdul Aziz Thebo, Representative DGH Services, Sindh.
11. Dr. Manzar Anwar Khan, Khyber College of Dentistry, Peshawar.
12. Dr. Muhammad Hayat Ronjho, Representative Director General Health, Baluchistan.
13. Dr. Jamshaid Ahmed, Representative WHO, Lahore.
14. Prof. Dr. Munir A. Saleemi, University of Lahore.
15. Dr. Khawaja Tahir Aziz, Focal Person, DGH Services, AJK.
16. Mr. Ehsan Ali, Focal Person, Secretary Health, Gilgit Baltistan.
17. Dr. Ambreen Munir, LUMHS, Jamshoro.
18. Dr. Salman Ahmed Tipu, Vice Dean, Isra University, Islamabad.
19. Dr. Sheikh Akhtar Hussain, CEO DRAP, Islamabad.
20. Dr. Amjad Hussain, Representative HEC, Islamabad.
21. Mr. Abdul Ghani Sasoli, Institute of Public Health (IPH), Quetta.
22. Prof. Tariq Mahmood Mian, President Pakistan Association of family Physicians.
23. Dr. Farkhanda Ghafoor, Ex-Principle Research Officer, PHRC.

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

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

1. Dr. Qibla Ayaz, Chairman, Council of Islamic Ideology, Islamabad.
2. Dr. Aamir Mustafa jafarey, Centre for Biomedical Ethics and Culture, Karachi.
3. Maj. Gen. Imran Fazal, Nominee Surgeon General Pakistan Army.
4. Dr. Jawad Habib Khan, Director Health Services, FATA Secretariat, Peshawar.

Members who were absent.

1. President, Pakistan Medical & Dental Council (PM&DC), Islamabad.
2. Representative President, Supreme Court Bar Association, Islamabad.
3. Registrar, Pakistan Nursing Council (PNC), Islamabad.
4. Director General Health, Khyber Pakhtunkhwa.
5. Chairman PPMA, Islamabad.

Mr Muhammad Ali Shahzada, Member Secretary NBC; welcomed the Members which was followed by the introduction of the Members.

Agenda Item-1 Approval of the minutes of 2nd Quarterly NBC Meeting held on Feb 16, 2018:

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

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

Agenda Item-2: 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.

2.1: PMDC Endorsement, for NBC “Guidelines for Introducing Bioethics to Medical and Dental Students and Handbook”

Member Secretary informed the committee that regarding the endorsement of the Guidelines and Handbook prepared by HCEC to help introduce bioethics to Medical and Dental students, there is no progress reported from PM&DC despite repeated contacts. One of the development is that Secretariat presented the case to the Secretary MoNHSR&C to take this issue to their next Adhoc Committee meeting to expedite the process.

Dr. Moazam debriefed members about a possible positive development with PMDC reported through another avenue. Dr. Ayesha Rauf of the National University of Medical Sciences

(NUMS), Rawalpindi in an email to Dr. Aamir (forwarded to Dr. Moazam) states that the VC of NUMS, who is a member of the current PMDC Executive Council to bring about reforms, has read and “appreciated” the HCEC document. Apparently a PMDC medical education committee has been formulated and the doc is to be presented to it and “then to the Council for endorsement.” Dr. Rauf has also emailed Dr. Moazam with an invitation for HCEC and NBC members to visit NUMS.

Dr Jamshed also informed the house that in a meeting of Medical Journal’s Editors the issue of the endorsement of this document came up and Maj Gen Imran and Maj Gen Aslam expressed their keen interest.

2.2: 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 and they extended their willingness whereas despite repeated contacts with PPMA there is no clarity on their will to hold it and thus the process is pending at their end.

2.3: Clinical Trials Registry:

It was informed by the Member Secretary that the issue of clinical trials registry 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. This was endorsed by the CEO DRAP Dr Sheikh Akhtar Hussain.

2.4: PBC Punjab:

The requested training workshop for PBC Punjab was carried out on May 9-10, 2018.

It was also decided in the last meeting that every region/ province will decide about having the fee structure for reviewing research proposals and will inform the Secretariat however, no progress from any Province/ Region is received in the Secretariat.

2.5: Server based domains:

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 and members will be notified once it is done.

2.6: PBC Sindh:

Upon request from DG Office Sindh; NBC representative met with the DG Health Sindh and consequently the Secretary Health Sindh for sensitizing them over allocation of funds for PBC and making it a regular activity of the health department. The concerns were communicated to

Secretary via a letter also and DG Office was requested for the follow up. It was further informed that the training workshop for the members of PBC Sindh was delayed and next dates will be circulated once Secretariat receives the request from DG Office.

2.7: PBC Baluchistan:

Consequent upon the decision of the meeting of NBC representatives with Baluchistan Curriculum Committee members that PBC will reorganize the Curriculum for Nursing and paramedics in accordance with the guidelines of NBC it was informed by the Focal Person that their committee met on April 26, 2018 in which the draft for nurses and paramedics along with ERC Application form was revised and shared with Secretariat which was forwarded to the chairs of NBC Subcommittees for review and suggestions.

On the issue of developing certain benchmarks for the provinces to report their progress on the member Secretary informed that the “progress indicators” list was developed by Secretariat and reviewed by the Chairs of subcommittees which were then circulated to the PBCS/ RBCs for compliance.

2.8: Amendments in Human Biological Material Transport Guidelines:

Member Secretary informed that the final draft from REC has been received in Secretariat and is being finalized there.

2.9: Secretarial Structure:

Consequent upon the decision of last NBC meeting; it was informed that secretarial structure & TORs have been finalized and notified with addition of Focal Person for NBC the Joint Secretary MoNHSR&C. These will be circulated to members soon for information.

2.10: Election of new NBC Members:

Member Secretary informed that the process of formalization of NBC has already been initiated with consultation from Law Division therefore, it is proposed that the new members may not be elected till this process is finalized. This suggestion was endorsed by the members.

2.11: Regional EMRO Summit on Bioethics:

The Member Secretary informed the house that the proposal for holding the EMRO regional Summit was approved by Prime Minister with a supplementary Grant of 10 Million. The bid was offered to EMRO office which has been accepted. Therefore, the Second EMRO Regional Summit will be held in Pakistan in Nov 2019.

2.12: Formalization of NBC:

Regarding the formalization of NBC, the law division was consulted, and it was proposed that the NBC may be gazette notified again with its TORs to resolve the issues related to its status and working. For this member Secretary proposed that if a subcommittee can look at the TORs and draft them for notification. To this the Chairperson suggested that the initial draft may be prepared by the Secretariat then Dr Aasim Ahmad and herself can review and comment on that.

Decision:

1. Secretariat will draft the TORs for NBC and its subcommittees for gazette notification and share them with the chairs of subcommittees for review before getting them notified.

Agenda Item-3: Update on HCEC:

Dr. Farhat Moazam, Chairperson HCEC, debriefed members about the Lahore bioethics workshop for PBC Punjab conducted on the two days, May 9-10, preceding the NBC meeting. Through efforts of the Punjab PBC Secretary, Dr. Jehangir, the workshop was held in an academic institution, the historic Patyala Block of KE University, with excellent facilities. In her opinion, all future workshops should be organized within academic institutes rather than in hotels.

In her report Dr. Moazam stated that a total of 19 people attended both days and the sessions were very interactive with good caliber of discussions by participants. The majority of them however were not PBC members (only 6) but folks invited from PHRC, some individuals with formal ethics education, and other interested healthcare professionals. She had suggested to the PBC Secretary and members that to enhance their functioning they should consider co-opting some of the interested workshop participants into PBC especially those with formal ethics education in the past.

Following this, Dr. Moazam highlighted major concerns, shared by the facilitators, about the experience of organizing and running the Lahore PBC workshop. She said that these problems characterize all bioethics workshops that are organized primarily to train and educate PBC members. For Lahore, the list of PBC Punjab members was provided very late, and of the 18 listed PBC members only 6 attended the workshop (additionally, Drs. Natasha and Farkhanda served as facilitators) reflecting a complete lack of interest. In addition, the (frequent) change in provincial DGs has meant that HCEC faces a brand-new set of PBC members each year. In reality therefore, although these workshops have been organized with each NBC meeting for almost 5 years, it has been an exercise in futility. There appears to be little if any provincial impact despite the time, effort and finances involved in each workshop.

Under these circumstances HCEC will no longer feel obligated to routinely offer bioethics workshops with each NBC meeting. Dr. Aasim agreed with this opinion as did most members. It was decided that henceforth requests for bioethics workshops will be initiated by the provincial DG Health office and not by the NBC. The request will be sent by the DG office to the NBC Secretariat accompanied by a list of PBC members at least 6 weeks ahead of proposed dates. The attendance of workshop participants will be assured by the DG office.

Decision:

1. Bioethics workshops for PBC will not be routinely offered concomitant to NBC meetings. Relevant DG Health Office/ Secretariat of PBC will initiate request for a workshop and send this to the NBC Secretariat with a list of PBC members at least 6

weeks prior to proposed dates. The DG office will be responsible for assuring attendance of PBC members in the workshop.

Agenda Item-4: Update on activity of REC:

Prof Dr. Aasim Ahmed, Chairperson REC, briefed the members on REC working and status since January 2018. REC has received 19 new projects for review. Of those 07 were approved already, 03 proposals were limited to Punjab only and were sent to PBC Punjab. He appreciated the REC Members for their voluntary efforts in reviewing the increasing number of proposals.

Agenda Item-5: Update from the representatives of Provincial and Regional Bioethics Committees (PBC/ RBCs)

a. PBC Punjab:

Dr. Abdul Majeed Akhtar, Chair REC - PBC Punjab; briefed the house about the activities of PBC Punjab which was first notified on March 14, 2014; with the two subcommittees REC and HCEC notified on February 25, 2015. The Directorate General Health Services, Punjab serves as the Secretariat. Currently comprises of 18 members and 02 Vacant seats. No funds allocation for its routine activities however, various options are under consideration. Their initial meeting was to be held on biannual basis, but quarterly meetings are proposed now. A dedicated website is launched 2nd May 2018.

He further stated that the PBC Punjab plans to register & train the IRBs in the Province and drafting the guidelines/proforma/mechanism for research studies. The proposed fee structure and timelines are Rs. 10,000 within 06 weeks. The online submission process is also proposed.

It is further proposed that the Members of the HCEC of PBC Punjab will visit two institutions each month e.g. a public sector and private sector to; establish the linkages, advocate the establishment of IBCs, provide technical support and arrange necessary orientation trainings of the IBC members.

a. PBC Sindh:

Neither the DG nor the Focal Person could attend the meeting and PBC Sindh was represented by Dr. Abdul Aziz Thebo, Representative DGH Services, Sindh. It was informed to the house that upon the recommendation of PBC itself under the Chairpersonship of Dr Ambreen Munir PBC/ NBC Member; the membership is revised and sent to the Secretary Health office for notification. Dr Ambreen pointed out that no formal meeting was held it was just a discussion with Focal Person and the notification issue is not in her knowledge which proves that there is a lot of disconnect between the PBC and DG Office Sindh.

It was also informed that a sensitization meeting was held with DG Health Sindh, Member Secretary and Coordinator NBC regarding the issues in functionality of PBC Sindh. NBC Secretarial team also met with the Secretary Health for the same. PBC plans to hold the due workshop for orientation of PBC Sindh Members after Eid-ul Fitr.

To the issue of ineffective PBCs the member NBC Dr Ambreen pointed out that one of the major issue is lack of ownership from the DG Office. Responding to this Member Secretary made a point that id PBCs invite the DG or Secretary for the PBC meeting formally every time they meet it will raise their sensitivity levels and will pave a way for the increased ownership.

Decision:

1. Training workshop for PBC Sindh will be held after Eid-ul Fitr and Secretariat will organize it once we receive a new request from DG Office Sindh.
2. PBCs shall formally invite the Director General Health or the Secretary Health for the PBC meetings every time they meet to raise their sensitivity levels.

b. PBC Baluchistan:

Dr Muhammad Hayat Rujhio, focal person for NBC from Baluchistan briefed on the PBC Baluchistan which was first established in 2015 and re-notified in 2016. Its subcommittees REC and HCEC were notified in 2017. Till date PBC met for 06 times. Two orientation workshops were arranged by NBC- HCEC for PBC Baluchistan. PBC Baluchistan has developed a Bioethics Curriculum document for nurses and Paramedics and a draft has just been forwarded to NBC Secretariat. The Secretariat has sent the document to Dr. Moazam and Dr. Aasim, Chairpersons of Subcommittees for their review and suggestions and comments. Dr. Moazam requested that a copy also be sent to Dr. Aamir Jafarey as he has been involved in this before. Once finalized it will be shared with PBC Baluchistan.

As far as a bioethics curriculum for medical students is concerned, the Baluchistan PBC has decided to work with the HCEC Guidelines to introduce bioethics to undergraduates and the accompanying Handbook.

Their short-term plans include Guidelines/Performa for Ethics Review of Research Proposal, Curriculum document for nurses and paramedics finalization and notification along with registration their IRBs operational in Baluchistan. They also plan to develop a mechanism for submission of research studies have a proper fee structure and defined review mechanism for ethical review of research studies.

The chair appreciated the progress of PBC Baluchistan and the fact that they are meeting regularly and have the progress to report. It was suggested by her that Mr. Abdul Ghani Sassoli is from Baluchistan and Member of NBC as well therefore the curriculum for nurses and paramedics developed by PBC should also be forwarded to him for his input.

Decision:

1. The Secretariat will forward a copy of the Balochistan PBC bioethics curriculum for nurses and paramedics to Mr. Abdul Ghani Sassoli.
2. A copy of the same curriculum will also be sent to Dr. Aamir Jafarey for his review.

RBC AJK:

Dr Khawaja Tahir Aziz represented the RBC of AJK. He stated that although he has retired but no new Focal Person is nominated by AJK therefore he had to attend this meeting. There is no progress to report as there was no meeting, no allocation of funds and severe lack of ownership from regional health directorate. To a question for the allocation of funds from NBC it was made

clear to the Focal person that it's the domain of Provinces/ Regions if they wish their PBCs to continue with its activity.

Gilgit Balitistan:

The Focal Person of GB stated that due to lack of any Medical College/ University there is no RBC in Gilgit and hence reporting on Indicators is not applicable.

Decision:

1. All PBCs shall work towards strengthening their HCECs, shall start trainings and develop guidance documents.
2. All RECs of PBCs shall define their TORs along with their processes for review and fee structures.
3. PBCs shall Coopt the members who shall be trained in Bioethics. The criterion for coopting shall be laid down by a subcommittee of NBC members.

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

Dr Saima Perwaiz Iqbal, Member NBC, briefed the committee that the subcommittee deliberated upon the content based on the scooping review from guidelines and literature from around the world. The Subcommittee agreed that the Guidelines by the NBC need to be developed for Health Care Professionals (Doctors, Nurses, Physiotherapists, Pharmacists, Paramedics etc) of Pakistan on interacting with patients through social media for which the social media shall be defined to share information, ideas, personal messages and other content. It should also deliberate upon the benefits and risks of using social media. The code of conduct shall address:

- Appropriate conduct and professional boundaries
- Respect for persons, patients and colleagues
- Patients' trust in health care profession
- Privacy and Confidentiality of Patient Data
- Disclosure of information
- Exploitation against patient vulnerability (esp. if advertising)
- Conflict of interest of health care professionals

The efforts of the subcommittee were highly appreciated by all members and the Chair. It was suggested that a draft contain the agreed points may be prepared by the subcommittee and shared with members before the next NBC meeting. It shall be deliberated upon as a separate agenda item in the next NBC meeting.

Decision:

1. A draft will be prepared by the subcommittee and shared with members before the next NBC meeting. It shall be deliberated upon as a separate agenda item in the next NBC meeting.

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

Prof. Dr. Aasim Ahmad briefed the house on the content of the Bioethics Summits held previously with the aim to orient the members on the content of the upcoming Summit in Pakistan. It was discussed and agreed that a subcommittee may be formulated to work on the content of EMRO Summit and present a lay out in the next meeting. It was suggested by the Member Secretary that the logistic arrangements for the summit may be housed within the Ministry for efficiently arranging the event.

Decision:

1. A subcommittee comprising of NBC Members needs to be formulated to work on the agenda and content of upcoming Summit and shall come up with a draft plan in next NBC Meeting.
2. Prof Dr Aasim Ahmad will present the draft agenda and contents in upcoming NBC meeting.

Agenda Item-8: Ethical Marketing to Healthcare Professionals Rules (2018):

Dr Sheikh Akhtar Hussain, CEO DRAP presented the revised regulations 2018 of DRAP regarding “Ethical Marketing to Healthcare Professionals Rules”. He briefed the committee that the purpose of these regulations is to bring transparency in interaction between healthcare professionals and Pharma industry by restricting the unethical prescribing practices especially excessive obliging and gifting. Documentation of agreements, related reports, invoices etc. To bring transparency in industry sponsored tour / conferences.

Among salient features he mentioned that regulations address the legal provision for implementation of ethical practices and defines conditions for industry to outsource the promotional activities, grants and donations, organizing educational conferences, business meetings and provision of medical technologies through third party settings.

The Chairperson and all members appreciated and congratulated the CEO of DRAP for the valuable and much needed regulations.

Agenda Item- 11: Any Other Business:

1. Election for new members:

Member Secretary briefed the house that the current election process requires its structural mechanism and proper formalization to enhance the scope. Efforts towards formalizing NBC have been initiated and the process of election will be held afterwards.

Decision:

1. Secretariat will hold the election process after the formalization of NBC is finalized.

2. Annual Work Plan:

Member Secretary pointed out that its 14 years since the establishment of NBC, but it is observed that the potential of this committee and the objectives of this committee are yet not well

defined, and progress is also very slow. He admitted that although the voluntary efforts from elected members is laudable and is honored at highest levels, but some tangible and visible progress is still missing. NBC is yet to gain the prominence and popularity even. Provincial chapter is still either absent or is in infancy. For this concrete and measurable step shall be planned in the form of annual work plan. This shall also serve as a guidance for the provinces to lay down their work plan and quarterly meetings shall monitor the committed progress. This progress shall be presented in the annual report format as well. This suggestion of member secretary was appreciated for its relevance and it was agreed that draft workplan shall be prepared by Secretariat with consultation from Members.

Decision:

1. Annual workplan shall be prepared by Secretariat with consultation from Members.

3. TORs of NBC:

Member Secretary briefed the house that for the new notification of NBC as a part of formalization of its processes and structure we need to also notify the objectives and TORs of NBC along with its subcommittees. For this he proposed that a team of senior Members shall prepare a draft.

To this, Chairperson Dr. Moazam stated that in light of her multiple professional commitments it is not possible for her to be involved in the formulation of such a draft. She would however be willing to review the draft and offer suggestions as could Dr. Aasim.

Decision:

1. The first draft of TORs of NBC and its subcommittees for gazette notification and formalization will be prepared by the Secretariat and shared with the members and Chairs of the NBC Subcommittees for review. It will be discussed as a separate agenda item in next meeting.

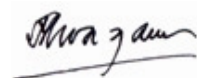
Agenda Item-10: Dates for the next NBC Meeting:

The next NBC meeting will be held in AJK during August September 2018.

Decision:

1. Secretariat will suggest a couple of dates of next NBC meeting after consultation with Secretary Health.

The meeting ended with a vote of thanks.



Prof. Dr. Farhat Moazam

Chairperson HCEC/ Member NBC