

MINUTES OF THE MEETING OF NATIONAL BIOETHICS COMMITTEE HELD ON MAY 22, 2010, AT PMRC RESEARCH CENTRE, JPMC, KARACHI

A second meeting of the National Bioethics Committee (NBC) was held on May 22, 2010 at PMRC Research Centre, Jinnah Post Graduate Medical Centre, Karachi. Professor Dr. Rashid Jooma, Chair NBC and Director General Health, Ministry of Health, Islamabad, sent his regrets due to him being busy in an official meeting abroad and asked Professor Dr. Zulfiqar Ahmed Bhutta to chair the meeting.

The following members attended the meeting:

1. Prof. Zulfiqar A Bhutta, Prof. of Paediatrics & Child Health, the Aga Khan University, Karachi.
2. Prof. S. Haroon Ahmed, Director, Psycho Social Centre, Director, Psycho Social Centre, 11-13 Hilal-e-Ahmer House, Clifton, Karachi
3. Prof. Anis Ahmad, Vice Chancellor, Riphah International University, Islamabad
4. Prof. Farhat Moazam, Professor & Chairperson, Centre of Biomedical Ethics and Culture, Sindh Institute of Urology and transplantation, Karachi.
5. Prof. Baqi Durani, Professor of Medicine, Bolan Medical College Quetta
6. Dr. Maqbool H. Jaffery, Consultant Physician/ Cardiologist, Karachi Institute of Heart Diseases, Karachi
7. Mr. Shaukat Ali Jawaid, Chief Editor, Pakistan Journal of Medical Sciences and Pulse International, Karachi
8. Prof. Aasim Ahmad, Chief Nephrologist, the Kidney Centre, Karachi.
9. Dr. Asmatullah, Assistant Professor, Islamic Research Institute, Islamic University, Faisal Masque Campus, Islamabad
10. Dr. Nadeem Akbar, Nominee, President, Pakistan Medical and Dental Council, Islamabad.
11. Maj Gen. Abdul Khaliq Naveed, Head Department of Biochemistry & Molecular Biology & Advisor in Basic Medical Sciences Dean Faculty of Medicine National University of Science & Technology - Nominee, Surgeon General Pakistan Army, Rawalpindi.
12. Dr. Muhammad Zaheen, Deputy Director Management MRE, Provincial Health Services Academy, Peshawar
13. Mrs. Anwar Aziz, Principal, Principal, State School of Nursing, Mirpur, Azad Kashmir
14. Dr Huma Qureshi, Executive Director, PMRC, Member / Secretary NBC

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

1. Dr. Khalif Bile Mohamud, WHO Representative in Pakistan
2. Qazi Muhammad Anwar, President, Supreme Court Bar Association, Islamabad
3. Dr. Zafarullah Chaudhry, President, College of Physicians and Surgeons of Pakistan (CPSP), Karachi
4. Prof. Muhammad M. Amin, Dean, Shifa College of Medicine, Islamabad.
5. Dr Anwer Nasim, Adviser Science, COMSTECH Secretariat, Islamabad
6. Dr Saeed-ul-Majeed, President, College of Family Medicine, Peshawar
7. Dr. Farid Khan, 68/1 Khyban-e-Mahafiz, Phase 6, DHA, Karachi

The meeting started with the recitation from the holy Quran.

Dr Huma Qureshi member /secretary NBC thanked the members of NBC for taking time out from their busy schedules to attend this important meeting. She informed the members that DG health had sent his regrets for not attending the meeting as he was traveling abroad with the Minister of Health. He had requested Professor Dr. Zulfiqar A Bhutta to chair the meeting in his absence. Dr Bhutta welcomed the participants of the meeting. After the introduction the Chair asked the Member/Secretary NBC to start the proceedings of the meeting. Since Dr Mubashir Khan is on 2 years leave since January 2010, therefore Dr Muhammad Arif Munir from PMRC has taken over the duties related to NBC. He was therefore requested to present details of activities performed so far. Dr Munir briefed the NBC members according to agenda items as follows:

Agenda Item 1: Confirmation of the Minutes of the Meeting held on 30-7-2009

The last meeting of National Bioethics Committee (NBC) was held on 30-7-09 in the conference room of PMRC Head office, Islamabad. The meeting was chaired Dr Rashid Jooma, Chairman NBC/Director General Health, Ministry of health, Islamabad.

Minutes were circulated to all members and no comments were received from any member. All members confirmed the minutes of the last meeting held on 30-7-2009.

Decision: Minutes of the NBC meeting held on 30-7-2009 were approved.

Agenda item 2: Over view of the NBC activities

2.1. Gazette notification of new NBC Members

The members were informed that in view of the nomination of new NBC Members, the composition of NBC has been re-notified for publication in the gazette of Pakistan. The Ministry of Health has already sent the list of NBC members to the printing press of Pakistan vide their letter 8-1/2010-MER, Dated 21-April 2010.

2.2. Gazette notification of Guidelines for health care professional's interaction with Pharmaceutical trade and industry (developed by the NBC sub-committee)

The NBC members were informed that the guidelines for health care professionals and pharma trade industry developed by the NBC sub-committee have been forwarded to the Director General Health, Ministry of Health for Gazette notification. Chair invited the NBC members to share their views/comments on the guidelines. The efforts put in the formulation of guidelines were appreciated by all NBC members. Dr Farhat Moazam and few others indicated that the institutional relation with the industry was missing while at some places the document needs redoing, they also suggested to replace terminology of medical professionals with health care related professionals. It was also highlighted that there is a conflict of interest when the CEO of a pharma industry is also a Board member. It was therefore decided a small group/subcommittee may be formed to look and redo these parts and submit them back in a weeks time.

Decision: The sub committee comprising of Mr Shaukat Ali Jawaid and Dr Farhat Moazam shall update the guidelines in one week. Dr Nadeem shall help in getting them vetted from law and justice department.

Time frame: One Month

2.3. Training of Institutional Ethic Review Committees (IERCs) plan

One of the functions of the NBC is to build capacity of various health institutes for the establishment of their own IERCs. The Members were informed that the NBC Secretariat has conducted a 02 days workshop at JPMC, Karachi on capacity building of teaching hospitals in Sind for the establishment of their institutional ethics review committees (IERCs). A total of 52 participants were trained from 17 Teaching hospitals (both public and private). The members were also informed that the NBC Secretariat would conduct 04 similar workshops in other provinces as per following plan:

Workshop 02 (Lahore): 16-17th June 2010
Workshop 03 (NWFP): 28-29th June 2010
Workshop 04 (Multan): 14-15th July 2010
Workshop 05 (Quetta): 28-29th July 2010

Professor Farhat Moazam inquired about the present capacity and membership of IERCs of different institutions. Professor Bhutta and Professor Farhat Moazzem informed that they had carried out this activity in 2000 and some baseline information is available but this needs to be updated. Professor Moazam informed the group that her associate Dr. Aamir Jafarey had conducted a survey for EMRO on existing ERCs in Pakistan a few years ago. She will request him to provide this data to NBC. Dr. Bhutta said that he would also email Dr. Aamir. Dr Nadeem volunteered to do it through PMDC with the consent and the guidelines of the NBC. Professor Bhutta and Professor Moazam agreed to share the proforma before PMDC circulates it to all medical institutions. Professor Moazam informed that her email address with the NBC is not correct, therefore she did not receive much information and in future the address should be corrected and all members informed beforehand about the training schedule for larger participation. Professor Bhutta appreciated the efforts of the NBC in conducting these workshops and informed that the experience shared with him by some trainees of the JPMC workshop was good.

2.4. Update on the NBC projects and review / approval of the pending projects

The members were updated on the projects submitted to NBC for review and accord of ethical approval. The Members were informed that to date a 45 projects were received out of which 24 have been approved, 13 are in process, 02 were not approved and 06 withdrawn by the Principal Investigators. The Members acknowledged the efforts of REC, and recognized that the number of projects that were reviewed and approved by the REC has almost doubled in the last few months.

2.5. Some Key Issues:

2.5.1. Enhancement of fee for expedited review

The members were informed that Rs 20,000 is being charged for the expedited review of the projects. This is not sufficient to handle the process of arranging a meeting of all members and pressurizing the members to do a fast job. This fee may be enhanced along with very clear reasons for an expedited review.

Decision: The committee agreed to enhance the fee for expedited review (only for the external funded projects to Rupees 50,000 per project. For regular review (12 weeks) the fee would remain the same i.e. Rs 10,000/- per projects. For externally funded regular review the fees would be Rs 20,000 and same would be charged for expedited review of locally funded projects.

2.5.2. Awareness about existence of NBC for research ethics at national level

Creation of awareness about NBC as pointed out by the Chair is very important and needs to be addressed on priority and wider information dissemination to all health institutions. These institutions and their faculty should clearly understand the important role of NBC in reviewing the projects for research ethics. It was proposed that for effective dissemination of NBC activities (e.g. SOPs and guidelines) Newsletter and website should be initiated.

Professor Anis Ahmed proposed the idea of disseminating awareness about NBC through News Letters being published by the Medical colleges, while Professor Haroon supported this idea. The Chair proposed that NBC should have its own News letter and a dedicated website.

Professor Moazam stated that she has been contacted on multiple occasions, by people in Pakistan and other countries that emails sent to NBC have failed to get a response. Such complaints leave a poor impression and this issue needs to be addressed. She suggested that a designated individual in the PMRC secretariat be given the responsibility to ensure that all emails sent to NBC are acknowledged and answered expeditiously."

Decisions:

1. NBC should have its own News letter and Mr Shaukat Ali Jawaid was nominated as the key person to help NBC with the News letter design and publication.
2. Professor Anis would help in improving the existing PMRC Web Site for NBC. For this purpose following persons will assist/coordinate with him:
 - Dr Nadeem Akbar, Nominee PMDC
 - Dr Muhammad Arif Munir, PMRC
3. All approved material e.g. Stem cell Guidelines, projects approved and in pipeline and the minutes etc. need to be placed on the Web

Targets for implementing the above decisions: By the next NBC meeting.

2.6. PC-1 for funding and manpower – Progress

It was recognized by the NBC that there is a paucity of resources for conducting the activities related to NBC. Efforts need to be enhanced for acquiring reasonable funds to continue these activities.

Decision: Duty of PC-I assigned to the group last time needs to expedite the PC-1 development process so that the PC-1 may be submitted to the Ministry of Health/ Planning Commission for funding.

Agenda Item 3: Any other matters

3.1. Should all externally funded projects need to be sent to NBC for ethical review / approval?

The chair informed that the DG Health had circulated a letter to all institutions that all externally funded projects should be sent to NBC for clearance. The chair showed concern that this would delay the projects as the capacity of ERC for reviewing the projects is limited. Dr Huma informed that the DG had requested that this matter may be delayed till the last meeting but she showed concern on behalf of the MoH that many a times drug trials are done for which the drug license to import or do the trial is not available. Some institutions have good IERC while some don't; therefore we cannot discriminate as far as compliance is concerned. It was decided that that only Surveys of National level, drug trials and trials on new products and devices projects should be reviewed by NBC. Externally funded projects on already registered drugs/devices with the MoH may be reviewed/ approved by the institutional ethic review committees, where these committees exist and are functional.

Decision: This is an important matter and need to be discussed in detail in the next NBC meeting in the presence of the Chair NBC, Dr Rashid Jooma, Director General Health, Ministry of Health, Islamabad.

3.3. Role of NBC in Medical Ethics

Professor Farhat Moazam raised the issue of role of NBC in Medical ethics. The chair informed that though PMDC was supposed to work on this but due to reasons known to all members the progress in this area has been slow. The separate committee on Medical Ethics needs to be activated with the active support from PMDC. Professor Farhat Moazam was proposed to chair the MEC to spearhead the medical ethics and to develop its TORs. Professor Moazam however, refused to accept proposal and explained the reasons for that.

Decision: Following committee was constituted:

1. Dr. Maqbool Jaffery, Member NBC
2. Dr Nadeem Akbar, Nominee, President PMDC

Agenda Item 4: Project Review:

A total of 7 new projects were reviewed by the NBC members. Following were the comments on each of these projects:

NBC-38: Comparison of Microscopy and Rapid Diagnostic Test (RDT) for the Diagnosis of Malaria in Field condition in Pakistan.

Project Approved subject to addressing the following:

- Protocol is silent about the treatment
- Consent form is very difficult in the districts are not identified.
- Add Phone numbers of PI in the consent
- Replace materials and methods with subjects/patients and methods.
- Consent form is not appropriate, its more like a research instrument. Consent should have a clear statement that sample will not be used for any other purpose.

NBC-39: Making birthing safe for Pakistan women

Project Approved subject to addressing the following:

- Revise the consent forms in easy understandable urdu language. Add phone numbers of PI in the consent forms
- Letters of support required from the district authorities.
- Delete NIC number unless there is some valid reason.
- How results will be disseminated to community as there is no mention of any contact with community once research is over.

NBC-40: Making MNH inclusive for disabled

Project approved subject to:

- Re-submitting the Simplify consent form in Urdu language.

NBC-42: Heartfile Health financing for protection against catastrophic expenditures on health

NBC comments:

- Research question not clear as to what the PI is looking for.
- Methods and summary not clear.
- No consent for controls.

Decision: Dr. Haroon, Dr Asim, Dr Shaukat and Dr. Jaffery will read full article and send their comments in 1 week's time.

NBC-43: Evidence for Innovating to Save Lives

Re-submit in the light of following comments:

- Comments of RAF on scientific contents of the proposal need to be reviewed by NBC members.
- Scientific design needs clarification.
- Not a quasi experiment, it is a predetermined randomization since they are allocating randomly
- Description of intervention is very weak. Need to explain different terms like management, marketing, etc.
- Govt level consent is required for intervention and control districts.
- MNCH collaboration for midwifery participation is required as this is an intervention.

NBC-44 Human resource for health (HRH) assessment in Baluchistan

Re-submit in the light of following comments:

- By the time year 3 data will be collected year 1 data would be obsolete, so duration may be reduced to 1 year.
- There is no mention of what will be the impact of project on future planning
- Human resources are contextualized with the environment so as the situations change in Baluchistan are frequent, so how this data would be generalized
- A support letter from health department, Baluchistan is needed.
- Project is over budgeted and over stretched
- Annexure 10 is missing

NBC-45: Myths & beliefs on MNH in Kalat

Project approved subject to following:

- Re-submission of consent in easy understandable Urdu language.

The NBC also gave approval to the following 02 in process projects awaiting ethical approval:

NBC-31: Disability and support mechanisms among older citizens studies among non-injured and injured in Islamabad (Pakistan)

NBC-37 (previously NBC-28): WHO Multi-country Survey on Maternal and Newborn health.