

**MINUTES OF THE NATIONAL BIOETHICS COMMITTEE MEETING HELD AT AGA KHAN
UNIVERSITY HOSPITAL, KARACHI
28th December, 2013**

A meeting of the Research Ethics Committee (REC) of NBC was held at Aga Khan University Hospital, Karachi on **28th December, 2013**.

Following members attended the meeting:

1. Prof. Dr. Aasim Ahmad
2. Prof. Dr. Asmatullah
3. Mr. Shaukat Ali Jawaid
4. Prof. Dr. Farhat Moazam
5. Prof. Dr. Zulfiqar Bhutta
6. Dr. Huma Qureshi
7. Prof. Syed Haroon Ahmed
8. Dr. Muhammad Zaman Afridi
9. Dr. Parvez Kamal Khan
10. Dr. Muhammad Arif Munir

The meeting started with recitation from Holy Quran.

The Executive Director PMRC/Member Secretary NBC, Dr. Huma Qureshi welcomed all participants and briefed the members that the meeting was originally scheduled to be held in Lahore but due to fog flights were being delayed therefore it was shifted to Karachi hence the Secretary Health who is the Chair of the committee and some members who had previously consented could not join.

As it was previously decided that in the absence of the secretary **a member of** the NBC may chair the meeting therefore Dr. Zulfiqar Bhutta was **nominated and seconded by members** to chair the meeting. Dr. Zulfiqar Bhutta suggested that as there are two subcommittees of NBC i.e. Research ethic and Medical/clinical ethics so in the absence of the Secretary of the Ministry, one sub-committee chair should act as the Chair on alternate basis, and this was agreed by all members. **It was noted that with this system in place, non-availability of a governmental representative as chair in the future would no longer serve as reason to postpone or cancel a regular schedule of NBC meetings.**

Dr. Muhammad Arif Munir, informed members about sad demise of Dr. Ameen (NBC member, from Shifa hospital, Islamabad). All members offered Fateha for the departed soul.

Members were introduced including two DG (health) i.e. Dr. Zaman Khan (Peshawar) and Dr. Parvez Kamal (FATA).

Member secretary NBC, Dr. Huma gave an introduction of the NBC and its sub committees i.e. medical ethics committee (MEC) and the research ethics committee (REC). One member inquired about the difference between the PMDC's ethics committee and the function of the NBC, and stated that NBC should play a role in monitoring and regulating the many unethical clinical practices in the country. Dr. Farhat Moazam highlighted the different scope of the two and explained that whereas NBC provides ethical guidelines for medical practice and research it has no regulatory powers. It is the PMDC that has legal authority to oversee and enforce ethical practices.

Discussions were made on the absence of PMDC in the NBC meetings and the 5 MEC meetings. DR. Zulfiqar Bhutta suggested having a formal meeting with PMDC secretary to have clarity that PMDC is ready/willing to enforce/own NBC recommendations. It was also decided that for MEC meetings their representative from Karachi may be nominated to attend the meeting.

Agenda item 1

Approval of minutes of last NBC meetings and 2 Pre NBC meetings

The minutes of these meeting were circulated to all members and all corrections were carried out. Minutes of NBC were signed by the cabinet secretary and for the 2 Pre NBC meetings they were signed by the Additional Secretary Cabinet.

Decision: Minutes were approved

Actions taken on the last NBC meetings

a) Formation of Provincial Bioethics Committees (PBC):

Secretary NBC informed that repeated letters were sent to the Secretaries of Health for the formulation of PBC from 2010 till 2013. DG health of all provinces have been identified as the focal person to work with NBC for the formulation of PBC but members have not been identified and therefore their trainings could not be done. Dr. Zulfiqar Bhutta suggested that if traditional channel is not working we should look for some alternative.

Members proposed that we should engage medical Universities/institutions **to assist with formulation of PBCs and coordinate with provincial Govt. officials.**

Mr. Shaukat Ali Jawaid volunteered to work with General Aslam who is the head of University of health sciences Lahore under which all medical colleges are working. UHS can be tasked to help in the formulating provincial ethics committee for Punjab.

Dr. Zaman suggested that Khyber Medical University also has most medical colleges under its umbrella therefore KMU and institute of Public Health can be given this task for KPK while he can pursue the case. Dr. Farhat Moazam mentioned that she knows Dr. Hafeezullah, Vice Chancellor of KMU, very well as CBEC has been running annual ethics workshops in Peshawar through KMU for several years. She requested that the NBC Secretariat write again to the KPK Health Secretary about the PBC with a copy of the letter to her. She will then contact Dr. Hafeezullah about this issue and seek his help. Dr. Zulfiqar Bhutta offered to talk to Dr. Najeeb on the matter. It was also suggested that FATA, GB and KPK could work together to have one Provincial committee.

For Sindh, Dr. Asim Ahmed suggested to approach DUHS, LNH and other institutional committees to formulate PBC. Dr. Zulfiqar Bhutta requested Dr. Asim Ahmed to move the case.

Dr. Farhat Moazam informed members that Balochistan in fact already has a notified PBC (since mid-2013), and one of its members, Mr. Ghani, has been co-opted as member into the clinical sub-committee. She requested that the NBC secretariat write a letter to DG health Balochistan, who chairs the PBC, mentioning that the NBC clinical committee plans to organize an ethics workshop in Quetta in early 2014. The letter should be copied to her, and she will then contact the DG directly and inform him of the workshop details.

Dr. Zulfiqar Bhutta appreciated the idea and commented that we should not ignore Provincial Governments in the process, therefore all the minutes of the meetings with the institutions should be sent to the DGs so that once these committees have been formed, the Provincial Governments should own them.

Dr. Parvez Kamal suggested that the **PBCs** should have a balance of both public and private sector representation.

- b) **Nomination of the representative from PMDC:** Dr. Moazam informed that she met DG of the ministry of NHSRC Dr. Orakzai **within the last few days** who had introduced Dr. Raja Amjad the **new** registrar/ secretary of PMDC to her. She said that she discussed the issue of absence of PMDC in the NBC and **the clinical sub-committee**; where in Dr Amjad **said** that he would attend the next meetings. Dr. Moazam requested the NBC secretariat to follow up with Raja Amjad, to which she was informed that all letters of NBC are sent to him as a member and these minutes shall also be sent to him.
- c) **NBC budget:** Dr. Huma Qureshi informed that that as the budget of NBC is not separate therefore if activities of NBC are not carried out then this amount is either used in other activities of PMRC or is surrendered. Dr. Zulfiqar Bhutta suggested that budget of NBC can be used to assist in organizing the Provincial committee meetings. Members requested that a regular report on budget expenditures of NBC should be submitted at the end of **each** year.

Prof Haroon mentioned that as we did not know the budget therefore we could not support some co-opted member's travel in last meeting of **clinical** sub-committee. Dr. Huma informed that we were sent one request which was fulfilled. **Dr. Moazam clarified that the support was asked for and provided to the Baluchistan member. However, in view of lack of knowledge about available funds, she said that two other co-opted members (from Islamabad) were actually being contacted via Skype which has not always been a very satisfactory arrangement.** Dr Bhutta proposed that in next fiscal budget, the startup cost of provincial committees should also be incorporated.

- d) **Inflated budget of RAF projects:** Dr. Huma Qureshi informed that NBC managed to get budget reductions in RAF projects. Dr. Asim said that though reductions were made but we still think that there are disproportionate distributions amongst personnel cost and field cost. Dr Bhutta said NBC should have a principle for personnel cost i.e. what percent of total budget can be allocated for personnel in a project. Dr Huma informed that right now we try to make it between 20-25% but at times it is difficult to keep this figure.
- e) **Replacement of NBC members:** Dr. Arif Munir showed the list of members along with their tenure. According to the list 8-members were completing their tenure by 2014 and using the CVs that were called for the 3 vacant posts 3 new members have been selected.

Dr. Muhammad Arif Munir gave details of the selection process in which letters were written to institutes (academics) for nominations for 3-vacant positions against which they received 41 nominations. The list was prepared for these 41 nominations dividing them into those with background or interest and academicians and others. **These lists** were circulated to all members for selection. **Dr. Moazam regretted that to the best of her knowledge, only 6 NBC members had bothered to cast their votes.**

For posts that shall become vacant in 2014, it was unanimously decided that 1-member from KPK, 1 from Baluchistan and 3 from Punjab should be selected from the list to have good representation of all

provinces. Mr. Shaukat suggested that for ex officio post from Pharma industry we should request PPMA instead of Pharma Burea for nominating someone when this vacancy is to be filled in future because PPMA represents the entire pharmaceutical industry.

It was decided that NBC secretariat shall circulate the list of nominations received earlier (excluding nominations from Sindh) within 1st week of January. Members shall send their selection within 10-days and then it will be finalized by the end of January. Notification should be sent to the nominated members once selection process has been completed and **all will** be invited **to attend** the next NBC meeting **to be scheduled for March 2014**.

Mr. Shaukat suggested that NBC should consider these nominations for provincial committees too.

- f) **Emails to Absentees:** It was decided that members who do not attend meetings without notifying should be informed/notified through e-mails informing them of their removal if they fail to attend 3 meetings. **If** they fail to attend 3 meetings then a **polite** letter **will** be sent to **them about their termination as NBC members**.
- g) **Permanent nominee of CPSP:** when informed to the members that nominee of CPSP did not come despite the invitation and reminders sent to the CPSP Office at Karachi, it was decided that the president CPSP **should** be informed of the situation with a copy to the nominee.
- h) **National surveys not seeking ethical clearance:** clarification was taken by the NBC secretariat for national surveys like DIHS, Economic survey, Census for taking NBC clearance. Dr. Aasim Ahmed said that it is better if these projects are sent to NBC and it is our domain to exempt them from taking ethical clearance or not. Dr. Farhat Moazam also agreed to this suggestion. Dr. Huma inquired from the members that about charging them processing fee to which Dr. Zulfiqar Bhutta responded it should not be a big concern as they have mega million budget, he also said that donors and Pakistan Bureau of Statistics should be informed about seeking ethical clearance for such surveys and this matter may be discussed with the secretary National Health Regulation and Coordination.

Dr. Zaman Khan showed concern about many field studies not getting any ethics approval and said that there should be some legislation for compulsory submission to NBC. Dr. Zulfiqar Bhutta mentioned that most of the time these are provincial studies therefore PBCs should take this up while for national studies NBC is working. As there is no legislation therefore we can only inform and warn.

- i) **NBC website:** Website operated by Riphah University was hacked 2 months back. University is working on it and matter will be resolved in due course.
- j) **Privilege to retain NBC members beyond tenure:** the issue of retaining an NBC member after completion of the tenure (4 yrs extendable to another 4 yrs) was discussed. Dr. Zulfiqar Bhutta disagreed to this proposal and said that we need constant fresh blood so we should try to change and replace the members every 4 years and may retain few for the next 4 years but not beyond. Dr. Haroon said that extension after 8 years **may be offered for a year and once only**. While supporting bringing in young members, **Dr. Moazam supported Dr. Haroon stating that NBC members should have the prerogative to offer extensions for one year in exceptional cases, and to meet specific needs of NBC at the time. Following a discussion the consensus reached was that this should be allowed.**
- k) **Next NBC meeting:** Next meeting of NBC shall be in Lahore on Monday, 10th March 2014.

- 1) Report on activities of the medical sub-committee of NBC: Dr. Farhat Moazam Chair of the NBC subcommittee on medical ethics (MEC) briefed members about the progress on development of national ethical guidelines for dental and medical undergraduates which is one of the major tasks the sub-committee has undertaken. Members of this committee (from NBC) include Dr. Asim Ahmed, Dr. Haroon, Mr. Shaukat, and Dr. Farid. She stated that Dr. Nadeem (previous PMDC registrar) and Dr. Feroze (DG health Sindh) have attended none of the 5 meetings to date and have not responded to reminders. She noted that the absence of a PMDC representative has been a major problem as these guidelines cannot be implemented on the ground without PMDC input and action. She requested that the Secretariat help to resolve this issue with PMDC.

She added that Dr. Asma Humayun, Dr. Saima Parvez Iqbal, Dr. Amir Jafarey and Mr. Abdul Ghani have been co-opted as members and have been extremely useful. Dr. Shahid Shamim is also assisting the committee on a voluntary basis to compile the undergraduate guidelines into a document. The committee is planning to keep these guidelines broad and simple in the form of a hand book for teachers that can be adaptable to government (with less resources) as well as private institutions.

Dr. Moazam informed members that at the postgraduate level, the committee will play a role in organizing workshops **in different provinces for trainees and healthcare related professionals** in which clinical ethics is **covered** along with research ethics. **The first is being planned in Baluchistan** (Quetta) and **she** requested the NBC Secretariat to write a letter to DG health, Baluchistan for support, with a copy to her. **Mr. Ghani who is a co-opted member of the sub-committee will** serve as the focal person in Quetta for this workshop. **To date, Drs. Jafarey and Aasim Ahmad have volunteered as teaching faculty, and Dr. Moazam requested that other NBC members should also help with this task.**

As has been requested by its members, Dr. Moazam proposed that **the current name of the sub-committee, Medical Ethics Committee, be changed to Health Care Ethics Committee (HCEC).** **The task of this subcommittee is not limited to clinical/medical areas but is broader** and will encompass dentists, **medical** technologists, students, nurses, etc. **The change of name to HCEC was approved.**

The next HCEC meeting is scheduled for Feb. 11, 2014. As before, the agenda and minutes of the meeting will be forwarded to the NBC Secretariat for information and needed actions. She repeated her request that steps be taken so that a PMDC member is also present at the meeting.

j) Any other item:

Mr. Shaukat Ali Jawaid suggested that from the NBC budget we should get stem cell guidelines, physician-pharma guidelines published so that hard copies may be sent to some relevant bodies like ministries and societies. He suggested that at least 500 copies should be published and sent to officials.

Dr. Zulfiqar Bhutta suggested the possibility of holding a workshop on bioethics concomitant with the next NBC meeting scheduled for Lahore on Monday, 10th May, 2014, but no final decision was taken on this.

Meeting concluded with vote of thanks by Dr. Zulfiqar Bhutta.