



## Original Article

### Structure and Function of Ethics Committee in Bangladesh: A pilot study

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**Abstract:** A cross-sectional study was done on 50 ethics committee members from 15 different Ethics Committee (EC) over a period of 6 months from February 2018 to June 2018 to understand the structure and function of ECs in Bangladesh. Most of the ECs were male predominant (66.3%) and maximum ECs had technical members (93.33%). Only 8.3% ECs had lay person. Forty percent of the ECs did not update SOP routinely. Most of the ECs had no provision of training for its members (79.2%) and had no budget (71.8%). Maximum ECs service were voluntary (82.22%). Different ECs had different quorum to start the meeting. A little less than half of the respondents (45.76%) felt that their decision had not been noted down if disagreed against majority of vote in the ECs and did not placed in the meeting's minutes. Maximum respondents (88.18%) did not know whether there was any law in Bangladesh to create a EC. A big percentage (89%) of ECs did not monitored by authorized body to guide and oversee the functioning of ECs. This article concluded that some ECs followed the international rules and regulation to formation and function the ECs but still a handsome number of ECs were lag behind in Bangladesh. The capacity of ECs can only be strengthened by training and various recognition/accreditation programs.

**Key words:** Ethics committee, IRB, ERC, EC Members, Ethics Committee structure, IRB function, IRB member's knowledge, research ethics, bioethics

**Introduction:** Ethics committee (EC) oversee the ethical issues on biomedical research to safeguard the rights, dignity, safety and wellbeing of all potential research participants. Therefore, understanding of ethical issues related to the study involving human

participants are utmost important for EC members. However, evidence based research from India, China and Croatia showed that the most of EC members have no formal training on research ethics or bioethics<sup>1,2,3</sup>. Most of the cases there was no regular follow-up of

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protocol, the adverse effects of clinical researches were not reported<sup>2</sup> and guidelines formation were neglected in most of the ECs<sup>3</sup>. Therefore, complicated ethical issues like reduced autonomy, cultural specificities in obtaining informed consent, vulnerable population, therapeutic misconception, conflict of interest, use of placebo, distributive justice, and compensation for study-related injury and post-trial access etc were overlooked<sup>1</sup>.

According to World Health Organization (WHO), 60% ECs was not properly constituted and functioning in India<sup>4</sup>. In China, there was lack of uniform SOP (Standard Operation Procedure) and no harmonized system of monitoring and supervising the ethics review on clinical research. Most of the cases head of the institution was the director of Ethics Committee and investigator was the in charge of physician of the subjects in China<sup>1</sup>, Head of Clinical Center of National institute of Health (NIH) of US Department of Health and Human Services Christine Grady said that the members of IRB are more concerned with protecting the institution rather than research participants<sup>5</sup> and almost half of the IRB members had financial Conflict of Interest (COI) with industry<sup>6</sup>. A study from UK indicated that lack of confidence in the subject of medical ethics is often a matter of individual integrity<sup>7</sup>.

No complete data regarding the EC are available in Bangladesh. Only an evidence-based pilot research in 2019 showed that knowledge and attitude of good number of EC members were not updated<sup>11</sup>. Actually professionals learn a little about medical ethics at undergraduate level in Bangladesh<sup>8,9</sup>. However, researchers of a post graduate institute had knowledge about research ethics but they were not practicing it properly in Bangladesh<sup>10</sup>. This study highlighted condition of the structure and function of ECs in Bangladesh.

**Methodology:** A cross-sectional study was done on 50 ethics committee members from 15 different Ethics Committees (ECs), where 10 Government institute and five private

institute were selected respectively in purposive technique. This study was done over a period of 6 months from February 2018 to June 2018 to understand the structure and function of ECs in Bangladesh. In this study, 40 technical and 10 not-technical members were interviewed by self-administered, structured questionnaires. Participants need approximately 15-20 minutes to complete the questionnaire.

Following ECs were included in this research. Government and Autonomous Sectors: 1. Bangladesh Medical Research Council (BMRC), 2. Bangabandhu Sheikh Mujib Medical University (BSMMU), 3. Bangladesh College of Physician (BCPS), 4. National Institute of Cancer Research & Hospital (NICRH), 5. National Institute of Cardio Vascular Disease (NICVD), 6. Dhaka Medical College, 7. Chittagong Medical College, 8. Sylhet MAG Osmani Medical College, 9. Barishal Medical College and 10. Rajshahi Medical College. The private Sectors: 11. National Heart Foundation of Bangladesh, 12. Bangladesh Medical College, 13. State University, 14. Bangladesh University of Health Science and 15. International Centre for Diarrhoeal Disease Research Bangladesh (ICDDRDB).

This research was done under the ethical clearance of Bangladesh Medical Research Council (BMRC). Ethical clearance no. BMRC/NREC/2014-2015/490 (1-16) dated 15.02.2018. Written informed consents were attained from the participants prior to collection of data. All the participants were given an explanation about the objective of the study and their right to withdrawal from the study. Privacy and confidentiality of the study participants were maintained strictly.

Data were analyzed by using SPSS version 22.0 software. Results were expressed as frequency, percentage distribution.

### Results:

**Demography:** The age of the respondents was range between 37 and 69 years. Mean±SD was 52.02±5.73. Most of the

respondents (95.83%) had post-graduation degree. Most of the respondent's (75.0%) institute had ethics committee. Those institute had no EC, the research was reviewed by BMRC (12.4%) and some institute form EC instantly when needed (4.2%) (Figure not shown).

**Structure of the ECs:** Maximum (66.3%) ECs had almost three times more male (66.7%) then the female (33.3%) members. Fourth fifth respondents were technical (93.3%). Among them almost half of the respondents were professor (47.92%), a little more than a quarter were associate professor (27.08%) and of 8.33% were assistant professor respectively (Figure not shown).

However, Table 1 showed that the types of professionals constituted the ECs in Bangladesh. Two third respondents said that their EC had religious leader (66.7%), Scientist (37.5%), lawyer (37.5%), female representative (33.3%). Whereas one third said their EC had dentist (25.0%), ethicist (20.8%), community leader (20.8%), journalist (14.6%) and statistician (18.8%) But only 8.3% ECs had lay person.

Table 1: Types of professionals present in the EC (n=48)

| Types of professionals | Percent (%) |
|------------------------|-------------|
| Physician              | 100.0       |
| Dentist                | 25.0        |
| Nurse                  | 18.8        |
| Scientist              | 37.5        |
| Lawyer                 | 37.5        |
| Religious leader       | 66.7        |
| Ethicist               | 16.7        |
| Elected Official       | 8.3         |
| Community member       | 20.8        |
| Journalist             | 14.6        |
| Female representative  | 33.3        |
| Lay person             | 8.3         |
| Statistician           | 18.8        |

At a question of whether respondents EC were approved by Government or not, more than one quarter of the respondents (33.33%) felt that their ECs were not approved by the government. Almost same percentage (31.25%) felt that their EC were approved by the government. Of 16.67% replied that they did not know whether their EC were approved

by the government and a little more than same percentage of respondents (18.75%) refrain from answer the question (Figure 1). The cumulative result of respondent's answers of "no", "don't know", and "not answer" carried a big percentage (68.75%) of respondents did not sure whether their EC were approved by Government (Figure1).

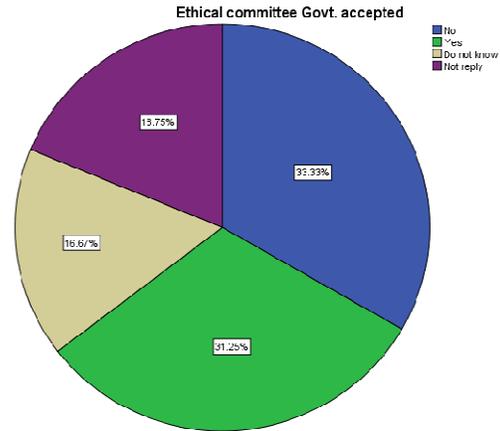


Figure 1 shows the percentage of respondent's ECs approved by the Government (n=48).

Most of the respondents (97.9%) had prior knowledge of research ethics/bioethics from different course or conference or self-reading. Only 2.1% respondents learnt bioethics while working with EC only. Of 12.5% respondent felt they had enough competence in bioethics because they learnt bioethics from all categories of learning system e.g. course, conference, self-reading and working with EC (Figure 2).

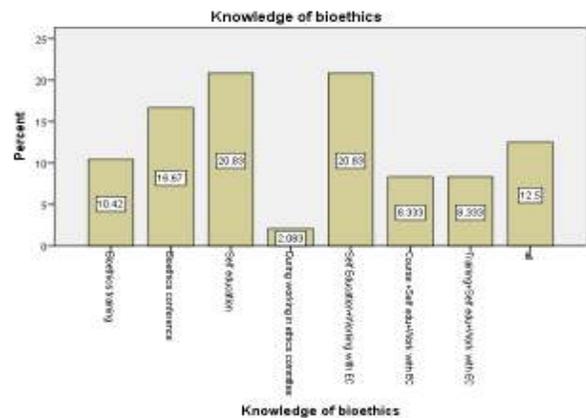


Figure 2 shows the percentage of various answer at a question of where they learnt bioethics (n=48).

Less than one fifth said that their EC had provision for training (18.8%). Majority

(79.17%) of the respondents said that their EC had no provision for training of its members. Only 2.1% do not know about it (Figure 3). However, more than half of the respondents (56.2%) felt that to be a member of EC they required training. Conversely more than one quarter respondents (31.25%) felt training is optional to be a member of EC and one tenth respondent (12.50%) felt that there was no need of training to be member of EC (Figure 4).

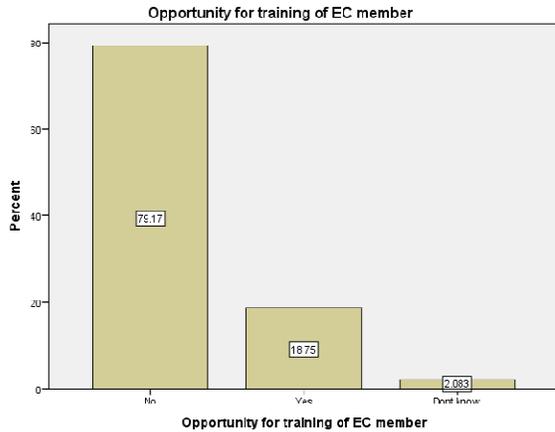


Figure 3 shows the frequency distribution of opportunity for training of EC member (n=48).

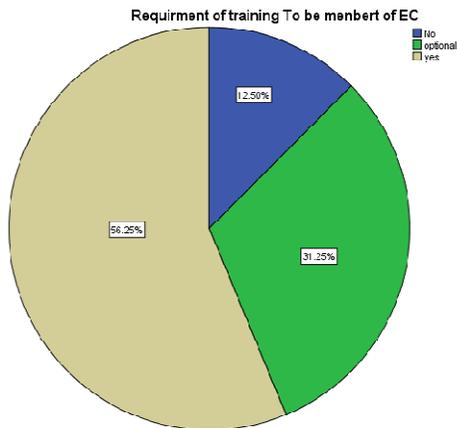


Figure 4 shows the frequency distribution of training needed to be a member of EC (n=48).

Majority of ECs (52.1%) had no budget. Less than one third (29.2%) had budget for service of EC. However, more than fifteen percent (18.8%) said that they did not know whether there was any budget allocation for the EC activity or not (Figure 5). The cumulative response of “no” and “don’t know” were 70.8%.

Most of the member’s service in EC were voluntary. Majority of the respondents (77.1%) said no remuneration were given to the member of the ethics committee for their service. On the other hand, 20.8% respondents said that there was provision to compensate for their service. Only 2.1% know nothing about remuneration (Figure 6).

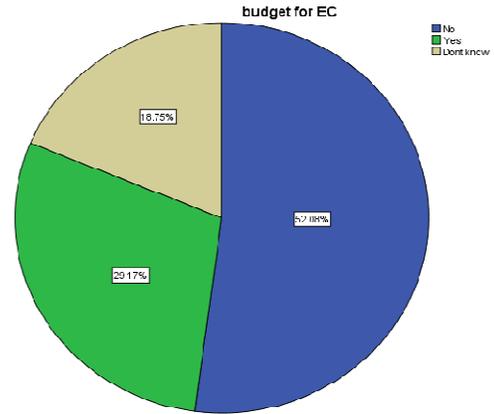
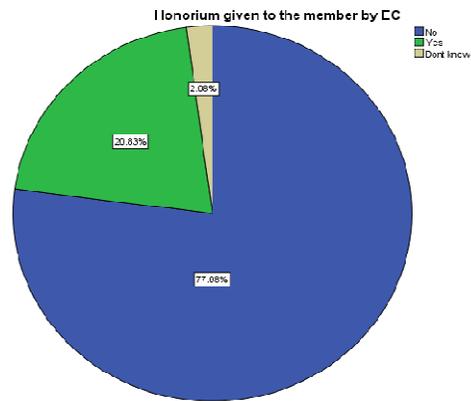


Figure 5: Frequency distribution of respondents’ opinion regarding the operating budget for EC. (n=48).



6: Distribution of response regarding opportunity for training of EC member (n=48).

**Function of ECs:** Majority of the respondents (87.5%) were aware about the quorum of the meeting. According to them almost half of the EC (47.9%) needed two third of the members followed by one third of the member (39.6%) to fulfill the quorum. Only 12.5% said that they don’t know what proportion make the quorum (Table 2).

Table 2: Fulfill the quorum (n=48)

| Quorum     | Frequency(n) | Percent (%) |
|------------|--------------|-------------|
| One third  | 19           | 39.6        |
| Two third  | 23           | 47.9        |
| Don't know | 6            | 12.5        |
| Total      | 48           | 100.0       |

Frequency of EC meeting were held  $7.02 \pm 4.17$  (Mean $\pm$ SD EC), median 7.00 and range 2-24 (Table not shown). Less than a quarter (20.83%) of respondents did not answer this question. Same number of respondents (20.83%) felt that their EC meeting held by 12 times a year. 12.50% respondent felt their EC held meeting 24 times a year and 10.42 % of respondents answered that their EC meeting held by and 4 times a year respectively. Only 2.5% respondents answered that their EC meeting held by 15 times a year (Figure 7).

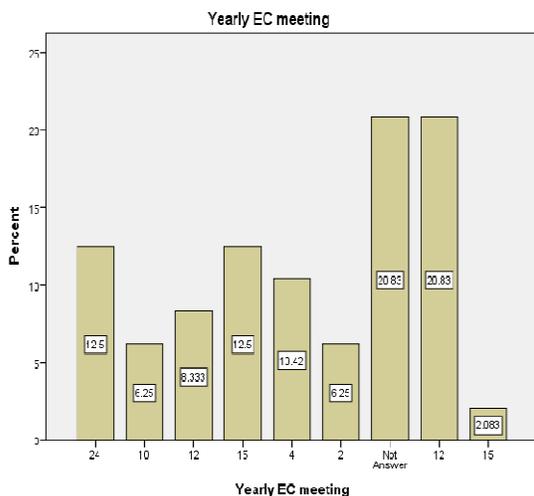


Figure 7. Shows the frequency of meeting per year.

Standard operating procedure (SOP) were updated routinely in 60.40% cases however, more than a quarter (27.1%) respondents felt that their SOP were not updated routinely and another 12.5% did not know the answer (Table-3). The cumulative result of respondent's answer of "no" and "don't know", was 39.60%. Almost 40 % of ECs did not update SOP in Bangladesh.

At a question of whether their own EC was monitored by authorized body to guide and oversee the functioning of EC, almost two third of the respondents (68.80%) felt that their ECs

Table 3: Update of SOP by EC (n=48)

| SOP Update | Frequency(n) | Percent (%) |
|------------|--------------|-------------|
| Yes        | 29           | 60.40       |
| No         | 13           | 27.10       |
| Don't know | 6            | 12.50       |
| Total      | 48           | 100.00      |

were not monitored by authorized body to guide and oversee the functioning of EC followed by less than a quarter (20.80%) did not had the knowledge the whether their EC was monitor by any authorized body (Table-4). The cumulative result of respondent's answer of "no" and "don't know" was 88.60%. Almost 89 % of ECs were not monitored by authorized body to guide and oversee the functioning of ECs in Bangladesh. Only 10.40% said that their EC were monitoring by authorized body.

Table 4: EC Monitored by Government authorized body (n=48)

| Monitoring by Govt. authorized body | Frequency(n) | Percent (%) |
|-------------------------------------|--------------|-------------|
| Yes                                 | 5            | 10.40       |
| No                                  | 33           | 68.8        |
| Don't know                          | 10           | 20.8        |

Maximum respondents (54.17%) felt that their EC noted down the decision if disagree against majority of vote in EC and placed the minutes in next EC meeting but more than a quarter of respondents (33.33%) felt negative to the answer (Figure-8).

At a question of whether there was any law in Bangladesh to create EC, majority of the participants (88.18%) did not know the answer. Less than a quarter (22.92%) felt that there was law in Bangladesh to create EC. Same number of respondents (22.92%) felt that there was no law in Bangladesh to create EC. Only 6.25 % respondent refrained to answer this question (Figure 9). The cumulative response of "no" and "don't know" were 88.18%. So Majority of the respondents (88.18%) were not

sure that there was any law in Bangladesh to create EC.

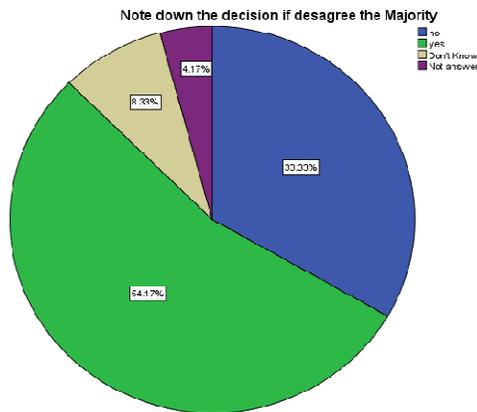


Figure 8 shows the frequency distribution of minute writing with disagreed decision (n=48).

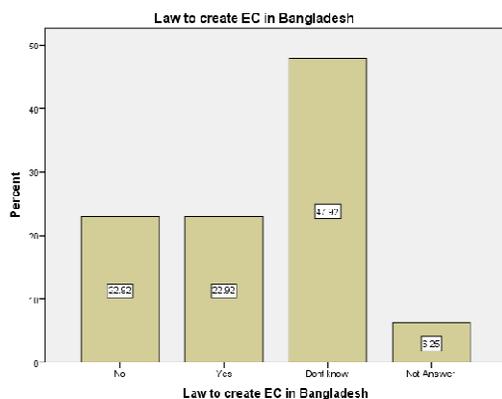


Figure 9 shows the frequency distribution regarding law to create EC (n=48).

**Discussion:** In our study mean age of the members of ECs was 52.02. A research in Croatia found that the average age of EC members was 48.65 years<sup>3</sup>. In our study half of the respondents were professor (47.92%). This may contribute a little above the average age of the EC members.

In our study, most of the members were technical (93.3%) and only few were nontechnical members. Nontechnical members had less active participation in the EC. There was lack of active participation by the nontechnical members in the discussions at the meetings due to different professions has different social value<sup>3</sup>. This result was

consistent with Croatian society<sup>3</sup>. Another study in India, also have incredibly low ratio of nonscientific members reveals the professionally biased and noncompliance with WHO guideline<sup>12</sup>. IRB (Institutional Review Board) should run by multidisciplinary approach for understanding that an ethics review must be guided by diverse viewpoints so that there should be an all-encompassing assessment of moral dilemmas that may arise before, during, and after a clinical trial/research study<sup>12</sup>.

In our study, only 8.3% ECs had lay person. Most of the ECs did not update SOP regularly. Most of the ECs had no provision of training for its members and had no budget for the purpose of running EC respectively. There was no uniform quorum system. Different ECs had different quorum to start the meeting. Most of the ECs service were voluntary. A big percentage (89%) of ECs did not monitored by authorized body to guide and oversee the functioning of EC. Decision had not been noted down if disagreed against majority of vote in the EC and did not placed in the minutes. Maximum respondents (88.18%) did not know whether there was any law in Bangladesh to create a EC. Similar result had been found in India and China.

In India, following Watershed amendments in Schedule Y, over the last few decades, research has increased rapidly, especially on the clinical trials<sup>13</sup>. However, the lack of awareness of IRB members to safeguard the safety of patients during clinical trials is a concern<sup>14</sup>. Pandiya (2011) reported that ECs in India are still insufficiently trained and have limited resources<sup>1</sup>. Most of the IRBs are not structurally multidisciplinary composition<sup>12</sup>.

In China most of the EC had the lack of qualified members, lack of systematic training, the Director of Ethics Committee is the head of the institution, conflicts of interest with the IRB member, physicians of the participants are the investigators, and no unified SOP, no regular traces and follow-up of approved projects, lack of a harmonized system of monitoring, lack of reporting of adverse effects of clinical research<sup>2</sup>.

The Ministry of Health and family welfare, Government of India passed a rule that all IRBs need compulsory registration with the Central Drugs Standard Control Organization (CDSCO)<sup>15</sup>. However, in Bangladesh there was not such registration process for the ECs till the writing of this article.

**Limitation:** There were certain limitations in the present study. This research was a questionnaire-based survey and hence the results relied upon the replies that were received. However, as this was a pilot study from Bangladesh, an effort to capture the existing situation of structure and function of EC's in the country. The sample size of this study was limited. Limited number of the questions had been explored as well. Hence it needs to be validated by further study with larger sample size across Bangladesh in the near future.

**Conclusion:** Though structure and function of some ECs were constituted according to WHO still a big percentage of ECs were lag behind in Bangladesh. This may be due to lack of training, monitoring plan and lack of quality control system for EC in Bangladesh.

#### Recommendation:

Following recommendation may help to improve the present situation.

1. Training of IRB/ EC members should be provided as necessary to improve their knowledge and attitude to apply it in their practice.
2. Monitoring of IRB/ EC by authorized body is needed periodically.
3. Quality control of IRB/ EC should be done by the national body.
4. Establishment of a National Bioethics Committee is needed to look after the all above matter.

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**Authors Contribution:** 1<sup>st</sup> author conceived the idea, done literature review and wrote the manuscript. 2<sup>nd</sup> and 3<sup>rd</sup> author guide to write the manuscript and check the manuscript meticulously.

**Conflict of interests.** The author declares that there was no conflict of interests in this study.

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