



Policy Brief

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Knowledge and attitude of ethics committee (EC) members on bioethics and structure & function of EC in Bangladesh: A pilot study

Shamima Parvin Lasker¹, Arif Hossain², M A Shakoor³

Background:

Research is done to solve a problem or to answer the questions where uncertainty exists. Therefore, every research protocol should be passed through Ethics Committee (EC). EC promotes greater understanding of ethical issues on biomedical research to safeguard the rights, dignity, safety and wellbeing of all potential research participants. Hence, it is essential for EC members to be aware of all ethical issues related to the study involving human subjects. But study from India, China and Croatia showed that most of EC members have no formal training on bioethics. EC members do not have a clear understanding of 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 access¹; head of the institution is the director of Ethics Committee, investigator is the in charge of physician of the subjects; no regular follow-up of protocol, adverse effects of clinical researches were not reported, lack of unified SOP (Standard Operation Procedure), no harmonized system of monitoring and supervising the ethics review on clinical research², guidelines formation were neglected in most of the EC³.

According to World Health Organization (WHO), only 40% ECs are properly constituted and functioning in India⁴. Moreover, Christine Grady, Head of Clinical Center, National institute of Health (NIH), US Department of Health and Human Services proposed that the members of IRB are more concerned with protecting the institution rather than research participants⁵ and almost half of the IRB members have financial Conflict of Interest (COI) with industry⁶. A study from UK entitled "Attitudes to research ethical committees" indicated that lack of confidence in the subject of medical ethics is often a matter of individual integrity⁷.

However, so far as we know a very few data is available from Bangladesh in this regard. In some studies it was found that professionals learn a little about medical ethics at undergraduate level in Bangladesh^{8,9}. In another study, Shakoor et al. found that the researchers of a post graduate institute of Bangladesh had knowledge about research ethics but they are were not practicing it properly¹⁰. Hence, this study was designed to assess the knowledge and attitude of EC members regarding bioethics and structure & function of EC in Bangladesh.

1. Professor & Head of Anatomy, MH Samorita Medical College; Secretary General, Bangladesh Bioethics Society; Co-Investigator of the Research Project. Email: splasker04@yahoo.com

2. Professor & Course Co-coordinator, Department of Human Rights, Etrat University, Vice President, Bangladesh Bioethics Society and Co-Investigator of the Research Project.

3) Professor of Physical Medicine & Rehabilitation, Bangabandhu Sheikh Mujib Medical University, Executive Member, Bangladesh Bioethics Society and Principal Investigator of the Research Project.

Objectives:

General objectives: To observe the knowledge, attitude, and practice of EC members on research ethics.

Specific objectives:

1. To assess the knowledge and attitude of EC members regarding bioethics.
2. To assess the knowledge of EC members regarding structure & function of EC.

Ultimate objective: By knowing the results of this study, DGHS (Directorate General of Health Services), Ministry of Health and Family Welfare will be able to develop policy for quality control of EC.

Materials and Methods:

An analytical, cross-sectional pilot study was designed using 50 self-administered, structured questionnaires conducted on 50 EC members from 15 different medical institutes in Bangladesh over a period of 6 months from February 2018 to June 2018 where 40 members were technical, and 10 members were not-technical. Two questionnaires from non-technical group were discarded due to improper filling of the questionnaire. Data were analyzed by using SPSS version 22.0 software. Results were expressed as frequency, percentage distribution and charts.

Ethical approval was obtained from Bangladesh Medical Research Council (BMRC) for this study. Written informed consents were taken from the participants prior to collection of data.

Results:

Demography: The EC members in Bangladesh were well educated in respective subjects and bioethics. Average age were above fifty years. Most of the EC members were male (66.3%). Maximum EC members (93.33%) were technical. Maximum respondents (97.9%) had prior knowledge of bioethics from different course or conference or self-learning and working with EC.

There were fifty questions. Important few results are mentioned here only.

Knowledge on bioethics:

- Maximum (93%) respondents felt that ethical clearance is needed for all research involving human subject. Maximum (89.3%) respondents agreed that signed consent form does not mean that participant will continue with the study up to its last day.
- Maximum respondents (62.50%) fully agreed or partially agreed that the goals of research are to cure disease and eliminate suffering of research subject rather than gather knowledge. A quarter (25%) respondents disagreed and only 8.33% respondents completely disagree the statement. A very few members (4.16%) did not know the answer (Figure-1).

- Only 16.65% respondents felt verbal informed consent is okay for illiterate, but 35.42 % member partially agreed to the statement and 423.75% did not agreed about it (Figure-2).

- Maximum respondents (56.25%) expressed strong agreement that mental patients have no decision making capacity and 25% participants partially agreed about it (Figure- 3).

- Fifty percent respondents believed that physicians should respect the patient’s refusal in treatment and 25% completely were not (Figure-4).

- Maximum participants (71.83%) believed that the advance directives were not helpful in dialogue among patient and family and physician and only a few respondent (14.58%) disagreed (Figure-5).

Though most of the EC member had good knowledge and understanding of bioethics, but still some EC members are not fully aware of bioethical issues.

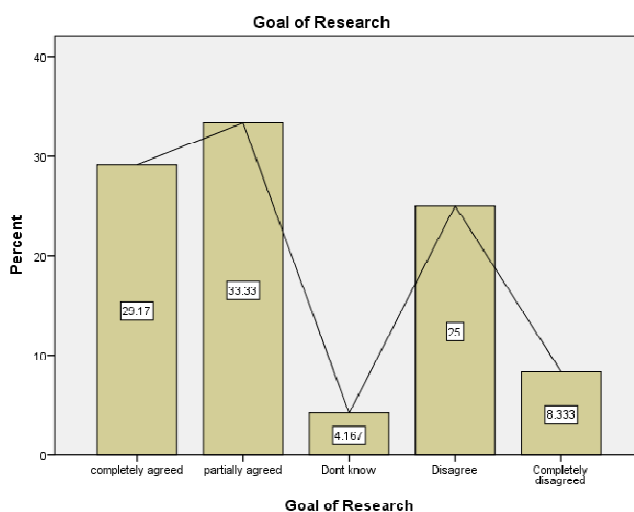


Figure 1: Shows the respondents reply at a question of goal of research is to cure disease not to gather knowledge. (n=48).

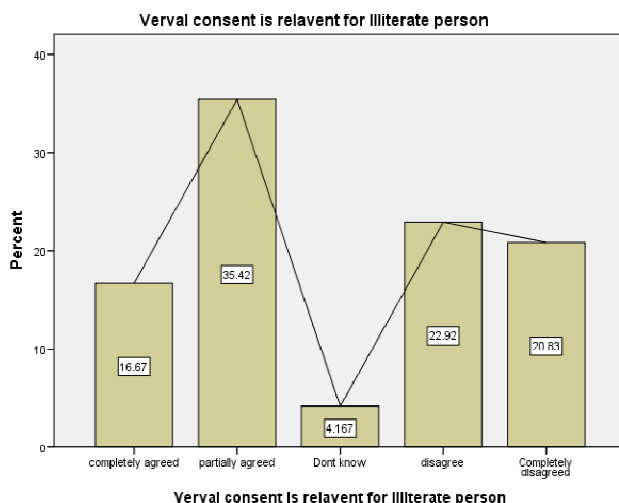


Figure-2: Distribution of the question whether the verbal informed consent is okay for illiterate participant (n=48)

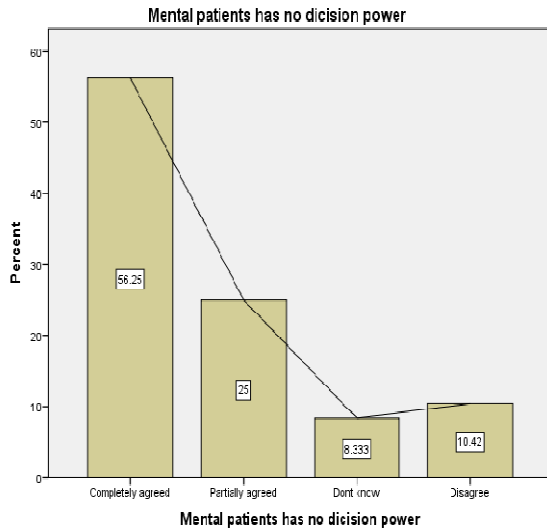


Figure-3: Distribution of the reaction of respondents at a question that mental patients has no decision-making capacity (n=48).

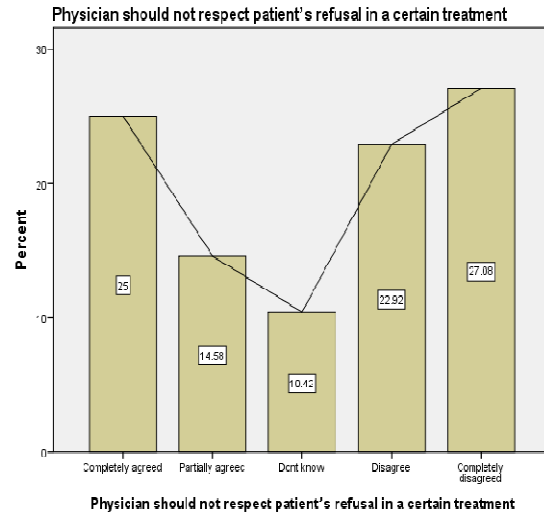


Figure 4 Shows the different answer of respondents at a question of physician should not respect the patient's refusal of a treatment (n=48).

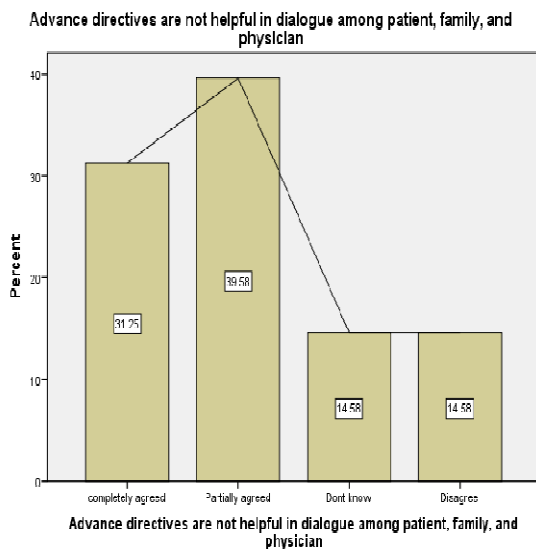


Figure -5: Distribution of the response about the question, whether advance directives were helpful in dialogue among patient and family and physician. (n=48).

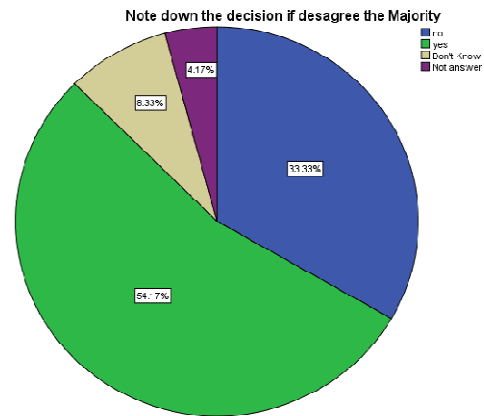


Figure 5 shows the frequency distribution of minute writing in EC if disagreed (n=48).

Structure and function of EC:

Standard operating procedure (SOP) were updated routinely in 60.4% cases but 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-1).

- Majority of the respondents (68.8%) felt that their EC were not monitored by authorized body to guide and oversee the functioning of EC and 20.8% respondents did not know the answer (Table-2)

- Maximum respondents (54.17%) felt that their EC noted down the decision if disagree against majority of vote in EC and placed the minute in next EC meeting but more than a quarter of respondents (33.33%) felt negative to the answer (Figure-5).

- More than a quarter (29.17%) respondents thought that there was law to control quality of EC and 16.57% respondents felt that there was no law to control quality of EC in Bangladesh. However, majority of respondents (45.83%) did not know the answer (Figure-6).

- Majority (79.17%) of the EC had no provision to training for their members (Figure-8). Most of the member's service in EC were voluntary (Figure 7) and they had no budget for EC (Figure-8).

Maximum EC members were aware about the structure and function of EC but still some number of EC members were lag behind.

Table 1: Update of SOP by EC (n=48)

SOP Update	Frequency(n)	Percent (%)
Yes	29	60.4
No	13	27.1
Don't know	6	12.5
Total	48	100.0

Table 2: EC Monitored by Government authorized body (n=48)

Monitoring by Govt. authorized body	Frequency(n)	Percent (%)
Yes	5	10.4
No	33	68.8
Don't know	10	20.8
Total	48	100.0

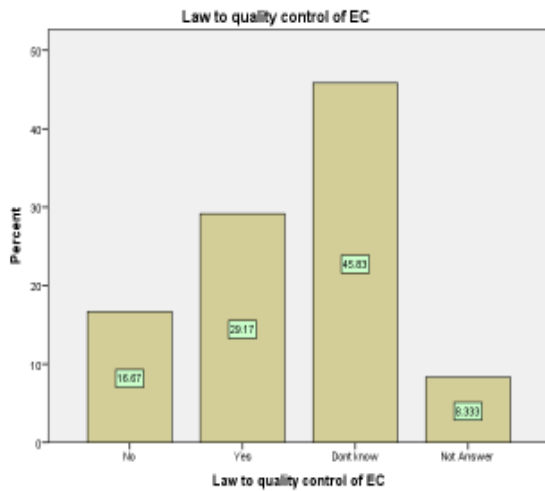


Figure 7 Shows the frequency distribution regarding law to quality control of EC in Bangladesh (n=48).

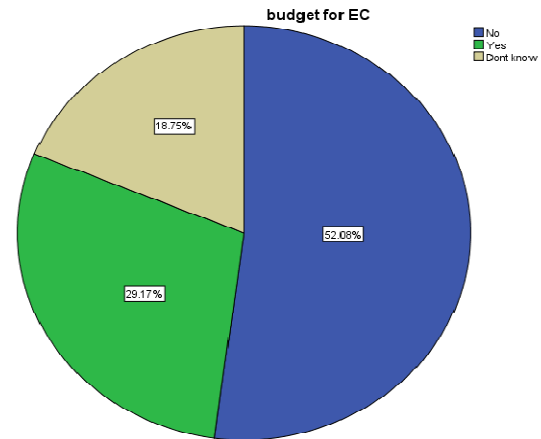


Figure 9: Frequency distribution of respondents' opinion regarding the operating budget for EC. (n=48).

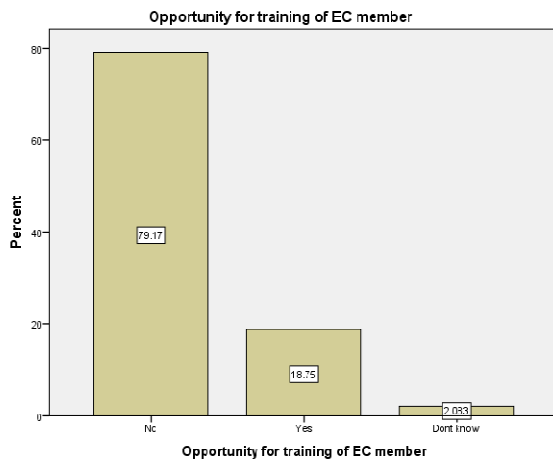


Figure-8: Distribution of response regarding opportunity for training of EC member (n=48).

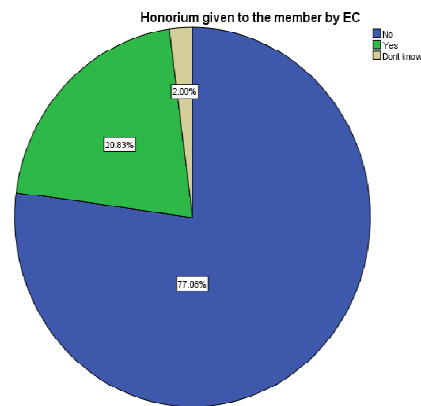


Figure-10: Distribution of response regarding honorium to the EC member for their service (n=48).

Conclusion:

- Though most of the indicators showed that the EC members participated in the study had good knowledge of bioethics but still some EC members were not applying their knowledge properly. They were in the position of physician to treat the patients, so they thought that what was done by them that is all the best for patients.

- Though maximum EC members were aware about the structure and function of EC but still some were lag. This may be due to lack of training, monitoring plan and lack of quality control system for EC in Bangladesh.

Recommendation:

By synthesizing the study results we recommends the following issues to improve the present situation.

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

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

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