Awareness about Ethics Committee amongst the Medical Teachers in a Medical College

Vikram Londhey¹, Charulata Limaye²

Abstract

Introduction: The Ethics Committees (EC) are established to safeguard the safety and rights of the subjects participating in a research study. No formal training about Ethics Committee is given to the medical students in undergraduate and post graduate education as a part of curriculum.

Aims and Objectives: To study the awareness about the composition and functioning of EC amongst the medical teachers.

Methodology: A prevalidated questionnaire was given to the medical teachers who consented to participate in the study, fill up the questionnaire immediately and return it. The questions consisted of knowledge about the composition of the EC and its functioning in general.

Results: Ninety two (51%) belonged to non-clinical branches; 88(49%) were clinicians. Forty (22%) had undergone ICH-GCP training (27 belong to clinical and 13 non-clinical branches). Forty four point four percent were well informed about the composition of EC in general. The most common wrong answer was “Dean” is the Chairperson of EC.

Conclusions: As the years of experience as Faculty in Nair increased, the knowledge about the composition of EC’s in general increased but the information about functioning of IEC did not improve significantly. The awareness about EC was significantly higher amongst the PG teachers.

Introduction

The Ethics Committees (EC) are established to safeguard the safety and rights of the subjects participating in a research study.1-5 It is mandatory that all research projects should be approved by EC before commencement. However, no formal training about Ethics Committee is given to the medical students in undergraduate and postgraduate education as a part of curriculum in most of the branches of medicine except a few. Therefore, as faculty members in a teaching institution, they would not have undergone training in research methodology or ICH-GCP or functioning of EC’s. Only the faculty members involved in clinical trials or institutional research projects would be aware of the EC, its composition and functioning. This study was planned to assess the EC awareness amongst the medical teachers in Topiwala National Medical College and BYL Nair Ch Hospital, Mumbai.

Aims and Objectives

To study the awareness about the composition and functioning of EC amongst the medical teachers.

Methodology

The study was approved by the Institutional Ethics Committee. The study was conducted in accordance with ICH-GCP guidelines and ICMR Schedule Y guidelines.1,2 A prevalidated questionnaire was given to the medical teachers who consented to participate in the study, fill up the questionnaire immediately and return it. The questions consisted of knowledge about the composition of the EC and its functioning in general (Table 1).

The questionnaires which were not returned immediately were excluded from analysis to avoid biased results. There were 15 questions, 12 pertaining to knowledge testing and 3 Yes/No types. Each question was awarded 1 point for a correct response. A maximum score obtained would be 12 and the minimum would be 0. (Yes/No questions were not scored).

¹Associate Professor, Department of Medicine, TNMC and BYL Nair Ch Hospital, Mumbai, Maharashtra, Visiting Consultant Rheumatologist, Seven Hills Hospital, Marol Maroshi, Mumbai. ²Assistant Professor, Department of Medicine, TNMC and BYL Nair Ch Hospital, Mumbai, Maharashtra.
Table 1: The questionnaire administered

<table>
<thead>
<tr>
<th>Name:</th>
<th>Age:</th>
<th>Sex: M/F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Designation:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. of Years in this institution:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PG Teacher: Yes/No</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Q.1. Research Projects in our institution are reviewed by ________.
   a. Institutional Ethics Committee – Nair Hospital  
   b. Independent Ethics Committee  
   c. Don’t know

Q.2. Ideally how many members should an Ethics Committee (EC) have as per ICMR guidelines?
   a. 1 – 4  
   b. 4 – 8  
   c. 8 – 12  
   d. 12 – 16

Q.3. How many non-scientific members are required in EC?
   a. 1  
   b. 2  
   c. 3  
   d. 4

Q.4. How many members are necessary (i.e. form a quorum) to conduct the meeting of EC?
   a. 5  
   b. 6  
   c. 7  
   d. 8.

Q.5. Who is the present Member Secretary of our EC?

Q.6. Who is the present Chairperson of our EC?

Q.7. How frequently does the meeting of EC take place?
   a. once a week  
   b. once in 2 weeks  
   c. once a month  
   d. once in 3 months.

Q.8. What is the deadline to submit the Research Projects before the meeting of EC?
   a. 1 week  
   b. 2 weeks  
   c. 3 weeks  
   d. 4 weeks.

Q.9. Is it necessary to obtain EC approval before a non-sponsored research project is started?
   a. Yes  
   b. No  
   c. Don’t know

Q.10. Is the Member Secretary of EC from our institution?
   a. Yes  
   b. No  
   c. Don’t know

Q.11. Is the Chairperson of EC from our institution?
   a. Yes  
   b. No  
   c. Don’t know

Q.12. Where is the office of our EC?

Q.13. Would you like to serve as a member in our EC?
   a. Yes  
   b. No

Q.14. Have you served as a member in our EC?
   a. Yes  
   b. No

Q.15. Have you undergone training for ICH-GCP?
   a. Yes  
   b. No

**Results**

Out of 250 faculty, 214 consented to participate. Thirty four questionnaires received late were excluded from analysis. One hundred and eighty questionnaires were analysed. Ninety two (51%) belonged to non-clinical branches; 88 (49%) were clinicians. Forty (22%) had undergone ICH-GCP training (27 belonged to clinical and 13 to non-clinical branches). 44% were well informed about the composition of EC in general. Figure 1 shows the number of correct responses to individual questions.

The overall scores were graded as very poor (0-3), poor (4-6), average (7-9) and good (10-12). Twenty-three (12.7%) had very poor score, 77 (42.7%) had poor score, 51 (28.3%) had average score and 29 (16.1%) had good score.

The faculty was grouped as per designation and number of years in the institution. The mean scores according to designation were 5.59 for the Lecturers (group 1), 6.63 for the Associate Professors (group 2) and 8.11 for Professors (group 3). The difference between group 1 and group 2 was significant, p=0.008 (95% CI=-2.28-0.28). The difference between group 1 and group 3 was significant p=0.001 (95% CI= -1.25-3.61) which is statistically significant. Between group 2 and group 3 the difference was not significant, p=0.078 (95% CI=-2.40-0.01) (ANOVA).

The data was further analysed depending on the number of years of serving in Nair as <5 years, 5-10 years and >10 years. The mean scores were 5.96, 7.03 and 6.76 in <5 years, 5-10 years and >10 years respectively. The knowledge about the composition of EC in general was statistically significant (p=0.043) between less than 5 years group and >10 years group. The knowledge specifically related to the institutional EC was statistically non-significant in these 3 groups (analysed by ANOVA) based on no. of years (p=0.071).

There were 106 (59%) postgraduate (PG) teachers and 74 (41%) were not PG teachers.
The awareness about EC was significantly higher amongst the PG teachers (p=0.01). Ninety nine (55%) faculty were willing to serve as EC members. One hundred and one (56%) were aware about the functioning of the institutional EC.

Discussion

The overall scores were below average to average about the knowledge and functioning of the EC. This shows that a formal training is mandatory to all the medical graduates and postgraduates and should be incorporated in the curriculum. As the years of experience as faculty in Nair increased, the knowledge about the composition of EC in general increased but the information about functioning of IEC did not improve significantly. The number of years and the experience as faculty gives an opportunity to serve in various committees like research society or ethics committee and hence the knowledge about the composition of EC in general increased. However, unless coming in contact with the ethics committee either as a member or an investigator, it becomes difficult to understand the composition and functioning of the ethics committee.

Amongst the faculty members, there was an overall enthusiasm to serve as members of EC. Only 48 (26%) were aware that chairperson should not be from the institution. The most common wrong answer was “Dean” is the chairperson of EC. Only 30 faculty (16.4%) knew the name of the chairperson correctly. More than fifty five percent knew the name of the member secretary. There are no similar studies published. Hence the results could not be compared with previous studies.

The limitations of this study were that only knowledge about the EC was tested. The attitudes and practices of faculty related to EC were not asked. This data may not be applicable to other institution.

Conclusions

Faculty of a medical college should be trained about research methodology and ICH-GCP. Basic knowledge about the composition and functioning of EC should be imparted to all the medical teachers. Information about ethics committee, their composition and functioning and research methodology orientation program should be included as a part of UG/PG curriculum. By the time this study will be published, the MUHS would have included research methodology program for the post-graduates and the faculty.

Acknowledgements

We would like to acknowledge all the teaching Faculty of Nair Hospital, EC Members and EC for permitting to conduct this study. We would like to acknowledge Dr. G.D. Velhal, Additional Professor of Community Medicine for helping in the statistical analysis.

References


