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ETHICS COMMITTEE AWARENESS AMONGST THE MEDICAL TEACHERS & POST GRADUATE RESIDENTS IN A MEDICAL COLLEGE

Shrikrishna S. Shende., Abhijeet V. Tilak., Bhalchandra Rane.,
Sayan Das., Tanya Gupta and Ritika Vaid

Department of Pharmacology, Dr. D.Y.Patil Medical College, Pimpri, Pune- 411018

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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 EC is given to the medical students in the undergraduate(UG) and postgraduate(PG) education as a part of curriculum.

Aim and Objectives: To study the awareness about the composition and functioning of EC amongst the faculty members and PG residents.

Methodology: A prevalidated questionnaire was given to the medical teachers and PG residents 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: Total of 149 subjects were enrolled. 64.71% of the faculty and 38.78% of the PG residents were well informed about the composition of the EC. 82 (55.03%) had undergone ICH-GCP training. The overall scores were graded as poor (0 – 3), average (4 – 6), good (7 – 9), and excellent (10- 12). The awareness about EC was significantly higher among faculty than PG residents.

Conclusions: The faculty and PG residents should be trained about ethics and regulations related to clinical research and good clinical practice(GCP) guidelines. Basic knowledge about composition, functioning etc. should be imparted to all faculty and PG residents. It can be initiated by workshop/awareness programmes compulsory for UG and PG students and also for faculty.

Editorial Viewpoint

- Poor awareness about ethics committee functioning is a problem.
- Regular induction courses regarding process of research methodology, ethics and publication should be mandatory across the country.

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INTRODUCTION

The EC is established to safeguard the safety and rights of the subjects participating in a research study. It is mandatory that all the research projects should be approved by EC before commencement. However, no formal training about EC is given to the medical students in UG and PG 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 the research methodology or ICH-GCP or functioning of EC. Only the faculty members involved in clinical trials or institutional research projects are aware of the EC, its composition and functioning. This study was planned to assess the EC awareness amongst the medical teachers & PG residents in Dr. D. Y. Patil Medical College, Hospital & Research Centre, Pune.¹⁻⁵

Aim and Objectives

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

METHODOLOGY

The study was approved by the Institutional EC. The study was conducted in accordance with ICH-GCP guidelines and The Indian Council of Medical Research (ICMR)-Schedule Y guidelines. A prevalidated questionnaire was given to the medical teachers & postgraduate students 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 pertaining to knowledge testing. Each question was awarded 1 point for a correct response. A maximum score

obtained would be 12 and the minimum would be 0. The scoring was done for Questions 1 to 12.

Table 1 The questionnaire administered

Name:
Age:
Sex: M/F
Designation:
Department:
No. of years in this institution:

Q.1. Research Projects in our institution are reviewed by _____.

1. Institutional Ethics Committee - Dr. D.Y.Patil Medical College
2. Institutional Ethics Committee-Dr. D.Y.PatilVidyapeeth
3. Independent Ethics Committee
4. Don't know

Q.2. Ideally how many members should be there in an Ethics Committee (EC) as per ICMR guidelines?

- a.1 – 4 b. 4 – 8c. 8 – 12 d. 12 – 16

Q.3. How many non-scientific members are required in EC?

- a. 1 b. 2 c. 3d. 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. Is the Member Secretary of EC from Dr. D.Y.PatilVidyapeeth?

- a. Yes b. No c. Don't know

Q.6. Who is the present Member Secretary of our EC?

Q.7. Is the Chairperson of EC from Dr. D.Y.PatilVidyapeeth?

- a. Yes b. No c. Don't know

Q.8. Who is the present Chairperson of our EC?

Q.9. 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.10. 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. 11. Where is the office of our EC?

Q. 12. Is ICH-GCP guidelines compulsory for EC members to undergo training for ICH-GCP guidelines?

- a. Yes b. No

Q. 13. Would you like to serve as a member in Dr. D.Y.PatilVidyapeeth of EC?

- a. Yes b. No

Q.14. Have you served as a member in Dr. D.Y.PatilVidyapeeth EC?

- a. Yes b. No

Q.15. Have you undergone training for ICH-GCP guidelines?

- a. Yesb. No

RESULTS

A total of 149 subjects were enrolled for the study. A written consent form was obtained from all the participants of the study. The data thus obtained was sorted and categorized. All captured data was entered into Microsoft Excel database. During data entry, data was checked for any error or missing data. After resolution of all issues, the database was analysed. Out of the 149 subjects, 51 subjects (34.23%) were faculty, and 98 (65.78%) subjects were PG residents.

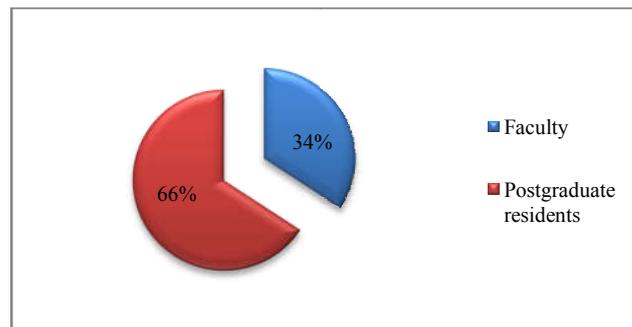


Figure 1 Distribution of subjects in different groups

64.71% of the faculty were well informed about the composition of the EC whereas, only 38.78% of the PG residents were well informed. 82 (55.03%) had undergone ICH-GCP training (among them, 36 were faculty and 46 were PG residents).

The overall scores were graded as poor (0 – 3), average (4 – 6), good (7 – 9), and excellent (10- 12). Among PG residents, 8 (8.16%) had poor scores, 52 (53.06%) had average scores, 32 (32.65%) had good scores, and 6 (6.12%) had excellent scores. Whereas, among the faculty, 5 (9.80%) had poor scores, 13 (25.49%) had average scores, 17 (33.33%) had good scores, and 16 (31.37%) had excellent scores.

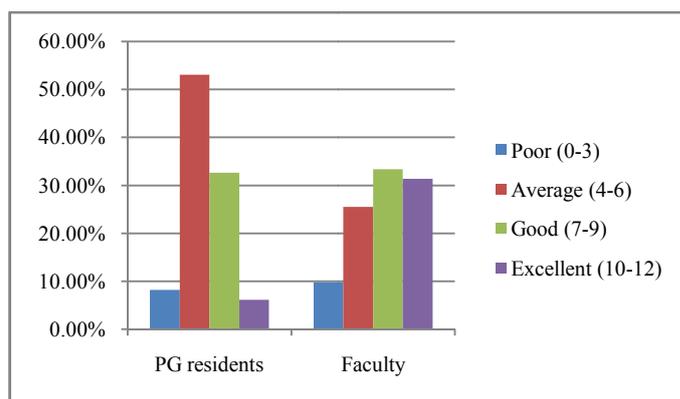


Figure 2 Graph showing percentage of scores of PG residents & faculty

The awareness about EC was significantly higher among faculty than PG residents. 32 (62.75%) faculty members were willing to serve as EC members, whereas 40 (40.82%) PG residents were willing to serve as EC member.

DISCUSSION

The overall scores were average to good about the composition and functioning of the EC. It was observed that the overall

scores were better among faculty than PG residents. As the knowledge about ECs poor among PG residents, formal training to medical graduates and PG residents may improve the situation. Unless the residents or faculty doesn't take active part as a member or investigator, it becomes difficult to understand the composition and functioning of EC. Faculty members were more keen to serve as members of EC in comparison to PG residents. Only 29 (56.86%) faculty members and 25(25.51%) PG residents were aware that chairperson should not be from the institution. 26 (50.98%) faculty members and 35 (35.71%) PG residents knew who is the current chairperson of our EC. There was a similar study done by Londhey V *et al.* Our findings of this study are in agreement with this existing literature.⁶

Limitation of this study: Sample size can be increased to spread awareness and to get a better statistical analysis.

CONCLUSION

The faculty and PG residents should be trained about ethics and regulations related to clinical research and ICH-GCP. Basic knowledge about composition, functioning etc. should be imparted to all faculty and PG residents. It can be initiated by workshop/awareness programmes compulsory for UG and PG students and also for faculty.

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