

**KNOWLEDGE, AWARENESS AND ATTITUDE ABOUT
ETHICAL CONSIDERATIONS IN RESEARCH AMONG
MEDICAL PROFESSIONALS IN A TERTIARY-CARE
TEACHING INSTITUTION**

REEJA R¹, RAKESH PRAVEEN RAJ M.R², BEENA JS³

**¹Associate Professor, Department of Pharmacology, Govt. Medical College, Kollam,
Kerala, India**

**²Professor, Department of General Surgery, Azeezia Institute of Medical Sciences &
Research, Kollam, Kerala, India**

**³Assistant Professor, Department of Pharmacology, Govt. Medical College,
Trivandrum, Kerala, India**

Corresponding author:

Dr. Rakesh Praveen Raj M.R.,

Address: GEETHAM, JNRA-89, JAWAHAR JN., PATTATHANAM P.O.

KOLLAM, INDIA. PIN-691021

Mob: +91 9447462531

Email: drrakeshpraveenraj@gmail.com

Abstract

Ethical considerations are the chief concerns in medical research. Present study assesses the knowledge, awareness and attitude of research ethics among medical faculty in a government teaching hospital in India. A self-administered pre-tested structured and validated questionnaire based on ICMR ethical guidelines was made available to all consenting participants. A total of 30 faculty members were enrolled in the survey. Descriptive statistics were applied for data analysis. Faculty was aware of the guidelines, 83% participants having read the ICMR guidelines. Except for one, all faculty members were aware of an Institutional Ethical Committee (IEC). 73.3% had the opportunity of being a part of research projects. 96.6% of participants responded correctly to questions on Informed consent, 60% to question on research involving children, while 96% responded correctly to questions on 'Confidentiality'. Less than 60% are aware about the details of IEC. 57% had knowledge of functions and roles of a research ethics committee. 42% were aware of the composition of IEC. Only 39% were familiar with proposal submission and review process by the IEC. Regarding the attitudes of faculty about research ethics all participants agreed that there is a need for an IEC in each institution and the members constituting the IEC should receive training in bioethics. All participants were of the view that research ethics should be taught mandatorily in medical curricula. 100% believed that all investigators should also have necessary training in research ethics. The attitude of all faculty members was favourable towards research ethics. All faculty felt the need for further education on research ethics.

Keywords: Research ethics, Knowledge, Awareness and attitude, Faculty, Professional college

Introduction

Human participation in clinical research has always posed ethical questions globally. The support provided by members of the public when agreeing to take part in research, helps create a true picture of society today. Without this support it would prove difficult for researchers to uncover findings of benefit to science and society. Research ethics warrants the application of fundamental ethical principles to the pursuit of research. There are many ethical considerations to be cognizant about when pursuing research. Key amongst these is the protection of human participants, handling of personal data and respect for intellectual property. With regard to research involving human participants, research should aim to maximise benefit for individuals and society and minimise risk and harm. The rights of individuals or groups should be respected and their dignity upheld. Wherever possible, subject participation should be entirely voluntary and the subject appropriately informed about the nature of research. Research ethics should ensure that all research participants are protected from abuse, harassment, exploitation and other forms of harm [1]. Various guidelines [2-11] have been proposed in the field of ethics in research. Nuremberg code, CIOMS, ICMR, Belmont report, Helsinki declaration are a few. However, in spite of all these guidelines, there are still a number of reported incidents of scientific misconduct and unethical behaviour of medical professionals with research participants. This may be partly due to a lack of pertinent practical ethical guidance during the course of their professional training. It has been argued that very few medical professionals are exposed to training in this important arena of research ethics in medical practice, yet on qualifying health care professionals are expected to know about ethical practice when applying their skills (12). Cognizant of this important aspect, current medical curriculum has included topics related to ethics; especially when studies stressing the importance of incorporating ethical and legal issues into medical curricula [13-15] revealed the ground reality. Nevertheless, traditional medical training is of little assistance in straightening-out the practical ethical problems faced by healthcare professionals. Inclusion of formal education of practical ethics in medical curricula [16] is seriously opined and debated as it has been found that ethics teaching has a profound influence on attitudes and decision-making skills of medical professionals [17,18]. Furthermore, recognizing the magnitude of this issue, some institutions have come forth and established institutional ethical guidelines in their clinical teaching and medical residency programmes [19-21]. The last few years has witnessed a small but growing body of research on researchers themselves, particularly on research behaviour [22-25] which has imparted a more comprehensive and critical understanding of research practices, particularly in the field of biomedical research. Research in this direction starts with the objective to determine the prevailing knowledge, awareness, attitude and practice of research ethics amongst healthcare professionals. In this context, a few studies have been conducted in different regions globally [22, 26, 27]. The present study has been done to assess the knowledge, awareness and attitude of healthcare ethics among medical faculty in a government teaching hospital in India.

Methodology

A cross-sectional study was conducted among medical professionals in Government Medical College, Kollam, India with the approval of the Ethical Committee of the institution. A self-

administered pre-tested structured and validated questionnaire based on Indian Council for Medical Research (ICMR) ethical guidelines was made available to all consenting participants. The questionnaire was close-ended with response choices and covered several domains about knowledge, beliefs and attitudes towards principles and practice of bioethics in clinical research, including demographic details, research experiences, ethical principles, informed consent, vulnerability, Institutional Ethics Committee- constitution, roles & responsibilities, proposal submission, review process; bio-banking /biological materials, conflict of interest, research misconduct. Respondents were selected on the basis of simple random sampling, and approached by at least one of the investigators in person. The questionnaires were completed in private by the participants and handed back to investigators in sealed, unmarked envelopes. The approximate completion time of the questionnaire was 15 min. A scoring system was used for the responses. Question numbers 10 to 50 were used for scoring. Wrong choices and “Don’t know” answers were given a score of zero. Correct responses were given a score of 1. The percentage of correct responses was calculated. Descriptive statistics (tables) were applied for data analysis.

Results

The survey was conducted among the teaching staff of Govt. Medical College, Kollam. A total of 30 faculty members were enrolled in the survey. Among the participants involved in the survey, 19 were females. All enrolled faculty possessed a Master’s degree. They included Associate Professors, Assistant Professors and Senior Residents [Table 1].

Except for one, all faculty members were aware of the existence of an Institutional Ethics Committee (IEC) in the institution. None of the participants have become a member of any of the Ethics Committee. Of the 30 participants, a good majority of 22 persons (73.3%) had the opportunity of being a part of research projects.

The faculty’s source of information about the principles of bioethics came from different avenues [Table 2].

Regarding knowledge of different guidelines in research ethics [Table 3] 25 participants had read the ICMR guidelines and 5 had not read any of the guidelines.

On analysis one faculty scored a maximum of 39 correct responses out of 40 questions and the least score was 8 out of 40. Maximum correct response is given for the questions on ‘Informed consent’ and ‘Vulnerability’ by 29 persons. 96.6% of participants responded correctly to questions on Informed consent. 60% of participants responded correctly to question on research involving children, while 96% responded correctly to questions on ‘Confidentiality’ in medical research.

Maximum wrong entry was for the questions on bio-banking and research process of IEC by twenty-one persons. A good majority of more than 70 % have knowledge of the term ‘Vulnerability’. The survey revealed that Bio-banking seems to be an area which most of the faculty are not familiar with. Only 30% had knowledge on ethical considerations regarding research involving biological materials.

Similarly Less than half of the participants answered correctly to questions on clinical trials and their conduct, especially about trials on new drug development. The term Research Misconduct is known to more than 60 % of the participants. But only less than 60 % are aware about the details of IEC. 57% had knowledge of functions and roles of a research

ethics committee. 42% were aware of the composition of IEC. Only 39 % were familiar with proposal submission and review process by the IEC.

Regarding the attitudes of faculty about research ethics all participants agreed that there is a need for an IEC in each institution for ethical review of research, and the members constituting the IEC should receive training in research bioethics. All participants were of the view that research ethics should be taught mandatorily in undergraduate and postgraduate curricula. 100% believed that all investigators should also have necessary training in research ethics. 87% agreed that ethical review of research is only necessary for international collaborative research. Again, 87% held the view that ethical review of research by an IEC would delay research and make it harder for the researcher.

Discussion

Majority of our participants indicated that they already had prior knowledge about research ethics and have undergone some type of training in research ethics. Majority of faculty was also cognizant of the different guidelines in research ethics, with a substantial number being well aware of the ICMR Guidelines. Furthermore, majority were already involved in independent research work.

The present study revealed that majority of researchers (96.6%) has knowledge about Informed Consent. Similar results of high familiarity with Informed Consent have also been observed in studies conducted across North India [29, 30, 31].

A large majority of the faculty are aware of the accepted practices regarding protection of confidentiality while pursuing research.

A good majority of more than 70 % have knowledge of the term Vulnerability. These results contrast with the concerns mentioned regarding informed consent practices by investigators in the Middle-East [28].

Knowledge and awareness of faculty regarding bio-banking, research about biological materials, new drug development and certain aspects of clinical trials was found lacking.

However, while the faculty in this study endorsed the existence of IECs, almost all of them held the opinion that such committees would also cause undue delay in commencing or performing the actual research. But only less than 60 % are aware about the details of IEC. This lack of awareness regarding the IEC in the present study is more than that of previous studies [22, 23, 26]. Indeed, less than half of all of the participants stated they were unfamiliar with the functions of IECs, including composition of the committee and operations of IEC underscoring that pertinent steps are required to augment awareness of faculty to the operations of the IECs.

The attitude of all faculty members at all levels was favourable towards research ethics. All of them recognized the need for an IEC for ethical review of all types of research designs. Faculty also felt that research ethics should be incorporated as a mandatory undergraduate and postgraduate module. This is in accordance with the study done by Dash S.K. in 2010 [8] where respondents expressed a favourable attitude towards training in research ethics. All faculty members were also in favour of training in research for investigators and IEC members.

We had several limitations in our study. First, our study was based on convenience sampling, thus due to potential selection bias; the faculty who responded to the survey might not reflect

the knowledge, awareness and attitudes about research of the entire faculty of the institution. Secondly, the questions chosen in our study do not reflect the whole broad range of topics in research ethics. However, the questionnaire for the survey do represent basic information that all faculty in the area of research ethics are expected to know.

Despite these limitations, our study shed light on the level of knowledge and awareness of faculty with respect to ethical principles and guidelines, the general conduct of research and their awareness of the roles of the IEC, and their attitudes towards issues in research ethics and towards IECs. Further studies are warranted to investigate the knowledge, awareness, and attitudes of the academia in other universities to confirm generalization.

Conclusion

This study reveals several important generalizations. First, there appears to be an unquestionable acceptance and need of IECs among the faculty. Second, there seems to be a general acceptance of the need for formal education in research ethics among all faculty members irrespective of academic designation. Our observations also reveal several lacunae in the awareness of research ethics amongst medical professionals, either *in toto* or in a few aspects of bioethics, which should necessitate the inclusion of awareness programmes or workshops on principles of research ethics as part of general curricula or institutional agenda. We therefore recommend zealous inclusion of educational training in research ethics for all faculty, with special emphasis on research involving biological materials, bio-banking, clinical trials, responsible conduct of research, and the roles and functions of IECs including research proposal submission and review process by IEC. It's also pragmatic to conduct studies at regular intervals to ascertain their knowledge, awareness, attitudes and practice of research ethics after the training in bio ethics.

Furthermore, we recommend qualitative studies in this regard, to investigate comprehensively the attitudes of faculty towards IECs and certain practices in research ethics.

Medical fraternity is not provided formal training in practical aspects of ethics in their medical curriculum. Therefore, it is imperative to include practical education of ethics to bridge this giant vacuum in knowledge, attitude, and practices regarding ethics in clinical research.

TABLES

Table 1: Academic designation of faculty and number surveyed

Academic position	Number
Associate Professor	8
Assistant Professor	21
Senior Resident	1

Table2: Source of knowledge of bioethics

Source of ethical knowledge	Curriculum	Research Training	Books	Journals	Others
No. of response	9	15	18	21	Internet- 1 Senior Faculty- 3

Table 2: Awareness of different research guidelines among faculty

Ethical Guidelines Read	Belmont Report	ASUGCP	CIOMS Guidelines	ICMR Guidelines	Helsinki Declaration
No: of people who read	8	2	1	25	9

Table 3: Data on faculty based on their knowledge, awareness and attitude about research ethics.

Research ethics variable	Response	Percentage of participants
Knowledge	Correct answers	60
	Wrong answers	40
Awareness	Aware	40
	Unaware	60
Attitude	Positive attitude	96.6
	Unfavourable attitude	3.3

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