

Knowledge, attitude and practice of research ethics among medical faculty in a teaching hospital

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ABSTRACT

Background: To assess the knowledge, attitudes and practice of medical faculty regarding research ethics and research ethics committees (RECs).

Methods: A cross-sectional, questionnaire-based study was conducted in ESIC medical colleges in Bangalore among faculty using a validated questionnaire. Questions were designed to assess the knowledge, attitudes and practice of medical faculty regarding research ethics and research ethics committees. Statistical analysis was done using descriptive statistics and chi-square tests.

Results: Majority (76%) of faculty had not undergone training in research ethics. Less than half of the participants answered correctly to a question on guidelines in research ethics, 60% responded correctly to question on research involving children. Majority responded correctly to question on role of a research ethics committee and confidentiality, informed consent and to question on composition of Institutional Ethics Committee. 68% taught that ethical review of research by an ethics committee would delay research. >90% were favourable towards research ethics training. Faculty held attitudes regarding certain research ethics practices that were not optimal, 96% believed that it is okay to fabricate data, 68% taught that if no surrogate is available to give informed consent for vulnerable groups, they could still be included.

Conclusions: We conclude that among the medical faculties participating in our study, there is acceptance of RECs and training in research ethics, while there are knowledge gaps in research ethics guidelines, research involving children. There is need to train researchers and students to make them aware about various aspects of research.

Keywords: Attitude, Ethics committee research, Ethics, informed consent, Medical

INTRODUCTION

Medical research has increased greatly in many developing countries during the recent decade, motivated by the need to improve health in these countries.¹ Since medical research involves human participants; such research needs to be guided by fundamental ethical principles to ensure the protection of their rights and welfare. Furthermore, international standards mandate the review of research by research ethics committees (RECs).^{2,3}

Medical ethics has been included in the training curriculum of health professionals in many countries and there has been a growth in the number of ethics specialists and ethics committees. Yet complaints from

the public appear to be proliferating.⁴ This may be a reflection of an increased public awareness as well as poor practices within the health care sector. Traditional medical training offers little help in resolving the ethical dilemmas encountered by health care professionals. It has been argued that very few physicians are exposed to training in this important area of medical practice, yet on qualifying health care professionals are expected to know about ethical practice when applying their skills.⁴

METHODS

A cross-sectional, questionnaire-based study was conducted in ESIC medical colleges in Bangalore among faculty using a validated questionnaire.⁵ The first part collected demographic information of the participants:

gender, academic position, number of research publications, and prior training in research ethics).The second part of the survey assessed the participant’s knowledge in research ethics. The third part of the survey assessed respondent’s attitudes regarding research ethics. Respondents were required to choose from a 5-point Likert scale ranging from 1 to 5 (1-strongly agree, 2-agree, 3-not sure, 4-disagree and 5-strongly disagree). The fourth part of the questionnaire assessed respondents’ attitudes towards certain practices in the conduct of research. Respondents were required to answer “yes”, “no”. Questionnaire was distributed to 50 participants and 20 min time was given before CME on research ethics.

Statistics

The data was entered from completed questionnaires into Microsoft Excel and analysed using SPSS. For purposes of analysis, the categories of “strongly agree” and “agree” were collapsed as agree. chi-square tests was used to determine, in bivariate analyses, the association of each of the independent variables (gender, academic position, prior ethics training, number of publication) with each of the main outcome of interest (dependent responses involving knowledge, attitudes and practices).significant level was set at p value <0.05.

RESULTS

Questionnaire containing 20 questions was distributed to the participants and 20 minutes time was given to answer the questions.

Table 1 shows the demographic data of the faculty, which shows that among the participants female were slightly more than male. Assistant professors were more compared to associate professor and professors. Majority (76%) of faculty had not undergone training in research ethics and 48% had >5 research publication

Table 1: Demographic information of the participants.

SN	Item	Total
1	Gender	
	Male	22(44%)
	Female	28(56%)
2	Academic position	
	Professor	6(12%)
	Associate professor	13(26%)
	Assistant professor	31(62%)
3	Number of publication	
	0	8(16%)
	1-2	5(10%)
	3-5	13(26%)
	>5	24(48%)
4	Prior training in ethics	
	Yes	12(24%)
	No	38(76%)

Table 2 shows participants responses to knowledge questions in research ethics. Less than half of the participants answered correctly to a question on guidelines in research ethics, 60% of participants responded correctly to question on research involving children. 96% responded correctly to question on role of a research ethics committee and Confidentiality in medical research, 80% responded correctly to question on Informed consent, 86% responded correctly to question on Composition of Institutional Ethics Committee, female faculty were significantly (p value <0.05) more likely to give correct response for question on Composition of Institutional Ethics Committee.

Female faculty, assistant professor, faculty who had not undergone training and who had published >5 research papers responded correctly to all knowledge questions.

Table 2: Knowledge in research ethics.

SN	AGGRE gate(%)	Gender (%)		Academic position		Prior training in ethics			Number of publication (mean)			
		Male	Female	Professor	Associate	Assistant	Any	None	0	1-2	3-5	>5
1	44	31.82	68.18	4.55	36.36	59.09	27.27	72.73	22.73	18.18	22.73	36.36
2	96	45.83	54.17	10.42	25.00	64.58	20.83	79.17	12.50	10.42	27.	50
3	96	43.75	56.25	12.50	27.08	60.42	25	75	16.67	10.42	25	47.9
4	80	40	60.00	12.50	25.00	62.50	30	70	17.50	7.50	25	50
5	60	36.67	63.33	13.33	26.67	60	33.33	66.67	10	13.33	30	46.67
6	86	34.88	65.12*	11.63	27.91	60.47	23.26	76.74	16.28	11.63	25.58	46.51

*p value<0.05, 1. Guidelines in research ethics, 2. Knowledge of the role of a research ethics committee, 3. Confidentiality in medical research, 4. Informed consent, 5. Research involving children, 6. Composition of Institutional Ethics Committee

Table 3 shows attitudes for participants regarding research ethics >90% of the participants agreed that there is a need

for a research ethics committee in each institution for ethical review of research, the members of a research ethics committee should receive training in research

bioethics and Research ethics should be taught as a mandatory postgraduate module. 100% believed that all investigators should have some training in research ethics. 80% believed that ethical review of research by an EC is not necessary since there are scientific committees. 90% agreed that ethical review of research is only necessary for international collaborative research. 68% thought that ethical review of research by an EC would delay research and make it harder for the researcher. Female faculty were significantly ($p < 0.05$) more likely to believe that ethical review of research by an EC would delay research and make it harder for the researcher.

Table 3 also shows the association between attitude and demographic variables. Female faculty, assistant professor, faculty who had not undergone training and who had published >5 research papers were more likely to think that there is a need for a research ethics committee in each institution for ethical review of research, ethical review of research by an EC is not necessary since there are scientific committees, ethical review of research by an EC would delay research and make it harder for the researcher, ethical review of research is only necessary for international collaborative research and believed that members of a research ethics committee, all investigators, post graduates should receive training in research ethics.

Table 3: Attitudes regarding research ethics.

SN	Aggregate (%)	Gender (%)		Academic position (%)			Prior training in ethics (%)		Number of publication (%)			
		Male	Female	Professor	Associate	Assistant	Any	None	0	1-2	3-5	>5
1	96	43.75	56.25	10.42	25	43.75	22.92	77	16.67	10.42	27.08	45.83
2	80	40	60	12.50	25	62.50	22.5	77	17.50	12.50	27.50	42.50
3	68	29.4	70.59*	14.71	20.59	64.71	23.53	76.47	17.65	14.71	29.41	38.24
4	98	44.9	55.10	10.20	26.53	63.27	24.49	75.51	16.33	10.20	26.53	46.94
5	100	44	56	12	26	62	24	76	16	10	26	48
6	98	42.86	57.14	12.24	26.53	61.22	24.49	75.51	16.33	10.20	24.49	48.98
7	90	40	60	11.11	28.89	60	20	80	17.78	11.11	26.67	44.44

*p value <0.05, 1. There is a need for a research ethics committee in each institution for ethical review of research, 2. Ethical review of research by an EC is not necessary since there are scientific committees, 3. Ethical review of research by an EC would delay research and make it harder for the researcher, 4. The members of a research ethics committee should receive training in research bioethics, 5. All investigators should have some training in research ethics, 6. Research ethics should be taught as a mandatory postgraduate module, 7. Ethical review of research is only necessary for international collaborative research.

Table 4: Attitudes towards certain practices in the conduct of research.

AGGREGATE (%)	Gender (%)		Academic position (%)			Prior training in ethics (%)		Number of publication (%)			
	Male	Female	Professor	Associate	Assistant	Any	None	0	1-2	3-5	>5
96	45.83	54.17	12.50	25	62.50	25	75	16.67	10.42	25	47.92
84	40.48	59.52	11.90	23.81	69.05	26.19	73.81	19.05	11.90	28.57	40.48
90	42.22	57.78	11.11	26.67	62.22	22.22	77.78	17.78	11.11	24.44	46.67
100	44	56	12	26	62	24	76	16	10	26	48
84	50	50	9.52	26.19	64.29	21.43	78.57	14.29	7.14	28.57	50
88	56.82	43.18	11.36	27.27	61.36	22.7	77.27	15.91	6.82	27.27	50
68	32.35	67.65*	14.71	20.59	64.71	26.47	73.53	14.71	11.76	23.53	50

*p value <0.05, 1. It is okay to fabricate data to improve outcome of research as long as there is no harms to the patients, 2. No need to obtain research informed consent for blood samples obtained for clinical tests, 3. Patients should not be told about potential risks of a study because they may not enroll in the study, 4. Informed consent from patients is necessary for use of their biological samples in research, 5. Vulnerable groups such as children and the mentally ill could provide informed consent, 6. Informed consent should always be obtained by having patients sign in a written form, 7. If no surrogate is available to give informed consent for vulnerable groups, they could still be included

Table 4 shows respondents attitudes towards certain practices in the conduct of research 96% believed that it is okay to fabricate data to improve outcome of research as long as there is no harms to the patients, 90% believed that patients should not be told about potential risks of a study because they may not enrol in the study >80% believed that no need to obtain research informed consent for blood samples obtained for clinical tests, vulnerable

groups such as children and the mentally ill could provide informed consent, informed consent should always be obtained by having patients sign in a written form, 100% believed that informed consent from patients is necessary for use of their biological samples in research and 68% thought that if no surrogate is available to give informed consent for vulnerable groups, they could still be included. Female faculty were significantly ($p < 0.05$)

<0.05) more likely to believe that if no surrogate is available to give informed consent for vulnerable groups, they could still be included. Table 4 also shows the association between research practice and demographic variables. Both men and women believed that vulnerable groups such as children and the mentally ill could provide informed consent. Male were more likely to believe that informed consent should always be obtained by having patients sign in a written form compared to female. Female faculty were more likely to believe that it is okay to fabricate data to improve outcome of research as long as there is no harms to the patients, no need to obtain research informed consent for blood samples obtained for clinical tests, patients should not be told about potential risks of a study because they may not enrol in the study, informed consent from patients is necessary for use of their biological samples in research, if no surrogate is available to give informed consent for vulnerable groups, they could still be included.

Assistant professor, faculty who had not undergone training and who had published >5 research papers were more likely to believe that it is okay to fabricate data to improve outcome of research as long as there is no harms to the patients, no need to obtain research informed consent for blood samples obtained for clinical tests, patients should not be told about potential risks of a study because they may not enrol in the study, informed consent from patients is necessary for use of their biological samples in research, vulnerable groups such as children and the mentally ill could provide informed consent, informed consent should always be obtained by having patients sign in a written form, if no surrogate is available to give informed consent for vulnerable groups, they still be included.

DISCUSSION

Table 1 shows the demographic data of the faculty, there were slightly more females (56%) compared to male, assistant professors were more compared to associate professor and professor, 48% of participants had >5 publication, 76% had no prior training in research ethics.

Table 2 assess respondent's knowledge in research ethics. Less than half of the respondents gave correct answers for question on guidelines in research ethics, while more than half of the respondents gave correct answer for other question on research knowledge.

Our study result is similar to study conducted by Kiran Kumar Mallela et al where >50% of participants responded correctly for questions on informed consent, research involving children and institutional ethics committee and about 8-35% participants had knowledge about various ethical guidelines. In a study by El-Dessouky HF et al 12% gave correct answers for question on guidelines in research ethics. In contrast to study conducted by El-Dessouky HF et al where <50% responded correctly, in our study >50% of participants

responded correctly for questions on role of a research ethics committee, confidentiality in medical research, research involving children. Our study result is similar to study conducted by Kiran Kumar Mallela et al where >50% of participants responded correctly for questions on informed consent, research involving children and institutional ethics committee and about 8-35% participants had knowledge about various ethical guidelines.^{5,10}

Majority of Assistant professors, participants who had >5 publication and who had no prior training in research ethics responded correctly to all knowledge questions. This was in contrast to study conducted by El-Dessouky HF et al where majority of participants with prior training in research ethics responded correctly to knowledge questions.

For question on Composition of Institutional Ethics Committee female faculty significantly (65%) (p value <0.005) responded correctly compared to male faculty (35%).

Table 3 shows the respondent's attitudes to RECs and research ethics education. 96% of the respondents agreed there is a need for an REC in each institution. 80% thought that the presence of scientific committees made the existence of an REC unnecessary this was in contrast to study by El-Dessouky HF et al where 10% of respondents thought that scientific committees made the existence of an REC unnecessary. 68% thought that RECs would delay research and would make research harder to perform in contrast to study by El-Dessouky HF et al where 44% thought that RECs would delay research and in study conducted by Kiran Kumar Mallela et al 20% had opinion that ethical committees would unnecessarily delay research.^{5,10} A large majority of the respondents (greater than 90%) were in favour of research ethics education for postgraduates, investigators, and members of RECs, this was similar to previous studies.^{5,10} 90% believed that ethical review is only necessary for international collaborative research, in study by El-Dessouky HF et al <20% believed that ethical review is only necessary for international collaborative research.

Majority of Assistant professors, participants who had >5 publication and who had no prior training in research ethics agreed there is a need for an REC in each institution, the presence of scientific committees made the existence of an REC unnecessary, RECs would delay research and would make research harder to perform, were in favour of research ethics education for postgraduates, investigators, and members of RECs, and believed that ethical review is only necessary for international collaborative research. In study by El-Dessouky HF et al Professors compared with the other faculty were significantly more likely to agree that ethical review of research is only necessary for international research, faculty "without any prior ethics training" were significantly more likely to think that an REC would be

helpful ($P < 0.01$). Furthermore, Mid- Level faculty and those with “prior ethics training” were significantly more likely to believe that an REC would delay research ($P < 0.05$).

In our study female faculty significantly (71%) (p value < 0.005) believed RECs would delay research and would make research harder to perform compared to male faculty (29%).

Table 4 shows the respondents attitudes toward several practices in research ethics. 96% respondents thought it is okay to fabricate data to improve the outcome of the research if such an act did not cause harms to patients. Slightly more than 10% respondents thought it is okay to fabricate data to improve the outcome of the research if such an act did not cause harms to patients in study by El-Dessouky HF et al.⁵ In previous study approximately 2% of respondents were willing to fabricate data.^{6,7} 84% responded that there is no need to obtain research informed consent for blood samples obtained for clinical tests similar results was seen in previous study.¹⁰ 90% believed that patients should not be told about potential risks of a study because they may not enroll in the study in contrast to 7% in study by El-Dessouky HF.⁵ 100% believed that Informed consent from patients is necessary for use of their biological samples in research in contrast to 87% in study by El-Dessouky HF, 84% believed that Vulnerable groups such as children and the mentally ill could provide informed consent in contrast to 39% in study by El-Dessouky HF and 46% in study conducted by Kiran Kumar Mallela et al.^{5,10} This result is made more significant by the findings of another study showing that research participants who participated in studies on oral health in Nigeria had poor understanding of several key elements of the informed consent process.⁹

88% believed that Informed consent should always be obtained by having patients sign in a written form in contrast to 91% in study by El-Dessouky HF.⁵ 68% believed that If no surrogate is available to give informed consent for vulnerable groups, they could still be included in contrast to 7% in study by El-Dessouky HF.⁵

Majority of Assistant professors, participants who had > 5 publication and who had no prior training in research ethics agreed 84% responded that there is no need to obtain research informed consent for blood samples obtained for clinical test, patients should not be told about potential risks of a study because they may not enrol in the Informed consent from patients is necessary for use of their biological samples in research, Vulnerable groups such as children and the mentally ill could provide informed .Informed consent should always be obtained by having patients sign in a written form. If no surrogate is available to give informed consent for vulnerable groups, they could still be included professors were more likely to agree that research performed on blood samples obtained for clinical purposes do not require informed consent compared with the other faculty.⁵ Asem and colleagues

observed similar results regarding this issue among the faculty at Cairo University.⁸ In our study female faculty significantly (68%) (p value < 0.005) believed If no surrogate is available to give informed consent for vulnerable groups, they could still be included compared to male faculty (32%).

CONCLUSION

Since majority of faculty were not trained in ethics. We therefore recommend further development of educational training in research ethics for all faculties, with special emphasis on vulnerable participants, responsible conduct of research, informed consent and the roles and functions of ECs.

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