Original Article

Implementation of an educational program to promote research ethics in undergraduate medical students

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Abstract

Background: MBBS students lack training in research ethics which is crucial when they enter clinical practice and venture into clinical research in future. This study was planned to implement an educational module to build concepts in research ethics

Objective: To assess the change in the knowledge and attitude of medical students towards research ethics.

Methods: The study was initiated after obtaining institutional ethics committee approval. It was an interventional study, conducted on 2nd MBBS students (N=130) subjected to an educational program which comprised of three modules viz., theme lectures, educational visits and small group case based learning. A prevalidated questionnaire(35 items), was administered at baseline and at the end of 3 modules, to assess the change in the knowledge gained and in the attitude towards ethics in animal and human research. Feedback was obtained from students and faculty to assess the outcome of this program.

Results: On analyzing the knowledge gained post intervention in 130 students, it was observed that in the post test for the items on ethics committee- need and composition, principles of research ethics was answered correctly by more number of students, which was statistically significant. The statistically significant positive change was observed for attitude of these students towards both animal and human research ethics. Case based discussions provided better understanding of ethical practices and its importance in conducting research as responded by majority students and faculty.

Conclusions: Educational program on research ethics enhanced learning and brought about the positive attitudinal change. Majority students' and faculty appreciated the program and considered it as relevant for undergraduate training.

Keywords: Animal research, case-based discussion, ethics committee

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INTRODUCTION

Research training is of utmost importance for any health-care professional as he/she practices evidence-based medicine in future. Research training imparts skills such as literature search, research methodology, collecting and analyzing data, and critical appraisal of evidence.[1] Conduct of research projects involves balancing science and ethics. All proposals on biomedical research involving animal or

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human participants need clearance of respective dedicated ethics committees (ECs), and therefore, knowledge of the ethical aspects of research is mandatory among medical students to ensure that these budding clinicians have understood the principles of research since the early years of medical education, which serves as a platform for all their future research endeavors.

The undergraduate (UG) medical students are often interested in participating in projects for short-term research scholarships, namely, ICMR short term studentship program or university research scholarship programs. These students take up research projects without having the background knowledge of the ethical responsibilities related to such research work.[1-6] It was, therefore, felt that an independent educational program needs to be developed for these students in order to increase their knowledge and awareness about research ethics and familiarizing them about certain procedures to be followed to practice ethical behavior while conducting research. Exposure of UG medical students to such a program may develop interest in them to pursue a research career in future as well. However, considering the time constraints, it was felt that such program should be intertwined in the current curriculum for II year MBBS.

Hence, the present study was undertaken to develop and implement an educational program on research ethics in UG medical students and assess their performance based on the knowledge gained and change in the attitude toward ethical research.

METHODOLOGY

Prior to initiation of this interventional study, the institutional ethics committee's (IEC) permission (EC/OA-89/2014) was taken. UG II year MBBS medical students in their 4th semester were eligible to participate and their written informed consent was requested.

Prior to participating in the program, a questionnaire entitled "Knowledge and attitude towards research ethics" was administered to the consented students. This questionnaire was prepared to assess the baseline knowledge and attitude of medical students toward research ethics involved in human and animal research. It had 35 items: 19 items were based on knowledge aspect with regard to animal and human research ethics, whereas 16 items were based on the attitude of these students toward animal and human research ethics. The questionnaire was validated by experts (n = 6) in the field of research and bioethics for its content.

The educational program included three modules as follows:

Module 1 – Theme lectures

Two theme lectures (1-h duration each) were conducted. The content of the lectures focused on the basic concepts, principles of ethical research, evolution of ethical guidelines, ethical practices involved in animal and human studies, and the roles and responsibilities of animal as well as human ECs.

Module 2 – Educational visit

In this module, the students were divided into batches of 10, and the visits were arranged to animal house in order to acquaint them about how animals for research purpose are housed and in-house working of animal house. Similarly, a visit was also arranged to the IEC office where they were briefed about the composition of IEC and explained the standard operating procedures of IEC, human research proposal documents needed to be submitted to IEC for getting approval, and the contents in the informed consent document template.

Module 3 – Small group case-based learning

In this module, the students were divided into small batches (14 each) and were given case scenarios on ethical issues pertaining to research ethics in animal as well as human research. These case scenarios (total seven cases on animal and seven cases on human research ethics) were finalized after taking the comments from the members of animal and human ECs. The animal case scenarios were prepared on different ethical issues related to animal research such as number of animals being used, painful procedures to be performed on animals, situations when one can use alternatives to animals, housing conditions, euthanasia, reusing animals, and on procedures to be followed after commencement of the research project. The human case scenarios were prepared on different ethical aspects such as language used in informed consent, consent in case of illiterate patients, confidentiality, pregnancy, re-consent, compensation, and conflict of interest. The answers to each case scenario were discussed with the faculty so as to have uniformity in the information conveyed to the students. The students in pair were asked to discuss and interpret two case scenarios: one on animal and the other on human ethical issue with the help of faculty who was present as a facilitator.

At the end of all the three modules, the students were re-administered the "knowledge and attitude towards research ethics" questionnaire so as to assess the change in the knowledge gained and in the attitude toward ethics in animal and human researches. Finally, the perception

of students and faculty on the program was evaluated by collecting their feedback on a prevalidated feedback questionnaire (10 items). This feedback form tried to gather information related to the utility of these three modules in imparting information pertaining to research ethics, content taught, clarity in information provided, its relevance, and, also, any suggestions on the way the program was implemented. The Faculty Feedback Questionnaire focused on students' understanding of ethical consideration in research, ability of students to participate in the case-based discussions and their effect on learning, enhancing interactivity, students' ability to apply the basic ethical principles in future research projects, and relevance of this program.

Statistical analysis

All data were compiled, entered in Microsoft Excel, and summarized as proportion using tables. Proportion of students attempting correct answers in the "knowledge and attitude towards research ethics" questionnaire, before and after the program, was compared using Chi-square test. Statistical significance was fixed at the level of $P < 0.05$.

RESULTS

We contacted 180 II year MBBS students, of which 172 consented to participate. Responses of 130 students completing all three modules were considered for final analysis. The proportion of students correctly answering ethics-related knowledge-based questions before and after program implementation is summarized in Table 1.

Post program the number of students responding correctly to the six items pertaining to ethical issues in animal research increased statistically ($P < 0.05$). It must be noted that for items – knowledge about existence of animal EC, permission to use animals for the purpose of demonstration to students, organizations that fight for animal rights even in the preprogram phase the number of respondents were 65%, 71% and 48% respectively. The number of student responders with accurate answers for the items viz., 3Rs in animal research increased from 1.5% to 24% while composition of animal EC increased from 6 to 50%. This accounts to the fact that though there was statistical increase in the number of students answering, still 76% and 50% students were lacking knowledge about these items respectively. Similarly, for the following items pertaining to ethical issues in human research, i.e., impact of Thalidomide incident on evolution of ethical guidelines, EC permission for any research in humans is necessary, steps regarding withdrawal of participant from the study and whom to approach in case any ethical issue arises; the number of students responding correctly even in the preprogram were 47%, 91%, 52%, and 67%, respectively. The number of student responders with

Table 1: Change in the knowledge based responses about ethical aspects in animal and human research before and after program implementation (*n*=130)

Question number	Question asked	Before the program, *n* (%)	After the program, *n* (%)
	Animal research ethics		
1	Three Rs related to animal research	2 (1.54)	31 (23.85)***
2	Composition of animals EC	8 (6.15)	65 (50)***
3	Knowledge about existence of animal EC	84 (64.62)	128 (98.46)*
4	Person to be informed in case of death of the animal during the study period	47 (36.15)	68 (52.31)*
5	Permission to use animals for the purpose of demonstration to students	92 (70.77)	115 (88.46)*
6	Organizations that fights for animal rights, in India	63 (48.46)	81 (62.31)*
	Human research ethics		
7	Basic principles/components of ethics in human research	49 (37.69)	91 (70)***
8	Impact of thalidomide incident on evolution of ethical guidelines	61 (46.92)	108 (83.08)***
9	Role of IEC in biomedical research conducting on human participants	8 (6.15)	39 (30)***
10	Existence of human EC (IEC) in the institution	11 (8.46)	129 (99.23)***
11	Composition of human IEC	52 (40)	105 (80.77)***
12	Researchers have a duty to avoid or minimize risk to study participants	10 (7.69)	76 (58.46)***
13	Documents need to be submitted for seeking approval of any research project	12 (9.23)	46 (35.38)***
14	Researchers must seek approval from EC if they intend to do collect the health record of patients	14 (10.77)	44 (33.85)***
15	Necessary to have EC permission for any research in humans	118 (90.77)	129 (99.23)*
16	The principle behind voluntary and informed consent is	17 (13.08)	70 (53.85)***
17	Need of taking informed consent from the research participant/s	3 (2.31)	40 (30.77)***
18	Regarding withdrawal of participant from the study	68 (52.31)	120 (92.31)***
19	Whom to approach in case any ethical issue arise	87 (66.92)	107 (82.31)*

*$P<0.05$, ***$P<0.0001$, using Chi-square test. EC=Ethics Committee, IEC=Institutional EC

Table 2: Change in the attitude based responses about ethical aspects in animal and human research before and after program implementation (*n*=130)

Question number	Question asked	Strongly agree/agree	
		Pretest, *n* (%)	Posttest, *n* (%)
	Human research ethics		
1	Research in the medical field is important	82 (63.08)	125 (96.15)***
2	Research ethics should be incorporated as a part of medical curriculum	7 (5.38)	36 (27.69)***
3	One must contribute in research	24 (18.46)	45 (34.62)*
4	Research ethics should be taught as integrated course	28 (21.54)	84 (64.62)***
5	Doctors must learn research ethics during clinical training	31 (23.85)	79 (60.77)***
6	Availability of plenty of alternatives for research	33 (25.38)	44 (33.85)
7	There is a difference between ethics in clinical practice and human research	46 (35.38)	100 (76.92)***
8	Ethical issues should be considered while planning any research project	69 (53.08)	102 (78.46)***
9	Undergraduate students need to read medical journals	50 (38.46)	88 (67.69)***
	Animal research ethics		
10	Use of animals in research is important	68 (52.31)	118 (90.77)***
11	Animals have same rights as humans	3 (2.31)	33 (25.38)***
12	Better housing conditions needed for animals used for research	71 (54.62)	110 (84.62)***
13	Use of stray animals not permitted for research purpose	83 (63.85)	100 (76.92)*
14	Rather see animal die than see human die for research purpose	86 (66.15)	116 (89.23)***
15	Need more regulations governing animal use in research	108 (83.08)	120 (92.31)*
16	Need for separate EC for animal and human research	108 (83.08)	122 (93.85)*

*$P<0.05$, ***$P<0.0001$, using Chi-square test. EC=Ethics Committee

accurate answers increased statistically ($P < 0.05$) for the items-role of IEC in biomedical research conducting on human participants (6%–30%), composition of human IEC (40%–81%), researchers have a duty to avoid or minimize risk to study participants (8%–58%), documents need to be submitted for seeking approval of any research project (9%–35%), need of taking informed consent from the research participant/s (2%–31%). It must be noted that certain items students were aware before the program while certain items they lacked information. Post program number of student responding accurately was statistically more but not every student grasped that information.

The proportion of student's responses for the attitude based items about ethical aspects in animal and human research before and after program implementation is summarized in Table 2. After the program, the questionnaire revealed that there were few areas where the students' attitude towards research distinctively changed and showed positive attitude towards research. Students felt that the research in medical field is important (96%) and they agreed (94%) that there is a need to have separate ECs for scrutinizing research projects involving animal and humans as the ethical issues involved in both are different. Students' (77%) realized the reason why patients involved in research are handled differently than patients in clinical practice. The students' (91%) attitude toward animal use in research showed positive trend. Though statistically significant number of students (28%) opined that ethics should be included in medical curriculum and 35% students felt that everyone must contribute in research while 65% students stated that ethics should be taught as an integrated subject; these responses were limited to few students who participated.

Analysis of students' feedback regarding all the three modules revealed a positive response towards usefulness of all the 3 modules in teaching research ethics. The student feedback on concept and importance of research ethics, process of informed consent, practical exposure and ethical issues is presented in Figure 1. The overall design of the program was rated as excellent by 63 (48.46%), and good by 51 (39.23%) students. Majority of students' (n = 90, 69.23%), responded by stating that the content was well organized, all the three modules collectively facilitated the understanding of the basic concepts of research ethics (n = 89, 68.46%). Many students' (n = 96, 73.85%) felt it is relevant to learn about ethical aspect of research at II year MBBS level. The knowledge and skill of faculty involved in teaching research ethics was also very much appreciated by many students (n = 83, 63.85%).

The training would definitely help them to write a research plan giving due consideration to ethical aspects was stated 92 (70.77%) students. When inquired about which module they enjoyed the most; 39 (30%) students appreciated all the three modules, followed by case based discussions (n = 36, 27.69%).

Feedback from the teachers [Figure 2] revealed that 8 out of 10 faculty members felt that with the help of three modules, viz., lectures, visits and case based discussions led to better understanding of the basic ethical principles and responsibilities needed while conducting any research.

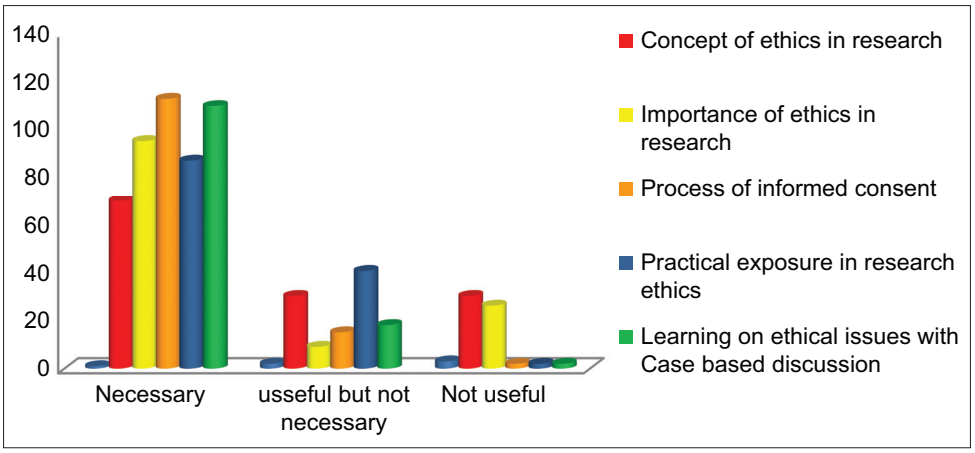

Figure 1: Student's (n = 130) feedback on importance of research ethics modules

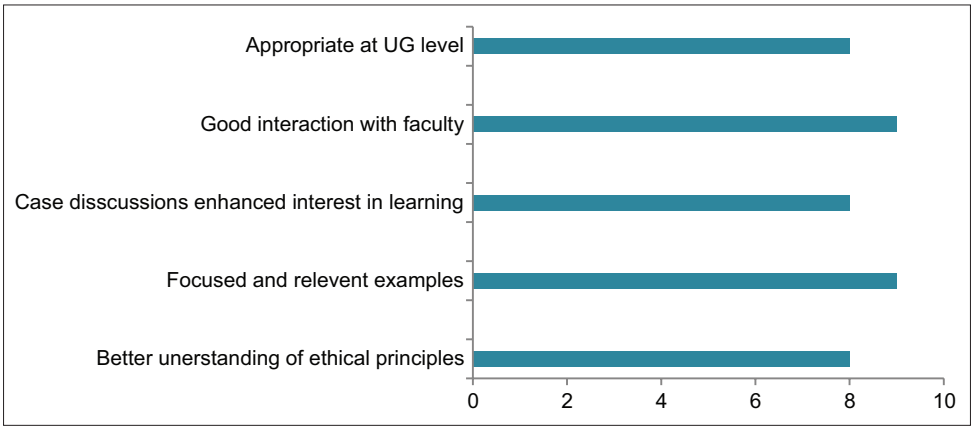

Figure 2: Faculty (n = 10) feedback about all the 3 modules of the educational program

All of them felt the cases designed were in fact relevant and focused on a specific ethical issue, generated healthy discussion among the students and the faculty. All faculty agreed that there was good interactivity during case discussions that enhanced the students' ability to provide appropriate answer with proper justification. All of them agreed that after learning the basics of research ethics, the students could assist in writing the research project and stated that at II year MBBS level when most of the students involve themselves in research projects it was apt that students underwent this training module.

DISCUSSION

Studies conducted to assess the knowledge and attitude of medical and dental students (UG students, postgraduate students, interns) and teachers, about research ethics have concluded that there is inadequate knowledge and lack of awareness among the medical students and teachers about research ethics.[1-7] Therefore, this study was planned with an objective of imparting the knowledge of research ethics in both animal and human research to UG medical students.

It was evident from the postprogram questionnaire results that there is improvement in knowledge aspect pertaining to research ethics. Though the knowledge gain was statistically significant it was seen that for certain vital questions on research ethics, students could not answer these questions correctly for example, 3 Rs. in context with animal research ethics (76% students responded inaccurately), reasons why informed consent is taken prior to any research study (69% students responded inaccurately), and the role of EC (70% students responded inaccurately). As the above information was delivered through lecture sessions, perhaps the learning was not achieved as expected hence, changing it to small group teaching may improve learning in students. This was also supported in the findings of Chatterjee and Sarkar stating that mode of teaching, predominantly didactic and text book-oriented, does not increase students' awareness of this subject.[4] Clinically-oriented approaches with interactive components through case studies and workshops may be more effective in understanding the overall concept in research ethics.

Similarly for questions on documents that needed to be submitted for seeking approval of any research project and

need of EC permission for a study, statistically significant number of students have responded correctly but again the knowledge was lacking in majority of the students (65% responded incorrectly). These findings reflect the fact that certain aspects of research can be learnt only if one becomes the part of any research project. On the other hand knowledge about composition of animal and human EC, whom to approach in case any ethical issue arises, necessary to have EC permission for any research in humans to be initiated was answered correctly by majority students. The probable reason for improvement in knowledge pertaining to these aspects is that all these was learnt in the visits to the EC office and also the same was discussed in case based small group teaching. These findings strongly supports that case based discussions in the form of small group teaching and actual visits enhanced learning as compared to classroom teaching, similar findings were stated by Chatterjee and Sarkar.[4]

Post program revealed that there were few areas where the students' attitude towards research distinctively changed and showed positive attitude towards research. Students (96%) appreciated the importance of research in medical field. The case-based discussions of faculty with students is most likely reason to be responsible for this change, as many practical aspects related to animal studies such as, animal housing, breeding and the process of scrutinizing research projects, restricting number of animals used in research, using alternatives whenever possible were discussed in depth with the help of case scenarios. Students'(77%) realized the reason why patients involved in research are handled differently than patients in clinical practice. The students' attitude towards animal use in research showed a positive trend. This positive change in attitude was perhaps due to the actual visits arranged to animal house as well as offices of animal and human ECs.

Though statistically significant number of students opined that ethics should be included in medical curriculum and everyone must contribute in research, it should be taught as an integrated subject. The Medical Council of India has taken cognizance of this and introduced AETCOM module in the medical curriculum but the focus is on ethics related to medical practice. This will not only sensitize them towards research but will also train them in their postgraduation. The students who participated in the study agreed that ethics should be the part of medical curriculum and one must contribute in research, unfortunately these responses were limited to only 36% of the students. We can only infer from these results that as the students are already facing the burden of studying the core subject and preparing for entrance examinations, they definitely deny introduction of a completely new subject in their curriculum. We may overcome this problem by gradually sensitizing the students towards research via videos or movies at regular intervals for them to imbibe the basic knowledge on research ethics and to apply this by undertaking some small research projects and reward them with some marks linked to their formative and internal assessment.

A small number of studies have evaluated the impact of interventions (for e.g. Web based training, focus group discussion and workshops on research ethics) to assess the knowledge gained and change in the attitude towards research ethics postintervention. A study conducted by Halkoaho *et al.*[8] used a web based training program to teach clinical research bioethics for PhD students. This program though effective, lacked group discussions was stressed by the researchers as limitation. Hence, in addition to lecture and EC visits, inclusion of group discussion with trained faculty on various ethical issues in our study was well appreciated and could be one of the reasons for better learning and understanding about the research ethics among the students.

Students as well as faculty feedback was found to be extremely encouraging. The small group discussions in the form of cases generated interest and were thought provoking. The student-faculty interactivity indeed facilitated the process of ethical reasoning in different situations and understand the significance of ethics in research. A study conducted by Goldie *et al.*[9] too supports our findings as they mentioned that the small group process facilitates transformative learning, an effective approach to bioethics teaching. The authors reiterated that their previous study too showed small group teaching to be more effective than lecture in teaching ethics.[9] These conclusions were reflected in our findings as well.

A study conducted by Imran *et al.*[7] on doctors for evaluating knowledge, attitude and practices of residents on bioethics also concluded that there is an urgent need to include practical education of ethics, in an interesting manner, with the multidisciplinary approach, to bridge the gap in the knowledge, attitude and practices regarding ethics in clinical practice and research. As suggested by Goldie *et al.*, that the ethical knowledge should be formally assessed in II–III MBBS, we implemented this program for II-MBBS students; this idea appeared to be acceptable to faculty.[9]

Challenges

Training faculty for the case discussions so as to maintain uniformity in the process of group discussions involved considerable efforts and time. In addition, designing the three modules to retain student interest and organizing all

modules without interfering with regular student teaching schedule was a challenge.

Recommendation

Training programs focusing on research ethics and professionalism should be an essential part of the medical curriculum to make the medical student competent in conducting research.

CONCLUSION

Students were sensitized to various aspects of research ethics and appreciated the research ethics program. Faculty also perceived the program as thought provoking and inculcated ethical reasoning among students.

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Conflicts of interest

There are no conflicts of interest

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