

The Assessment of Proficiency in Research Ethics Among Researchers in Academic Institutions

Research Article

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Abstract

Introduction: The research ethics provides guidelines to apply moral regulations and professional codes of conduct in the various steps of research. The research ethics plays a very vital role in the collection, analysis, reporting, and publication of details about research subjects, in particular active acceptance of participant's right to privacy, confidentiality and the informed consent of the participant.

Aims: To assess the Knowledge, awareness and attitudes about research ethics among the faculty and students of medical and dental colleges and the requirement for a regular teaching about research ethics among the faculty and students of medical and dental colleges.

Materials & Methods: A cross-sectional study was conducted by assessing the responses to 39 selected basic questions regarding Knowledge, awareness and attitudes about research ethics among a total of 415 faculty members and post graduate students of the medical and dental institutions in Karnataka. The questionnaire was made into 5 categories. Chi-square tests was used to determine, in bivariate analyses, the association of each of the independent variables like their speciality, their academic position, prior ethics training, and their prior involvement with research with each of the main outcome of interest. The students t-test was done to assess the respondents scores on the 5-point Likert scale ranging from 1 to 5 (1-strongly disagree, 2-disagree, 3-not sure, 4-agree and 5-strongly agree). The average of their scores were compared among the various variable like their speciality and academic position by using the ANOVA test.

Results: A total of 415 responses were obtained from the participants of the study. Out of this we had 273 respondents as female and 142 respondents as male. Among these 225 respondents were from the medical speciality and 190 from the dental speciality. The P value was kept at 0.05 for this study.

Conclusion: The participants of the questionnaire survey showed that the institutional ethics committees would be very useful for promoting health research and are imperative for appraisal of the health research projects. The majority of the respondents agreed that they were well aware of the ethical guidelines governing the human research, but when we assess the respondent's knowledge and attitudes towards research ethics there seems to be a lacuna in complete awareness and knowledge of research ethics. The results of the study also helped us to assess the requirement for a regular teaching about research ethics among the faculty and students of medical and dental colleges.

Introduction

Research is defined as the systematic investigation into and study of the materials and sources in order to establish facts and reach new conclusions. Another definition of research was given by John W. Creswell, which states that "research is a process of steps used to collect and analyse information to increase our under-

standing of an issue or topic". It consists of three steps: to pose a question, to collect data to answer the question, and to present an answer to the question.

Ethics is the branch of philosophy which deals with the moral aspects of human behaviour. The ethics deals with the principles and the theories of values and the basic perceptions & justifica-

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tions of values.

The research ethics provides guidelines to apply moral regulations and professional codes of conduct in the various steps of research. The research ethics plays a very vital role in the collection, analysis, reporting, and publication of details about research subjects, in particular active acceptance of participant's right to privacy, confidentiality and the informed consent of the participant. The research ethics provides guidelines for the responsible performance of research on human participants.

Need for the Study

The researchers have to take the whole and sole responsibility for the ethical conducting of their research in an ethically. First and the foremost responsibility of a researcher is to take care of the safety, well-being, dignity, and rights of the participants. Researchers have to be very careful of the various other issues at different stages of the research process. Both the participants and researcher have many important roles to play. The researchers have to take care of the participants' right and must consider their research from the participants' perspective.

The researcher must make sure that their research shall be done honestly. The research should be done impartially, without any prejudice and absence of bias. The researcher should never forget to follow integrity and probity while conducting research. The researcher must seek consent from the participants for their participation. They must respect people, their cultures, values, religions, economic status and so on. Researchers have an obligation to take care of the confidentiality and personal information or identity of the participants as per her choice. Researchers should avoid experiments which may pose a threat to both the participants and the researchers themselves. Apart from the participant's, the researcher has also an obligation towards society, her colleagues or other researchers and funders of the project.

On the other side, the participants have the exclusive right to give consent to participate, withdraw from, or refuse to take part in research projects. Participants have right to seek confidentiality and stop personal information or identifiable data from publishing or sharing. They have right to seek their safety and security. Whenever required, the data should be kept secure and participants should not be exposed to unnecessary or disproportionate levels of risk.

The regulatory bodies like Central Drugs Standard Control Organization (India) mandatorily recommends that any type of research on human participants requires the ethics clearance from the accredited ethics committee. The researcher should compulsorily obtain the ethics clearance for his/her research study on human participants. And hence it has become an obsolete necessity for the researcher that the principles of research have to be learnt, understood and strictly followed while doing any type of research on human participants.

Good Knowledge about research ethics among the faculty and PG students in Health Institutions has become very important for the benefit of researcher & his team, to provide good quality of ethically made research not only for the benefit of the participants of the study, but for the whole humanity.

However, there has been very few studies which have investigated the attitudes of medical & dental faculties toward concepts of research ethics, including the acceptability of regional or institutional ethics committees. This study will help us to know the level of understanding, the attitude and practice of following principles of research ethics while doing research on human participants at professional institutions. Understanding about the Knowledge, awareness and attitudes regarding research ethics among the faculty and PG students in health institutions shall help us to know the necessity for teaching research ethics related classes/courses among them.

Review of Literature

The Nuremberg code (1946-1947), Helsinki declaration (1964-2013), and Belmont report (1979) provided the basis of systematic ethically uniform research to which stringent rules and consequences for violating them were mentioned. The laws of government and regulations concerning the responsible conduct of researches have ever since been developed for research that involves both human beings and animal subjects.

In India, the detailed requirement & guideline for undertaking the clinical trial are specified under schedule Y of said rule and this schedule further provide that clinical trial are required to be conducted and data generated, documented and reported in compliance with the approval protocol and Good clinical Practice (GCP) guidelines published by Central Drug Standard Control Organization (CDSCO), Directorate General of health services, Govt. of Indian as well as application regulation. It is therefore, necessary that the clinical trial is conducted in compliance to the provision of the Drug & Cosmetics Rule and the care is taken to protect the right, safety and well-being of the subjects participating in the Clinical trial and data generated is scientifically and ethically and sound.

As the regulatory world is dynamic and the flow of new information from clinical trial is arising at rapid rate and issues related to clinical trial involving more and more. The changes should be made to the existing regulations and amendments to address and resolve these evolving issues.

Recently changes in Schedule Y, then how clinical trial or pharmaceutical industries affected. Since Jan. 2013 to last update of 28 June 2014 the Indian regulatory authorities have announced a spate of laws and guidelines, which will have a huge impact on the clinical trial sector in India.

Aim of the study

To assess the Knowledge, awareness and attitudes about research ethics among the faculty and students of medical and dental colleges by using an online questionnaire survey.

Objectives of the study

To statistically measure the Knowledge, awareness and attitudes about research ethics among the faculty and students of medical and dental colleges by using an online questionnaire survey.

To assess the requirement for a regular teaching about research ethics among the faculty and students of medical and dental colleges

Materials and Methods

Source of Data: The faculty and post-graduate students of various dental and medical colleges in Karnataka.

Inclusion Criteria: The faculty and the post graduate students of Institutions in Karnataka who are interested to participate in the online questionnaire study.

Exclusion criteria: The participants who are not willing to give written the consent to answer the questions in the online questionnaire.

Methodology

- A cross-sectional study was conducted by assessing the responses to 39 selected basic questions regarding Knowledge, awareness and attitudes about research ethics among a total of 415 faculty members and post graduate students of the medical and dental institutions in Karnataka.
- A link for answering the online questionnaire survey was sent to the Head of the Institution/ Principal through an email. The Head of the Institution/ Principal were requested to circulate the link for submitting the response to the questionnaire and the participant information letter to all the faculty and post-graduate students of his/her dental or medical Institutions. The request letter to the principal also included the ethics approval certificate obtained for this study.
- The participants of the online questionnaire survey were mandatorily requested to give their consent for participation before starting to submit their response to the questionnaire.
- The participants of the online questionnaire survey were allowed at any time to withdraw from the questionnaire study before submitting their response.
- The participants were mandatorily made answer all the 39 questions in the online Questionnaire before the final submission of their responses.
- The questionnaire was made into 5 categories. Before beginning the questionnaire, the in the first category we had set of questions to collect the demographic information of the participants like age, gender, academic position, prior participation in human research subjects, number of research projects involved in and their prior training in research ethics.
- The second part of the questionnaire was used to assess the participants self-awareness towards ethical principles and functions of the ethical committees.
- In the third part of the questionnaire the respondents were asked to choose their response about research ethics committee from a 5-point Likert scale ranging from 1 to 5(1-strongly disagree, 2-disagree, 3-not sure, 4-agree and 5-strongly agree).
- In the fourth part the respondents were asked again choose from the 5-point Likert scale regarding their attitudes towards practicing of research like obtaining the informed consent from the participant, the involvement of vulnerable individuals in their study, confidentiality and conduct of research in a responsible manner.
- The fifth part of questionnaire had questions regarding assessment of knowledge about research ethics. The questions were

based on case scenarios regarding the informed consent, describing risks and benefits to the participants, research-involving children, retrospective research on stored human tissue samples originally collected for clinical purposes and also about maintaining confidentiality in the research.

- Once the participants submitted their responses to the online questionnaire, these responses were sent to google forms account of the researcher, which was digitally protected through a password by the researcher. The researcher never collected the email id, name of the participants or the name of the Institution of the participant.
- A total of 415 responses from the participants was collected and stored in a password protected electronic format. This data was statistically analyzed and conclusions were drawn depending on the results obtained.
- To protect the confidentiality of the participant, the survey did not contain any type of information that will personally identify the participant like their email ID, name, designation or the name of their Institute.
- This study was a self-funded by the Principle Investigator and the participants were not given any kind of monetary benefits for their participation.
- Timeline for the study: The online questionnaire survey will be carried out for a period of three months from September to October 2018.

Statistical analysis

All the responses obtained from the participants were entered in the excel spread sheet as a result score. The collected data was statistically analyzed by using the non-parametric statistical test using the SPSS software. Chi-square tests was used to determine, in bivariate analyses, the association of each of the independent variables like their speciality, their academic position, prior ethics training, and their prior involvement with research with each of the main outcome of interest (dependent responses involving knowledge, awareness, and attitudes). The students t-test was done to assess the respondents scores on the 5-point Likert scale ranging from 1 to 5 (1-strongly disagree, 2-disagree, 3-not sure, 4-agree and 5-strongly agree). The average of their scores were compared among the various variable like their speciality and academic position by using the ANOVA test. The P value was kept at 0.05 for this study.

Results

A total of 415 responses were obtained from the participants of the study. Out of this we had 273 respondents as female and 142 respondents as male. Among these 225 respondents were from the medical speciality and 190 were from the dental speciality. We assessed the responses from the following categories of the respondents. (Table no:1)

Discussion

The results of our study showed some very interesting facts regarding the knowledge, awareness and attitudes of the medical and dental professional from various academic positions like professors, reader/associate professors, senior lecturers and post graduate students. The responses for our study was obtained from various medical and dental institutions in Karnataka state.

Table 1. We assessed the responses from the following categories of the respondents.

	Dental	Medical
Professor	36	9
Reader/Associate Professor	73	27
Senior lecturer	45	27
Post Graduate student	36	162
Total	190	225

Table 2. The responses to details regarding involvement of the respondents in research ethics earlier.

S No	The details regarding involvement in prior research ethics expressed as	Response percentage		
		% Yes	% No	% Not sure
1	Done research involving human subjects earlier	70.2	29.8	NA
2	Done research involving human biological samples earlier	55.3	44.7	NA
3	Had undergone any training in research ethics before	66	34	NA
4	Familiar with ethical principles in human subject research	76.6	4.3	19.1
5	Familiar with the functions of a research ethics committee in their Institutions	83	6.4	10.6

Table 3. The responses of the respondents to the knowledge and awareness-based questions on research ethics.

S No	Knowledge based questions	Response percentage		
		% Yes	% No	% Not sure
1	Absolute necessary take the informed consent from the patient before doing any research involving human subjects	93.6	4.3	2.1
2	Absolute necessary to take an informed consent/assent from the patient/guardian before doing any research involving Children	97.9	2.1	0
3	Necessary to get ethical committee approval before doing a retrospective research involving tissue samples for clinical purposes	85.1	4.3	10.6
4	Need to keep the participants details very confidential while doing a research study	100	0	0
5	Need to obtain an approval from the ethical committee before doing any type of research on human subjects	100	0	0
6	Need to obtain an approval from the ethical committee before doing any type of research involving retrospective study of patient's data or investigation reports	83	4.2	12.8

Table 4. The number of participants responses to attitudes towards the research ethics committees and research ethics education.

S No.	Variable	Strongly Disagree	Disagree	Not sure	Agree	Strongly Agree
1	The Institutional Ethical Committee is very helpful and necessary for doing any type of research on human subjects	9	18	73	93	222
2	Every Medical/Dental Institution where human research is being done, should have its own Institutional Ethical Committee	18	9	6	56	326
3	Ethical review of research is only necessary for international collaborative research	233	28	28	72	54
4	Ethical review of research by an Ethical Committee would delay research and make it harder for the researcher	190	64	64	69	28
5	The members of a research ethics committee should receive training in research bioethics	10	9	45	55	296
6	Research ethics should be taught as a mandatory postgraduate module	0	27	65	128	195
7	All investigators should have some training in research ethics	0	18	54	128	215
8	Ethical review of research by an Ethical Committee is not necessary since there are scientific committees	253	63	45	36	18

Table 5. The number of participants responses to attitudes regarding practices in research ethics.

S No	Variable	Strongly Disagree	Disagree	Not sure	Agree	Strongly Agree
1	There should be measures to protect patient data from being accidentally exposed	9	27	9	74	296
2	Patients should be informed of the full details of research including risks and benefits	0	18	9	46	342
3	Informed consent from patients is necessary for use of their biological samples in research	0	9	18	82	306
4	Informed written consent should always include patients' signature	0	9	9	91	306
S No	Variable	Strongly Disagree	Disagree	Not sure	Agree	Strongly Agree
5	When involving patients with invasive procedures informed consent must be sought from each patient	0	18	9	46	342
6	Patients should be told about potential risks of a study because they may not enrol in the study	18	27	18	92	260
7	No need to obtain research informed consent for blood samples obtained for clinical tests	267	30	64	9	45
8	Vulnerable groups such as children and the mentally ill could provide informed consent	234	19	55	19	88
9	If no surrogate is available to give informed consent for vulnerable groups, they could still be included	234	28	102	24	27
10	Is it okay to fabricate data to improve outcome of research as long as there is no harm to the patients	322	18	18	20	37
11	Retrospective studies should be exempted for ethical consideration	199	27	80	45	64

Table 6. The responses in percentage regarding case scenarios regarding Knowledge involving various aspects of research.

S No	Case scenarios regarding Knowledge involving various aspects of research	Correct	Wrong
1	Case 1: Informed consent describing risks and benefits	332	83
2	Case 2: Research involving children	277	138
3	Case 3: Retrospective research on stored samples originally collected for clinical purposes	215	200
4	Case 4: Maintaining confidentiality in Health research	358	57

The participants of the questionnaire survey showed a high acceptance for the requirement of research ethics committee and were had a truistic opinion that the institutional ethics committees would be very helpful and useful for promoting health research and are imperative for appraisal of the health research projects.

It was very evident from our study that most of the respondents were aware of the research ethics committee's importance in doing health research. Majority of our respondents showed that they already had prior knowledge about research ethics and have undergone some type of training Though about 67% of the population have shown that they had prior training in research ethics. The proportion of the respondents 141 (34 %) who have mentioned that they have not attended any type of research training,

were all post graduate students. Whereas the professors, reader/ associate professors, senior lecturers have mentioned they had attended any type of research training programs earlier. It is reasonably clear from our study that most of the faculty and students at medical and dental institutions do studies on human subjects compared to studies done on human samples. The majority of the respondents agreed that they were well aware of the ethical guidelines governing the human research, but when we assess the respondent's knowledge and attitudes towards research ethics there seems to be alacuna in complete awareness and knowledge of research ethics. A similar finding was also observed regarding the functioning of institutional ethical committees.

The response to the question in the section five was a case scenar-

io question regarding the requirement of the informed consent from the patient for conducting a retrospective research on stored human tissue samples originally collected for clinical purposes. It was very surprising to know that nearly 50 % of the respondent's responses were wrong. The response to this question from all the post graduate students was wrong. It is only the faculties who have answered this question correctly. This is very evident from this information that the post graduates are unaware and uneducated regarding the mandatory requirement of informed consent from patients while doing any type of research on the already collected biological samples of humans.

The respondents showed a deal of optimistic and pragmatic opinion regarding the role of the institutional ethics committees in reviewing research protocols. Majority of the respondents were very propitious attitude towards the institutional ethics committees.

A vast majority of the respondents very clearly showed their interest in learning about research ethics on regular and systematic manner by means of research ethics teaching modules. This information from our study should be utilised to encourage the authorities in the academic field of medical and dental speciality at central and local bodies to formulate systematic teaching modules on research ethics. Such well-planned and fastidiously constructed teaching modules must be established and regularly conducted at every institution where health related researches are done.

The findings of our study congruous with the study done by R. Sudhakara Reddy et al (2018) in their cross-sectional questionnaire-based survey carried out among 100 dental professionals in a dental institution in southern part of India. Their suggestion regarding having a teaching module in research ethics was found to be consistent with the results of our study done on both medical and dental speciality and at multicentric study unlike the single centre study involving only the dental professionals by RSudhakara Reddy et al.

The results of our study regarding acceptance of regional ethics committee by the medical and dental speciality of various academic positions at multicentric level was found to be very compliant with findings of the study by Hadir F. El-Dessouky et al. (2007), who conducted a study to understand the level of knowledge, awareness and attitudes regarding ethics in research and ethics committees among the dental faculty members.

We had several limitations in our study. Firstly, for our study the responses from the participants were obtained through a convenience sampling. Hence, due to potential selection bias, the responses of our participants might not be representative of their respective faculties and post graduate students in each of the participating institutions.

Another important limitation that appears with the use of a self-report questionnaire is that of possibility of a social desirability bias, i.e., the tendency of respondents to reply in a manner that will be viewed favourably by others. Another factor that might have reduced the reliability of our responses includes involving respondents who have limited or no involvement in research like the first year post graduate students of the medical and dental speciality, in which case their responses regarding research ethics and the institutional ethics committees might not have much relevancy.

Despite these limitations, our study provided the details about faculty and post graduate students in the medical and dental speciality the knowledge and awareness with ethical principles that steer the conduct of research and their awareness of the roles of the institutional ethics committees, the extent of their previous training in research ethics, and their attitudes towards issues in research ethics and the towards institutional ethics committees.

In our online questionnaire study, we were able to demonstrate that participants with prior ethics training stated they were more aware of principles of research ethics and the functions of the institutional ethics committees. compared with those without prior training like the post graduate students of both medical and dental speciality. The participants with prior training in ethics comparatively with participants without training in research ethics were more likely to agree with several questionable practices regarding research ethics. These findings of our study highlight the need for conducting a well-structured research ethics training to faculty and post graduate students of the medical and dental speciality possibly as part of an obligatory module during their academic progress and postgraduate course.

Conclusion

This study was indeed very useful study to statistically measure the Knowledge, awareness and attitudes about research ethics among the faculty and students of medical and dental colleges by using an online questionnaire survey. The results of the study also helped us to assess the requirement for a regular teaching about research ethics among the faculty and students of medical and dental colleges. But it is necessary to more such multicentric studies at many more institutions where health research related activities are done. We recommend that the central and local health educational bodies should implement teaching of health research teaching modules in the health education in India among all the faculties and students in health institutions.

We also recommend a study to evaluate the knowledge, awareness, attitudes and practice of health research should be conducted among the undergraduate, post graduate students, faculties and also the nursing staff and students and medical, dental and nursing institutions in India and abroad. Studies should also be done at regular intervals to assess their knowledge, awareness, attitudes and practice of research ethics before and after the training in research ethics. The information obtained from such studies will be very useful and also guide to construct improved training programs and modules on research ethics.

References

- [1]. Gillett GR. Ethics and dental research. *J Dent Res.* 1994 Nov;73(11):1766-72. Pubmed PMID: 7983264.
- [2]. El-Dessouky HF, Abdel-Aziz AM, Ibrahim C, Moni M, Abul Fadl R, Silverman H. Knowledge, Awareness, and Attitudes about Research Ethics among Dental Faculty in the Middle East: A Pilot Study. *Int J Dent.* 2011;2011:694759. Pubmed PMID: 21754933.
- [3]. Reddy RS, Ramya K, Raju MA, Rayudu GS, Kiran CS, Jyothirmai K. Knowledge, awareness and attitudes about research ethics among dental professionals in a dental institution of south India. *Journal of Education and Ethics in Dentistry.* 2013 Jan 1;3(1):34.
- [4]. Gopinath NM, John J, Senthilkumar E, Nagappan N. Knowledge awareness and attitude about research ethics among dental faculties in India. *J Contemp Dent Pract.* 2014 Sep 1;15(5):608-13. Pubmed PMID: 25707834.

- [5]. Gopinath NM, John J, Senthilkumar E, Nagappan N. Knowledge awareness and attitude about research ethics among dental faculties in India. *J Contemp Dent Pract.* 2014 Sep 1;15(5):608-13. Pubmed PMID: 25707834.
- [6]. Deolia SG, Prasad K, Chhabra KG, Kalyanpur R, Kalghatgi S. An Insight Into Research Ethics among Dental Professionals in A Dental Institute, India- A Pilot Study. *J Clin Diagn Res.* 2014 Sep;8(9):ZC11-4. Pubmed PMID: 25386512.
- [7]. Kandeel N, El-Nemer A, Ali NM, Kassem H, El-Setouhy M, Elgharieb ME, et al. A multicenter study of the awareness and attitudes of Egyptian faculty towards research ethics: a pilot study. *J Empir Res Hum Res Ethics.* 2011 Dec;6(4):99-108. Pubmed PMID: 22228064.
- [8]. Kjellström S, Ross SN, Fridlund B. Research ethics in dissertations: ethical issues and complexity of reasoning. *J Med Ethics.* 2010 Jul;36(7):425-30. Pubmed PMID: 20605998.
- [9]. Chae S, Lim K. [Learning objectives achievement in ethics education for medical school students]. *Korean J Med Educ.* 2015 Jun;27(2):131-5. Korean. Pubmed PMID: 26044051.
- [10]. Munung NS, Tangwa GB, Che CP, Vidal L, Ouwe-Missi-Oukem-Boyer O. Are students kidding with health research ethics? The case of HIV/AIDS research in Cameroon. *BMC Med Ethics.* 2012 Jun 11;13:12. Pubmed PMID: 22686445.
- [11]. Loue S. The Impact of a Research Ethics Training Program: Romania as a Case Study. *J Empir Res Hum Res Ethics.* 2014 Dec;9(5):46-55. Pubmed PMID: 26247075.
- [12]. Nikravanfard N, Khorasanizadeh F, Zendehelel K. Research Ethics Education in Post-Graduate Medical Curricula in I.R. Iran. *Dev World Bioeth.* 2017 Aug;17(2):77-83. Pubmed PMID: 27527640.