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Original Research

Knowledge, Attitudes and Practice about Research Ethics among Dental Faculty in the North India

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Abstract:

Background: Research activities in dentistry are increased greatly in India during the recent decade, but there is limited of information about the knowledge and attitude of dental faculty for research ethics. To assess the knowledge and attitudes of dental faculty of North India regarding research ethics.

Materials and Methods: Through convenience sampling, a questionnaire was sent either via printed copies or E-mails to 1240 dental faculty, while protecting confidentiality and anonymity of all the participants.

Results: Our response rate was 76% (942). Majority (>90%) are aware of ethical committee but have poor knowledge (8-35%) about various ethical guidelines laid down at international level; however almost 20% believe that research ethics committees would delay research. A large number of researchers (78%) want some training in research ethics. There is fair knowledge about informed consent among researchers.

Conclusions: We conclude that ethical norms should be strictly followed by giving due respect to confidentiality or privacy of research participants to achieve the goal of minimal risks and maximum benefits to patients and there is need of training to researchers and students to make them aware about various research principles.

***Key Words*:** Informed consent, research ethics, research ethical committee

Introduction

Research can be defined as "a detailed study of a subject, especially in order to find new information or to reach a new (better) understanding." Research in dentistry has increased rapidly in recent decades to improve the oral health for the overall health of the patients.[1]

Since health researchers involve human participants, so fundamental ethical principles are deemed necessary in order to protect their rights, dignity and welfare.[2] "Ethics" is defined as "norms for conduct" that distinguishes between reasonable and unreasonable behavior. However, ethical norms are learnt since childhood at home, school, society, religious places, etc., it is affected throughout the life by various experiences in life which explains the subjective variability in interpretation of ethical norms among different individuals.[3]

Research ethics govern the standards of conduct for scientific researchers. Following ethical norms is vital because it protects the medical practice against immoral use of that elite knowledge which has been acquired in an attempt to offer real benefits to suffering people.[4,5]

To maintain ethical standards in health research and publication certain norms are laid down by various National and International Agencies. Some of these are as follows: (i) National Institute of Health, (ii) Food and Drug Administration, (iii) National Science Foundation, etc. The Nuremberg Code and Declaration of Helsinki by World Medial Association is the benchmark in ethical standards followed worldwide for biomedical research and uniform requirements for manuscripts submitted to biomedical journals (formulated by International Committee of Medical Journal Editors) for publication in scientific journals.[6]

Regardless of the existing guidelines for research ethics, in the developing nations regulations do not exist and there is an alarming concern about the existence of functional ethical review systems of individual and institutional research ethics.[7] The values of ethics should be imparted to every dental graduate as a responsibility toward achieving the highest standards of dental health services.[8]

Since, there is a dearth of research which has investigated the knowledge and attitude of dental faculty toward research ethics. So, the present study was conducted with an objective

to assess the knowledge and attitudes of the dental faculty of North India regarding research ethics and research ethics committee.

Materials and Methods

A cross-sectional survey was carried out over a period of 3 months from January to March, 2015 with the approval of the Ethical Committee of the institution. All the participants have given their consent for being a part of the study. The study participants included faculty members from dental colleges of North India.

A questionnaire (Table 1) was developed in order to assess the knowledge, awareness and attitude of dental faculty regarding research ethics. A pilot study on 50 randomly selected people from a single academic institution was carried out to estimate the reliability of the questionnaire. The questionnaire was re-evaluated, and minor modifications were made for better understanding. Another pilot study on 30 different randomly selected people from some other academic institution was done to determine the reliability of questionnaire (Cronbach's alpha = 0.74). Through convenience sampling, a questionnaire was sent either via E-mails or by printed copies to 1240 dental professionals, while maintaining anonymity of all the participants. Questionnaire consisted of four parts; first part contains demographic details of participants, second part comprise of set of knowledge-based questions, third part and fourth part comprise questions to assess attitude regarding research ethics educations and research ethics practice respectively. In third and fourth part of the questionnaire the respondents were asked to choose from a Likert scale ranging from 1 to 5 points (1 - Strongly agree, 2 - Agree, 3 - Not sure, 4 - Disagree, and 5 - Strongly disagree).

The data obtained were subjected to statistical analysis using Statistical Package for Social Sciences (SPSS, version 14, Chicago, Illinois, USA) software. Responses of participants were collected. Distribution of answers to all questions was calculated and presented as percentage of subjects answering particular answer to each question.

Results

A 76% positive response rate (942) was obtained from the study sample. Majority (>90%) are aware of ethical committee, but have poor knowledge (8-35%) about various ethical guidelines laid down at international level; however, almost 20% believe that Research Ethics Committees (RECs) would delay research. Large number of researchers (78%) want some training in research ethics. 90% of them have a strong opinion that informed consent (IC) should be taken before commencement of the study (Tables 1-5).

Discussion

The participation of human subjects in medical research has raised ethical concerns from time to time. So, the international community has made several ethical regulations/guidelines or codes to prevent gross exploitation of human subjects.

Table 1: Basic demographics.

Name	Optional
Age (in years)	
20-30	18
31-40	56
41-50	26
Gender	
Males	68
Females	32
Experience (in years)	
<10	30
10-20	52
>20	18

Table 2: Percentage of participants having knowledge involving various aspects of research.

S. no.	Knowledge based questions	Response (percentage)
1	Informed consent	88
2	Research involving children	58
3	Retrospective research involving tissue samples for clinical purposes	24
4	Confidentiality in medical research	48
5	Institutional ethical committee	62

Table 3: Awareness of different guidelines among faculty.

S. no.	Guidelines	Faculty response
1	Nuremberg code	13.5
2	Revised ICMR guidelines	24.6
3	Helsinki declaration	34.8
4	CIOMS guidelines	8.5

ICMR: Indian Council of Medical Research, CIOMS: Council for International Organizations of Medical Sciences

The present study showed that dental faculty has poor knowledge about various ethical guidelines such as Nuremberg Code, Revised Indian Council of Medical Research Guidelines, Helsinki Declaration, Council for International Organizations of Medical Sciences Guidelines (Table 3). These guidelines are a tool for researchers themselves and do not serve the same function as laws. They identify relevant factors that researchers should or ought to take into account, but which must often be weighed against each other, as well as against other important considerations.

IC is the cornerstone of clinical practice, with temperate patient standards typically considered to be suitable in the developed countries; however, it is still challenged in several developing nations.[9]

However, the present study revealed that majority of researchers (88%) has knowledge about IC. Similar results of high familiarity with IC have also been observed in a recent study conducted across Punjab region (Table 2).[10] IC requires that patient fully understand the information given, but if the patient is debilitated due to a serious illness, a suitable surrogate

Table 4: Attitude based questions regarding research ethics education.

S. no.	Attitude based questions regarding research ethics education	Strongly agree	Agree	Not sure	Disagree	Strongly disagree
1	Research ethics committee is helpful	76	20	4	0	0
2	Need for research ethics committee	68	22	8	2	0
3	Research with human subjects must be reviewed by a research ethics committee	72	21	6	1	
4	Ethical review of research is only necessary for international collaborative research	18	8	2	52	20
5	Ethical review of research by an REC would delay research and make it harder for the researcher	12	8	6	44	30
6	The members of a research ethics committee should receive training in research bioethics	62	22	10	6	0
7	Research ethics should be taught as a mandatory postgraduate module	42	30	13	12	3
8	All investigators should have some training in research ethics	46	32	8	12	2
9	Ethical review of research by an REC is not necessary since there are scientific committees	18	16	8	26	32

REC: Research Ethics Committee

Table 5: Attitude based questions regarding research ethics practice.

S. no.	Questions	Strongly agree	Agree	Not sure	Disagree	Stongly disagree
1	There should be measures to protect patient data from being accidentally exposed	62	28	6	4	0
2	Patients should be informed of the full details of research including risks and benefits	74	18	8	0	0
3	Informed consent from patients is necessary for use of their biological samples in research	68	22	4	6	0
4	Informed written consent should always include patients signature	63	28	4	5	0
5	When involving patients with invasive procedures informed consent must be sought from each patient	62	30	6	2	0
6	Patients should be told about potential risks of a study because they may not enroll in the study	8	10	12	42	28
7	No need to obtain research informed consent for blood samples obtained for clinical tests	6	8	8	42	36
8	Vulnerable groups such as children and the mentally ill could provide informed consent	18	32	4	30	16
9	If no surrogate is available to give informed consent for vulnerable groups they could still be included	14	10	27	32	17
10	Is it okay to fabricate data to improve outcome of research as long as there is no harm to the patients	10	34	12	12	32
11	Retrospective studies should be exempted for ethical consideration	72	10	6	12	0

should make decisions which are in the best interest of the patient, or if the patient is the child then the IC can be given by the parent or guardian.[11]

According to guidelines laid by Committee on Publication Ethics if no such representative is available or if the research cannot be delayed, the study can be conducted without IC provided that the valid reasons for including the condition of subjects which makes them unable to give IC have been described in the research protocol and approval for study has been taken by a research ethics committee.[12]

More than half of the respondents (58%) have knowledge about research involving children and minority of researchers (24%) have knowledge of retrospective research involving tissue samples for clinical purposes. There is a big question that whether retrospective studies need IC or not? A consensus has been reached regarding this issue in most countries, such that retrospective and epidemiological research is exempted from IC. However, it is subject to pre-approval by ethics or institutional review boards.[13]

Only 28% researchers have accurate knowledge about confidentiality in medical research and they believed in the need for protection of confidentiality of research participants' data but a higher percentage of 56% has been observed in South India in a different study conducted by Reddy *et al.* in 2013.[1]

There is need to make clinicians or researchers more aware to maintain confidentiality in medical research as it is the duty of the researchers to establish a bridge for better health to need to respect the privacy of research participants.

The majority of researchers (96.2%) have accurate knowledge about Institutional Ethical Committee. They were asked about its composition, role and finally their satisfaction about the role of the ethics committee. Similar higher percentage have also been obtained by Reddy *et al.* in South India,[1] El-Dessouky *et al.*[14] in Saudi Arabia and Mohammad *et al.* in JN Medical College, Aligarh, India.[15]

The majority of researchers (96%) believe that there is need for research ethics committee and 76% have an opinion that REC is helpful to check the exploitation of human subjects. Fairly high percentage of participants believes that research involving human subjects must be reviewed by a research ethics committee. Only 20% of them have opinion that ethical committees would unnecessarily delay research and make it more cumbersome. A similar finding was identified from western countries where it was of the opinion that excessive bureaucratic details caused delay in research.[16] The evidence suggests that researchers continue to be frustrated by delays and unnecessary duplication of effort to secure approval.

Unnecessary delay in research may be because of lack of complete understanding of process of REC. So, there is need of training for researchers to be more familiar with working of REC. High percentage (78%) of participants have opinion that investigators should have some training in research ethics.

However, 78% of the respondents believe that research conducted on blood samples obtained for clinical purposes do not need IC. We observed that almost 46% of the participants believed that certain vulnerable subjects (e.g. mentally ill or children) could provide IC to participate in research. Due to a serious illness/mental condition, an appropriate surrogate should make the decisions, ideally one who knows the patient's preferences and can therefore act in his best interest. The patient must be told what has been done and why, as soon as he has sufficiently recovered his mental faculties. When IC was not given despite needing life-saving intervention, the majority of respondents considered intervention without IC to be justified. In an extreme emergency situation, where a patient is unable to give consent due to unconsciousness, a doctor may perform emergency treatment based on the doctrine of necessity or implied consent to save lives.[9] The present study showed that an equal number of respondents was in agreement and disagreement for fabrication of data in order to improve the research outcome as far as it is not harmful to patients.

Although there is fair knowledge among dental faculty; there is need to initiate educational events in the developing regions of the world to increase knowledge, awareness and acceptance of principles of research ethics among researchers. Faculty or students should be educated by holding seminars or continuing dental educational programs. The curriculum for students needs to be more detailed in regard to research ethics.

The limitation of our study is that it was a convenience sampling with small sample size, so results cannot be generalized to the whole dental faculty of North India. Further research is required to address the existing knowledge gaps in research ethics.

The academic research enterprise is created on the ground of trust. Researchers trust that the results produced by other investigators are original. Society trusts that the results of research are sincere attempt by researchers to describe the world accurately without bias. However, this trust withstands only if the research community commit itself to demonstrating and broadcasting the values associated with conduct of ethical research.[17]

Conclusion

There is fair knowledge of research ethics among dental faculty. Ethical norms should be strictly followed by giving due respect to confidentiality or privacy of research participants to achieve the goal of minimal risks and maximum benefits to patients.

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