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Original Article

Dentistry Section

An Insight Into Research Ethics among Dental Professionals in A Dental Institute, India- A Pilot Study

SHRAVANI G DEOLIA[1], KVV PRASAD[2], KUMAR GAURAV CHHABRA[3], RAMYA KALYANPUR[4], SHRIVARDHAN KALGHATGI[5]

ABSTRACT

Background: Research activities are increasing in all the fields of medicine including dentistry but there is dearth of information about the knowledge, attitude and behaviour of dental professionals for ethical principles in research, especially in the developing countries like India.

Objective: To assess knowledge, attitude and behaviour among dental professionals pertaining to research ethics.

Methodology: A self-administered, close ended questionnaire survey with cross-sectional design was conducted in a private dental institute in India. All the house-surgeons, post-graduate students and the faculty of the same institute were included for the assessment of the knowledge, attitude and behaviour regarding research ethics using a 24, 8 and 8 items.

Results: A total of 213 of 230 dental professionals participated (response rate of 92.6%). Mean knowledge, attitude and behaviour scores were 43.3%, 82.5% and 46.37%, respectively. Significant correlations were observed of age and gender with the attitude about the research ethics among study subjects (χ^2=14.383, p=0.006 and χ^2=7.769, p=0.021, respectively).

Conclusion: Participants had favorable attitude towards research ethics, but their knowledge and behaviour needs considerable improvements. The age and gender were associated with attitude. The present pilot study highlights the need for further nationwide study and development of research ethics curriculum in detail for dental education in India.

Keywords: Awareness, Dentists, Ethical research

INTRODUCTION

Practicing ethics in the day-to-day obligations is regarded as "moral" [1]. The values of ethics should be inculcated in every dental graduate as a responsibility towards rendering the highest standards of dental health care [2]. In current scenario, to neglect a section on ethical issues when considering the overall topic of Critical Issues in Dental Clinical Research would be a significant mistake [3]. This clearly emphasis that, non-clutching the ethical principles in the course of research involving both human and non-human participants holds the action of penalty in the court of law thus, mandating its enormous importance.

Since most of the medical and oral health care research involves human participants, such research needs to be guided by fundamental ethical principles to ensure the protection of the rights, integrity, safety and welfare of research participants [4-7]. According to consciences the research ethics are basically guided by four pillars which are regarded as: respect for the individual; beneficence, non-maleficence and justice [8].

The inception of ethical guidelines which primarily includes Nuremberg Code(1948), Declaration of Helsinki(1964), Belmont report(1979) and Council for International Organizations for Medical Sciences(CIOMS) can be traced back at the time when Nazis did atrocious human experiments at the time of II World War and Tuskegee syphilis study in America [9,10]. Despite the availability of these guidelines violations of the rights of research participants continue to occur in both higher and lower income countries [4,5,8]. Recently Cochrane Collaboration Oral Health Group emphasized that, the existing standards for research ethics involving clinical trials have not yet come into frequent practice in oral health community [11].

The horizons of oral health research are widening everyday in developing but the extent of individual and institutional research ethics capacities and capabilities are not improving in that proportion for which observers have expressed grave concerns. Stringent research regulations do not exist in many developing countries like India as they face barriers due to lack of trained professionals, weak financial status, under-representation of diverse cultural groups and under-developed health care system [8]. This clearly paves the way for assumption of an inherent relationship of investigators research competency in terms of their knowledge, attitude and practices of research ethics on the quality of research as a final outcome.

According to Nundy and Gulhati, [12] out of half a million practicing doctors and 1400 general hospitals in India, only 200 have been trained in good clinical practice and no more than 150 hospital have the adequate infrastructure to conduct trials. Anant Bhan reported that Clinical trials in India are conducted with little relevance to the public health needs of the country [13].

Faculty and post-graduates students are involved in research projects, but there are fistful of dental colleges in India where under-graduates are involved in research activities, nevertheless the present institution is one of them. To assess their level of understanding and applicability of ethical principles in the research work, they were included in the study.

Thus present study was carried out with the aim of assessing awareness, attitudes and practices of dental professionals regarding research ethics. The study results might help institutional officials understand better how well research ethics are accepted in their institution and also help them develop relevant educational programs in research ethics directed towards dental professionals.

MATERIALS AND METHODS

This study was conducted in a private dental institute in southern region of India from 1st September 2013 to 15th October 2012. Ethical clearance was obtained from the Ethical Review Committee of the Institutional Review Board. The head of the institution and tutors were informed about the purpose of the study. The study population consisted of all the house surgeons, post-graduates and staff attending the aforementioned institution.

Academic position	Total n (%)	Gender		Mean age (in years)
		Male n (%)	Female n (%)	
House-surgeon	60 (28.16)	15 (25)	45 (75)	22.9
Post graduate	100 (46.94)	47 (47)	53 (53)	25.6
Staff	53 (24.88)	25 (47.16)	28 (52.8)	36.8
Total	213 (100)	87 (40.84)	126 (59.15)	27.6

[Table/Fig-1]: Distribution of the study subjects according to gender and academic position

Variables		Number of subjects	Percentage
Knowledge	≤ 6 (Poor)	33	15.49
	7 to 14 (Fair)	150	70.42
	≥ 15 (Good)	30	14.08
Attitude	≤ 28 (Poor)	30	14.08
	29 to 37 (Fair)	149	69.95
	≥ 38 (Good)	34	15.96
Behaviour	≤ 11 (Poor)	29	13.61
	12 to 25 (Fair)	151	70.89
	≥ 26 (Good)	33	15.49

[Table/Fig-2]: Knowledge, attitude and behaviour scores among study subjects

Academic position	Knowledge		Attitude		Behaviour	
	Mean	SD	Mean	SD	Mean	SD
House-surgeon	9.85	3.72	32.25	4.66	17.28	6.89
Post-graduates	11.46	4.35	33.76	4.28	19.47	6.53
Staff	9.01	3.94	32.43	5.23	18.26	6.42
Total	10.40	4.20	33.00	4.68	18.55	6.64
F value	6.937		2.515		2.120	
P value	0.001*		0.083		0.123	
Pair wise comparison with Scheffe's test for knowledge						
House surgeon- post graduate			0.057			
House surgeon- staff			0.560			
Post graduate to staff			0.002*			

[Table/Fig-3]: Knowledge, attitude and behaviour among different academic position by using one way ANOVA

The study proforma consisted of informed consent, demographic information and questionnaire. The questionnaire was self administered and closed ended. Subjects were given one hour to fill the questionnaire and to return it back.

The questionnaire consisted of a total of 40 items on research ethics, with 24, 8, and 8 items assessing knowledge, attitude, and behaviour, respectively. The items for this questionnaire were generated from four sources: theory, research, observation, and expert opinion [14]. Attitude was assessed on a five-point Likert scale: definitely yes, yes, neutral, no, and definitely no. The response options for behaviour were as follows: < 1mnth, 1-6 months, 6-12 months, > 1yrs and never (for first 3 items) and always, very often, often, rarely and never (for items 4-8). A total of 24 questions on research ethics focused on principles of ethics in research, ethical considerations in the Indian scenario, various international agencies responsible for laying down guidelines for ethical consideration in research and some unethical practices in research. Questions related to attitude included: whether dentists should be actively involved in ethical practices in research activities, if they should act in coordination with other professionals toward research ethics, if they should constantly update their knowledge on research ethics. Questions pertinent to behaviour assessed how frequently the respondent perused scientific journals and Internet regarding research ethics, if they maintained accurate patient records during the research and if they attended training programs regarding research ethics. The range of possible scores for knowledge, attitude, and behaviour were 0-24, 8-40, and 8-40, respectively. Correct answers for knowledge questions were given a score of "1" and wrong answers were given a score of "0." Attitude scores ranged from 5 (definitely yes) to 1 (definitely no), and behaviour scores ranged from 5 (<1 month) to 1 (never). Prior to the start of the study, the questionnaire was tested on 50 study subjects. Cronbach'salpha and split-half reliability values for knowledge were 0.796 and 0.644; for attitude were 0.81 and 0.88; and for behaviour were 0.88 and 0.93 respectively. The questions underwent subsequent revisions before the main study for the understanding of subjects. The revisions were related to clarity of 7 questions of knowledge and 3 questions each from attitude and behaviour. The results of the pilot study were not included in the main study, only the reliability and validity was assessed. The pilot study subjects did not take part in the main study.

	Knowledge		Attitude		Behaviour	
	r	p-value	r	p-value	r	p-value
Knowledge	-					
Attitude	0.351	0.000**	-			
Behaviour	0.056	0.415	0.103	0.133	-	

[Table/Fig-4]: Correlation analysis of knowledge, attitude and behaviour among study subjects by using Pearson correlation
**Correlation is significant at the 0.01 level (2-tailed)

Demographic variables	Knowledge		Attitude		Behaviour	
	X^2 value	p-value	X^2 value	p-value	X^2 value	p-value
Age	6.840	0.145	14.383	0.006	1.589	0.811
Gender	2.260	0.323	7.769	0.021	1.323	0.516
Academic position	7.075	0.132	1.809	0.771	5.513	0.239

[Table/Fig-5]: Correlation analysis of demographic variables with knowledge, attitude and behaviour about research ethics among study subjects by using chi-square test.

STATISTICAL ANALYSIS

The data were entered into the MS Excel (MS Office version 2007 developed by Microsoft, Redmond, WA) and Intercooled STATA version 9.2 (StataCorp, TX, USA) was employed to perform statistical analysis. Kruskal-Wallis test was used to assess the differences in knowledge, attitude, and behaviour among academic position. Scheffe's test was used to assess pair-wise differences in knowledge of study subjects with respect to academic positions. Pearson's correlation analysis was used to assess associations between knowledge, attitude, and behaviour of study subjects. Chi-squared test was used to assess associations of age, gender and academic position with knowledge, attitude, and behaviour of study subjects.

RESULTS

A total of 213 out of 230 study subjects responded, with a response rate of 92.6%. A total of 87 respondents were males (40.8%), while 126 were females (59.15%) [Table/Fig-1]. Knowledge, attitude and behaviour scores were categorized as 'good', 'fair' and 'poor' by using mean ± 1Standard deviation values, i.e., values less than mean – 1 standard deviation were categorized as poor, values in the range of mean + 1 standard and mean – 1 standard deviation were categorized as fair and values more than mean + 1 standard deviation were categorized as good [Table/Fig-2].

A statistical significant difference for knowledge scores was observed between the academic position (F=6.937, p=0.001). The difference between academic positions was statistically insignificant for attitude and behaviour (F=2.515, p=0.083 and F=2.120, p=0.123, respectively) [Table/Fig-3].

Correlation analysis revealed that there was a statistically significant association between knowledge and attitude on research ethics among study subjects (r=0.351, p=0.000) [Table/Fig-4]. Chi-square test indicate that there was a statistically significant association of age and gender with the attitude about the research ethics among study subjects ($\chi2$=14.383, p=0.006 and $\chi2$=7.769, p=0.021) [Table/Fig-5].

DISCUSSION

The present study was conducted to explore various issues related to involvement of dental professionals in research ethics in India. This is the first study, which investigates knowledge, attitude and behaviour about research ethics among dental professionals in a private dental institute in India.

MJ Bebeau and EL Davis [15], surveyed the leaders of The American Association for Dental Research (AADR) to determine their perceptions about the prevalence of problematic research practices. Although, the respondents had observed some form of research misconduct one or more times, they did not perceive that such problems exists more in dentistry than in other areas of science.

In a study, by Taiwo and Kass [16], (2009) the post-consent understandings among dental subjects who were participating in oral health research in Nigeria were assessed, and reported that nearly all the respondents, (93.8%) claimed that voluntariness to participate in the study was not asked. In addition, participants also poorly understood key elements of informed consent. Main issues of the study participants identified for compromised understandings were poverty, illiteracy and therapeutic misconception.

Results of the present study indicate that mean knowledge and behaviour of study subjects were 43.3% and 46.37% respectively, indicating awareness and implications of ethics into research were unsatisfactory. This might be due to deficiency in the Indian educational system which don't include research ethics topics in theory and its applicability in detail in the dental curriculum either in the under or post-graduate, both in formal and informal ways. A high attitude score (82.5%) among the respondents is a positive indicator and the respondents may be more receptive regarding research ethics training. Low knowledge scores were also reported in dental faculty by Hadir F. E –Dessouky et al., [5].

Again all the scores were found highest in post-graduates, followed by staffs and house-surgeons which was significant for knowledge scores. The involvement of post- graduates in research projects as a part of their curriculum might have resulted in more knowledge and better attitude and behaviour scores regarding ethics. Lesser scores of staffs may be due to less upgrading and less involvement in research activities, due to private practice/patient load, personal or family problems or promotions which are not based on research work. Furthermore, faculty received their education and work habits at a time when there were different behaviour standards [5]. And the lack of research ethics in the under-graduate curriculum and less participation in research activities might have accounted for their lower scores. Further research should probe for the factors that account for any differences in knowledge gaps between different academic positions.

The study revealed a statistically significant association between knowledge and attitude scores of respondents, while there were no statistically significant association between knowledge and behaviour and also between attitude and behaviour. Knowledge, attitude and behaviour might not share a linear relationship and further qualitative studies involving in-depth interviews are warranted to explore the relationships among these variables.

Correlation analysis revealed that there was a statistically significant relationship between gender of the respondent and their attitude on research ethics indicating females had more positive correlation with attitude than males. This might be contributed to more sensitivity towards moral values of the females [17]. Large proportion of females in the study sample might also have led to such results. Correlation analysis also revealed that there was a statistically significant relationship between age of the respondent and their attitude on research ethics. The fact that with increasing age and experiences, the level of maturity and sense of responsibility [18] also increases leading to better attitude. Direct effect of age on awareness of conflicts of interests issues have also been found in a study by Schwartz et al., in 2007 [19]. Additional studies are required to explore any possible relationships between these demographic variables and knowledge, attitude and behaviour of respondents regarding research ethics.

In the past few years, number of formal and online training programs in research ethics has been started but their access is still limited. At the same time, the involvement of health professionals in research has increased tremendously [4]. The emphasis on ethical aspects of research, either formal or informal is important to avoid any sort of misdemeanors. While clinical trials are important and should be conducted, accompanying them with the ethical standards helps in maintaining the dignity and integrity of the science. Any mistake, crucial or trivial brings defame both to the researcher and to the entire scientific community. Public faith in science and clinical trials gets jeopardize. It is the duty of health professionals to conduct such research that respond to local health conditions and improve existing infrastructures while protecting the right and integrity of study participants [4]. Nundy and Gulhati [12] highlighted that, despite having a humongous number of health professionals in India only few have been trained in good clinical practice. Moreover, only a limited number of institutes and hospitals have adequate infrastructure to conduct trials and institutional review boards. Even the operational capacities of existing boards are unsure. Even though there is the swarming growth in the number of dental colleges and postgraduate seats in various dental colleges in India, with grossly inadequate student: teacher ratio have resulted in lack of time to guide the students into research design, its execution, analysis, and more importantly, into research norms and ethics [20]. The increased regulations on western countries on research have led to the outsourcing of the research projects to India, which makes it more important to have a thorough knowledge about the concepts and application of research ethics. Furthermore, illiterate/illiteracy and poor population of the country make the situation graver [12].

Results of this study have to be viewed in light of its limitations. Firstly, only one dental institute was included in this study, which might not be representative of all dental institutes in India, thus limiting the generalizability. Since it was a questionnaire study, application of these ethical principles to the respondents work may or may not be predicted, reflecting the inherent limitations of such studies. Further studies are warranted to investigate the knowledge, attitude and awareness pertaining to the research ethics by some better tools.

Nonetheless this study gives us information necessary to tailor research ethics with the health policies and improving the standards of the existing research projects in India. The modification in the dental curriculum with inclusion of more formal training in ethical aspects of research including the real world examples, stimulating the thinking capabilities is prerequisite. Every research project

should be thoroughly scrutinized and strict action against any form of misconduct is essential.

CONCLUSIONS

Despite the involvement of dental professionals in the institute, the knowledge and behaviour regarding research ethics among the study subjects was low, but their attitude towards the same was good. Results indicate that the study subjects might be more receptive to training programs on research ethics. Thus present study highlights the need for further nation-wide surveys and development of research ethics curriculum in detail for undergraduates and postgraduates in India for wider understanding and applicability of ethical principles in different settings of the research. There is also a need for providing continuing dental education programs for dental professionals on research ethics in India. The dental profession, by its meaningful involvement in research following the ethical standards to the highest level, will be rewarding its responsibility of safeguarding and protecting the health and welfare of the research participants in particular and the nation as a whole.

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PARTICULARS OF CONTRIBUTORS:

1. Assistant Proffesor,Department of Public Health Dentistry, Sharad Pawar Dental College and Hospital, Wardha, India.
2. Professor and Head, Department of Public Health Dentistry, SDM College of Dental Sciences and Hospital, Dharwad, India.
3. Assistant Professor, Department of Public Health Dentistry, Jodhpur Dental College General Hospital, Jodhpur, India.
4. Assistant Professor, Department of Public Health Dentistry, SDM College of Dental Sciences and Hospital, Dharwad, India
5. Assistant Professsor, Department of Public Health Dentistry, Mansarovar Dental College, Bhopal, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:
Dr. Shravani G Deolia,
Department of Public Health Dentistry, SharadPawar Dental College and Hospital,
Sawangi (M), Wardha, Maharshtra, India.
Phone : +9503523656, E-mail : deoliashravani@gmail.com

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