**Knowledge and practice on current regulatory requirements for members of ethics committee amongst dental colleges in India**

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**ABSTRACT**

Regulatory guidelines have been made stringent to safeguard human rights, integrity, safety and welfare. The present study was designed to elucidate the knowledge and practice on current regulatory requirements for members of ethics committee (EC) amongst dental colleges in India. A validated questionnaire was sent through an e-survey to 750 members, of which 300 participants (response rate: 40%) replied. Less than 50% participants correctly answered about guidelines of biomedical research, composition of EC, serious adverse effect and vulnerable population. 16.3% of the participants had registered EC and only 28.7% applied universal ethical principles. A statistically significant association (p <0.001) was found between training received in research ethics and number of years of experience in ethics committee with knowledge and practice. Despite the presence of ethics committee in the dental institute, the knowledge and practice regarding current regulatory requirements was found to be insufficient for proper functioning.

**INTRODUCTION**

Due to an enormous rise in research on human subjects in dental teaching institutions today, it is important for ethics committee members to address the ethical concerns of the subjects involved in the research. According to Indian Council of Medical Research (ICMR) it is compulsory for any biomedical research to be approved by the Institutional Ethics Committee (IEC)/ Institutional Review Board (IRB) before its initiation. This is supported by the revised Schedule Y in Amendment 2005 of the Drugs and Cosmetics Act, 1940 (1). According to this Act, all the institutions undertaking research should have their IEC accredited to a central agency (2).

The horizons of dental research are widening with time but individual and institutional research ethics capabilities are not improving in the required and ideal proportion (3). ICMR with the World Health Organization (WHO) conducted a survey on 223 IEC in India which shows that maximum committees did not meet regulatory requirements in terms of composition and function. Recently a survey conducted to assess the existence, structure and functioning of IEC in dental teaching institutions in Kerala found that out of 17 colleges, 13 had a functioning IEC and only 4 colleges were accredited to a central agency (4).

Regulatory guidelines has been made stringent to safeguard human rights, integrity, safety and welfare (5). Also, there is an insufficient interaction between researchers’ and ethics committee members leading to misconduct in implementing ethical guidelines. It is imperative that ethics committee members should have requisite knowledge on current regulatory requirements which is in accordance with Schedule Y of Drugs and Cosmetics Act. The present study was designed to elucidate the knowledge and practice on current regulatory requirements for members of ethics committee amongst dental colleges in India.

**METHODOLOGY**

The study was approved by the institutional review committee of Dr. D.Y. Patil Vidyapeeth, Pune, India.

**Study setting:** A cross sectional questionnaire-based study was conducted amongst the ethics committee members of various post graduate dental colleges representing North, South, East, West and Central zones through an e-survey using Google forms between May and October 2016.

**Study population and sampling technique:** State wise list of post graduate dental colleges was obtained from the Dental Council of India (DCI) website (6). A list of email address of ethics committee members was collected through convenience sampling. Sample size was calculated using EpiInfo software based on results from Deolia S where knowledge was 43.3% (7). The final sample size was 300 and e-mails were sent to 750 members through google form.

**Study tools and Data collection:** The 18-item closed questionnaire was framed in accordance with Schedule Y of Drugs and Cosmetic Rules 1945 and Indian-GCP guidelines.

Lawshe’s method (8) was used for content validity using judgments from a panel of 10 subject matter experts (SMEs). The reliability was also established by test – retest amongst 20 volunteers of similar population. The kappa value was 0.9 which indicated high reliability. This was followed by pilot testing amongst 10 volunteers who were asked to answer the questionnaire and provide feedback on content, clarity and brevity of the questionnaire.

The demographic details were collected Followed by questions on knowledge and practice. Check boxes were provided and participants had to click on any one option for each question. Care was taken that one person could answer the questionnaire only once and all questions were mandatory. Effort were made to get completed forms by sending three reminders via emails. The responses were directly recorded through google forms. Since this was an e-survey, the informed consent were included in the Google form.

**Statistical analysis:** The online recorded information was converted into codes and analyzed using Statistical Package for Social Sciences (SPSS) Version 20 software package (SPSS inc., IBM, and Chicago, IL, USA). Analysis was done using descriptive statistics and expressed in the form of frequency and percentages. Chi-squared test was applied to compare knowledge and practice based on demographic variables. Knowledge was categorized into no knowledge (score was 0), inadequate knowledge (score was <5) and adequate knowledge (score >5). Practice was categorized into poor practice (score was 0), fair practice (score was <5) and good practice (score >5). p-value ≤ 0.05 was considered as statistically significant.

**RESULTS**

Out of 750 EC members, 300 responded giving a response rate of 40%. 46.3% of the participants were MDS and representation of lay person was only 5.6%. 37% of the participants belonged to South zone. Only 38.6% of the participants received training in research in ethics. Table 1 presents the characteristics of the study participants.

Nearly 64% had adequate knowledge about informed consent, but only 14.7% knew about the continuing review of an approved protocol. 46.3% of EC members were aware of the ICMR guidelines on ethics for research and only 11.3% of the participants knew about the current regulatory requirements. Table 2 presents the responses to questions on their knowledge.

Only 16.3% of the participants had registered ethics committee and 39.3% of the participants would review all research studies at least annually. Less than 50% of the participants maintain confidentiality and apply universal ethical principles while reviewing a protocol. Table 3 shows the EC members responses regarding their practice.

A statistically significant association [p<0.001] was found between training received in research ethics and number of years of experience in ethics committee with knowledge. Knowledge scores declined with increase in number of years of experience in EC. [Table 4]

A statistically significant association [p<0.001] was found between training received in research ethics and number of years of experience in ethics committee with practice. Practice scores declined with increase in number of years of experience in EC. [Table 5]

**DISCUSSION**

India is considered as an ideal, cost-effective location for undertaking clinical trials, meeting international regulatory requirements (9). Ethics committee members are responsible for the safety of research participants. In India, institutional mechanisms for ethical review of research involving human subjects are weak and vulnerable and collaborative effort is required to strengthen them to fulfil their stated missions (10). Due to an inherent need for strengthening the ECs, ICMR has started promoting the establishment of ECs and providing training modules for EC members and researchers in ethics (11).

In our survey, we included only post graduate institutions because there is an enormous increase in the number of research projects carried out in these institutions. In addition, numerous independent studies are also undertaken by the faculty as a part of professional enrichment. We had a response rate of 40% which was better than the one ( 24.8%) reported by Mirzae A (12).

A study on ethics committees in Croatia in the healthcare institutions (13) highlighted that everyone knew about Declaration of Helsinki but less than 1% knew about informed consent which is in contrast to the results obtained in our study. In the present study, 46.3% of the members of IECs were aware of ICMR guidelines which governs biomedical research on human subjects and 64% of the members were aware of the procedure followed in informed consent.

In a study (14) conducted to check the competence of ethics committees, a survey questionnaire was developed and sent to 20 EC representing various parts of the state. 83% said that the decision to approve/ reject the protocol was taken during the meeting with all members participating in the final decision making and 93% of the members said that periodic ethics review of ongoing trials was conducted. The results obtained in our study are in contrast where only 32.6% of the members were aware about the ICMR guidelines on final decision making and 14.7% of the members knew that continuing review of an approved protocol should be done at least annually.

A survey (4) found that only 23.5% of IECs were accredited to Central Drugs Standards Control Organization (CDSCO), 91.6% had more than one dentist as clinicians. The results of the present study also indicate that only 16.3% of the EC are registered and 46.3% of the respondents had MDS degree which suggest that findings in this study are not necessarily generalizable because sometimes dental institutions have sub-committee which function at college level whereas the university have IEC/IRB which is probably registered with CDSCO.

The present study throws light on the fact that only 34% of the members invited expert in special area similar to a study (15) done in compliance with Schedule Y / ICMR Guidelines 2006 where legal experts were not present in approval meetings. It was observed that in most institutes, the chairperson was affiliated to the same institution like in the present study. 39.3% of the respondents said that the chairperson was from the same institution which could potentially induce a conflict of interest while reviewing the proposals.

Members who had received training in ethics showed adequate knowledge and good practice (17) which was similar to this study showing that training is significantly (p<0.001) associated with knowledge and practice of the EC members. The overall knowledge regarding various regulatory requirements was found to be discouraging amongst EC members in this study justifying the requirement for compulsory training and up gradation in knowledge. [Table 4]

In a study (18) it was observed that higher qualifications (p=0.004), those with more than 20 years of research experience (0.023) and those with more experience of working with ECs (p=0.032) were more likely to attend meeting. Results obtained in this study, showed the number of years of experience in ethics is significantly associated with knowledge and practice. [Table 5]

Practice of the EC members might not have been evaluated appropriately because some of the questions were not based on individual decisions rather policies made by institutions. However, this survey from dental colleges in India is an effort to capture the existing level of knowledge of EC members about current regulatory requirements, which can be validated further by undertaking a larger study across India in the near future.

This study highlights the need for mandatory training for EC members in the form of workshops and lectures to keep abreast with the current regulatory requirements and appropriate institutional support to IEC for proper functioning.

**CONCLUSION**

Despite the presence of ethics committee in the dental institute, the knowledge and practice regarding current regulatory requirements was found to be insufficient for proper functioning. This study was an attempt to bring awareness amongst members of EC to follow ethically high standards which will help in safeguarding and protecting the health and welfare of the research participants in particular and the nation as a whole.

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**TABLES**

**table 1: demographic details**

|  |  |  |
| --- | --- | --- |
| Demographic Details | Number | Percentage |
| TOTAL NUMBER OF responses | 300 | 100 |
|  |  |  |
| 1. *Qualification* |  |  |
| *MDS* | 139 | 46.3% |
| *MD/MS/DNB* | 84 | 28% |
| *Phd* | 27 | 9% |
| *Others* | 50 | 16.7 |
|  |  |  |
| 1. *Zone* |  |  |
| *North* | 43 | 14.3% |
| *South* | 111 | 37% |
| *East* | 34 | 11.3% |
| *West* | 66 | 22% |
| *Central* | 46 | 15.4% |
|  |  |  |
| 1. *Number of Years of experience in ethics committee* |  |  |
| *≤ 2 years* | 106 | 35.3% |
| *3 – 5 years* | 68 | 22.7% |
| *6-10 years* | 96 | 32% |
| *≥ 10 years* | 30 | 10% |
|  |  |  |
| 1. *Role you are playing as ethics committee member* |  |  |
| *Chairperson* | 39 | 13% |
| *Member Secretary* | 36 | 12% |
| *Basic Medical Scientist* | 13 | 4.3% |
| *Clinician* | 161 | 53.6% |
| *Legal Expert* | 14 | 4.6% |
| *Social Scientist/ Representative of NGO* | 5 | 1.6% |
| *Philosopher/ Ethicist/ Theologist* | 16 | 5.3% |
| *Lay Person* | 20 | 5.6% |
|  |  |  |
| 1. *Have you received any training in research ethics?* |  |  |
| *Yes* | 116 | 38.6% |
| *No* | 184 | 61.4% |

**TABLE 2: KNOWLEDGE REGARDING CURRENT REGULATORY REQUIREMENTS, AMONGST ETHICS COMMITTEE MEMBERS OF DENTAL COLLEGES IN INDIA**

|  |  |  |
| --- | --- | --- |
| Questions | NO. OF PARTICIPANTS | Total Responses  (%) |
|  |  |  |
| 1. Guidelines of biomedical research on human subjects should be governed by- |  |  |
| *Nuremberg Code* | 101 | 33.6 |
| *ICMR Guidelines* | **139** | **46.3** |
| *Declaration of Helsinki* | 26 | 8.6 |
| *Belmont report* | 20 | 6.6 |
| *Don’t know* | 14 | 4.9 |
|  |  |  |
| 1. Ideally how many members should an ethics committee have |  |  |
| *1-4 members* | 36 | 12 |
| *4-8 members* | 51 | 17 |
| *6-12 members* | 80 | 26.7 |
| *8-12 members* | **84** | **28** |
| *Don’t know* | 49 | 16.3 |
|  |  |  |
| 1. As per ICMR Guidelines (2006) the final decision on each proposal discussed in the meeting shall be made- |  |  |
| *At chairperson ’s discretion* | 39 | 13 |
| *Chairperson’s and member secretary’s approval* | 43 | 14.3 |
| *Voting of ethics committee members (Quorum)* | 86 | 28.6 |
| *Broad consensus of ethics committee members* | **98** | **32.6** |
| *Don’t know* | 34 | 11.5 |
|  |  |  |
| 1. *Research study proposals that can be exempted from ethics committee review for-* |  |  |
| *Minimal risk to participants* | 62 | 20.8 |
| *Less than minimal risk to participants* | **121** | **40.3** |
| *High risk to participants* | 37 | 12.3 |
| *Moderate risk to participants* | 46 | 15.3 |
| *Don’t know* | 34 | 11.3 |
|  |  |  |
| 1. *After closure of regulatory clinical trial , files at EC Secretariat are-* |  |  |
| *Stored with active files for next 5 years* | 96 | 32 |
| *Disposed and discarded immediately* | 21 | 7 |
| *Returned to the respective investigator to store for next 5 years* | 49 | 16.4 |
| *Archived separately for 5 years* | **62** | **20.6** |
| *Don’t know* | 72 | 24 |
|  |  |  |
| 1. *Continuing review of an approved protocol by EC must-* |  |  |
| *Occur only when the level of risk changes* | 36 | 12 |
| *Ask for only severe adverse reports* | 49 | 16.3 |
| *Occur at least annually* | **44** | **14.7** |
| *Include copies of all signed consent forms* | 142 | 47.3 |
| *Don’t know* | 29 | 9.7 |
|  |  |  |
| 1. *Ethics committee should forward report on serious adverse effect related to clinical trial to Drug Controller General of India within* |  |  |
| *21 days* | 42 | 14 |
| *24 hours* | 78 | 26 |
| *14 days* | 64 | 21.4 |
| *30 days* | **34** | **11.3** |
| *Don’t know* | 82 | 27.3 |
|  |  |  |
| 1. *What should be done to obtain informed consent from a literate participant who cannot understand English* |  |  |
| *The participant should be given a consent form written in his/her language* | **192** | **64** |
| *A family member who is fluent in English can be asked to read the consent form to the participant* | 32 | 10.7 |
| *A family member who speaks English can be asked to orally translate the consent form to the participant* | 24 | 8 |
| *A witness should be present while administering an English consent form* | 40 | 13.3 |
| *Don’t know* | 12 | 4 |
|  |  |  |
| 1. *Informed consent for clinical trials involving vulnerable population should be in the form of-* |  |  |
| *Audio visual recording* | **82** | **27.3** |
| *Written informed consent* | 89 | 29.7 |
| *A witness should be present* | 49 | 16.3 |
| *Family members should be asked* | 30 | 10 |
| *Don’t know* | 50 | 16.7 |

**TABLE 3: PRACTICE REGARDING CURRENT REGULATORY REQUIREMENTS, AMONGST ETHICS COMMITTEE MEMBERS OF DENTAL COLLEGES IN INDIA**

|  |  |  |
| --- | --- | --- |
| Questions | NO. OF PARTICIPANTS | Total Responses  (%) |
|  |  |  |
| 1) Have you registered your ethics committee? |  |  |
| *Yes* | **49** | **16.3** |
| *No* | 189 | 63 |
| *Don’t know* | 62 | 20.7 |
|  |  |  |
| *2) Is the chairperson of your ethics committee from the same institution?* |  |  |
| *Yes* | 118 | 39.3 |
| *No* | **182** | **60.7** |
|  |  |  |
| *3) You must review all research studies , at least annually, in order to-* |  |  |
| *Keep research administration appraised of any publications* | 62 | 20.8 |
| *Protect the rights and welfare of participants in research studies* | **118** | **39.3** |
| *Enable the funding agencies to learn about the progress* | 49 | 16.3 |
| *Learn about the numbers of amendments and severe adverse events in the study* | 71 | 23.6 |
|  |  |  |
| *4) Waiver of consent is approved by your EC when-* |  |  |
| *Students are interviewing participants for their professor* | 46 | 15.3 |
| *Study is only on left over biological material which is anonymized* | **98** | **32.7** |
| *Study is on a marketed drug or device* | 54 | 18 |
| *All of the above* | 102 | 34 |
|  |  |  |
| *5)* *Full review is undertaken in presence of –* |  |  |
| *Chairperson* | 98 | 32.7 |
| *Subject Expert* | 48 | 16 |
| *Member Secretary* | 84 | 28 |
| *Entire committee* | **70** | **23.3** |
|  |  |  |
| *6)* *Does your institutional ethics committee invite non-members in special area when needed ?* |  |  |
| *Yes* | **102** | **34** |
| *No* | 198 | 66 |
|  |  |  |
| *7)* *Which universal ethical principles are applied in your institution while reviewing a protocol?* |  |  |
| *Autonomy and beneficence* | 56 | 18.7 |
| *Beneficence and Justice* | 42 | 14 |
| *Autonomy , beneficence , non – maleficence and justice* | **86** | **28.7** |
| *Autonomy , beneficence , non – maleficence and justice and local cultural norms* | 96 | 32 |
| *Don’t know* | 20 | 6.6 |
|  |  |  |
| *8)* *In case of minors, assent can be taken from the age of -* |  |  |
| *7 years up to 18 years* | **112** | **37.3** |
| *7 years up to 14 years* | 64 | 21.3 |
| *5 years up to 14 years* | 42 | 14 |
| *9 years up to 18 years* | 82 | 27.4 |
|  |  |  |
| *9)How do you maintain patient’s confidentiality during medical research ?* |  |  |
| *Patients research files should be coded* | **98** | **32.7** |
| *No need of confidentiality* | 24 | 8 |
| *I don’t maintain confidentiality* | 42 | 14 |
| *It is left to the investigator to decide* | 136 | 45.3 |

**TABLE 4: ASSOCIATION OF TRAINING IN RESEARCH ETHICS AND NUMBER OF YEARS OF EXPERIECE IN ETHICS COMMITTEE WITH KNOWLEDGE**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | YES | NO | Chi-square | <2 YEARS | 3-5 YEARS | 6-10 YEARS | >10 YEARS | CHI-SQUARE |
| No Knowledge (score 0) | 4 | 23 | \*51.029 | 1 | 4 | 16 | 6 | \*53.65 |
| Inadequate knowledge (score <5) | 60 | 143 | 73 | 34 | 73 | 23 |
| *Adequate knowledge (score >5)* | 52 | 18 | 32 | 30 | 7 | 1 |

**\* Statistically significant (p value - <0.001)**

**TABLE 5: ASSOCIATON OF TRAINING IN RESEARCH ETHICS AND NUMBER OF YEARS OF EXPERIECE IN ETHICS COMMITTEE WITH PRACTICE**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | YES | NO | CHI-SQUARE | <2 YEARS | 3-5 YEARS | 6-10 YEARS | >10 YEARS | CHI -SQUARE |
| Poor practice (score 0) | 10 | 39 | \*61.44 | 5 | 1 | 31 | 12 | \*82.21 |
| Fair practice (score <5) | 41 | 120 | 60 | 29 | 56 | 16 |
| *Good practice (score >5)* | 65 | 25 | 41 | 38 | 9 | 2 |

**\* Statistically significant (p value - <0.001)**