**Knowledge, attitude and practices of informed consent documentation among medical researchers in Tamil Nadu - a questionnaire based study**

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Competing interests and funding support : NIL

Submissions of very similar work : NIL

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**Abstract:**

Aiming at the increasing number of health research in this scenario of pandemic, there is a need to understand the knowledge, attitude and practices of the medical researchers on the informed consent documentation process in their research studies. Academic research in medical colleges is booming on two exclusive reasons, 1, need for research papers for promotions 2, student projects guided by the faculty. In these scenario the knowledge about the faculties on the importance of informed consent need to be assessed and also their practices along with their expectations. This article is based on a survey conducted through an online questionnaire exploring the knowledge, attitude and practices of medical researchers on the informed consent documentation process and the suggestive measures for imbibing ethically strong research processes at the level of every individual researcher.

Keywords: informed consent, ethics, medical research.

**Introduction:**

Medical research involving human participants has increased greatly in the developing countries with an expectation to improve the quality of healthcare in them, especially in India.1 Researchers have the responsibility of revealing the complete informations about the research to their prospective study participants in order to keep them informed about the proposed research, procedures involved, goals and even the potential risk along with the benefits. International ethical guidelines consistently impose researchers to follow some kind of informed, voluntary and competent informed consent documentation in order to minimize the chance of exploitation of the study subjects.2

As human participants were involved in medical research, in order to maintain the participants autonomy and rights, and also for the research to be guided by fundamental ethical principles to ensure the protection of their welfare, it is mandated by various national and international regulatory bodies to insist upon the collection and maintenance of informed consent documentations.3,4

Informed consent documentation, among all the other ethical practices in research has gained the most attention among researchers. It may be because of the fact that the practice of informed consent prior to any research had become the fundamental element that serves to protect both research participant and the researcher from any prosecution.5 Informed consent documentation is consistently required in order to ensure that research is informed, voluntary and there is no exploitation of the study subjects.2

With the Indian council of medical research(ICMR) releasing its revised guidelines on ethics in the year 2017 and with an increased medical research involving human participants in India in the recent years, we decided to assess the knowledge, attitude and practices of informed consent documentation among researchers in medical colleges of south India especially in the state of Tamilnadu.

**Materials and methods**

The research was launched after approval by the Institutional Ethics Committee and written informed consent was obtained from each study participant. The choice of participation was inducted within the online survey form and only who have consented was given the choice to go further steps in taking up the questionnaire of the survey.

This cross sectional descriptive study was conducted with an online questionnaire which was emailed to researchers in different medical colleges across the state of Tamilnadu and the responses were collected online only (google forms). The total number of samples was determined to be of 241 participants based on an earlier publication (5), with a desired confidence interval of 95% and an expected drop out of 10%. Both male & female faculties working in medical colleges within the state of Tamilnadu, who have completed atleast 1 year of service as Assistant professor. Atleast one research work and one publication would be another category for inclusion. Tutors, Assistants with less than 1 year of experience and those without any publication were excluded from the study.

Standardized questionnaire with 30 questions on KAP was designed in Google forms - a free survey tool provided by the google search engine was used to collect the data. The study questionnaire was emailed to most of the researchers in the state through email and their responses were populated in the Google response sheet again freely provided by the Google.co.in. Care was taken such that one person can submit only one response such that duplication was avoided. The responses were collected between the months of May 2019 to December 2019. Responses were then transferred to a MS office-Excel sheet and was coded to perform the required statistical analysis.

Both the face and content validation of the questionnaire was done before the initiation of the study. Questionnaire had a brief introductory note and a statement on confidentiality of the data collected to the respondents. Percentage distribution of the medical researchers in the various sections of the study objectives was analysed for statistical significance and is described in the results of the study. Descriptive statistics is used to explain the demographic data.

**Results**

The study included a total of 241 participants from medical colleges across Tamil Nadu. Out of the selected study participants, 153 were males and 88 were females. As the study was focused on medical research, the questionnaire was distributed among Professors (30.3%), Associate Professors (17%), Assistant Professors (22.4%) and Tutors (17%), who are involved in research across all disciplines in Medical colleges of Tamil Nadu. 51.9% of the selected population had minimum of 1 to 5 publications and 24.5 % of them had more than 10 publications. Though 94.6% of the participants had a registered Institutional Ethics committee in their working Institution, only 79.7 % had undergone some training in Ethics.

**Knowledge about Informed consent documentation (ICD)**

The results obtained from the participants on their existing knowledge regarding the rights of the study participants, procedures and requisites for obtaining ICD are shown in table 1. All the questions were excerpts from the regulations for ICD in ICMR guidelines 2018. On an average, 37.5% of right answers were obtained from the participants. Remaining 62.5% of answers chosen by the participants were incorrect which lead to a significant value.

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| --- | --- |
| **Table 1: Knowledge of Researchers towards Informed Consent Documentation (ICD)** | |
| **Variable** | **Responses**  **N (%)** |
| Mandatory requirement of ICD for any research involving human participants | 220 (91.3) |
| Autonomy of the research participant in participation in any research | 92 (38.2) |
| ICD process is continuous except in assessing the competency of the individual | 96 (39.8) |
| ICD process does not promote individual’s right to go for legal help | 89 (36.9) |
| Informed consent is purely voluntary | 191 (79.3) |
| Incapable participant can give consent through legally acceptable representative | 154 (63.9) |
| Reconsent need not be done in extension of study period | 44 (18.3) |
| Witnesses in the ICD process from any illiterate cannot be a legal or lawyer person | 45 (18.7) |

Figure 1: Participant responses on the knowledge on situations when waiver of informed consent is applicable.

Only 47 of the total participants were aware of the fact that the studies involving biological hazards are not to be exempted from any informed consent waiver. 23.7 % of them were aware of the use of community consent which is applicable in situations when individual consent cannot be obtained as it will change the behaviour of the individual. Forty nine percentage of participants agreed that the prospective study subjects should not be intimidated while obtaining informed consent. The importance of obtaining informed assent and written informed consent from children between 12 to 18 years of age is less understood by 35 % of participants as shown in the figure 2.

Figure 2: Participants knowledge on obtaining written informed consent from children between12-18 years of age.

**Attitude towards Informed consent documentation (ICD):**

When the respondents were questioned about their opinions on the method of obtaining consent, 23.7% indicated that it was a complicated process. An equal amount of participants accepted it to be a mandatory process as well (29.5%).

Figure 3: Participants attitudes towards the process of obtaining an informed consent process from research participants.

In comparison, only 60.6% are mindful of the need for informed and written approval from ICD. as shown in the fig 3.

Table 2 displays the participants' responses to questions regarding the attitude towards obtaining informed consent for research involving human subjects. More than 65% of positive responses have been recorded for the questions on importance of maintaining ICD. < 10% of the participants is yet unaware of the advantages of maintaining ICD. 14.1% of participants have expressed opinion of requirement of training for the process to be more accurate and proper.

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| **Table 2: Attitude of Researchers towards Informed Consent Documentation (ICD)** | | | |
| **Variables** | **Responses (%)** | | |
| **Yes** | **No** | **Don’t**  **know** |
| Safeguards the rights of the research participant | 207(85.9) | 23(9.5) | 11(4.6) |
| Addresses participants concerns of any kind | 191(79.3) | 27(11.2) | 23(9.5) |
| Makes an impact on quality of good health care | 141(58.5) | 46(19.1) | 54(22.4) |
| Protects researchers against litigation | 180(74.7) | 30(12.4) | 31(12.9) |
| Should be in the language understood by the participant | 208(86.3) | 14(5.8) | 19(7.9) |
| Suggests training for researchers | 157(65.2) | 50(20.7) | 34(14.1) |
| Increases the participants’ trust in the researcher | 195(80.9) | 21(8.7) | 25(10.4) |

**Practices of Informed consent documentation (ICD):**

Table 3 demonstrates the existing practices of ICD by the research participants in their research studies.

Nearly 93% of participants report that they regularly maintain ICD in their research studies. 31.5% of participants were unaware or do not follow the procedure of giving a copy of ICD to their research participants. Only 57.3% of participants have reported that they regularly obtain informed consent before the start of the study. Others have been doing it during the course of the study or after that just for documentation purpose. 33.2% of participants store the obtained ICD and the data for up to 5 years. 24.5% of participants have reported that they do not store the data after the completion of the study.

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| **Table 3: Practice of Researchers during Informed Consent Documentation (ICD)** | | | |
| **Question** | **Responses** | | |
| **Yes** | **No** | **Don’t know** |
| Regularly obtaining informed consent from research participants | 223(92.5) | 18(7.5) | 0(0) |
| Preferring signature even after verbal consent | 199(82.5) | 24(10) | 18(7.5) |
| Providing copy of consent form to participant on request | 165(68.5) | 35(14.5) | 41(17) |
| Explaining nature of study, risks and benefits to the participants | 196(81.3) | 22(9.1) | 23(9.5) |
| Documentation of refusal of consent | 171(71) | 46(19.1) | 24(10) |

**Discussion:**

Our study was unique in conducting an assessment after the roll out of the revised guidelines on Ethics by the Indian council of medical research in the year 2018. The questionnaire served by itself a tool to sensitize the participants about the revised and recently modified guidelines. The response rate was acceptable and the results were showed the standards of the medical researchers across the state with respect to their knowledge, attitude and practices of Informed consent documentation in their research.

**Knowledge aspects of ICD:**

The study participants were from medical colleges across the state of Tamil Nadu in India. All the participants were medical college affiliates and about 1/3rd of them were women. There was a significant gap in the knowledge of obtaining Informed consent and its documentation as per ICMR guidelines, 2018. Quality of research depends on the participant’s understanding of the processes involved in giving consent. Voluntary participation, processes involved in obtaining consent, and confidentiality of data obtained are some of the elements to be necessarily known and followed by the researchers involved in Medical Research(6). There was also a substantial lack of information among the researchers about the requirements for obtaining consent from children. Before giving permission, all children have the right to get the necessary information in their own comprehensible language (7). The revised medical curriculum ie the Competency based undergraduate curriculum and the importance of the AETCOM module introduced by the Medical council of India from the year 2019-20 might inculcate the knowledge of ethics in clinical practice and research. It involves the evaluation component also which assures the learning of bioethics at a very early part of the career (8). The need for reconsent and the role of a legally accepted representative in informed consent documentation is also less understood by the researchers. There is an existing need for the central agencies like ICMR to enhance the sensitization programs (preferably online with certification) and also the institutional ethics committees to ensure that their dynamic medical researchers are aware of the existing as well as the recently revised guidelines of the ICMR.

**Attitude aspects of ICD:**

Though majority of the participants opine the process of ICD as a simple and responsible one, about one fourth of the participants felt it to be a difficult or painstaking process. Nijhawan et al have reported that this might be due to language barriers, religious and cultural influences, patients’ false perceptions about the process and the fear (9). Our study participants have demonstrated a constructive attitude about the need to obtain and retain informed consent for research purposes. Shared decision making and explaining patients about their concerns for participation with documentary evidences, especially with regard to the risks and benefits involved in the research could be some of the strategies that can be adopted for increasing the validity and reliability during Informed consent documentation (10,11). They also acknowledged the point that the autonomy and anonymity of the patient or participant is always the central point of medical ethics (12). Majority of the participants have suggested for trainings on ICD processes, which is possible that every registered Institutional ethics committees can organize and conduct annual review meetings or sensitization programmes on ICD process.

**Practice aspects of ICD:**

While most participants documented their practice of recording informed consent during their study, only half of them did the procedure before collecting data from their research subjects. The data collected after the end of the study was never retained by one fourth of the participants, and it was only 33.2 percent who have been able to retain it for 5 years. The participants are unaware of the need for the data protection in support of any legal proceedings arising from their research study. They were also not much familiarized with the participant’s right to receive a copy of the informed written consent form. Educating the medical researchers with the revised guidelines and help them imbibe good ICD processes in their research studies would bring out healthy and safe research environment and better research in the entire nation.

**Limitations:**

This study was conducted among the medical researchers in the southernmost state of India. The prevalence and practices of ICD in other parts of the country should be explored for more valuable information. Data was collected using anonymous questionnaire using google forms and hence the opinions are very qualitative yet subjective. ICD practices among other healthcare sectors also should be explored to find the extent of ICD practices and the reasons for any setbacks.

**Conclusion:**

This is an unique study exploring the KAP on the informed consent documentation process by medical researchers using human participants. The knowledge about ICD was better yet provides scope for updating the researchers with the revised guidelines on ethics by ICMR, their positive attitude on the importance of ICD is promising as this paves wave for further sensitization and empowerment of the researchers with information on the revised guidelines. Their practices on ICD was good yet the legal aspects of the ICD and need for reconsent are some areas they require updates. We conclude here that the fact that ICD process is appreciably being carried out by the medical researchers in this part of the country however, they are in dire need for trainings on improvising themselves with the revised guidelines of the regulatory body.

**Conflict of Interest** : The authors declare that there is no conflict of interest in any kind.

**Acknowledgements :** Authors hereby acknowledge the support rendered by Dean, Shri Sathya Sai Medical College & RI.

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