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RESEARCH ARTICLE

Knowledge, attitude, and practices regarding informed consent for research purposes among postgraduate resident doctors

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ABSTRACT

Background: Informed consent is an ethical and legal requirement for research involving human participants. Postgraduate (PG) residents are budding doctors who are in their interim phase of education and are engaged in thesis/research work, which mandates adequate knowledge of informed consent and regulatory guidelines. There exists paucity of data in literature on the informed consent process with regard to PG residents; therefore, this study was conducted to assess the knowledge, attitude, and practices (KAP) of informed consent among PG residents. **Aims and Objectives:** The aim of the study was to assess the level of knowledge and attitude about the informed consent process and assess practices adopted by PG residents for research purposes. **Materials and Methods:** It was a cross-sectional, observational and questionnaire-based study conducted from January 2018 to March 2018 at a tertiary care teaching hospital, Navi Mumbai. The study included PG residents of either sex pursuing specialty MD/MS courses. A validated KAP questionnaire was used to assess KAP of the informed consent process. Responses from the eligible participants were obtained and analyzed. **Results:** A total of 100 PG residents participated; 39% of males and 61% of females. Overall, the knowledge score was high and attitude toward informed consent was average. However, 34% participants felt that witness is not necessary, 20% felt that once the patient participates, they should not be allowed to withdraw and few felt that on voluntary withdrawal, participants are not liable for further standard care and compensation. In practice, few participants failed to explain consent in the local language and neglected to take the signature of an impartial witness. **Conclusions:** Overall, the KAP of informed consent among PG residents were adequate. Structured continuing medical education/workshops are necessary to advance informed consent practices.

KEY WORDS: Informed Consent; Postgraduate; Residents

INTRODUCTION

Informed consent is based on the declaration of Helsinki and the Nuremberg Code and now has become the gold standard for conduct in medical research.[1-3] It is an ethical and legal mandate for biomedical research involving human participants. In the informed consent process, the participant is updated about all the facets of the trial essential to make a decision, and after analyzing all the aspects of the trial the participant voluntarily sanctions his or her willingness to participate in a particular clinical trial.[4]

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Revealing information to the patient regarding the study to take consent, does not necessarily assure that the patient has fully understood the extent of participation in clinical research and what it involves.[5,6] Signed informed consent forms can merely be considered as documentary evidence that patients have consented to participate and had received

the required information.[7] Historically, informed consent is an ancient method employed for taking permission from the patient, but its legacy styles have been taking very varied shapes with the passage of time, and despite being a worthwhile practice, informed consent has not been taken seriously sometimes by the researchers and sometimes by the patients themselves.[8-10] The importance of taking proper informed consent has now become an essential part of any biomedical research study. The ability to take an appropriate informed consent from the participants is the principal responsibility of the researcher.

A study conducted by Shakoor *et al*. in Bangladesh among doctors and postgraduates (PG) documented that most of the researchers were having adequate knowledge about informed consent but had a poor attitude to apply it in practice.[11] PG residents are upcoming doctors who are in their transitional phase of education and research. As a part of the academic career, they are engaged in thesis/research work, which mandates adequate and sound knowledge of informed consent and regulatory guidelines for biomedical research. There exists a paucity of data in Indian literature on the process of informed consent among PG residents. With this viewpoint, the present study was aimed to assess the knowledge, attitude, and practices (KAP) of the informed consent process among PG residents at a tertiary care hospital in Navi Mumbai.

MATERIALS AND METHODS

Setting

The study was conducted at a tertiary teaching medical college and hospital in Navi-Mumbai.

Ethics

Permission of the Institutional Ethics Committee (IEC) was taken before the commencement of the study (IEC approval number-2018/1/6).

Study Design

This study was a prospective, cross-sectional, observational, and questionnaire-based survey for a duration of 3 months. Informed written consent was taken from each participant before being included in the study. The study included PG residents currently pursuing MD/MS courses, irrespective of age, sex, or specialty. We excluded non-MD/MS residents, participants below the age of 18 years, and those not willing for informed consent from the study. The survey tool was a pretested and structured questionnaire adapted from an earlier study by Shakoor *et al*.,[11] which assessed the knowledge and attitude of the participants and the practices adopted by them with regard to the informed consent process.

Sample Size

A total of 100 individual participants pursuing postgraduation were approached and their responses to the study questionnaire were assessed.

Statistical Analysis

Data obtained were entered into MS-Excel 2016 and analyzed. Numerical data were summarized using mean and standard deviation. Categorical data were expressed using percentage.

RESULTS

Demographics

A total of 100 participants participated in the study; the mean age of the participants was 27.39 years.

Out of the total, 39% were males and 61% were females, as shown in Figure 1. PG residents from all 3 years were involved in the study, 50% from the 1st year, 28% from the

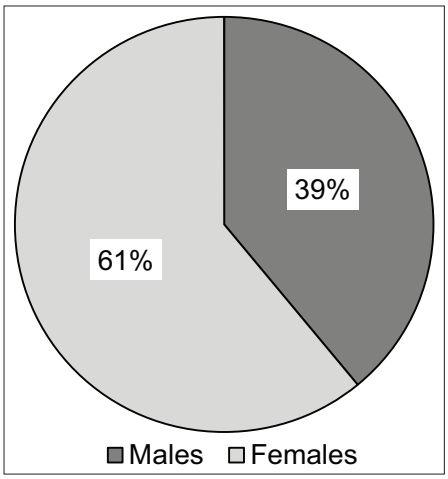

Figure 1: Gender distribution

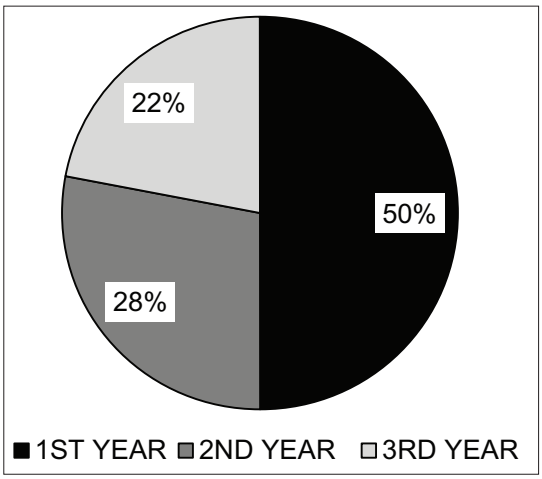

Figure 2: Postgraduate year-wise distribution

2nd year, and 22% from the 3rd year [Figure 2]. Overall, the knowledge score was high and attitude toward informed consent was average.

Knowledge

The knowledge regarding informed consent was high among PG resident doctors. The responses of the knowledge domain aspects are summarized in Table 1. Informed consent includes a statement on confidentiality and privacy, but 7% disagreed with the statement and 7% were ignorant about it. IC includes the duration of the study, but 19% felt that duration should not be included, and rest (1%) expressed their ignorance about it. Around 10% of the participants did not feel that informed consent is mandatory for an observational survey and 17% were ignorant about it.

Attitude

The attitude of the PG resident doctors toward informed consent was average. The responses of the attitude domain are summarized in Table 2. However, around 34% of participants felt that witness is not necessary; 20% felt that once patient participated in the study they must not be allowed to withdraw. In this study, 14% felt that on voluntary withdrawal the participants were not liable for further standard care and compensation, and 9% felt that participants were not liable for compensation due to research-based adverse events.

Practices

The responses of the practice domain are summarized in Table 3. In this study, 9% of the participants responded that

Table 1: Questions related to knowledge

Knowledge-related questions	Yes (%)	No (%)	Not aware (%)
Informed consent is only a verbal consent	0	100	0
Informed consent should include information that it is a research study	100	0	0
Informed consent contains information on the risks and benefits of participation in the research study	93	6	1
Informed consent can be given by a child	0	100	0
Informed consent does not include a statement on confidentiality and privacy	7	86	7
Informed consent includes the duration of the research study	80	19	1
Informed consent includes the autonomy of the subjects so that they can withdraw themselves from the study at any time	100	0	0
Informed consent is a decision to participate in research	100	0	0
Informed consent should be obtained with undue inducement	0	100	0
Informed consent is not mandatory in the case of prospective subjects	0	100	0
Informed consent is not mandatory in case of observational survey	10	73	17
Informed consent protects the individual's freedom of choice	99	0	1

Table 2: Questions related to attitude

Attitude-related questions	Yes (%)	No (%)	Not aware (%)
Do you think that informed consent should be taken before starting a research work?	99	1	0
Do you think that a witness is absolutely necessary to take informed consent?	66	34	0
Do you think that written document should be taken during taking informed consent?	98	2	0
Do you think that aims and procedures of the study should be explained to the participants?	100	0	0
Do you think the informed consent should be explained to the patient in their local language?	100	0	0
Do you think once the patient signs informed consent, they should not be allowed to withdraw from a research study?	15	80	5
Do you think the once the participant voluntarily withdraws, they are not liable for further standard care/treatment?	14	86	0
Do you think the participant is liable for any compensation due to research-based adverse events?	79	9	12

Table 3: Questions related to practice

Practice-related questions	Yes (%)	No (%)
Had you taken informed consent during your research work?	100	0
If yes, what type of consent taken from the study subject?	Verbal-1 written-99	
Had you explained to the participant that they are taking part in a research-based study?	98	2
Had you explained the informed consent to the participant in their local language apart from English?	91	9
Had you handed over the participation sheet while obtaining informed consent?	95	5
Had you taken signature of impartial witness along with the participant on consent form?	81	19

they did not explain consent in the local language and 19% neglected to take signature of impartial witness.

DISCUSSION

PG doctors are the future of medical research in India, and hence it is essential to ensure that their knowledge regarding informed consent is satisfactory which can cascade into adequate ethical practices. This study was mainly directed toward PG resident doctors to assess their level of knowledge and attitude as well as the practices followed by them. In this study, it was observed that researchers were knowledgeable about informed consent, but some had differences in attitude.

The informed consent is a universally recognized procedure to ensure that the patient's rights are safeguarded, and now across the world the requirement for informed consent is well established.[8,12,13,14]

In this study, the knowledge regarding informed consent among PG resident doctors was found to be high, which was similar to the finding in a study done by Hussain *et al*.[15] All the participants (100%) responded that informed consent is mandatory for a research study and this number was found to be greater in comparison to the study done by Shakoor *et al*.[11] These findings are in concurrence with the Drugs Controller General of India (DCGI) guidelines which recommended that informed consent is to be obtained before commencement of all clinical trials.[12] Most of the participants felt that informed consent must include risks and benefits, but a minority did not agree or were unaware. Every research has some risks and probabilities of harm involved, and therefore, protection of participants should be inculcated into the design of the study.[13] Around 14% did not agree or were not aware agreed that informed consent must include a statement on confidentiality and privacy of this which was similar to another study[11] DCGI guidelines specify that the confidentiality of records identifying the subject and the researchers having access to this information must be documented.[12] Around 20% of the respondents felt that duration of the subject's participation should not be mentioned in the informed consent form which was only slightly better than that observed in a similar study.[11] Biomedical research is a long process taking even years, and in this case, it is crucial for the research participant to be aware of the duration of the trial. The DCGI guidelines also mention that the expected duration of the subject's participation must be mentioned.[12] Indian council of medical research (ICMR) has laid down guidelines strictly asserting that no undue inducement must be offered to the participants[13] and based on the responses gathered in this study all the participants agreed to this statement as opposed to the study done by Shakoor *et al*., in which only 50.9% of the participants felt that informed consent should be taken with undue inducement. This is an encouraging observation as it shows us that there is an awareness of research ethics among investigators, and they are not resorting to unscrupulous practices. Informed consent is mandatory before conducting any kind of research, but in this study, 27% of respondents did not feel the requirement to take consent before an observational survey demonstrating that there were some lacunae in the knowledge about different types of study methodologies. The attitude of the researcher is of utmost importance as a person might have enough knowledge but unwillingness to apply it, which may prove detrimental to the research study. In this study, most of the respondents felt that informed consent should be taken before starting a research work. The consent of the legally authorized representative (LAR) should be obtained for an individual who is incapable of giving informed consent. If a participant or LAR is illiterate, a literate impartial witness should also be present during the informed consent process[13] 34% felt that witness is not absolutely essential while taking informed consent which was similar to the findings observed in the study done by Shakoor *et al*. Around 15% of the respondents felt that once a patient signs informed consent, they should not be allowed to withdraw from research study and 5% were not aware. The attitude of some researchers is negative toward withdrawal as it hampers their research study and so they feel that once a participant enrolls, they must not be allowed to withdraw. Around 14% of the respondents also felt that once the participant voluntarily withdraws, they are not liable for further standard care/treatment, but majority agreed that treatment should be continued. DCGI states that the participation of the subject is voluntary and the subject can withdraw from the study at any time.[12] The majority felt that the participant is eligible for compensation, 9% disagreed and 12% were not aware, but the guidelines by the ICMR state that compensation should be given to any participant when the injury is related to the research.[13] Knowledge ultimately has to translate into correct practices among the

researchers. All the PG residents had taken consent during their research work and explained to the patient that they are taking part in a research study. About 9% failed to explain informed consent in their local language, and 5% neglected to hand over the participation sheet while obtaining informed consent. The majority of the PG doctors took the sign of an impartial witness when required, but 19% neglected to do so.

We recognize the limitations of our study. First, the study was conducted in a limited sample size and in a single hospital setup. Multicentric studies with a larger sample size will yield better results and will help gauge the KAP toward informed consent among PG doctors. Second, our study relied on a convenient sampling method, which included only 100 residents. Thus, the residents who completed the survey may not reflect the KAP of all PG residents. Third, there may be a possibility of subjective bias while answering the questionnaire.

CONCLUSIONS

From this study, it can be concluded that the overall knowledge score was high and attitude toward informed consent was average. Awareness should be increased among the researchers by arranging structured seminars, symposium and workshop to advance informed consent practices and protect human rights. Regular activities taken up at an institutional level can also help to hone and refine the research skills of PG resident doctors at an early stage.

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