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Knowledge, attitude, and practices regarding informed consent among postgraduate and undergraduate medical students at a tertiary care teaching hospital in central India

[1]Dr. Rahulkumar K. Kodape, Junior Resident, Dept. of Pharmacology, IGGMC, Nagpur

[2]Dr. Mohini S. Mahatme, Assistant Professor, Dept. of Pharmacology, IGGMC, Nagpur

[3]Dr. Sachin Hiware, Associate Professor, Dept. of Pharmacology, IGGMC, Nagpur

Corresponding Author: Dr. Mohini S. Mahatme, Assistant Professor, Dept. of Pharmacology, IGGMC, Nagpur

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Abstract

Introduction: Informed consent is an ethical and legal requirement for research involving human participants. Postgraduate (PG) and undergraduate (UG) medical students are budding doctors who are in their interim phase of education and are engaged in thesis or research work, which requires adequate knowledge of informed consent and regulatory guidelines. There is a meagerness of data in the literature on the informed consent process with regard to PG and UG medical students. Hence, this study was conducted to assess the knowledge, attitude, and practices (KAP) of informed consent among postgraduate and undergraduate medical students at a tertiary care teaching hospital in central India.

Methods: It was a cross-sectional, observational, online questionnaire-based study. The study included 50 postgraduate (PG) and 50 undergraduate (UG) medical students of either sex. A validated KAP questionnaire adapted from an earlier study (1) was used to assess the knowledge, Attitude and Practices of the informed consent process. The questionnaire was provided in the form of Google forms through e-mails and social media to participants. Responses from the eligible participants were obtained and analysed.

Results: A total of 100 participants were enrolled in the study. Out of total, 48% were males and 52% were females. 50% of undergraduate MBBS students of final year (part 1 and part 2) and 50% of post-graduation students of MD/MS courses were involved in the study. It was observed that knowledge, attitude and practices were 58.91%, 55.25% and 55.20% among postgraduate students and 34.91%, 34.12% and 32.40% among undergraduate medical students respectively. Overall, the knowledge regarding informed consent was high and the attitude of medical students towards informed consent was average. Practices regarding informed

consent were suboptimal in medical students. **Conclusion:** The results revealed that although a majority of the students were aware of the concept of informed consent, there were significant gaps in their knowledge regarding the legal and ethical requirements of obtaining informed consent. Structured continuing medical education and workshops are necessary to advance informed consent practices.

Keywords: Informed Consent, Postgraduate, Undergraduate, KAP.

Introduction

Informed consent is a fundamental ethical principle in medical practice that ensures patients are aware of the risks and benefits of any proposed treatment or procedure before enrolling themselves for a study or trial. In health care, patient safety is a major focus and effective informed consent contributes to patient safety.(2) The importance of informed consent cannot be overstated, as it is essential for patient autonomy and the protection of their rights. Research compliance with informed consent is governed by the Helsinki Declaration and the Nuremberg Code, which have become the gold standard in medical research.(3)(4)(5) There are many types of consent, such as consent for treatment, consent for the dissemination of patient information, consent for surgical procedures, consent for blood transfusions, and consent for anaesthesia. In medicine, informed consent involves the following: 1. describing the proposed intervention 2. emphasizing the patient's involvement in decision-making 3. discussing alternatives to the proposed intervention 4. describing the risks of the proposed intervention, and 5. obtaining the patient's preference (usually by signature). (2) Informed consent is an area that is frequently emphasized in medical education, as it is critical to the practice of medicine. It is important that medical professionals understand the significance of informed consent and effectively communicate it to their patients or participants. The informed consent process not only ensures that patients are well-informed about their medical care but also establishes trust and fosters a positive doctor-patient relationship. Medical professionals have a responsibility to ensure that patients understand the implications of their treatment options and have the opportunity to make informed decisions about their care. Moreover, in view of growing research models all over the world, the government of India has taken initiative to inculcate and promote research activities which are being taken up by undergraduate and postgraduate medical students monitored by ICMR India and various other institutions by granting funds. Informed consent is the founding principle of research. Studies have shown that the informed consent process is often inadequate in developing countries like India, where healthcare systems face various challenges such as limited resources, inadequate training and a lack of awareness among healthcare providers. Medical students are taught the principles of informed consent and are expected to apply them in their future practice. However, there is evidence to suggest that the level of understanding and implementation of informed consent may vary among medical students. Therefore, it is essential to assess their knowledge, attitudes and practices regarding informed consent to determine whether they are adequately equipped to communicate with patients about informed consent. Additionally, if informed consent is not entailed, it may result in legal and ethical issues for healthcare providers, which can negatively impact their careers. Therefore, this study was planned to evaluate the level of knowledge, attitudes,

and practices of postgraduate and undergraduate medical students at a tertiary care teaching hospital in central India regarding informed consent.

Materials And Methods

Study setting The study was conducted at the Department of Pharmacology, Indira Gandhi Govt. Medical College and Hospital, Nagpur.

Ethics Permission of the Institutional Ethics Committee (IEC) was taken before the commencement of the study (IEC approval number- IGGMC/IEC/1328-29/2023)

Inclusion Criteria

- Postgraduate residents of either sex pursuing Speciality MD/MS courses
- Undergraduate students of final year MBBS (part 1 and part 2)

Exclusion Criteria

- Those who have not submitted the forms.
- Incomplete information forms.

Sample size A total of 120 individual participants pursuing under graduation and post-graduation were approached and their responses in the google forms were assessed. The responses of first 100 participants were analysed.

Study design

It was a cross-sectional, observational, online questionnaire-based study. The study included postgraduate (PG) and undergraduate (UG) medical students of either sex. A validated questionnaire adapted from an earlier study (1) was used to assess the knowledge, Attitude and Practices of the informed consent process. A questionnaire was circulated to 60 postgraduate residents pursuing MD/MS courses and 60 undergraduate students of final year MBBS (part 1 and part 2). The validated questionnaire was provided in the form of Google forms through e-mails and social media to participants. Responses from the eligible participants were obtained and analysed. There was no enforcement for the postgraduate and undergraduate students to fill the online google forms.

Statistical analysis

Data obtained was entered into MS Excel and analysed. Numerical data were summarized using mean and standard deviation. Categorical data were expressed using percentage.

Results

Demographics

Data obtained from first 100 participants (50 PG and 50 UG) was analysed. As shown in figure 1, out of total, 48% were males and 52% were females

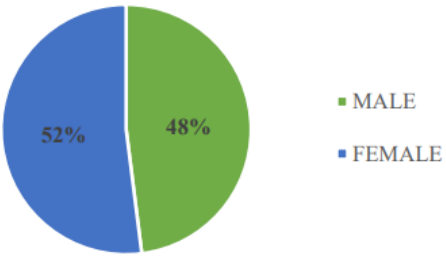

Figure 1 : Gender Distribution

Knowledge

The knowledge regarding informed consent was high among participants. The knowledge-related questions are summarized in Table 1. The responses to the knowledge-related questions are summarized in Figure 2. All the participants strongly agreed that informed consent is a decision to participate in research. 6% of respondents disagree and 8% were unaware of the fact that confidentiality and privacy are part of informed consent. The majority of participants agreed to the question that subjects are free to withdraw from the study at any time. Although informed consent includes the duration of the study, 5% felt it should not be included, and 3% were

unaware of it. According to the study, around 12% of participants did not believe informed consent was mandatory for observational surveys, while 14% were unaware of it. Participants strongly agreed that informed consent is not only verbal consent and it protects participant's freedom of choice.

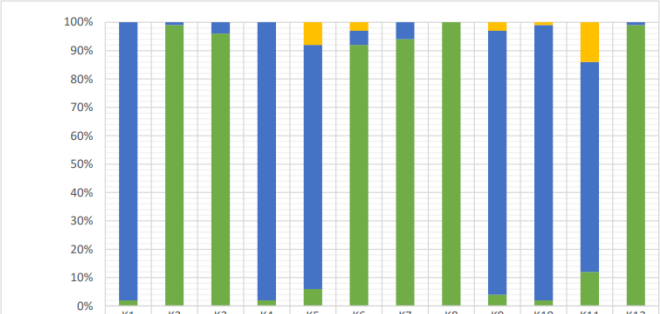

Figure 2 : Responses of Knowledge related questions

Table 1 : Knowledge related questions	
K1	Informed consent is only a verbal consent ?
K2	Informed consent should include information that it is a research study?
K3	Informed consent contains information on the risks and benefits of participation in the research study ?
K4	Informed consent can be given by a child ?
K5	Informed consent does not include a statement on confidentiality and privacy ?
K6	Informed consent includes the duration of the research study ?
K7	Informed consent includes the autonomy of the subjects so that they can withdraw themselves from the study at any time ?
K8	Informed consent is a decision to participate in research ?
K9	Informed consent should be obtained with undue inducement ?
K10	Informed consent is not mandatory in the case of prospective subjects ?
K11	Informed consent is not mandatory in case of observational survey ?
K12	Informed consent protects the individual's freedom of choice ?

Attitude

The attitude of the participants toward informed consent was average. The attitude related questions are summarized in table 2. The responses to the attitude-related questions are summarized in figure 3. Most of the participants think informed consent should be taken before starting research work. Nonetheless, 31% of participants did not believe that witnesses were necessary, and 11% opined patients should not be allowed to withdraw once they had participated in a study. In this study, 12% of respondents felt that participants were no longer liable for compensation after voluntary withdrawal, and 11% felt that participants were not liable for compensation after adverse events arising from research. It was widely agreed by all participants that the study's aims and procedures as well as informed consent should be explained to them in their local language.

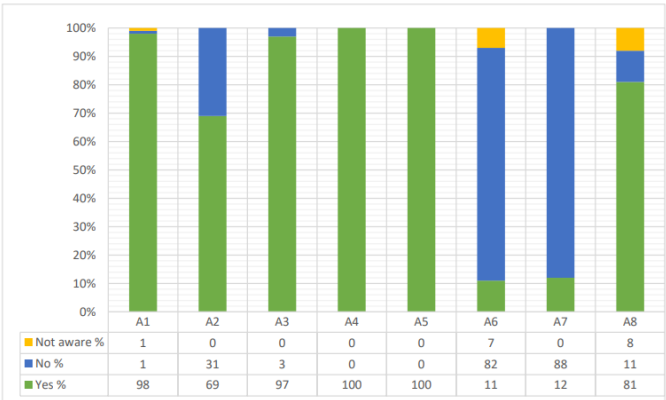

Figure 3 : Responses of Attitude related questions

Table 2 : Attitude related questions	
A1	Do you think that informed consent should be taken before starting a research work?
A2	Do you think that a witness is absolutely necessary to take informed consent?
A3	Do you think that written document should be taken during taking informed consent?
A4	Do you think that aims and procedures of the study should be explained to the participants?
A5	Do you think the informed consent should be explained to the patient in their local language?
A6	Do you think once the patient signs informed consent, they should not be allowed to withdraw from a research study?
A7	Do you think the once the participant voluntarily withdraws, they are not liable for further standard care/treatment?
A8	Do you think the participant is liable for any compensation due to research-based adverse events?

Practices

The practice related questions are summarized in table 3. The responses of the practice-related questions are summarized in figure 4. The majority of medical students had obtained informed consent before their research and had explained to the patient that they were participating in a research study. However, approximately 11% of respondents failed to explain informed consent in the patient's local language. In this study, most of the participants had handed over patient information sheet while obtaining informed consent but

19% undervalued the importance of patient information sheet. Although most participants obtained an impartial witness signature when required, 17% did not.

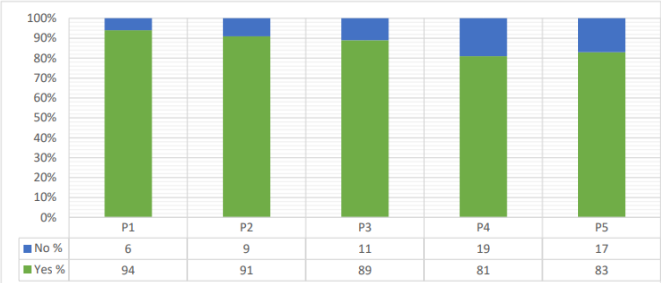

Figure 4 : Responses of Practice related questions

Table 3 : Practice related questions	
P1	Had you taken informed consent before your research work?
P2	Had you explained to the participant that they are taking part in a research-based study?
P3	Had you explained the informed consent to the participant in their local language apart from English?
P4	Had you handed over the information sheet while obtaining informed consent?
P5	Had you taken signature of impartial witness along with the participant on consent form?

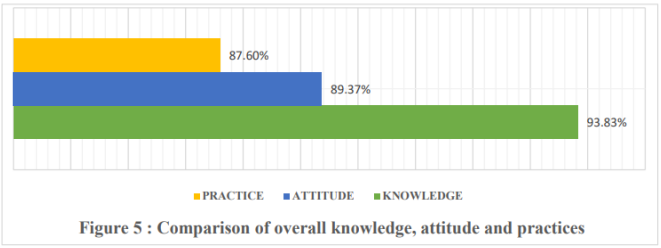

Figure 5 : Comparison of overall knowledge, attitude and practices

Figure 5 depicts the comparison of overall knowledge, attitude and practices regarding informed consent among medical students

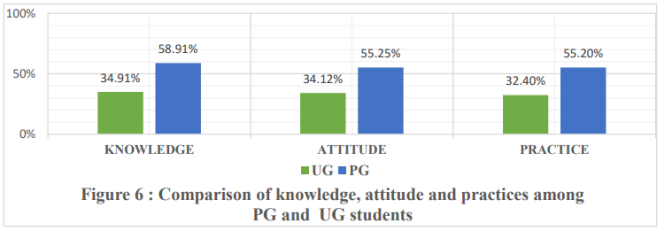

Figure 6 : Comparison of knowledge, attitude and practices among PG and UG students

Figure 6 represents the comparison of knowledge, attitude and practices regarding informed consent among postgraduate and undergraduate medical students. It was observed that knowledge, attitude and practices were 58.91%, 55.25% and 55.20% among postgraduate students and 34.91%, 34.12% and 32.40% among undergraduate medical students respectively.

Discussion

Medical students, as future physicians, play a critical role in upholding ethical and professional standards in patient care. The issue of informed consent is a critical one in medical practice, as it involves obtaining permission from patients to undergo medical procedures, treatments or participate in research studies. The practice of obtaining informed consent is widely acknowledged as a crucial step in protecting the rights of patients. Nowadays, the need for informed consent is firmly established throughout the world.(6)(7)(8) This study aims to investigate the knowledge, attitudes and practices of undergraduate and postgraduate medical students in central India regarding informed consent. This study was conducted among 100 medical students from tertiary teaching hospital in Nagpur, in central India using validated questionnaire. (1)(9) The results revealed that although a majority of the students were aware of the concept of informed consent, there were significant gaps in their knowledge regarding the legal and ethical requirements of obtaining informed consent. In this study, the overall knowledge regarding informed consent was high, which is similar to the finding of the study done by Noopur Vyas et al(1) and Hussain A et al.(10) The knowledge among post graduate medical students (58.91%) was higher than undergraduate students (34.91%). The difference might be due to the fact as postgraduate students are more involved in the research. So they are more knowledgeable as compared to undergraduate students. The guidelines issued by the Drugs Controller General of India (DCGI) specify that informed consent must be acquired prior to the commencement of any clinical trials.(6) Many of the participants thought informed consent should be taken before starting research work and this was found to be

similar to the study done by Noopur Vyas et al(1). All research studies carry inherent risks and the possibility of harm, making it essential to incorporate participant protection into the study design.(7) The majority of the participants believed that informed consent should outline both the potential risks and benefits of the study. However, a minority either disagreed with this or were not aware of it. Similar results were seen in study done by M. Rajshree et al.(11) Some participants did not believe that witnesses were necessary and very few believed that informed consent can be given by child. In cases where an individual is not capable of providing informed consent, the legally authorized representative (LAR) must provide consent. If the participant or LAR is unable to read, an impartial literate witness should be present during the informed consent process.(7) The study also found that the attitudes of the medical students towards informed consent were generally positive, with most of them agreeing that it was an essential component of medical practice. However, a significant proportion of the students also believed that informed consent was not always necessary. The current study's result showed that the overall attitude score was better among postgraduate students. These results are similar with the study done by Sivakumar A et al.(12) Also Similar results were seen in the studies done by Noorelahi et all(13), Pallamparthy et al.(14)

As per the recommendations of Drug Controller General of India (DCGI), participation in research studies is voluntary, and participants have the right to withdraw at any time.(6) The Indian Council of Medical Research (ICMR) guidelines state that compensation should be awarded to participants if research-related injury occurs.(7) The majority of survey participants believed that compensation should be provided to participants, however, few were unaware of compensation guidelines. Around 11% of individuals who participated in the survey expressed their belief that once a patient provides informed consent for a research study, they should not have the right to withdraw from it. Furthermore, about 7% of respondents were not knowledgeable about the withdrawal process. Some researchers held unfavourable opinions towards the withdrawal procedure, as they considered it to be a hindrance to their study. Consequently, they may had opined that participants should not be permitted to withdraw once they have enrolled. Roughly 12% of the respondents believed that if a participant voluntarily withdraws, they will not bound to receive further treatment or standard care. Nonetheless, the majority of the respondents were in agreement that the treatment should persist. Furthermore, this study revealed that the practices of medical students regarding informed consent were suboptimal, with many of them admitting to not always obtaining informed consent from patients before carrying out medical procedures or treatments or research. This study highlights the need for medical students to be adequately trained in the legal and ethical requirements of obtaining informed consent. It underscores the importance of instilling positive attitudes towards informed consent among medical students, emphasizing its vital role in patient autonomy and respect for patient rights. The findings of this study have several implications for medical education and practice. Finally, this study emphasizes the need for medical students to improve their practices in obtaining informed consent, ensuring that it is obtained in all situations where it is legally and ethically required. As medical research is an evolving discipline for medical students, they should be subjected to research

methodology at regular intervals during their medical study curriculum. To enhance informed consent practices and safeguard human rights, researchers and medical students should be educated by organizing structured seminars and workshops. The findings of this study will provide insight into the current state of informed consent practices among medical students in India. This information can be used to identify gaps in medical education and develop interventions to improve patient care and communication in the healthcare setting. Ultimately, the goal of this study is to ensure that medical professionals in India are equipped with the knowledge and skills necessary to provide high-quality, patient-centred care. This will improve patient outcomes, strengthen the doctor-patient relationship, and ensure that medical students are adequately prepared to uphold ethical and professional standards in patient care.

Limitations

The findings presented in this research were based on self-reported survey data, and it was not feasible to verify the accuracy of individual responses. Moreover, the study had a cross-sectional design, which did not allow for observation of changes over time or causal inferences. Additionally, the sample size was limited and only students from one college were included in the study. Furthermore, the study did not explore various obstacles to research practice, including organizational, strategic, and policy barriers, communication barriers, cultural and linguistic barriers, and funding issues.

Conclusions

Based on the findings of this study, it can be inferred that participants exhibited a high level of knowledge but an average attitude towards informed consent. The knowledge regarding informed consent of post graduate students was more than that of undergraduate medical students. Post graduate medical students exhibit better attitude towards informed consent than that of undergraduate students. Practices of medical students regarding informed consent were suboptimal. Institution-level initiatives, such as regular activities, organizing research method workshop foundation courses can also aid in the development and improvement of research skills for undergraduate and postgraduate medical students at an early stage.

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