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Original Research

Informed Consent in Medical Practice: Perspectives Explored by Undergraduate Students

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Abstract:

Informed consent means getting permission from patients before doing any test or treatment, making sure they understand what will happen. This study was done at St. Peter's Medical College, Hospital, Hosur, Tamil Nadu, to check how well healthcare workers know about informed consent and to train undergraduate students in research and writing. The goals were to see the level of awareness among healthcare staff and to help students learn how to do research and publish articles. For the study, forensic medicine elective students made questions on informed consent and asked healthcare professionals who agreed to take part. The answers were collected and studied, and ethics approval was not needed. The results showed that most healthcare workers had good knowledge about consent, and students enjoyed the new way of learning. In conclusion, healthcare staff showed fair understanding of informed consent, and students gained useful experience in research, which motivated them to think about publishing their work.

Key Words: Informed consent, research oriented medical education, undergraduate training

Introduction:

Consent means permission or agreement. Informed consent, often used from a legal perspective, implies that the process of securing consent from a person that meets the required standards.[1]Informed consent to a medical treatment is a difficult topic; medically, legally, and ethically. The 'informed' element of consent depends upon the provision of information by the doctor, together with a degree of understanding of that information from the patient.[2]

Informed consent is a way of providing necessary information to the patients and helping them for decision making which forma the fundamental basis of patients' autonomy.[3] All the pros and cons of procedure must be explained to the patients in the language he or she can understand.[4,5]

Obtaining patient consent in medical practice is characterized by three domains: (provision of) Information, Comprehension (of information by the patient), and Voluntariness (of the patient's decision without coercion).[6]

Beauchamp and Childress (1994) stated seven components in the process of obtaining informed consent (IC); stated as preconditions: includes, competence in understanding and making decisions, voluntary participation (in decision making) and the elements of information, disclosure (the material information), recommendation (of a plan), understanding (in disclosure and recommendation) and elements of consent, the decision (in favor of the plan), and authorization (of the chosen plan).[7]

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IC is based on one of the main bioethical principles: the principle of respect for autonomy.[8] Nowadays there are physical attacks on practitioners about bad patient outcomes. According to a study by the Indian Medical Association, over 75% of doctors have faced violence at work.[9] There may be multiple reasons behind this but the study by Neeraj Nagpal[10], stated that one of the reasons is consent taking (other reasons are poor communication or meager health budget and poor-quality healthcare etc). It also suggested that proper steps should be taken to avoid such incidences by taking proper informed consent.[9]

This questionnaire-based study was basically done to determine the healthcare personnel understanding on IC and formally train the undergraduate students on the importance of consent in medical practice along with to acquaint them to the research activity and publication.

Objectives:

1. To know the level of understanding of consent among healthcare professionals for UG teaching purpose
2. To inculcate the process of research article publication among undergraduate students.

Methodology:

Some students at St. Peter's Medical College, Hospital, Hosur, Tamil Nadu, who had opted for the subject of Forensic Medicine, for electives were given a task of preparing the questions on what they think is important in the topic of informed consent. They also covered few topics under consumer protection act (CPA). For the sake of uniformity, the CPA questions were not included in this analysis. The students interviewed the healthcare professionals whomever they met who consented for the process and the results were obtained, by Google forms.

They selected few open-ended questions and some yes/no/other type questions.

Microsoft excel was used to generate the diagrams. Microsoft copilot was used to form tabulations and find suitable words for limitations in the study.

Results:

Total 39 professionals were interviewed. Two of them did not give consent for publication of the data. Hence, a total of 37 responses were included in this study.

Discussion:

Fig 1 gives the information that the participants felt that knowledge regarding the procedure related to which they are taking informed consent plays most common role as a factor in obtaining the consent.

Majority have felt difficulty of explaining the procedure in the local language**.** Effective doctor-patient is essential for correct medical diagnosis and adherence to treatment to reach the level of patient satisfaction. Globally, doctors face difficulties while communicating in the patient's first language. This complicates the treatment process and may become the triggering factor for violence in the hospitals. Learning the native language and active listening to the patients, supports the communication process and may uncap the linguistic barriers. It is also important that medical graduates must be made to appreciate the value of effective communication with the patients during the training period.[11]

A qualitative study establishes the unfavourable effects of language barriers on doctor-patient relationship, indicating medical educationists and policymakers in designing a curriculum to minimize such impacts. It also suggested introducing a course module for undergraduates that focuses on the language translation of various terminologies related to the field. Suggestion on as to include 'teaching doctor-patient communication skills' into the medical school curriculum was also stated.[12]

Focus	Findings
Professional background of participants	Doctors: 33 (89.2%), Dietician: 1 (2.7%), Laboratory Technicians: 2 (5.4%), Health Information Technician: 1 (2.7%)
Years of experience	Range: <1 year to 20 years (distribution varied across categories)
Factors considered in assessing patient's capacity for consent	Knowledge: 42%, Understanding capacity: 18%, Sound mind/mental health: 10%, Intelligence: 8%, Level of education: 8%, Language: 5%, Competency: 3%, Research: 3%, Emotional state: 3%
Language as a barrier	Yes: 22 (59.5%), No: 14 (37.8%), Sometimes: 1 (2.7%)
Elements communicated before obtaining consent	Indications, benefits, complications: 64%, Type of procedure: 10%, Consent form details/confidentiality: 15%, Alternative treatment plan: 2%, Title of project: 3%, Introduction of healthcare personnel: 3%, Everything: 3%
Time given to patient for understanding	Options ranged from <5 minutes to 24 hours; majority clustered around 5–10 minutes
Opinion on sufficiency of time	Yes: 34 (91.9%), No: 3 (8.1%)
Opinion in emergency situations	Proceed without consent if life-saving: 33 (89.2%), Call police: 3 (8.1%), Wait for consent: 1 (2.7%)
Primary purpose of informed consent	Respecting patient autonomy: 50%, Legal protection for doctors: 47%, Minimizing expenses: 3%
Consequences of not obtaining consent	Legal issues (litigation/negligence): 57%, Ethical issues: 27%, Harm to patients: 11%, Post-op changes: 2%, No idea: 3%

Table 1: Showing the focus of the study and the findings

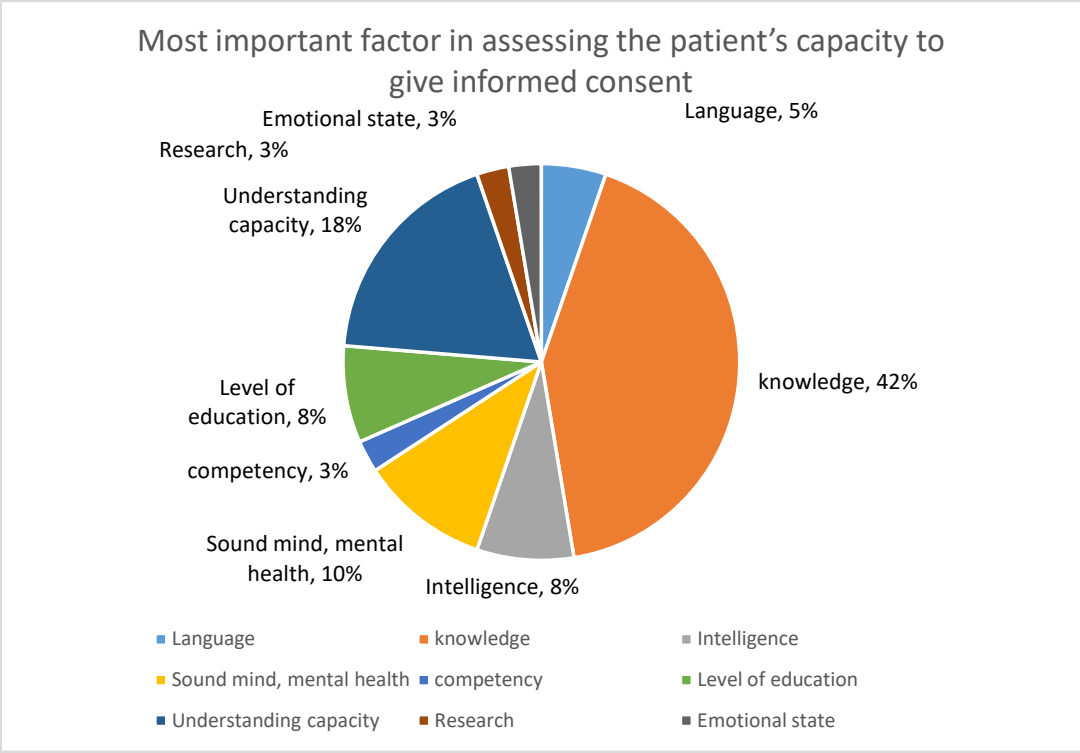

Fig 1: Factors to be considered in assessing the patients' capacity to give informed consent.

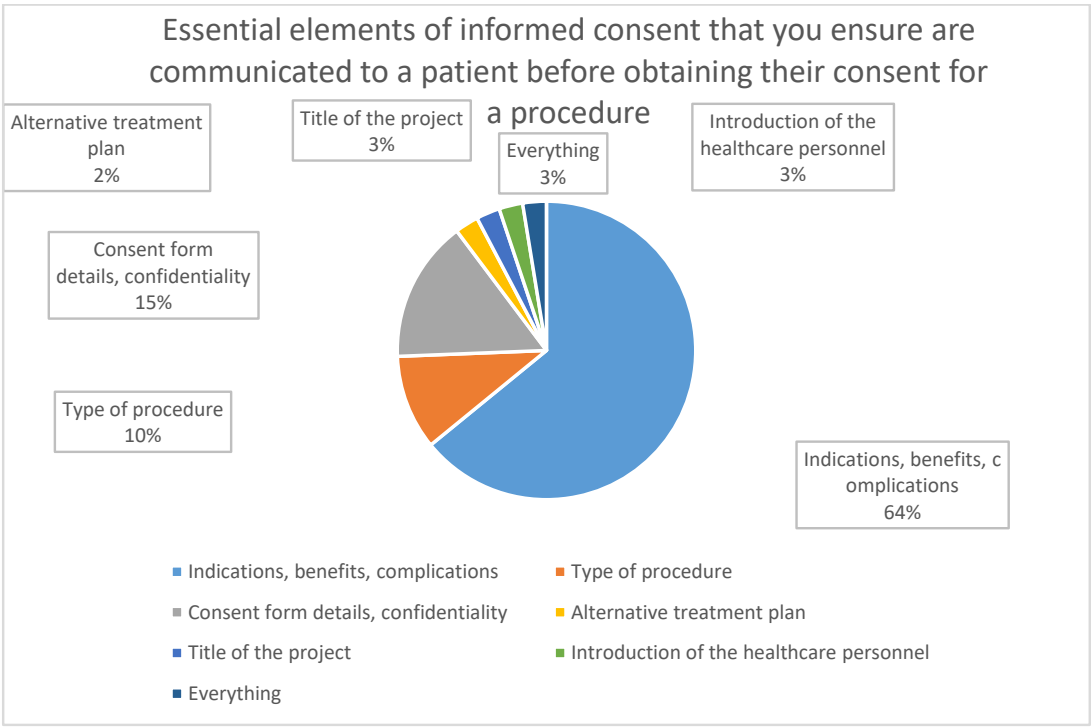

Fig 2: shows the various factors communicated by the healthcare personnel to the patient before obtaining informed consent.

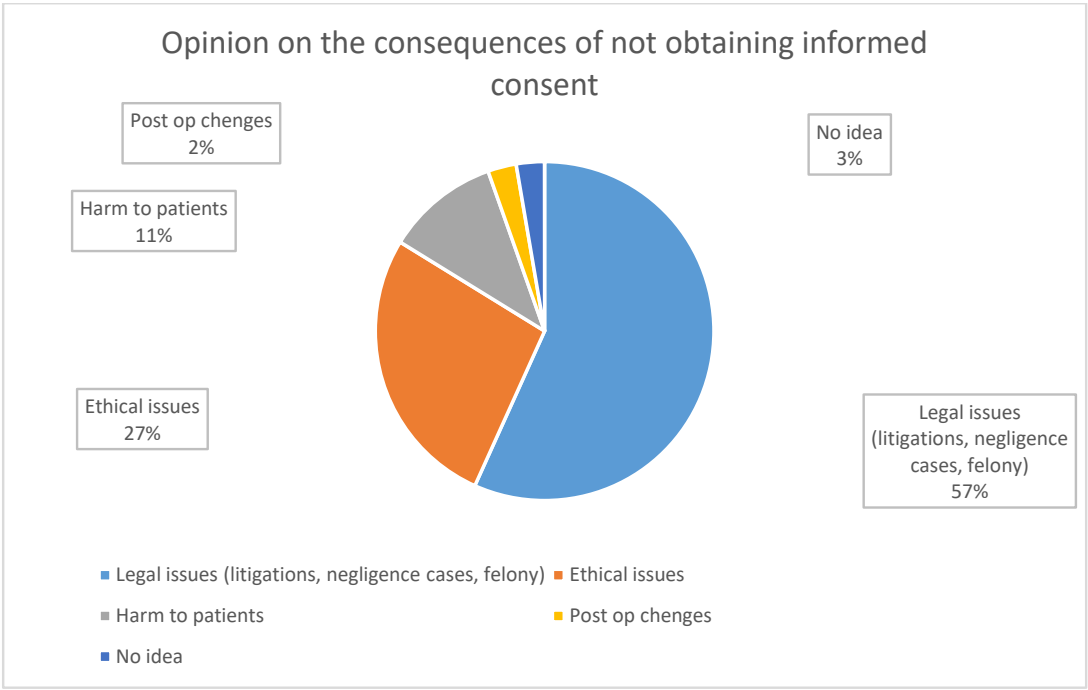

Fig 3: opinion on what are the consequences of not obtaining the informed consent.

In ***Fig 2,*** *m*ajority responded on indications, benefits, and complications. Though collectively all the areas of IC were covered. The law also presumes that the medical practitioner is in a dominating position concerning the patient. Therefore, it is the duty of the doctor to obtain proper consent by providing all the necessary information. According to Nandimath OV, consent without necessary information is no consent at all,[13] and authors agree with it.

Opinion on time taken by the doctors and patient for the process of informed consent varies. It would be practical to involve the patients in decision making. Hall DE et al., observed that often patients' comprehension of a particular procedure involved in the consent is overestimated, where time factor is only one aspect of it.[14]

Responses were majorly on proceeding with the procedure if it is lifesaving in emergency. The Supreme Court of India stated that Article 21 imposes an obligation on the State to safeguard the right to life of every person. All government hospitals must provide timely medical treatment to a person in need of such treatment and failure to do so results in the violation of his right to life guaranteed under Article 21.[15]The same is applicable to all medical practitioners under oath. Indian courts are not very clear on what if the patient refuses treatment in emergencies. The decision on, not to deny treatment during emergencies was keeping in mind the accident victims - as those are denied of treatment fearing a medico-legal case.[13]If patient does not consent for any form of treatment, it is the medical practitioner's duty to prove that the same was not attempted due to the patient refusal. Especially in a case where the patient is not alive to give evidence. Consent is implied if a patient submits himself/herself to the doctor. Its absence must be proved by the patient alleging it".[16]

Participants responded with majority of considering patient' autonomy and legal protection for doctors. IC in health care ensures that patients are fully informed about the medical procedures or treatments, enabling them for autonomous decisions about their care. The process of IC serves ethical and legal purposes by safeguarding patient rights, fostering transparency, and promoting trust between healthcare professionals and patients. IC ensures that patients understand the risks, benefits, alternatives, and potential consequences of medical interventions, allowing them to understand available options utilize the treatment plans.[17]

In ***Fig 3,*** more than 50% responded with legal litigations, followed by ethical considerations. Regarding the legal implications, the omission or lack of prior information to be provided to the patient and the lack of obtaining a valid informed consent are the factors leading to liability for healthcare professionals, which may later lead to various legal proceedings including huge amount of monetary compensations.[18]

Once the study was completed, the students who participated in this survey process were asked the following questions by the preceptor/facilitator:

1. The research activity as a posting in electives was useful to me.
2. The topics covered in the research activity as a component of electives was best perceived by me compared to the usual lecture classes.
3. This activity has helped me to develop my research conducting capacity to the 100% level.
4. In the future this type of research project-based training is helpful for all the UG students as a prospective PG student.

All agreed with the above points, but there was lack of confidence in performing the activity independently among 30 - 40% students.

Limitations:

This project had some important limitations. It was conducted in a single institution with a small group of participants, so the findings cannot be generalized. The questionnaire was designed by undergraduate students, which limited the depth of questions and introduced possible bias from self-reported answers. The analysis was descriptive only, without statistical testing or validated measures, making the results less robust. Overall, the project should be viewed as an educational exercise rather than formal research.

Conclusion:

Healthcare personnel in this study demonstrated fair and comprehensive knowledge of informed consent, emphasizing patient autonomy and legal protection as its primary purposes. Challenges such as language barriers and time constraints were noted, while emergency scenarios highlighted the prioritization of life-saving interventions. This project provided undergraduate students with valuable exposure to research methodology, ethics, and publication processes. It promoted the experiential learning.

Despite the limitations, this study offers preliminary insights into informed consent practices and serves as an innovative educational exercise. It provides a foundation for larger, multi-centre investigations and supports the integration of research-based electives and communication skills training into medical curriculum.

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