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To Assess the Knowledge Attitude & Perception Towards Informed Consent Among Medical Students, Navi Mumbai

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ABSTRACT

Informed consent is a fundamental ethical and legal requirement in medical practice in both the field of research and therapeutics. This ensures that patients are made aware of and agree to the proposed intervention. Medical students at all levels of education are taught to provide clear and understandable information about the risks, benefits, and alternatives to patients, allowing them to make autonomous and informed decisions. A cross-sectional study assessed knowledge, attitudes, and perceptions regarding informed consent among medical students in and across Navi Mumbai. A cross-sectional, observational, questionnaire-based study was conducted using a validated questionnaire. Data were collected, observed, and analyzed. Suitable tables and graphs were created. Of the 426 participants, 94.6% had heard of the term Informed Consent. Medical education in India welcomes new updates, including the inclusion of informed consent in the curriculum and priming students regarding its importance, techniques, and legal implications. The present study on IC, conducted within a hospital setting, yielded significant insights into the current level of understanding among medical students, interns, and residents. These findings will inform the development of targeted interventions, such as increasing the allocation of teaching hours dedicated to IC in medical practice and incorporating case-based scenarios into existing AETCOM models. Such measures aim to enhance students' comprehension of the practical implications of IC.

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Introduction

Informed consent (IC), as defined by the Declaration of Helsinki in 1964, refers to a physician's rights and duties to promote and safeguard a patient's health and well-being in clinical and research settings[1,2]. It emphasizes patients' right to accept or refuse certain interventions based on the information provided by the physician. With the rise of medico-legal cases and enhanced scrutiny by standardized bodies, every physician is always faced with the dilemma of 'too much information.' Striking the correct balance between informing the patient of possible complications and risks and the benefits of an intervention is an art mastered only by practice. With the advancement of medical knowledge in the public, the belief that the 'doctor knows best' has long gone. Patients now have insights into their health status, available treatments, and possible complications. Keeping this in mind, the Medical Education of India received an uplift, with a practical focus and testing on patient counseling, medical ethics, and its importance. Students from their first year of training are taught various patient communication methods, primarily the Kalamazoo Consensus Statement, which establishes a step-by-step guide for counseling and consent. [3]Medical students are encouraged to undertake research in their courses. Monetary gains, institutional fame, and IC should not be overlooked for personal career advancement. Researchers bear the legal and professional responsibility of informing candidates of the details of the intervention, maintaining confidentiality, and using data solely for scientific purposes. An informed consent process is considered complete, valid, and meaningful only when all four criteria—information disclosure, competence, comprehension, and voluntariness—are met effectively[4]. Patients are likely to trust their doctors when they engage in open, communicative, and supportive interactions, fostering a therapeutic relationship built on transparency and mutual respect.

Materials & Methods

This study was conducted in a tertiary medical care facility and teaching hospital in Navi Mumbai, India.

Ethics: The Institutional Ethics Committee granted permission to conduct the study before its commencement.

Study design: A cross-sectional, observational questionnaire-based survey was created and circulated among all medical students (undergraduate and postgraduate), irrespective of age, sex, or specialty, over a period of four months. The study excluded students who belonged to allied health sciences and dental sciences, as well as students who were not pursuing medicine.

Sample size: In total, 426 responses were obtained and assessed.

Statistical analysis: Data were analyzed using SPSS 22 software.

Result

A total of 426 participants participated in the study. Of the total patients, 26.5% were male and 73.5% were female. Among undergraduates, 33.8% were in their 1st year, 27.5% in their 2nd year, 20.0% in their 3rd Part I, and 2.3% in their 3rd Part-2 years. A total of 4.2% of responses were obtained from the Internet. Among postgraduates, 3.3% of responses were obtained from 1st year, 7.3% from 2nd year, and 1.6% from 3rd year residents.

Knowledge, attitude, and perception: Upon analysis of the data (Table 1), it was observed that 94.6% of the participants had heard of the term IC, with a mere 3.1% being unsure of whether they had heard the same. A total of 98.1% of the medical students felt the necessity of obtaining the patient's consent. 32% of the participants agreed on the validity of consent obtained after the procedure was completed. Of the participants, 93.4% felt that it was necessary to maintain medicolegal records, and 4.5% were unsure of the same. In the case of mentally ill patients, 56.3% denied the validity of the given consent, while 30.9% were unsure about the course of action.

The data presented in Table 2A reveal that the vast majority of respondents (87.6%) preferred obtaining written consent before any surgical intervention, underscoring the importance of formal documentation in medical practice. A smaller proportion (4.7%) favored verbal consent, while 7.7% of the respondents were uncertain about the method to be used. This distribution reflects strong knowledge of written consent as the preferred and more reliable method for ensuring that patients are fully informed and legally protected. The study also inquired into the knowledge of the minimum age for consent in physical examination (Table 2B). A total of 60.5% felt that 18 years was appropriate, while 23.3% chose 12 years as the legal age. This highlights the gap in knowledge between practical training and formal guidelines. IPC 87, 88, 89, and 90 provide protection to medical practitioners in case of any untoward outcomes of a medical intervention, provided IC was taken prior to the commencement of the intervention. This is also applicable for IC given by guardians if a patient is a minor or has unsoundness of mind. The physician may be asked to present the case and explain the circumstances

Table 1: Knowledge, attitude & perception in medical students

	Yes %	No %	Not sure %
Have you heard of the term "Informed Consent"?	94.6	2.3	3.1
Do you think taking consent of a patient before examination is important?	98.1	0.2	1.6
Is it necessary to take the signature of a patient in verbal informed consent?	63.8	19.7	16.4
Do we need to take the signature of the patient in written informed consent?	94.4	0.9	4.7
Is it valid to take consent from the patient after completion of treatment?	32.9	50.0	17.1
Are you aware whether consent taken from the patient by the doctor will help him in future medical negligence cases?	86.2	3.5	10.3
Are you aware of the Consumer Protection Act?	75.6	13.6	10.8
Do you think a witness is required while documenting an informed consent?	71.8	10.3	17.8
Do you think minor patient consent is valid while documenting an informed consent?	36.7	43.5	19.8
Is it necessary to maintain medico legal records of informed consent?	93.4	2.1	4.5
Have you attended any CME/Webinar/Seminar/Conference regarding informed consent?	40.4	59.4	0.2
Is consent through electronic media valid?	32.2	22.1	45.8
Do we need to take consent for a post mortem examination in a MLC case, for a patient who died in the hospital from their relative?	76.8	5.9	17.4
If a patient is mentally ill, will his given consent be considered valid?	12.7	56.3	30.9

Table: 2A	*METHOD TO OBTAIN CONSENT IN SURGERY*			
		Verbal %	Written %	Not sure %
	How to obtain consent before any surgical intervention	4.7	87.6	7.7
Table: 2B	*AGE FOR CONSENT IN PHYSICAL EXAMINATION*			
		12 Years %	15 Years %	18 Years %
	What is the minimum age for giving valid consent for examination?	23.3	16.2	60.5
Table: 2C	*CONSENT FOR MENTALLY ILL PATIENT*			
		Patient himself %	Near relative %	Treating physician %
	Whose consent is to be taken for a mentally ill patient?	9.4	77.6	10.8
Table: 2D	*CONSENT IN AN EMERGENCY / UNCONSCIOUS STATE*			
		Patient himself %	Near relative %	Accompanied person %
	Whose consent should be taken in an emergency state or when the patient is unconscious?	5.4	49.8	44.8
Table: 2E	*CHOICE OF LANGUAGE TO TAKE CONSENT FROM PATIENT*			
		English %	Regional language %	Language understandable to the patient %
	In which language should informed consent be taken?	4.2	7.3	88.5

surrounding the outcome to their peers for educational and documentational purposes. Of the participants, 12.7% agreed with the validity of IC of a patient with an unsound mind, and 10.8% felt that the onus of IC fell on the treating physician in such a situation (Table 2C). In the case of an emergency or an unconscious patient, 44.8% of the participants would take IC from the accompanying person, 49.8% from a relative, and 5.4% would choose to take IC from the patient himself (Table 2D). This underscores the participants' unawareness and experience in tackling IC in emergency scenarios. In the case of unconscious or emergency situations, IC is taken from a relative. If not available, the police must be informed and serve as custodians of the patient. This highlights the need for a CME/Webinar/Conference/Seminar on IC. A total of 59.4% had never attended any IC training, while 40.4% had attended IC training. The choice of language determines the validity of the IC. The foundation of IC is to ensure that the patient

or his custodian is aware of possible complications and benefits of an intervention. This must be communicated by the physician in simple words, not using medical jargon, and in a language that is most comfortable to the patient. Furthermore, 88.5% agreed to take IC in a language understandable to the patient, while 4.2% chose English as the medium (Table 2E).

Discussion

In a study by Vyas et al., 100% of participants agreed to provide consent in their local language. (5) IC must be taken to respect patient autonomy, legal documentation, and safeguard medical practice. Several standard guidelines have been established to obtain valid and acceptable IC. Performing medical interventions without IC can lead to tort or criminal actions[6]. Our study uniquely focuses on practitioners moving toward research, therapeutics, and policymaking in the future. The new competency-based medical education (CBME) curriculum has included IC as a theory and viva voce module for undergraduate and postgraduate students to instill the habit of getting go. In a study involving 156 participants by Gupta et al. in Bathinda, 97.4% of dental practitioners knew about consent, compared to 94.6% in our study, revealing an increase in knowledge about the same. In the same study, 53.2% of the participants agreed with the need for a patient's signature in verbal IC, which is comparable to our study, where 63.8% agreed. In the Bathinda study, 53.2% of participants were aware of the Consumer Protection Act, which is contrastingly low compared to 75.6% in the one conducted by us in Navi Mumbai. [7] A study on IC documentation in research was conducted on faculty members, where only 57.5% of professors, 73.1% of associate professors, 55.5% of assistant professors, and 69.8% of tutors would consent from a legally acceptable representative if the patient was incapable of giving IC. In our study comprising students, 77.7% of the participants consented from a near relative in such a case[8]. A comparative study of knowledge, attitude, and practice (KAP) regarding IC between residents of clinical and paraclinical branches revealed that residents of clinical subjects performed significantly better in all three domains of KAP. This can be attributed to more practice correlating with our study on early IC exposure in medical education[9]. Our study highlights an emerging issue of IC taken via online media, where 32% of participants agreed on its validity, 22.1% did not, and 45.8% were not sure of the same. With the growing use of telemedicine, it is imperative that definite standard operating procedures, validity, and the process of taking IC via online media are established and protected legally.

Conclusion

Our study on IC, conducted in the hospital, provided valuable insight into the current understanding among medical students, interns, and residents. These observations will help us develop targeted interventions, such as increasing the number of teaching hours dedicated to IC in medical practice and incorporating case-based scenarios into existing AETCOM models. This will help students clarify the practical implications of IC. We also encourage case-scenario-based problem-solving workshops during the orientation programs for undergraduates, postgraduates, and interns. In addition, conducting CME/Webinar/Seminar/Conference on IC will refresh the knowledge of medical practitioners and students to prevent legal implications in the future. The National Medical Council (NMC) welcomes new updates on IC in the curriculum and encourages students to prioritize their importance and techniques.

Author contributions

All authors contributed to the study design and conception, drafted the manuscript, and approved the final draft of the manuscript.

Conflict of interest

The authors have no conflicts of interest to declare.

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None.

Ethical Clearance

Ethical clearance was takenobtained from the Institutional Ethics Committee. (IEC 2022/141 dated 02/10/2022).

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