

## Patients' Perceptions Regarding Preoperative Informed Consent: A Tertiary Care Hospital Based Survey from India

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### Abstract

**Background and Objectives:** The doctor-patient interaction depends heavily on patient autonomy, often known as the freedom to make healthcare decisions without being pressurised, and informed consent, a thorough process of information disclosure. In India, however, there hasn't been much investigation into informed consent. As a result, the study's objective was to evaluate patients' knowledge of and comprehension of informed consent as well as their perspectives at a tertiary care facility in western India.

**Materials & Methods:** A cross-sectional survey was carried out. Patients who had undergone elective or urgent surgery in several surgical departments were the focus of the survey. A pre-structured questionnaire was used to randomly choose 405 post-operative patients for interviews.

**Results:** Only 69.81% of patients were told about their prospective procedure, a sizeable fraction of them had little knowledge of it. Additionally, only 33.80% of patients were aware of other treatment alternatives, which is a significantly low number. About half of the patients (45.71%) were informed about the type of anaesthesia used, while only 13.57% were informed about the potential consequences. Notably, despite the existence of data that clearly show otherwise, patients believed that informed permission was not acquired in 5% of cases.

**Conclusion:** Informed consent is essential in clinical practise because it safeguards patients' rights and lowers the risk that they would sue medical professionals for treatment-related problems. It is crucial to educate medical professionals and other healthcare workers on the value of getting informed consent.

**Keywords:** Informed Consent, Patient Rights, Autonomy, Surgery, India.

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### Introduction

Autonomy is the ability of a patient to choose their own course of treatment without being coerced by medical professionals. The process of informing patients about their medical condition, available diagnostic options, and information on intervention techniques for their illness extends well beyond simply getting their signature on a document. Patients are also told of any potential alternative treatment alternatives and related hazards [1, 2].

A patient's right to informed consent serves as a foundation for building trust and a successful doctor-patient relationship. It is crucial that the permission procedure uses simple, straightforward language that is accessible to patients with all levels of medical knowledge in order to enable effective

communication. Equally crucial are ensuring that patients completely understand the information given and that the entire process is properly documented to guarantee accountability and transparency [3,4].

It is essential to give patients a thorough grasp of the benefits and drawbacks of a specific medical procedure so they can decide freely and intelligently about their treatment options [5,6]. Informed consent procedures differ between nations and among medical specialisations. For a surgeon, doing surgery may be routine, but not for a patient [7]. Surgery entails additional dangers, complicating and stressing out the patient's decision-making process [8]. To ensure that patients can successfully traverse this procedure, it is crucial to make sure they receive

clear and comprehensive information. Therefore, when getting consent for a surgical procedure, it is crucial for both the surgeon and the patient to engage in interactive and thorough discussions.

Therefore, when getting consent for a surgical operation, it is crucial for the surgeon and the patient to engage in interactive and thorough discussions. This makes it possible to fully comprehend and take in all the information and hazards involved [9,10]. To ensure clarity, patients should be given the chance to ask questions and participate in discussions. Instead than being thought of as a single event, informed consent should be seen as a continuous and ongoing process [11].

There have only been a few studies on informed consent undertaken in India [12]. In light of this, the current study was carried out at a tertiary care facility in western India. The study included two dual goals and objectives. First, the study sought to gauge patients' levels of knowledge and comprehension of what constitutes informed consent. In order to do this, it was necessary to assess how well-informed patients were about the details that had been given to them on their treatments, possible hazards, and other treatment alternatives. The study also sought to examine patients' perceptions on the informed consent procedure in a tertiary care hospital setting. In order to identify areas for improvement and strengthen patient-centered care, this study involved examining the patients' perspectives, experiences, and satisfaction with the informed consent procedure.

### Material & Methods

A cross-sectional survey was carried out among patients who had undergone either elective or emergency surgery in different surgical departments at a tertiary care teaching hospital in western India to collect data for the study. General surgery, obstetrics and gynaecology, orthopaedics, otolaryngology, ophthalmology, urology, and plastic

surgery were among the surgical specialties. In order to provide a more thorough understanding of the informed consent process and its ramifications in the context of various surgical procedures and patient groups, the survey aimed to capture an in-depth view of patients across several surgical specialties. The study's execution followed accepted ethical standards [13, 14].

For this study, a total of about 405 individuals who had undergone surgery were chosen at random. The study utilising a pre-structured questionnaire and conducting the interviews in the patients' native tongue. The patients were informed of the goal and design of the study, and those who freely agreed to participate were enrolled. Information was gathered from either the patient or their attendant in cases involving children after gaining their agreement. The questionnaire covered a range of topics regarding knowledge and comprehension of the consent form and its contents. Epi Info software was used to do the analysis after the data were entered into Microsoft Excel.

Patients who choose not to take part in the trial were not included in the study's sample. Additionally, individuals who were uncomfortable or ill as a result of things like pain, the implantation of a nasogastric tube, or any other acute post-operative problems were not interviewed for the study. This made guaranteed that the data collection method only included patients who were qualified and willing to give truthful answers.

### Results

The study included 405 postoperative patients in total. Postgraduate students got the vast majority of informed consents (70.33%), followed by junior residents (15.86%), and the house surgeon/consultant themselves (11.51%). In 15 instances, consent was not obtained, amounting to a 3.70 percent non-compliance rate. Please refer to Tables 1–5 for more specific information.

**Table 1: Socio-Demographic variables of the study population**

	N	%
<b>Age (in years)</b>		
<19	41	10.12
20–39	207	51.11
40–59	92	22.72
≥ 60	65	16.05
<b>Gender</b>		
Male	206	50.86
Female	199	49.14
<b>Education</b>		
None	157	38.77
Upto Primary School	86	21.23
Upto Middle school	59	14.57
Upto Matriculation	70	17.28
Diploma	12	2.96

Graduate	15	3.70
Above graduate	6	1.48
<b>Employment</b>		
Nonskilled worker	112	27.65
Semiskilled worker	28	6.91
Skilled worker	31	7.65
Office work/shop maintenance	28	6.91
Agriculture	15	3.70
Homemaker	134	33.09
Student)	20	4.94
Professional	6	1.48
No employment	31	7.65
<b>Per capita monthly Income</b>		
<Rs. 1700	58	14.32
Rs. 1701–4909	181	44.69
Rs. 4910–8109	105	25.93
Rs. 8110–12,019	35	8.64
Rs. 12,020–17,019	15	3.70
Rs. 17,020–33,049	6	1.48
>Rs. 33,050	5	1.23

**Table 2: Mode of Admission and type of surgery**

	N	%
<b>Type of admission</b>		
Emergrncy Room	181	44.69
Routine OPD	224	55.31
<b>Type of surgery</b>		
Urology	20	4.94
Plastic surgery	11	2.72
Orthopedics	124	30.62
Obstetrics and gynecology	100	24.69
General surgery	83	20.49
Ophthalmology	24	5.93
Otolaryngology	43	10.62
<b>Nature of surgery</b>		
Planned	350	86.42
Emergency	55	13.58

**Table 3: Awareness regarding Informed Consent among patients**

	N	%
<b>Was the informed consent obtained?</b>		
Yes	390	96.30
No	15	3.70
<b>Type of informed consent</b>		
Verbal	15	3.84
Written	375	95.91
<b>Informed consent was provided by</b>		
Spouse	140	35.81
Patient	131	33.50
Sibling	80	20.46
Parents	33	8.44
Friends	6	1.53
<b>Was the consent provided voluntarily?</b>		
Yes	380	97.19
No	10	2.56
<b>Patient was given information regarding consent by</b>		
Postgraduate resident	275	70.33
Junior resident	62	15.86

House Surgeon	45	11.51
Nurse	5	1.28
Paramedical personnel	2	0.51
Intern doctor	1	0.26

**Table 4: Awareness regarding Informed Consent among patients**

	Yes		No	
	N	%	N	%
A local language explanation of informed consent was given	377	96.67	13	3.33
Patient had knowledge of information on their surgical status	325	83.33	65	16.7
The patient was informed of the surgical indication.	383	98.21	7	1.79
Patient was informed about the planned surgery	368	94.36	22	5.64
The patient was aware of other possibilities.	272	69.74	118	30.26
Patient received explanations on alternative therapies	132	33.85	258	66.15
Patient was told of the advantages and results of the procedure.	116	29.74	11	2.82
The patient was warned of the potential side effects of the procedure.	315	80.77	75	19.2
The type of anaesthesia was explained to the patient.	214	54.87	176	45.1
Patient was advised of potential side effects from the anaesthetic	178	45.64	212	54.4
Patient was made aware of potential medication allergies	53	13.59	337	86.4
The patient was advised of the likely length of their hospital stay.	130	33.33	260	66.7
The patient approved of the information given.	251	64.36	139	35.6
Patient was satisfied with the information provided	346	88.72	44	11.3

**Table 5: Perceptions regarding Informed Consent among patients**

	Yes		No	
	N	%	N	%
A local language explanation of informed consent was given	379	97.18	11	2.82
Patient understood the given information	323	82.82	67	17.2
Patient was informed about the proposed surgical operation	271	69.49	119	30.5
The patient was informed of alternatives available	130	33.33	260	66.7

## Discussion

The age range of the participants in our study was broad, and both sexes were almost equally represented. But it's crucial to remember that about 38.77% of the participants were deemed illiterate. The patients in a research by Ochieng et al. ranged in age from 18 to 80 years, with an equal number of men and women, but had a higher literacy rate of 94% [8]. Similar to this, Falagas et al. stated that 56% of their study participants were between the ages of 18 and 55 [3], while 43% were older. A study by Simha et al. found that 45.5% of the patients were between the ages of 20 and 40, which is quite similar to the 50% proportion seen in our study [15].

Before beginning any therapy, including surgical treatments, doctors have a moral and legal duty to have the patient's informed permission. In our study, about 66.50% of patients gave their own consent for surgery, whereas about 33.50% received approval from a relative. In a study by Ochieng et al., more patients (81%) were reported to give their own consent. In contrast, our study discovered that 3.70 percent of patients believed they had not provided their agreement, although Bhugri et al. reported a greater percentage of 20% in the same situation [2].

Nearly all of the participants in our study were aware of their current surgical state. 98.71% of

patients did learn the precise reason for the procedure, nevertheless. In contrast, Ochieng et al. [8] stated that in their study, a larger proportion of 80% of patients had their surgical indications conveyed to them. In our study, 122 patients (33.8%) and a total of 252 patients (69.81%) were educated about other therapy alternatives. It's important to note that the majority of patients received information regarding the different therapy possibilities. In a research by Ochieng et al., 17% of patients refused to consent to surgery, and a comparable percentage were uninformed of the type of operation they would have.

Patients may have given consent but either did not remember or it did not register with them during our study if there was a record of consent in the medical files in cases where patients believed that no informed consent was obtained. Furthermore, only 178 patients were told about potential consequences related with the anaesthesia, while almost half of the patients received information about the type of anaesthesia. In our study, a sizable part of patients (33.33%) claimed that no issues were discussed with them regarding their hospital stay, in contrast to the findings of Ochieng et al., where 98% of patients thought that all aspects of the treatment should have been communicated to them before surgery [8].

In line with the findings of Ochieng et al. (80%) and a study carried out in Greece by Falagas et al., the majority of patients in our study expressed satisfaction with the procedure of informed consent. Additionally, these studies [8, 4] noted a high level of satisfaction with the informed consent procedure. According to our study, patients' levels of knowledge about their pre-surgery state, the reason for the operation, the suggested surgical treatment, and its advantages were sufficient. It is interesting to note that some patients gave their consent but were still in the dark about these crucial details. This result is consistent with the research by Purcaru et al., which found that a sizable majority of participants (35.3%) do not inquire further and that patients from lower socioeconomic backgrounds frequently assent without asking for more information [11].

The limitations of the current study should be taken into account when interpreting the results. First off, because just one tertiary care hospital was used for the study, it may be difficult to extrapolate the findings to other healthcare facilities, especially those with fewer resources and a diverse workforce. The results might not apply to hospitals with various patient demographics, levels of infrastructure, and staffing. Additionally, the study relied on patient self-reported data, which is vulnerable to social desirability bias and recollection bias. The study's sample size was also somewhat small, which might have reduced the statistical power and accuracy of the findings. Despite these drawbacks, the study offers insightful information about the informed consent procedure in the particular hospital.

Several suggestions can be made to enhance the informed consent procedure and guarantee the preservation of patients' rights in light of the study's findings. First, medical professionals should make a conscious effort to tell patients about the type of anaesthesia being used, any potential side effects, and any unforeseen drug allergies that might exist. For patients to make wise choices and take an active role in their own treatment, this knowledge is essential. The availability of alternative treatment alternatives should also be discussed with patients, giving them a thorough grasp of the many ways to manage their illness. Additionally, it is important to take into account the use of video recordings throughout the informed consent procedure as this can be a useful documentation tool and possibly lessen the probability of various issues leading to legal challenges. Healthcare professionals can promote patient autonomy and trust in the healthcare system by putting these guidelines into practise and improving the quality and transparency of the informed consent process.

## Conclusion

The idea of informed consent is essential to clinical practice because it protects patients' rights and lessens the risk that healthcare practitioners would face legal ramifications in the event of therapy-related difficulties. Although the quality of the present informed consent process is subpar, the study's findings indicate the need for adjustments. It is crucial to improve both patients' and doctors' comprehension and knowledge of the value and application of informed consent. This calls for educational campaigns to enlighten and sensitise healthcare professionals about the significance of holding in-depth and thorough informed consent discussions. By addressing these issues and spreading awareness, the informed consent procedure's overall quality can be improved, resulting in improved patient-provider relationships.

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