

Barriers to Obtaining Informed Consent Among Surgeons: A Cross-sectional Study at a Tertiary Care Hospital in Dakshina Kannada, India

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ABSTRACT

Introduction: Informed consent involves the patient in shared decision-making by providing adequate information about the disease, recommended plan of care and authorisation to proceed. During the consent process, factors such as the educational status, regional background, health literacy and anxiety of the patient are often overlooked. Recognising these barriers would be a stepping stone to finding ways to improve the informed consent process, thereby enhancing the trust and understanding between the surgeon and the patient.

Aim: To identify the sociodemographic barriers and the ethical challenges faced by surgeons while obtaining informed consent.

Materials and Methods: A cross-sectional, validated questionnaire-based study was conducted over three months from January 2023 to March 2023 at the Department of Surgery, Justice KS Hegde Hospital in Mangaluru, Dakshina Kannada district, South India. The study included 218 consenting consultants and postgraduate students from the surgical departments. Participants were selected using purposive sampling. Data collection was facilitated through Google Forms, which included three sections: sociodemographic barriers, components of informed consent and the doctors' perspectives on barriers and challenges in obtaining informed consent. The reliability of the questionnaire was assessed using Cronbach's alpha coefficient. The results were analysed using

frequencies and percentages with Statistical Package for the Social Sciences (SPSS) software version 23.0.

Results: Among the 218 surgeons surveyed, 138 were male and 80 were female. The patient's age was perceived as a barrier by 141 surgeons, while 181 cited the patient's level of education. Language was reported as a barrier by 204 surgeons and 202 identified the patient's personality traits as contributing factors. Additionally, 170 surgeons noted a lack of trust in the healthcare system and 143 considered cultural and religious beliefs as barriers. The use of complex medical terminology was reported by 169 participants, while 188 highlighted issues related to the content and readability of consent forms. Furthermore, 125 surgeons felt that excessive online health information complicated the consent process. A majority, 163 respondents, agreed that the informed consent process upholds the principles of bioethics.

Conclusion: Informed consent is a major aspect of surgical practice and the present findings indicate that the majority of surgeons in the Indian context are proficient in obtaining it. Surgeons have a challenging task when communicating specialised clinical information to patients from various sociocultural backgrounds, particularly those with low health literacy, impaired autonomy and debilitating conditions. Therefore, it is crucial to identify and overcome the barriers and challenges faced in obtaining legally valid informed consent.

Keywords: Communication barriers, Health literacy, Surgeons' perspectives, Surgical ethics

INTRODUCTION

Informed consent is a cornerstone of bioethics and includes the patient's ability to be involved in shared decision-making related to their treatment, thereby respecting the patient's autonomy and dignity [1]. The majority of the Indian population has poor health literacy and is not competent enough to fully understand the consequences of treatment [2,3]. Therefore, it is essential for health professionals to provide information tailored to the patient's level of understanding for informed decision-making. Informed consent is a process of gaining information, making decisions and consenting; it is not merely an event [1,2].

Obtaining informed consent is a responsible duty of healthcare professionals that requires expertise in helping patients understand, allocating adequate time, building trust and providing appropriate recommendations [1]. While it can be delegated to someone else, that person must be trained, qualified and possess sufficient knowledge of the procedure. It is often observed that healthcare professionals who are not yet certified to perform surgical procedures may lack full awareness of the associated risks and consequences, yet they are still involved in obtaining informed consent from patients.

Additionally, it has been noted that information is often sugar-coated due to concerns that discussing possible complications may discourage patients from proceeding with surgery. An effective informed consent process necessitates thorough documentation of the discussion, which should include the nature of the procedure, its risks and benefits, reasonable alternatives, the risks and benefits of those alternatives and an assessment of the patient's understanding [4,5].

Beyond these legal elements, the process requires a good doctor-patient relationship, trust, and effective communication. No patient should be compelled to accept treatment, even if it is potentially beneficial without risks or life-threatening consequences [1]. Communicating highly technical, complex and specialised clinical information to participants with limited literacy, diverse sociocultural backgrounds, diminished autonomy and debilitating diseases presents a significant challenge for clinical physicians and researchers [4,5].

Despite the critical role of informed consent, existing literature reveals several gaps, particularly regarding its implementation in the Indian context. Few studies have addressed the specific barriers

that treating surgeons encounter while obtaining consent in India [6-9]. Furthermore, the consent process often overlooks crucial patient factors, such as educational status, regional background, health literacy and anxiety. Recognising these barriers is essential for improving the informed consent process and fostering greater trust and understanding between surgeons and patients.

The present study is crucial for identifying and overcoming the challenges faced by surgeons when obtaining legally valid informed consent, especially given their difficulties in communicating specialised clinical information to patients from diverse sociocultural backgrounds with varying health literacy levels and conditions. The novelty of the present study lies in its focused investigation of these barriers from the perspective of surgeons in South India, contributing to a more nuanced understanding of the informed consent landscape in this specific regional and cultural context. Thus, the present study aimed to explore healthcare professionals' views on the informed consent process and identify the social and demographic barriers, as well as the ethical challenges faced by surgeons while obtaining informed consent.

MATERIALS AND METHODS

A cross-sectional, validated questionnaire-based study was conducted from January 2023 to March 2023 at the Department of Surgery, Justice KS Hegde Hospital in Mangaluru, Dakshina Kannada district, South India, after obtaining Institutional Ethical Clearance (IEC number: INST.EC/EC/201/2022). The study included 218 surgeons from all surgical departments, selected through purposive sampling.

Sample Size Justification: As per Bushraf A et al., 2014 [10], the sample size was calculated using the following formula:

$$n = (Z^2 \times p \times q) / d^2$$

where,

- n = required sample size.
- Z = Z-score at 95% Confidence Interval = 1.96.
- p = expected proportion = 0.285 (28.5%) based on Bushraf A et al., study on doctors acknowledging the necessity of surgical informed consent [10].
- q = $1 - p$ = 0.715.
- d = absolute precision = 0.06 (6%).

Substituting values:

- $n = (1.96)^2 \times 0.285 \times 0.715 / 0.06^2$.
- $= 3.8416 \times 0.203775 / 0.0036$.
- $= 0.7833 / 0.0036$.
- $= 217.58$.
- $n = 218$.

The final value of 218 matches the number of responses received and aligns with the minimum required sample size for the desired confidence and precision level.

Inclusion criteria: All consultants (faculty) affiliated with the surgical departments of the tertiary care center, as well as postgraduate trainees (residents) currently enrolled in surgical training programs within the same institution.

Exclusion criteria: Surgeons and postgraduate trainees not affiliated with the surgical departments of the tertiary care centre; individuals who declined to provide informed consent for participation in the study; healthcare professionals on extended leave or not actively involved in clinical duties during the study period.

Study Procedure

Questionnaire Design and Administration: The study employed a structured, self-administered questionnaire divided into three sections:

- Section I: Addressed social, economic and demographic details of the patients that could pose barriers in obtaining informed consent, utilising multiple-choice and yes/no questions.
- Section II: Focused on the aspects that were explained in detail to the patients while obtaining informed consent, featuring multiple response questions.
- Section III: Explored doctors' perspectives on barriers and challenges in obtaining informed consent, with items measured on a 5-point Likert scale ranging from "strongly agree" to "strongly disagree."

The questionnaire was developed using Google Forms, a user-friendly online survey platform that facilitates efficient data collection and analysis. To ensure broad participation, the survey link was distributed electronically to eligible consultants and postgraduate trainees in the surgical departments via institutional email lists and professional messaging platforms. Participants were provided with clear instructions and informed about the study's purpose, ensuring informed consent was obtained prior to participation. The survey was sent to 300 participants, with 218 responding.

The data collected on a 5-point Likert scale was converted to a 3-point scale during data interpretation: "Strongly agree" and "agree" were combined to represent agreement, while "Strongly disagree" and "disagree" were combined into a category of "disagree" for the ease of presenting the results. The results were analysed using frequencies and percentages with SPSS software version 23.0.

Validation of Questionnaire: Internal consistency was assessed using Cronbach's alpha. The reliability coefficient for Section I was 0.723, while Sections II and III, which examined doctors' perspectives on challenges in obtaining informed consent, yielded a coefficient of 0.659. Although the latter falls slightly below the conventional 0.70 threshold, values between 0.60 and 0.70 are considered acceptable in health services, behavioral and social science research, particularly when assessing perceptions, attitudes, or complex, multidimensional constructs such as communication and consent [11].

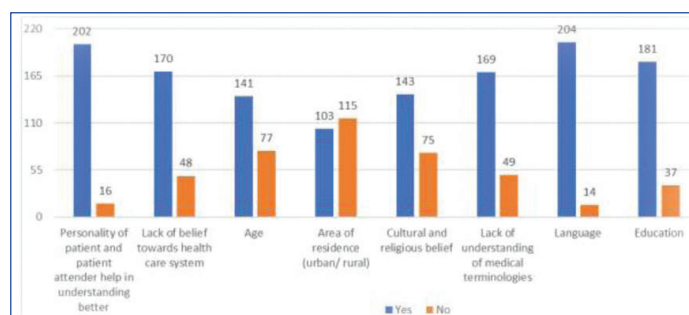
STATISTICAL ANALYSIS

The results were analysed using frequencies and percentages with SPSS software version 23.0.

RESULTS

Among the 218 surgeons, 138 were males and 80 were females. There were 108 consultants and 110 postgraduate students from different surgical branches. Among the 108 consultants, 28 were Professors, 38 were Associate and Assistant Professors and 42 were Senior Residents.

Section I: Social, Economic and Demographic Barriers: Surgeons reported that various patient-related factors significantly influenced how well patients understood and agreed to the informed consent process. These factors included age, level of education, personality type, language proficiency, trust in the healthcare system and cultural or religious beliefs. These findings are summarised in [Table/Fig-1]. The most commonly cited barriers were language issues, the use



[Table/Fig-1]: Sociodemographic barriers.

of medical terminology and lack of trust. Surgeons emphasised that patient personality significantly influenced how effectively consent was obtained.

Section II: Components of Informed Consent: The majority of surgeons explained the diagnosis and procedure, along with its risk factors and potential complications in detail. However, aspects like disease pathogenesis, alternative treatment options, cost, medications, team involvement, procedure duration, hospital stay and postoperative care were discussed less frequently.

Section III: Doctors' Perspectives on Barriers and Challenges in Obtaining Informed Consent: This section explores surgeons' experiences and attitudes toward various systemic, ethical and practical barriers in the informed consent process. The data from the questionnaire are detailed in [Table/Fig-2]. Surgeons acknowledged that systemic and interpersonal factors-including time constraints, readability of forms, use of protocols and communication skills-shaped the consent process.

Questions		Disagree	Neutral	Agree
An informed consent is the key to autonomy, beneficence, non maleficence and justice	n (%)	33 (15.35)	22 (10.09)	163 (74.56)
It is difficult to explain the informed consent when the patient comes with excessive online information regarding his condition	n (%)	44 (20.18)	49 (22.47)	125 (57.33)
It is difficult to take informed consent in the presence of patient bystander	n (%)	145 (66.51)	48 (22.01)	25 (11.46)
Informed consent form is adequate to protect the doctor from unforeseeable legal liability which may occur following treatment	n (%)	31 (14.22)	29 (13.30)	158 (72.48)
Content and readability of the consent form matters in patients understanding of an informed consent	n (%)	12 (5.50)	18 (8.3)	188 (86.23)
Time is a constraint for a doctor in taking informed consent	n (%)	65 (29.81)	89 (40.82)	64 (29.35)
Informed consent provides high expectations of cure to patients	n (%)	104 (47.70)	67 (30.73)	47 (21.55)
For elderly patients not in a state of giving consent, legal guardian can give informed consent	n (%)	13 (5.96)	22 (10.09)	183 (83.94)
Use of visual information aid in explaining the informed consent decreases the refusals	n (%)	14 (6.42)	34 (15.59)	170 (77.98)
SPIKES Protocol reduces the chances of refusal of an informed consent (S-Setting, P-Perception of patient, I-Information, K-Knowledge, E-Empathy, S-Summarise/Strategise)	n (%)	7 (3.21)	25 (11.46)	186 (85.32)
Bias within the treating team become a barrier while taking informed consent	n (%)	15 (6.88)	43 (19.72)	160 (73.39)
Treating doctors' communication and presentation towards their patient is a barrier in taking informed consent	n (%)	18 (8.25)	38 (17.43)	162 (74.31)

[Table/Fig-2]: Section III questionnaire with results.

Section II has been explained in the manuscript titled "Surgeons' Perspectives on Barriers in Obtaining Informed Consent."

DISCUSSION

Although it is often presumed that a patient presenting for consultation, examination, or surgery is aware of the proposed treatment, such assumptions do not fulfill the legal requirements for valid informed

consent. The law does not provide explicit directives concerning the content or structure of the consent dialogue between physician and patient; however, it is generally recognised that the more invasive or high-risk the medical intervention, the greater the physician's responsibility to ensure that the patient receives, comprehends and voluntarily agrees to all relevant information before proceeding [12].

Various studies have shown the barriers faced by patients in the consenting process, such as a paternalistic approach to medicine, lack of ethics education, essential information not conveyed and varying levels of expertise [13-16]. It is not only the patients who face challenges in the consenting process; doctors also encounter difficulties in obtaining consent. In order to determine whether socioeconomic barriers affected the consent-taking process and the ethical dilemmas faced in surgical practice, the study examined these barriers from the perspective of surgeons in southern India.

The legal paradigm in India emphasises the importance of informed consent and the law presumes that a patient is competent to give legally effective consent, if they have the ability to weigh the risks and benefits of the proposed treatment [17]. Hence, it is the surgeon's duty to provide all necessary information to the patient in a language that is understandable to them. Being a multilingual country, one of the primary barriers identified was language, as reported by 204 participants, consistent with findings from other studies [10,18].

The signed written consent form serves as some evidence of a contract between the patient and the doctor [2]; however, this is often misused and can mislead patients, especially those who are unable to read or comprehend the content of the document. In this regard, education plays an important role. It enhances patients' ability to understand the information provided during the consent process. Chaisson LH et al., reported that patients' education potentially influences their understanding of the consent [19]. Most of the surgeons (83.02%) in this study shared this opinion. It was also noted that 86.23% felt that the content and readability of the consent form contributed to better understanding. About 77.52% believed that the use of medical terminology would be a barrier, which posed a challenge for the surgeons as well. It is the surgeons' duty to explain in an understandable way and avoid using medical jargon as much as possible.

Allen KA et al., reported that more than 9 out of 10 survey respondents preferred clinicians who communicated without medical jargon. Participants perceived doctors who used jargon more negatively, describing them as cold, condescending and difficult to understand, while those who communicated without jargon were viewed more positively, being described as empathetic, approachable and good communicators [20].

Cultural and religious beliefs influence individuals' attitudes toward medical interventions and their decision-making processes. Being a multicultural society, this was perceived as a primary barrier by 143 surgeons. Elbarazi I et al., reported that 81% of participants in the UAE felt that their health decisions were shaped by spiritual or religious beliefs [21]. Healthcare professionals should be sensitive to these beliefs, respect diverse perspectives and ensure that patients from different cultural and religious backgrounds fully understand the information presented during the consent process.

The findings of the present study suggest that patients in India are more cognizant of consent compared to those in rural and urban settings of Middle Eastern backgrounds, as shown in a study by Alaei M et al., [22]. The authors found that both males and females comprehended informed consent equally well and there was no difference between either gender in giving consent. The majority opined that individuals with Type A personality understood consent better, likely attributed to their ambitious, focused, determined and strong-willed characteristics.

Informed consent upholds the main principles of bioethics: autonomy, beneficence, non maleficence and justice. Autonomy ensures that

patients have the right to make decisions about their own healthcare; beneficence promotes their well-being; non maleficence ensures they are aware of potential risks; and justice ensures equality in the process [23]. In the current study, 74.56% of surgeons also agreed that informed consent is key to these principles.

The informed consent form is an essential document that protects both the doctor and the patient. It is a legal and ethical requirement that must be fulfilled before any medical procedure is carried out. This form represents the patient's agreement to the medical action plan proposed by the doctor after receiving sufficient information to approve or reject the treatment [24]. It specifies the diagnosis, prognosis, risks and objectives of the proposed treatment. Additionally, it provides legal protection to the doctor against unexpected negative consequences, such as unavoidable risks of treatment, even when the doctor has acted with great care. In the present study, 72.48% of surgeons opined that a properly obtained informed consent form is adequate to protect them from unforeseeable legal liability that may arise during treatment.

Relatives or bystanders play a substantial role in the informed consent process, as their presence can assist the physician in conveying information more effectively and enhancing the patient's understanding, thereby facilitating informed decision-making [25]. Gilbar R (2011) emphasises that family members often serve as important sources of emotional support and aid in communication, especially when patients face complex decisions. Surgeons in the present study also preferred having a bystander present, noting that it reduces patient stress and provides humanistic comfort during consent. However, Gilbar R cautions that when family members become overly dominant in the process, they may hinder direct communication between physician and patient, potentially compromising the patient's autonomy and self-determination [25].

Often, relatives request that doctors hide unfavourable information from the patient, putting doctors in a dilemma, as this contradicts the principles of the informed consent process. About 78% of the surgeons agreed that this creates an ethical barrier since the legal implementation of informed consent requires doctors and healthcare personnel to disclose treatment information to patients, who have the legal right to accept or deny any treatment. However, the practical implementation of informed consent is much more challenging. The fear of 'scaring' the patient or causing psychological deterioration often leads to the decision to withhold certain information.

The informed consent process is grounded in the principle of autonomy, requiring that patients are provided with sufficient information to make informed decisions about their treatment options. This process not only fulfills a legal requirement but also upholds ethical standards by respecting the patient's right to self-determination [26]. In a cross-sectional study conducted by Henley L et al., it was noted that doctors disclosed most of the legally required information, except regarding alternative forms of treatment and remote serious risks and almost never provided information on medical costs [27]. In the present study, we found that most surgeons explained the diagnosis and the procedures involved, along with their associated risks and complications in detail, while comparatively less information was provided regarding alternative treatment options and the team involved.

The study conducted by Wood F et al., noted that doctors used a range of communication techniques to inform patients about the procedure and its risks, including quantifying risks, personalising risks, simplifying language and using drawings [3]. Similarly, the authors found that 78% of surgeons opined that the use of visual aids helped patients better understand informed consent, thereby decreasing the chances of refusal. About 85.32% of the surgeons agreed that using the SPIKES protocol during consent helps reduce refusal rates. Baile WF and Aaron J found that trained oncologists and students felt more confident delivering bad news and obtaining consent, especially in terminal cases [28].

The study found that time constraints, driven by competing clinical demands and lengthy consent procedures, represent a significant barrier to obtaining informed consent, consistent with findings from Arshad MA et al., [29]. Environmental challenges, such as noise and lack of privacy, may further complicate the process. These findings underscore the need for strategies including the simplification of consent materials, environmental improvements and enhanced communication training [30]. However, 40% of surgeons neither agreed nor disagreed that time constraints affected them. Interestingly, 74.31% agreed that surgeons' communication skills could be a barrier to informed consent. Levinson W et al., noted that while surgeons explain procedures well, they often overlook patients' emotions and concerns [31].

When a patient comes with excessive online information regarding their condition, it can be challenging to explain informed consent. Patients may have misconceptions or unrealistic expectations about their condition, which can make it difficult to provide them with accurate information, as mentioned by 57% of the surgeons in the present study. However, it is essential to ensure that patients understand the risks and benefits of their treatment options before giving informed consent.

Some barriers identified in other studies include patients' inability to comprehend the information, limited time to explain the procedure, physician concerns about providing too much information, confusion among clinicians, poorly written informed consent forms, inadequate awareness among patients/communities regarding investigations, the use of medical jargon and the lack of a legal system to support medical professionals during difficult situations, such as ethical dilemmas [1,29].

Limitation(s)

The present study has several limitations, including its setting in a single region and the use of purposive sampling, which may affect generalisability and introduce selection bias. The reliance on self-reported data raises concerns about recall bias. Additionally, the absence of patient perspectives, the use of a structured questionnaire that did not capture the complex communication challenges faced by surgeons and the cross-sectional design further limit the depth and scope of the findings.

CONCLUSION(S)

This study highlights that while most surgeons are aware of the ethical and legal importance of informed consent, multiple patient-related and systemic barriers hinder its effective implementation. Language differences, low health literacy, cultural beliefs and lack of trust in the healthcare system were among the most frequently encountered challenges. Additionally, institutional factors such as time constraints and inadequate training in communication further complicate the consent process. Despite these challenges, the majority of surgeons recognised informed consent as a fundamental component of ethical surgical practice. There is a clear need for structured training in consent communication, simplified consent documentation and policies that support patient-centered care. Bridging these gaps can significantly enhance the quality of surgical consent and foster better doctor-patient relationships.

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