Nigerian Medical Journal
NIGERIA MEDICAL ASSOCIATION
Print ISSN 0300-1652, E-ISSN 2229-774X

Original Article

Assessment of Informed Consent Practices in Surgical Procedures at a Tertiary Care Hospital of Northeast India: A Cross-Sectional Study.

***Nani Gopal Das[1], Abhik Sil[2], Nirmalendu Das[3], Papiya Paul[4].**

[1]Department of Forensic Medicine & Toxicology, Tripura Medical College & Dr. BRAM Teaching Hospital, Hapania, Agartala, Tripura, India, Pincode-799014. [2]Department of General Surgery, Tripura Medical College & Dr. BRAM Teaching Hospital, Hapania, Agartala, Tripura, India, Pincode-799014. [3]Department of Anatomy, Tripura Medical College & Dr. BRAM Teaching Hospital, Hapania, Agartala, Tripura, India, Pincode-799014. [4]Department of Obstetrics & Gynaecology, Tripura Medical College & Dr. BRAM Teaching Hospital, Hapania, Agartala, Tripura, India, Pincode-799014.

Abstract

Background: Informed consent is an ethical and legal prerequisite for surgical care, yet its quality and comprehensibility vary widely across clinical settings. Factors such as communication barriers, limited patient understanding, and time constraints, especially in emergency surgeries, can compromise the consent process. This study assessed the quality of informed consent practices in major surgical departments of a tertiary care hospital in Northeast India and examined determinants of patient understanding and satisfaction.

Methodology: A cross-sectional study was conducted among 400 postoperative patients recruited consecutively from General Surgery, Orthopaedics, Obstetrics and Gynaecology, ENT, and Ophthalmology departments. Data were collected using a pre-validated Informed Consent Quality (ICF) checklist, a structured interview schedule, and a five-point satisfaction scale. Statistical analysis included chi-square tests, independent t-tests, ANOVA, Pearson's correlation, multivariable logistic regression to identify predictors of satisfaction, and multiple linear regressions to determine predictors of ICF quality. A p-value <0.05 was considered statistically significant.

Results: The mean ICF Quality Score was 7.8 ± 1.9, and the mean Satisfaction Score was 4.1 ± 0.8. Elective surgeries showed significantly higher ICF quality and satisfaction than emergency procedures ($p < 0.05$). Time spent on consent ($\beta = 0.34$, $p < 0.001$), patient awareness ($\beta = 0.28$, $p < 0.001$), and understanding ($\beta = 0.22$, $p < 0.001$) emerged as independent predictors of ICF quality. Satisfaction was significantly associated with higher ICF scores, local language use, and adequate discussion of complications. Emergency status remained a negative predictor in regression analysis.

Conclusion: Effective communication, adequate time allocation, and use of local language substantially improve the ethical quality of surgical informed consent. Structured templates and AETCOM-based training may strengthen consent practices in Indian teaching hospitals.

Keywords: Informed Consent, Autonomy, Patient Satisfaction, Documentation, Communication.

***Correspondence:** Dr. Nani Gopal Das, Assistant Professor & HOD (i/c), Department of Forensic Medicine & Toxicology, Tripura Medical College & Dr. BRAM Teaching Hospital, Hapania, Agartala, Tripura, INDIA, Pincode-799014. Email: ngdas153@gmail.com

How to Cite: Das NG, Sil A, Das N, Paul P. Assessment of Informed Consent Practices in Surgical Procedures at a Tertiary Care Hospital of Northeast India: A Cross-Sectional Study. Niger Med J 2025; 67 (1): 2765-2776. https://doi.org/10.71480/nmj.v67i1.1181

Quick Response Code:

Introduction

Informed consent is a fundamental ethical and legal requirement in medical practice, grounded in the principles of patient autonomy, self-determination, and transparent communication between clinicians and patients. Standard forensic and medical ethics texts emphasize that valid consent must be voluntary, informed, and competently provided, with adequate disclosure of the nature of the procedure, associated risks, benefits, and alternatives [1-2]. The Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations reinforce the physician's duty to ensure that consent is both ethically sound and clearly understood by the patient before any invasive intervention is undertaken [3].

The introduction of Attitude, Ethics, and Communication (AETCOM) competencies by the National Medical Commission highlights the national priority to strengthen communication skills and ethical reasoning among medical graduates, especially in contexts where informed consent is both clinically and legally crucial [4-5].

Despite its universal recognition, empirical studies consistently describe deficiencies in surgical informed consent, particularly related to inadequate documentation, poor comprehension, and limited patient engagement. Research has shown that patient understanding varies widely and is strongly influenced by the complexity of information, the communication skills of the provider, and the clarity of the consent process [6]. Systematic reviews indicate that patients often retain only a fraction of the information conveyed, underscoring the need for improved educational approaches and communication strategies during the consent process [7].

However, real-world adherence to these competencies remains inconsistent, particularly in high-volume government hospitals and emergency surgical settings where time pressure and emotional distress further compromise the quality of consent discussions.

Studies from diverse global settings have reported variability in consent quality, patient satisfaction, and comprehension, reflecting differences in health literacy, cultural expectations, and institutional practices [8-10]. These findings reinforce the need for context-specific evaluation of informed consent practices, especially in resource-limited regions such as Northeast India, where linguistic diversity, rural patient populations, and constrained healthcare infrastructure pose additional challenges to effective communication.

The present study was undertaken to assess the quality of informed consent practices in surgical departments of a tertiary care hospital in Northeast India, examining the completeness of consent documentation, patient awareness, understanding, and overall satisfaction. By identifying gaps and determinants of consent quality, the study aims to contribute evidence that can inform institutional protocols, strengthen AETCOM-based training, and enhance patient-centered communication in surgical care.

Materials And Methods

Study design and setting

This was a hospital-based cross-sectional observational study conducted in the major surgical departments of Tripura Medical College & Dr. BRAM Teaching Hospital, Agartala, Tripura, India. The study assessed informed consent practices using postoperative patient self-reports and contemporaneous review of consent documents, without real-time observation of consent encounters. Data collection was carried out over a three-month period in this tertiary care teaching hospital, which serves both urban and predominantly rural populations.

Study participants and sampling

The study population comprised adult postoperative patients admitted to the departments of General Surgery, Orthopaedics, Obstetrics and Gynaecology, Otorhinolaryngology, and Ophthalmology. Patients aged 18 years and above who had undergone elective or emergency surgical procedures and were clinically stable to participate were eligible for inclusion. Patients who were critically ill, cognitively impaired, unable to communicate, or unwilling to participate were excluded.

A total of 430 eligible patients were screened during the study period, of which 400 were consecutively enrolled after applying the inclusion and exclusion criteria. Consecutive sampling was employed to minimize selection bias and ensure representation across departments and surgical urgency.

Data collection tools and technique

Data were collected through face-to-face interviews conducted in the postoperative period using three instruments:

1. **Informed Consent Quality (ICF) Checklist: Validation, Reliability, and Scoring:**

   The Informed Consent Quality (ICF) checklist used in this study was a pre-validated instrument [11] developed based on established ethical guidelines, standard forensic medicine textbooks, and recommendations of the National Medical Commission. The checklist assessed key domains of informed consent, including completeness of documentation, disclosure of procedural details, risks and complications, benefits, available alternatives, language used during the consent process, patient understanding, and presence of patient, guardian, and witness signatures. **Content validity** was established through independent review by a panel of subject experts comprising faculty from the Departments of Forensic Medicine & Toxicology and Surgery, along with members of the Institutional Ethics Committee. Each item was evaluated for relevance, clarity, and representativeness of ethically valid informed consent. Minor modifications in wording were incorporated based on expert feedback to improve contextual clarity and applicability. The checklist was pilot tested on a subset of 40 postoperative patients (10% of the final sample) who were not included in the main analysis, to assess feasibility, comprehension, and reliability. Internal consistency reliability analysis demonstrated acceptable reliability, with a Cronbach's alpha of 0.78, indicating good consistency across checklist items. To ensure scoring consistency, inter-rater reliability was assessed independently by two trained investigators who applied the checklist to the same set of consent documents and patient interviews during the pilot phase. Agreement between raters was found to be satisfactory, with a Cohen's kappa coefficient of 0.81, indicating strong inter-observer agreement. Each checklist item was scored dichotomously as present (1) or absent (0), yielding a total ICF Quality Score ranging from 0 to 10, with higher scores reflecting better quality of informed consent. The final validated checklist was applied uniformly across all departments during the study.

2. **Structured interviewer-administered questionnaire:**

   This captured sociodemographic variables, type and urgency of surgery, duration of consent discussion, patient awareness, and self-reported understanding of the procedure.

3. **Five-point satisfaction scale:**

   A Likert-type scale was used to assess overall patient satisfaction with the informed consent process, where higher scores indicated greater satisfaction and were analyzed as a secondary outcome, recognizing that satisfaction reflects patient perception and does not alone indicate ethical adequacy of consent.

All tools were pilot-tested for clarity and feasibility prior to data collection. Interviews were conducted in the participant's preferred language to ensure comprehension.

Ethical considerations

Ethical approval was obtained from the Institutional Ethics Committee of Tripura Medical College & Dr. BRAM Teaching Hospital (Ref. No. IEC/SFTMC/2025/01/003; dated 13th January 2025). Written informed consent for participation in the study was obtained from all participants after explaining the study objectives, the voluntary nature of participation, and confidentiality safeguards. No identifying information was recorded, and data were anonymized prior to analysis. The study adhered to the ethical principles outlined in the Declaration of Helsinki, ICMJE guidelines, and National Medical Commission regulations.

Intervention

No therapeutic or educational intervention was performed as part of this study. The research was purely observational and involved assessment of existing informed consent practices without altering standard clinical care or consent procedures.

Data analysis

Data were entered and analyzed using IBM SPSS Statistics (version 26). Descriptive statistics were used to summarize participant characteristics and study variables. Categorical variables were analyzed using chi-square or Fisher's exact tests; while continuous variables were compared using independent samples t-tests or one-way analysis of variance (ANOVA), as appropriate. Pearson's correlation coefficient was used to assess relationships between ICF Quality Score, satisfaction, awareness, and understanding.

Predictors of patient satisfaction (defined as satisfaction score ≥ 4) were examined using bivariable and multivariable logistic regression, with results reported as adjusted odds ratios (AORs) and 95% confidence intervals. Determinants of ICF Quality Score were assessed using multiple linear regressions, with model fit evaluated using R^2 and adjusted R^2 values. A p-value < 0.05 was considered statistically significant for all analyses.

Results

Participant flow and baseline characteristics

A total of 430 postoperative patients were approached during the study period. After excluding 30 patients who either declined participation or did not meet the eligibility criteria, 400 patients were finally enrolled and analyzed in Figure 1.

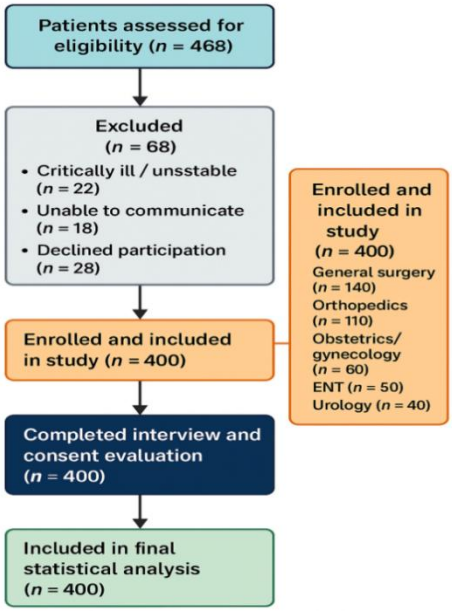

Figure 1: Participant flow diagram showing screening, eligibility assessment, exclusions, and final inclusion of study participants (N = 400) for analysis.

The sociodemographic and clinical characteristics of the study population are summarized in [Table 1]. The mean (± SD) age was 41.2 ± 13.8 years, with a slight male predominance (55.0%; n = 220). The majority of participants were from rural areas (65.0%; n = 260), and 45.0% had completed secondary or higher-secondary education. Bengali was the most commonly preferred language for communication (60.0%; n = 240), followed by other local languages.

Table 1: Sociodemographic & Clinical Characteristics (N = 400)

Variable	Category	N (%)	p-value
Age (years)	Mean ± SD	41.2 ± 13.8	
Sex	Male	220 (55.0)	
	Female	180 (45.0)	
Residence	Rural	260 (65.0)	0.032*
	Urban	140 (35.0)	
Education level	Illiterate/Primary	110 (27.5)	0.021*
	Secondary/Higher Secondary	180 (45.0)	
	Graduate & above	110 (27.5)	
Type of surgery	Elective	240 (60.0)	<0.001*
	Emergency	160 (40.0)	
Major/Minor surgery	Major	280 (70.0)	0.041*
	Minor	120 (30.0)	

Preferred language	**Bengali**	**240 (60.0)**	
	Other languages	160 (40.0)	

Table 1: Values represent frequencies and percentages; p-values from Chi-square tests. A p<0.05* denotes significance.

Overall, 60.0% (n = 240) of surgeries were elective, and 40.0% (n = 160) were emergency procedures. Major surgeries accounted for 70.0% (n = 280) of cases. The mean time spent on obtaining surgical consent was 8.9 ± 4.5 minutes, the mean Informed Consent Form (ICF) Quality Score was 7.8 ± 1.9, and the mean Satisfaction Score was 4.1 ± 0.8. Adequate understanding of the procedure was reported by 75.0% (n = 300) of participants, guardian involvement was documented in 95.0% (n = 380), and witness signatures in 92.5% (n = 370). Complications were explicitly discussed in 75.0% (n = 300) of cases, and a local language was used in 77.5% (n = 310).

Comparison between elective and emergency procedures

Elective and emergency cases differed significantly on several communication-related parameters shows [Table 2] that the Mean ICF Quality Score was higher in elective procedures compared with emergency ones, and the mean Satisfaction Score was likewise higher.

Table 2: Elective vs. Emergency Surgery Comparison

Parameter	Elective (n=240)	Emergency (n=160)	p-value
ICF Quality Score	8.2 ± 1.7	7.2 ± 2.0	0.008*
Satisfaction Score	4.3 ± 0.7	3.9 ± 0.9	0.021*
Understanding adequate (%)	83.3	62.5	<0.001*
Awareness high (%)	73.3	52.5	<0.001*
Complications discussed (%)	80.0	67.5	0.004*
Local language used (%)	81.7	71.3	0.013*
Time spent (minutes)	10.1 ± 4.2	6.9 ± 4.1	<0.001*

Table 2: Values are expressed as mean ± standard deviation for continuous variables and percentages for categorical variables. An independent samples *t*-test was used to compare continuous variables between elective and emergency groups, while Chi-square test was applied for categorical variables. A *p*-value < 0.05 was considered statistically significant (*).

Patients undergoing elective surgery were more likely to report adequate understanding and high awareness of the procedure than those in the emergency group. Complications were discussed more frequently in elective cases, and local language was used slightly more often. The mean time spent on consent was significantly longer in elective than in emergency cases. Differences in guardian involvement and witness signatures did not reach statistical significance. These findings indicate that emergency status is consistently associated with constraints on communication and lower measured quality of the consent process.

Department-wise patterns in informed consent quality and satisfaction

Informed consent quality and patient satisfaction varied across surgical departments. General Surgery contributed the largest share of participants, followed by Obstetrics and Gynaecology, Orthopaedics, ENT, and Ophthalmology. Mean ICF Quality Scores differed significantly between departments (ANOVA, $p = 0.0016$), ranging from lower scores in General Surgery to higher scores in Ophthalmology and Obstetrics and Gynaecology. Patient satisfaction also showed modest but significant departmental variation (ANOVA, $p = 0.0043$), with higher scores observed in Ophthalmology and Obstetrics and Gynaecology. These differences should not be interpreted as performance ranking and are likely to reflect variations in case mix, emergency workload, and communication practices rather than departmental performance, and should be interpreted cautiously.

Correlation between consent quality, awareness, understanding, and satisfaction

Pearson's correlation analysis demonstrated strong positive associations among the major study variables. ICF Quality Score correlated strongly with Satisfaction Score ($r = 0.56$, $p < 0.001$), Awareness Level ($r = 0.52$, $p < 0.001$), and Understanding ($r = 0.47$, $p < 0.001$).

Satisfaction Score also showed significant positive correlations with Awareness ($r = 0.49$, $p < 0.001$) and Understanding ($r = 0.44$, $p < 0.001$). Time spent on consent was moderately correlated with both ICF Quality and Satisfaction (r values in the 0.3–0.4 range), reinforcing the importance of counseling time in achieving both ethically robust and patient-acceptable consent. All correlations were statistically significant at $p < 0.001$ and are visually represented in Table 3.

Table 3: Pearson Correlation Matrix for Key Study Variables

Variable	ICF quality	Satisfaction	Awareness	Understanding
ICF Quality	1.00	**0.56***	**0.52***	**0.47***
Satisfaction	**0.56***	1.00	**0.49***	**0.44***
Awareness	**0.52***	**0.49***	1.00	**0.51***
Understanding	**0.47***	**0.44***	**0.51***	1.00

Table 3: All correlation coefficients (r) were statistically significant at $p < 0.001$ (two-tailed). Strong positive correlations indicate that higher ICF quality aligns with better patient satisfaction, awareness, and understanding.

Predictors of patient satisfaction

Predictors of high patient satisfaction (Satisfaction Score ≥ 4) were examined using bivariable and multivariable logistic regression [Figure 2]. In bivariable analyses, higher ICF Quality Score, longer time spent on consent, higher awareness, adequate understanding, use of local language, discussion of complications, and elective status were all significantly associated with higher odds of satisfaction ($p < 0.05$).

Figure 2: Forest plot showing multivariable logistic regression predictors of patient satisfaction following surgical informed consent.

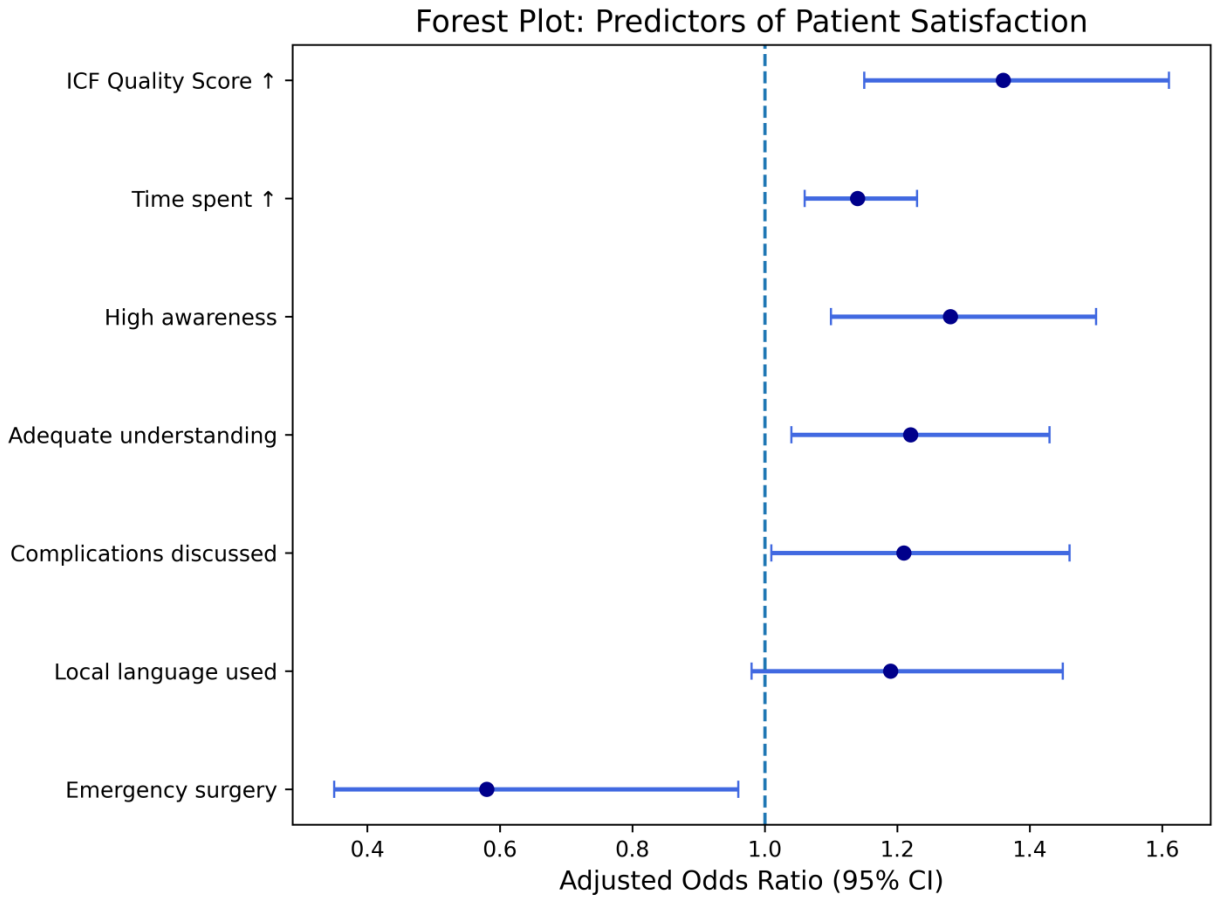

Figure 2: Adjusted odds ratios (AORs) with 95% confidence intervals from multivariable logistic regression. The dashed line denotes AOR = 1.0. Models adjusted for age, sex, residence, education, and department; $p < 0.05$ was considered significant.

In the multivariable logistic regression model, after adjustment for age, sex, residence, education, and department, several variables remained independent predictors of satisfaction. Each one-point increase in ICF Quality Score was associated with 36% higher odds of being satisfied (adjusted OR [AOR] 1.36; 95% CI 1.15–1.61; $p < 0.001$). Each additional minute spent on the consent discussion was associated with a 14% increase in odds of satisfaction. High awareness of the procedure (vs. low) remained a significant predictor, as did adequate understanding.

Discussion of complications showed a modest but significant association with satisfaction. Use of local language showed a favourable trend but did not reach conventional significance in the adjusted model. Emergency surgery status was an independent negative predictor of satisfaction, indicating lower odds of high satisfaction among those undergoing emergency procedures.

Model performance metrics indicated good fit and discrimination: Nagelkerke R^2 was 0.36, suggesting that the model explained 36% of the variance in satisfaction status; the Hosmer–Lemeshow goodness-of-fit test was non-significant (χ^2 (8) = 7.42, p = 0.492), and the area under the ROC curve (AUC) was 0.81, indicating good discriminative ability.

Determinants of informed consent quality in routine surgical care

Informed consent quality was significantly influenced by modifiable communication and contextual factors rather than patient demographics. Longer time spent on counseling was the strongest positive determinant of ICF Quality Score ($p < 0.001$). Higher patient awareness ($p < 0.001$) and adequate understanding ($p < 0.001$) were also independently associated with better consent quality, and together these variables explained a substantial proportion of variability in ICF scores (adjusted $R^2 \approx 0.39$). Use of the local language during consent discussions ($p = 0.012$) and explicit discussion of potential complications ($p = 0.027$) were additional significant contributors to improved consent quality.

Emergency surgical procedures were independently associated with lower ICF Quality Scores ($p = 0.004$), reflecting the ethical and practical constraints inherent to time-critical care. Educational status showed a positive but non-significant trend ($p = 0.099$), while age ($p = 0.224$) and sex ($p = 0.691$) did not significantly influence consent quality. Overall, these findings demonstrate that ethically robust informed consent is primarily determined by clinician-controlled communication processes rather than fixed patient characteristics.

Discussion

The present study provides a comprehensive evaluation of informed consent practices in a tertiary care surgical setting in Northeast India, integrating both document quality and patient-reported experiences. The findings demonstrate that informed consent practices are influenced by multiple communication-related and contextual factors, a pattern consistent with established medico-legal principles described by Reddy and Mukherjee, who emphasize informed consent as an ethically grounded communication process rather than a perfunctory signature event [1-2]. Although regulatory frameworks such as the Indian Medical Council Ethics Regulations mandate adequate disclosure and patient understanding, the variability observed in this study highlights persistent gaps in real-world implementation [3-5].

The multivariable logistic regression results reinforce that ICF Quality Score, time spent on consent, awareness, and understanding were strong independent predictors of patient satisfaction. These associations directly parallel the work of Fink et al., who documented that patient comprehension sharply improves when clinicians spend adequate time explaining procedures and risks [6]. Glaser et al. also demonstrated that enhanced communication strategies significantly improve patient comprehension across surgical settings [7]. The current study's regression model further quantified these relationships, with time on consent ($\beta = 0.34$), awareness ($\beta = 0.28$), and understanding ($\beta = 0.22$) exerting the largest positive effects on ICF quality, corroborating the fundamental importance of communication clarity. Awareness and understanding were analyzed separately to test whether higher consent process quality translated into improved patient comprehension, rather than assuming comprehension as an intrinsic component of documentation quality.

A key finding of this study was the significant difference between elective and emergency procedures, where emergency cases consistently showed lower ICF Quality Scores and satisfaction levels. Lower consent quality in emergency surgeries reflects well-recognized contextual constraints rather than novel deficiencies. These findings underscore the need for pragmatic mitigation strategies, including deferred consent where appropriate, simplified emergency consent templates, and structured involvement of legally authorized surrogates. This aligns with international evidence suggesting that emergencies inherently constrain communication due to time pressure, emotional distress, and reduced opportunity for shared decision-making [12]. Kituuka et al. similarly reported that emergency contexts frequently result in compromised disclosure and reduced patient comprehension [13].

Pearson's correlation showed strong associations among ICF quality, awareness, understanding, and satisfaction, highlighting the interconnectedness of communication variables. These findings resonate with studies by Drake et al., Sayfi et al., and Ayre et al., who demonstrated that simplifying language through plain-language tools, structured formats, or supplementary materials substantially enhances patient comprehension and decision-making confidence [14-16]. In the linguistically diverse population of Northeast India, these interventions may be particularly impactful.

The department-wise analysis revealed meaningful variation in ICF quality and satisfaction across specialities, with departments demonstrating higher scores also exhibiting higher communication adequacy and use of local language. Similar interdepartmental differences have been observed in multicenter evaluations in Spain, Portugal, and Nepal, where disparities were linked to differences in clinician training, workload, and documentation culture [17-19]. Such patterns underscore the need for department-specific training and standardized consent templates.

The Tukey post-hoc comparisons identified specific departments with significantly better or poorer performance, indicating opportunities for targeted quality improvement. This granular insight parallels findings from Agozzino et al. and Calle-Urra et al., who showed that structured, audit-driven interventions can substantially improve consent completeness and patient understanding over time [20-21].

Overall, the present study reinforces that effective communication rather than form completion is the foundation of ethical informed consent. The strong quantitative relationships between communication variables and both satisfaction and ICF quality confirm the need for explicit training in communication skills, as emphasized in the AETCOM curriculum and NMC Skill Training Modules [4-5,22]. For regions like Northeast India, where literacy, cultural norms, and language diversity present additional challenges, communication training becomes even more critical.

Medico-Legal Implications

From a forensic and medico-legal perspective, incomplete or poorly documented informed consent represents a recognized source of litigation risk. The observed variability in consent quality highlights vulnerabilities in legal defensibility, particularly in emergency settings. Strengthening consent documentation and communication practices, therefore, serves not only ethical obligations but also institutional risk management and patient safety.

Limitations and Recommendations:

The study's strengths include its large sample size, multi-departmental sampling, and use of validated tools, multiple regression models, and detailed correlation analyses. However, limitations remain: the cross-sectional design precludes causal inference; satisfaction data may be influenced by recall and social desirability bias; and findings from a single institution may not generalize to all Indian settings. Nonetheless, similar patterns documented across Ethiopia, Uganda, Nepal, Spain, and Pakistan suggest that the issues identified are global and systemic rather than institution-specific [8-9,23-24].

This study demonstrates that the quality of informed consent is determined by communication clarity, time investment, patient awareness, understanding, and contextual factors like emergency status. Improving consent practices will require a combination of structured templates, bilingual communication tools, dedicated communication training, and periodic audits. By aligning institutional practices with national ethical guidelines and global evidence, surgical departments can enhance patient autonomy, satisfaction, and medico-legal safety.

The results emphasize the need for structured ethics and communication training at both undergraduate and postgraduate levels. Integration of simulated consent exercises, AETCOM-based assessments, and specialty-specific training for emergency settings can strengthen ethical competence and improve real-world informed consent practices.

Conclusion

The present study demonstrates that the quality of the surgical informed consent process is strongly influenced by communication effectiveness, patient understanding, and contextual factors such as emergency status. Higher informed consent quality and patient satisfaction were consistently associated with longer discussion time, use of the local language, and comprehensive explanation of risks and complications. These findings reaffirm that informed consent is not merely a procedural requirement but an ethical dialogue central to patient autonomy and shared decision-making.

Emergency settings, however, showed significantly lower ICF quality and satisfaction scores, underscoring persistent challenges when time, emotional distress, and clinical urgency limit meaningful communication. Strengthening consent practices in such settings will require structured, simplified, and bilingual consent formats alongside clear emergency-specific protocols.

Overall, the study highlights the need for institutional reforms that prioritize communication training, standardized consent templates, and routine audits of consent quality. Integrating AETCOM-based educational strategies for interns and residents can further enhance ethical competence and ensure that consent processes remain patient-centered, transparent, and legally sound. Improving both the documentation and interpersonal aspects of consent will ultimately strengthen patient trust, medico-legal protection, and the quality of surgical care in Indian teaching hospitals.

References

1. Reddy KSN. Medical Law and Ethics. In: The Essentials of Forensic Medicine & Toxicology. Jaypee Brothers Medical Publishers (P) Ltd, 2022, p. 23.
2. Mukherjee JB, Karmakar RN. In: J.B. Mukherjee's Forensic Medicine & Toxicology. Academic p. Kolkata: Academic Publishers (P) Ltd, 2017, p.48.
3. Medical Council of India. Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002. Available from: https://www.nmc.org.in/wp-content/uploads/2017/10/Ethics-Regulations-2002.pdf. Accessed 5 Jan 2026.
4. Medical Council of India. Attitude, Ethics and Communication (AETCOM*)* competencies for the Indian medical graduate. New Delhi: Medical Council of India; 2018. Available from: https://www.nmc.org.in/wp-content/uploads/2020/01/AETCOM_book.pdf. Accessed 5 Jan 2026.
5. National Medical Commission. Skills training module for undergraduate medical education programme. New Delhi: Board of Governors in supersession of the Medical Council of India; 2019. Available from: https://www.nmc.org.in/wp-content/uploads/2020/08/Skill-Module_23.12.2019.pdf. Accessed 05 Jan 2026.
6. Fink AS, Prochazka AV, Henderson WG, Bartenfeld D, Nyirenda C, Webb A, Berger DH, Itani K, Whitehill T, Edwards J, Wilson M, Karsonovich C, Parmelee P. Predictors of comprehension during surgical informed consent. J Am Coll Surg. 2010 Jun; 210(6):919-26. doi: 10.1016/j.jamcollsurg.2010.02.049. PMID: 20510800.
7. Glaser J, Nouri S, Fernandez A, Sudore RL, Schillinger D, Klein-Fedyshin M, Schenker Y. Interventions to Improve Patient Comprehension in Informed Consent for Medical and Surgical Procedures: An Updated Systematic Review. Med Decis Making. 2020 Feb; 40(2):119-143. doi: 10.1177/0272989X19896348. Epub 2020 Jan 16. PMID: 31948345; PMCID: PMC7079202.
8. Biyazin T, Taye A, Belay Y. Patient satisfaction with surgical informed consent at Jimma Medical Center, Ethiopia. BMC Med Ethics 23, 103 (2022). https://doi.org/10.1186/s12910-022-00841-5

9. Kituuka O, Mwaka E, Munabi I, et al. Experiences of patients and next of kin on informed consent process for emergency surgery in two urban university teaching hospitals in Uganda: a comparative cross sectional study. BMC Emerg Med 23, 82 (2023). https://doi.org/10.1186/s12873-023-00856-0
10. Kumru S, Albayrak H, Kaya S. Informed consent in surgical practice: Patients' experiences and perspectives. Patient Experience Journal. 2023; 10(3):57–69. doi:10.35680/2372-0247.1768
11. Calle-Urra JE, Parra-Hidalgo P, Saturno-Hernández P, Fonseca-Miranda Y, Martínez-Martínez MJ. Evaluation and Improvement of the Informed Consent Documents in 9 Hospitals, Spain. Rev. Esp. Salud Publica 2015, 89, 307–319.
12. Muskens IS, Gupta S, Robertson FC, Moojen WA, Kolias AG, Peul WC, Broekman MLD. When Time Is Critical, Is Informed Consent Less So? A Discussion of Patient Autonomy in Emergency Neurosurgery. World Neurosurg. 2019 May; 125:e336-e340. doi: 10.1016/j.wneu.2019.01.074. Epub 2019 Jan 26. PMID: 30690144.
13. Kituuka O, Munabi IG, Mwaka ES, Galukande M, Harris M, Sewankambo N. Informed consent process for emergency surgery: A scoping review of stakeholders' perspectives, challenges, ethical concepts, and policies. Sage Open Medicine. 2023;11. doi:10.1177/20503121231176666
14. Drake BF, Brown KM, Gehlert S, Wolf LE, Seo J, Perkins H, Goodman MS, Kaphingst KA. Development of Plain Language Supplemental Materials for the Biobank Informed Consent Process. J Cancer Educ. 2017 Dec; 32(4):836-844. doi: 10.1007/s13187-016-1029-y. PMID: 27037699; PMCID: PMC5047847.
15. Sayfi S, Charide R, Elliott SA, Hartling L, Munan M, Stallwood L, Butcher NJ, Richards DP, Mathew JL, Suvada J, Akl EA, Kredo T, Mbuagbaw L, Motilall A, Baba A, Scott SD, Falavigna M, Klugar M, Friessová T, Lotfi T, Stevens A, Offringa M, Schünemann HJ, Pottie K. A multimethods randomized trial found that plain language versions improved adults understanding of health recommendations. J Clin Epidemiol. 2024 Jan; 165:111219. doi: 10.1016/j.jclinepi.2023.11.009. Epub 2023 Nov 25. PMID: 38008266.
16. Ayre J, Bonner C, Muscat DM, Cvejic E, Mac O, Mouwad D, Shepherd HL, Aslani P, Dunn AG, McCaffery KJ. Online Plain Language Tool and Health Information Quality: A Randomized Clinical Trial. JAMA Netw Open. 2024 Oct 1;7(10):e2437955. doi: 10.1001/jamanetworkopen.2024.37955. PMID: 39378036; PMCID: PMC11581667.
17. García-Álvarez JM, Díaz-Agea JL, Suárez-Cortés M, Molina-Rodríguez A, Jiménez-Ruiz I, García-Sánchez A. Formal Quality and Compliance of Informed Consent Forms in Critical Care and Surgical Areas in Spain: An Observational Study. Nursing reports; 13(1): 43–50. https://doi.org/10.3390/nursrep13010004
18. Vieira AL, Infante C, Santos S, Asseiro M, Ferreira C. A survey on current practice of informed consent process in surgical specialties of a Portuguese tertiary teaching hospital center: What is the state of play? Ethics Med Public Health. June 2023; 28:100910. http://doi:10.1016/j.jemep.2023.100910.
19. Basukala S, Shrestha O, Thapa N, Karki S, Pandit A, Thapa BB, et al. How informed is informed consent? Evaluating the quality of informed consent among surgical patients in a tertiary care hospital in Nepal. PLOS ONE 18(7): e0288074. https://doi.org/10.1371/journal.pone.0288074.
20. Agozzino E, Borrelli S, Cancellieri M, Carfora FM, Di Lorenzo T, Attena F. Does written informed consent adequately inform surgical patients? A cross-sectional study. BMC Med Ethics. 2019; 20(1):1. http://doi:10.1186/s12910-018-0340-z.
21. Lal S, Sehgal P. Integration of attitude, ethics, and communication competencies into competency-based UG curriculum. Indian J Community Med. 2022; 47(1):4-7.
22. Kebede BF, Tesfa TB, Hiwot AY et al. Knowledge of surgical informed consent and associated factors among patients undergone obstetric and gynaecologic surgery at Jimma Medical Center, Jimma, Ethiopia, 2020: an institutional based cross-sectional study. Perioper Med. 2023; 12, 6. https://doi.org/10.1186/s13741-023-00295-2.
23. Mbonera F, Chironda G. The relationship between knowledge and perception of patients regarding informed consent in surgical procedures in Rwanda. Int J Res Med Sci. 2018; 6(2):408-16.
24. Amir M, Rabbani MZ, Parvez MB. Informed consent in elective surgical procedures: "What do the patients think?". J Pak Med Assoc. 2009; 59(10):679-82.