

# Application of Standard Informed Consent Procedure Amongst Practicing Anesthetists in Tertiary Care Hospitals of Karachi

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#### Keywords

Contributions

Informed consent, anesthesia, anesthetists, patient safety, compliance, tertiary care hospitals, Karachi, risk

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#### **ABSTRACT**

**Background**: Informed consent is a critical component of anesthesia practice, ensuring patient autonomy and safety. However, variability in the application of consent procedures among anesthetists may impact patient understanding and care quality.

**Objective**: To evaluate the application of standard informed consent procedures among practicing anesthetists in tertiary care hospitals in Karachi.

Methods: A cross-sectional study was conducted from February 15, 2021, to August 14, 2021, across five tertiary care hospitals in Karachi. A total of 112 anesthetists, including consultants and residents with at least two years of experience, were recruited through consecutive sampling. Data were collected using a custom-made 16-item questionnaire. Responses were scored from 0 to 64, with scores ≥32 considered acceptable. Data were analyzed using SPSS version 25, employing descriptive statistics and Chi-square tests for comparisons.

**Results**: The mean age of participants was  $34.04 \pm 8.15$  years, with  $5.43 \pm 5.9$  years of experience. Compliance with consent standards was 99.11%, with 111 out of 112 participants scoring  $\geq 32$ . No significant differences were observed across age, gender, or qualification (p > 0.05).

**Conclusion**: Anesthetists in Karachi showed high adherence to informed consent standards, though enhancements in risk disclosure are recommended to further improve patient care.

# INTRODUCTION

Informed consent is a fundamental aspect of patient care, providing a structured approach that ensures patients are adequately informed about the medical procedures they will undergo, the associated risks and benefits, and the available alternatives. This process upholds the ethical principle of autonomy, enabling patients to make wellinformed decisions about their treatment options, thereby safeguarding their rights and interests. The concept of consent encompasses ethical, professional, and legal dimensions, making it a critical element of medical practice (2, 3). The term "informed consent" originated from the landmark Salgo case in 1957, highlighting the necessity for healthcare providers to offer comprehensive and comprehensible information about proposed medical interventions (2). This process not only facilitates shared decision-making between healthcare providers patients but also strengthens the therapeutic alliance and addresses legal obligations (6, 7).

Despite the established significance of informed consent in clinical practice, its implementation remains inconsistent, particularly in specialized fields such as anesthesia. Anesthetists often face challenges in conveying complex information to patients within the limited time available, potentially leading to variations in the quality of consent obtained. A survey conducted by Cafferkey et al. in Ireland

revealed that 63.8% of anesthetists do not routinely document consent for anesthesia, with most relying on the anesthetic record rather than a distinct consent form. The survey also found that only a small fraction of anesthetists consistently discuss the rare but serious risks associated with anesthesia, underscoring the variability in practice (8). Similarly, Olatosi et al. reported that while 57.14% of anesthetists in Nigeria inform patients about the anticipated benefits of anesthesia, a significant proportion fail to provide a comprehensive explanation of the procedure, highlighting a gap in the consent process (9). These findings underscore the need for standardized protocols to ensure that patients receive adequate information about anesthesia, including the risks, benefits, and alternatives, as recommended by professional guidelines (3, 10).

The complexity of modern anesthetic practice, which spans a wide range of procedures and patient populations, further complicates the consent process. Anesthetists are tasked with managing patients of varying ages and comorbidities, often in high-stakes perioperative settings where the risks of anesthesia are compounded by underlying medical conditions. This dynamic environment necessitates a tailored approach to consent, where information is adapted to the specific needs and concerns of each patient. However, there is currently no universally accepted protocol for delivering this information, and the amount of detail provided can vary significantly depending on the

anesthetist's experience, the care model employed, and the overall risk profile of the case (5-11).

The aim of this study is to evaluate the adherence of practicing anesthetists in tertiary care hospitals in Karachi to standard informed consent procedures for anesthesia. By assessing the extent to which anesthetists comply with established guidelines, this study seeks to identify gaps in current practices and propose recommendations for improvement. In particular, the study will explore whether anesthetists provide comprehensive information about the potential risks and benefits of anesthesia, discuss alternative treatment options, and ensure that patients have sufficient time to understand and consent to the proposed procedures. Additionally, the study aims to generate localized data that can inform the development of tailored consent protocols and contribute to the broader discourse on informed consent in anesthesia, advocating for the global adoption of best practices. Ultimately, the goal is to enhance the process of obtaining informed consent from anesthetists, thereby improving patient care and ensuring compliance with ethical and legal standards (12-19)).

# **MATERIAL AND METHODS**

A cross-sectional study was conducted over six months, starting from February 15, 2021, to August 14, 2021, across various tertiary care hospitals in Karachi, including The Indus Hospital, Aga Khan University Hospital, Civil Hospital, Jinnah Postgraduate Medical Centre (JPMC), and the National Institute of Cardiovascular Diseases (NICVD). The study aimed to evaluate the practices of informed consent among anesthetists working in these institutions. The sample size was determined using the OpenEpi calculator version 3.01, with a 95% confidence level and a 9% margin of error. The sample size was calculated based on the frequencies of a self-designed tool assessing the practices of obtaining consent among anesthetists, with a final sample size of 112 participants. A consecutive sampling technique was employed, including consultants with qualifications such as FCPS, FRCA, American boardcertified diploma, specialists with MCPS or diploma in anesthesia, and FCPS residents of anesthesiology with at least two years of experience in a tertiary care setting. Residents of MCPS were excluded from the study.

Ethical approval for the study was obtained from the Institutional Review Board (IRB) of The Indus Hospital. Prior to the commencement of the study, meetings were held with the heads of anesthesia departments at each participating hospital to explain the study's objectives and secure permission to conduct the research. A list of eligible anesthetists was obtained from each institution, and eligible participants were contacted either by phone or in person to secure verbal consent. A specific date and time were arranged for completing the questionnaire, which was administered in person by the principal investigator or a member of the study team. The custom-made questionnaire consisted of 16 items, with each question having five response options scored from 0 to 4 (never=0, rarely=1, some of the time=2, most of the time=3, always=4). The scores ranged from 0 to 64, with a score below 32 considered unacceptable and scores equal to or above 32 deemed acceptable adherence to the standards.

The data collection process involved distributing the questionnaire to participants, who completed it in approximately 15 to 20 minutes. The questionnaire assessed the timing, influences, and concerns related to obtaining consent, as well as the disclosure of risks, benefits, and alternatives associated with anesthesia. The collected data were analyzed using SPSS version 25. Descriptive statistics were used to summarize demographic variables such as age, gender, qualifications, and years of experience. Quantitative data, including age and years of experience, were reported as means with standard deviations or medians with interquartile ranges, depending on the normality of the distribution. Categorical variables were summarized using frequencies and percentages. The practice of obtaining consent was evaluated based on the total scores from the questionnaire, which were categorized into acceptable and unacceptable practices.

To assess the association between anesthetists' practices and various demographic factors, a Chi-square test was employed to compare the acceptable and unacceptable practice groups. The analysis was stratified by age, gender, years of experience, qualification, and type of institution (public versus private) to control for potential confounding variables. Effect modifiers were further controlled through stratification, and the Chi-square test was applied within these strata. A p-value of less than or equal to 0.05 was considered statistically significant. The study adhered to ethical standards as per the Declaration of Helsinki, ensuring that participants' autonomy, confidentiality, and rights were respected throughout the research process (12). All participants provided informed consent prior to their inclusion in the study, and no personal identifiers were collected to maintain the anonymity of the respondents. The findings aimed to provide insight into current practices and identify areas for improvement in the informed consent process among anesthetists in tertiary care settings in Karachi.

# **RESULTS**

The study included a total of 112 participants with a mean age of  $34.04 \pm 8.15$  years and a mean experience of  $5.43 \pm 5.9$  years. Among the participants, 72 (64.29%) were male, and 40 (35.71%) were female. A majority of participants were residents, with 53.57% employed in private hospitals and 46.43% in public sector hospitals. The compliance rate of anesthesiologists with consent criteria was found to be 99.11% (111 out of 112). Stratification analysis by age, gender, qualification, and type of institution did not reveal any significant differences in compliance rates.

Overall, the majority of anesthetists demonstrated adherence to the standards of informed consent, with very few reporting practices below the acceptable threshold. The stratification analysis indicated no statistically significant differences in compliance based on age, gender, qualification, type of institution, or years of experience, as indicated by p-values greater than 0.05 in all comparisons.

Table I: Descriptive Statistics of Participants' Age and Experience

Statistics	Age (Years)	Experience (Years)	
Mean	34.04	5.43	
Standard Deviation	8.15	5.9	
Minimum	22	2	
Maximum	69	39	

Table 2: Responses Regarding the Practice of Obtaining Consent - Timing, Influences, and Concerns

Questions	Never/Rarely/Some of the time	Most of the time/Always
I give the patient sufficient time to digest the information provided.	5 (4.5%)	106 (95.5%)
The anesthetic technique I propose is influenced by the patient's wishes.	17 (15.3%)	95 (85.6%)
The anesthetic technique I propose is influenced by my skills/experience.	16 (14.4%)	96 (86.5%)
I am sure of my ethical and legal obligations when obtaining consent for anesthesia.	15 (13.5%)	97 (87.4%)
My practice for obtaining consent for anesthesia is adequate.	15 (13.5%)	97 (87.4%)
I am concerned regarding litigation stemming from inadequate consent for anesthesia.	27 (24.3%)	85 (76.6%)
Having a separate written consent form for anesthesia would improve the standard of consent.	30 (27.0%)	82 (73.9%)
Having a separate written consent form for anesthesia would provide better protection against litigation.	28 (25.2%)	84 (75.7%)

Table 3: Responses Regarding the Practice of Obtaining Consent - Disclosure of Benefits, Risks, and Alternatives

Questions	Never/Rarely/Some of the time	Most of the time/Always
I explain to the patient the benefits of my proposed technique.	12 (11%)	100 (89.3%)
I explain to the patient all of the risks associated with my proposed technique.	23 (21%)	89 (79.5%)
I explain to the patient common risks that have benign consequences (e.g., sore throat, nausea, vomiting, injury to teeth).	19 (17%)	93 (83.0%)
I explain to the patient rare risks that have severe consequences (e.g., paralysis, death, myocardial infarction).	52 (46%)	60 (53.6%)
I explain to the patient risks that are of particular relevance to them (e.g., intubating a singer).	43 (38%)	69 (61.6%)
I explain to the patient at least one alternative to my proposed technique.	47 (42%)	65 (58.0%)
When I offer an alternative, I ask the patient which technique they would prefer.	50 (45%)	62 (55.4%)
I influence the patient's decision by encouraging one technique over another.	57 (51%)	55 (49.1%)

Table 4: Compliance with Standards of Consent Stratified by Demographic Variables

Variables	Cutoff	Unacceptable Practice	Acceptable Practice	P-Value
Age (Years)	≤35	I (I.2%)	83 (98.8%)	0.56
	>35	0 (0%)	28 (100%)	
Gender	Male	0 (0%)	72 (100%)	0.17
	Female	I (2.5%)	39 (97.5%)	
Qualification	FCPS	0 (0%)	20 (100%)	0.80
	MCPS / Diploma	0 (0%)	14 (100%)	
	American Board	0 (0%)	0 (0%)	
	FRCA	0 (0%)	0 (0%)	
	Resident	I (1.3%)	77 (98.7%)	
Institute	Private	0 (0%)	60 (100%)	0.28
	Public	I (1.9%)	51 (98.1%)	
Experience	≤4	I (I.3%)	78 (98.7%)	0.51
	>4	0 (0%)	33 (100%)	

The data suggest a high level of compliance among anesthetists in adhering to the established protocols for obtaining informed consent in anesthesia across various tertiary care settings in Karachi.

# **DISCUSSION**

The findings of this study revealed that the majority of anesthetists in tertiary care hospitals in Karachi adhered to the standard informed consent procedures, with a compliance rate of 99.11%. This high adherence rate underscores the commitment of anesthetists to meeting ethical and legal obligations in patient care, particularly in obtaining informed consent for anesthesia. The results align with previous studies, such as those conducted in the United Kingdom and Ireland, where a substantial proportion of anesthetists demonstrated awareness of the importance of informed consent and consistently engaged in the practice (8, 9). The emphasis on documenting the consent process and providing patients with detailed information about the risks, benefits, and alternatives associated with anesthesia reflects the ongoing efforts to enhance patient autonomy and safety in clinical settings (3, 10).

Despite the overall high compliance, the study identified variability in how specific aspects of consent were addressed. While most anesthetists adequately explained the benefits and common risks of anesthesia, fewer provided comprehensive information on rare but severe risks, such as paralysis or death. This gap in communication aligns with findings from studies in Ireland and Nigeria, where anesthetists often prioritized common risks but were less consistent in discussing rarer, more severe complications (8, 9). The tendency to focus on less alarming information may stem from concerns about patient anxiety or a lack of standardized protocols guiding the extent of risk disclosure. Additionally, the limited time available for preoperative consultations in busy tertiary care settings might constrain anesthetists' ability to deliver exhaustive information, particularly for complex procedures involving high-risk patients (8, 11).

The study's strengths include a robust sample size and the inclusion of multiple tertiary care hospitals, enhancing the generalizability of the findings within the context of Karachi's healthcare system. The use of a standardized questionnaire allowed for consistent data collection and facilitated comparisons with previous studies on informed consent practices in anesthesia. However, several limitations should be noted. The study relied on self-reported data, which may be subject to reporting bias, as participants could overestimate their adherence to best practices. Additionally, the cross-sectional design precludes the assessment of causal relationships between anesthetists' characteristics and their consent practices. The exclusion of MCPS residents may also have introduced selection bias, limiting the applicability of the findings to all categories of anesthetists (13-20).

Cultural factors and varying levels of patient literacy in the region may also impact the effectiveness of the informed consent process. Previous studies have highlighted that patients with lower levels of education often struggle to

comprehend complex medical information, which can impede their ability to make informed decisions (15, 16). In the context of Karachi, where a significant portion of the population may have limited access to education, it is crucial for anesthetists to adapt their communication strategies to the individual needs of patients, ensuring that consent is truly informed rather than merely procedural (18). To address these gaps, there is a need for developing and implementing standardized guidelines that clearly delineate the scope of information that should be communicated during the consent process for anesthesia. Such guidelines should emphasize the importance of discussing all relevant risks, including rare but serious complications, and providing patients with sufficient time to understand and consider their options. Training programs for anesthetists could incorporate modules on effective communication strategies and risk disclosure, tailored to the diverse patient demographics encountered in tertiary care settings. Moreover, introducing separate consent forms specifically for anesthesia, as suggested by some study participants, could enhance the clarity and completeness of the consent process, thereby reducing potential legal and ethical complications (3, 5).

Future research should explore the impact of specific interventions, such as patient education materials or decision aids, on the quality of informed consent in anesthesia. Studies could also investigate the role of patient factors, such as health literacy and cultural beliefs, in shaping their understanding of the consent process. By addressing these factors, healthcare providers can better align their consent practices with the needs and expectations of patients, ultimately improving patient outcomes and satisfaction. Additionally, longitudinal studies could provide insights into how consent practices evolve over time and in response to targeted interventions, offering valuable guidance for continuous quality improvement in anesthesia care (3, 7, 21).

While the current practices of obtaining informed consent among anesthetists in Karachi's tertiary care hospitals largely meet established standards, there remain opportunities for improvement. By enhancing the scope and quality of information provided, and by tailoring communication strategies to patient needs, anesthetists can further strengthen the informed consent process, ensuring that it fulfills its intended purpose of protecting patient autonomy and promoting ethical, patient-centered care. The development of specific consent protocols and educational initiatives could play a crucial role in achieving these goals, contributing to the broader effort to standardize and improve informed consent practices in anesthesia globally (21, 22).

# CONCLUSION

In conclusion, the study demonstrated that anesthetists in tertiary care hospitals in Karachi largely adhere to informed consent standards, reflecting a strong commitment to ethical and legal practices in patient care. However, gaps in communicating rare but severe risks and the need for standardized consent protocols highlight areas for

improvement. Addressing these gaps through enhanced guidelines and tailored communication strategies could significantly improve patient understanding and decision-making, ultimately fostering greater patient autonomy and satisfaction. The findings underscore the importance of comprehensive consent processes in anesthesia, with direct implications for enhancing patient safety, trust, and overall quality of healthcare delivery.

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