



Original Research Article

Informed Consent Practice and It's Associated Factors in Gynaecology and Obstetrics Setting

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Abstract: Background: Informed consent is an ethical and patient-centered healthcare concept, but its sufficiency in obstetrics and gynecology practice is understudied in Pakistan. The objectives of the study were to evaluate informed consent practice and determine factors related to poor informed consent. **Methods:** The cross-sectional study was carried out for six months at Jinnah Postgraduate Medical Center, Karachi. Consecutive sampling was used to select 384 patients undergoing obstetric or gynecological procedures. A structured questionnaire was used to collect data. Adequate consent was considered to provide information about the nature, risks, benefits, alternatives, type of anesthesia, the opportunity to ask questions, and ample time to decide. Analysis of data was done in SPSS through chi-square test, Fisher's exact test, and stratified analysis to eliminate confounders. **Results:** Every participant gave written consent, and 65.1% received adequate informed consent. Stratified analysis showed no statistically significant correlations between adequacy of consent and age, education, parity, type of procedure, occupation, or person signing consent ($p > 0.05$). **Conclusion:** Although written consent is usually documented, patients were not provided with sufficient information to make informed choices. It is essential to reinforce patient-centered communication, provider training, and institutional policies to improve the informed consent practice, patient autonomy, and the quality of the obstetric and gynecological care.

Keywords: Informed consent, obstetrics, gynecology, patient autonomy.

INTRODUCTION

Informed consent is a fundamental principle of medical ethics and patient care.(1) It is a process that involves continuous communication of healthcare professionals to patients about a proposed medical or surgical intervention, its nature, potential risks and benefits, the available alternatives, and possible complications. (2) Three key factors are required to be met for informed consent to be considered as valid, i-e, the patient has to have a reasonable capacity to make decisions, he must be provided with adequate and understandable information, and his

choice also has to be free of coercion, as well as not influenced by any undue pressure. (3)

Properly organized informed consent is an essential part of the shared decision-making process and a guarantee of adherence not only to ethical principles but also to legal standards in healthcare systems.(4) It protects patient autonomy and the right to self-determination as it allows individuals to get actively involved in the process of making decisions that impact their health.(5) Physicians have a responsibility in this process of offering clear and detailed explanations of diagnostic evaluations,

treatment choices, and prognostic factors according to their professional understanding of what is most useful to the patient.(6)

Inability to receive proper informed consent can lead to severe litigation risks, such as medical negligence, battery, patient injuries, improper or unauthorized procedures, poor treatment results, and claims of financial damages.(7) The most frequently mentioned claim in malpractice cases is the poor disclosure of surgery risks and possible adverse effects.(8, 9) These legal issues demonstrate the role of proper communication and documentation in clinical practice.

Socioeconomic and educational constraints are additional factors that exacerbate the challenge of informed consent practices in Pakistan.(10) Although Pakistan ranks as the sixth most populous country in the world, the country has a very low literacy rate, and a significant number of the population is living below the poverty line.(11) As a result, there is a low level of patient awareness and knowledge of healthcare rights and informed consent. Moreover, the consent procedure is largely affected by systemic healthcare inefficiencies, as well as cultural and societal norms.(12)

The Pakistani society is highly hierarchical and male-dominated, with decision-making on healthcare being dominated by male members of the family, especially in issues concerning the health of women.(13) Women are often deprived of autonomy and are supposed to be submissive to decisions made by others, which undermines voluntary consent.(14) Other determinants of informed consent are socio-demographic factors, like age, level of education, occupation, language barriers, and cultural diversity; organizational factors, including absence of standard consent forms, improper training, time, workloads, lack of interpreters, and poor institutional policies; healthcare provider factors, including knowledge, attitudes, and professional experience.(15)

Informed consent is particularly challenging in the gynecology and obstetrics set-up, based on the type of care that is delivered.(16) There are usually emergency or urgent interventions, increased patient distress, emotional stress, and ethical complications that are related to reproductive health. In an emergency when patients are unconscious or incapable of providing consent, clinicians can use the doctrine of implied consent to save lives. Nevertheless, these conditions also make the ethical dilemma of patient autonomy and clinical necessity more challenging.(17)

The process of obstetric care is known to promote childbirth in women using effective communication and meaningful consent, and care delivery without

consent may dishearten the use of skilled birth services. (18) Written permission for obstetric procedures, such as cesarean sections, is a fundamental component of maternity care. Obstetrics is also ranked as one of the most risky specialties on medicolegal claims in the world, as it contributes a significant percentage of malpractice compensation in a number of healthcare systems.(19) The acute gynecology and the labor ward setting could be replaced by the need to quickly resolve the clinical situation, the lack of time to discuss it, and an increase in emotional and physical pain. Women might show up with minimal previous experience with labor ward procedures, little knowledge of obstetric decision-making, excruciating pain, anxiety, or the impact of analgesics. The circumstances can include acute worsening, unconsciousness, or excessive engagement of the family, all of which make the consent process more complex and require a rapid clinical intervention.

Jinnah Postgraduate Medical Centre (JPMC), Karachi, is a large tertiary care hospital in Pakistan that receives obstetric and gynecological cases with high complexities, referred by primary and secondary healthcare facilities, home deliveries, and other institutions in the Sindh area and beyond, including the Balochistan region. Although the patient load and clinical complexity are high, there is not much local data that addresses the obstacles to effective informed consent in obstetrics and gynecology units. The factors that drive informed consent practices are thus important to understand, as clinical decisions in such specialties have far-reaching implications. The beliefs and emotional vulnerability of the culture, as well as the medical complexity, are powerful influencers of patient understanding and autonomy. Understanding the current issues and effective interventions to enhance informed consent can be used to fine-tune the communication strategies and minimize the risks, enhance maternal and gynecological outcomes, and improve the overall quality of care. This study aimed to determine the factors that affect informed consent practice in the gynecology and obstetrics practices.

Methodology

This descriptive cross-sectional study was based in the Department of Obstetrics and Gynecology in Jinnah Postgraduate Medical Center in Karachi, and it was conducted over a six-month time duration between 1st August, 2024 to 31st January 2025. The study received ethical approval from the Institutional Review Board of JPMC with approval number: No.F.2-81/2024-GENL/12/JPMC dated: 29th-07-2024.

The formula used to calculate the sample size was Epi-Info software version 6 with a prevalence of 58.3%, a margin of error of 5%, and a 95%

confidence level.(20) The estimated sample size based on these parameters is 384 participants. Non-probability consecutive sampling was applied to recruit the participants. Potential patients were determined on the day of admission to the hospital and were recruited and interviewed on the second day of hospital admission or on the first day of postoperative, as necessary. All participants signed an informed consent before enrolling. Those who could not read or write were provided with the verbal consent that occurred in the presence of a witness, and consent was noted by means of thumb impressions.

The patients were aged 18 years and above because this is the legal age of informed consent as specified by Pakistani law. They were eligible to participate in both major and minor obstetric and gynecological surgeries, such as cesarean sections, obstetric and gynecological hysterectomies, laparotomy, debulking surgery, myomectomy, endometrial sampling, dilatation and evacuation, manual vacuum aspiration, and vaginoplasty. The study also involved patients who undergo medical procedures, including antibiotic treatment, blood transfusions, and intravenous iron infusion. Patients whose cognitive impairment or altered consciousness was known were excluded to ascertain that they could give a valid informed consent. Moreover, patients who were under 18 years old, showed severe illnesses, as well as patients with gross communication difficulties, such as deaf and mute individuals, were not eligible as participants.

The structured, predesigned questionnaire was used to gather the data and was created based on the recommendations of related literature and adapted to the aims of the study. It was carried out by a face-to-face interview filled out by trained researchers at the Department of Obstetrics and Gynecology. Eligible participants were contacted either on the second day of admission to the hospital or on the first postoperative day when they were well enough to undergo the interview. Interviews were done in a language that the participants could understand (Urdu or local language) to guarantee proper understanding and quality responses.

The questionnaire consisted of four major sections. The initial part gathered socio-demographic data, such as age, marital status, occupation, educational level, and the person who signed in informed consent. The second part evaluated obstetric and gynecological features such as parity, past cesarean section, vaginal birth, or gynecological surgery, whether the cesarean section was determined after the beginning of labor, and the type of intervention or management, which was either an elective section or an emergency.

Attitudes and awareness of patients and relatives concerning essential aspects of the informed consent procedure were evaluated in the third section. The participants were questioned about whether they knew what kind of surgery or medical intervention was performed on them, what signs and symptoms might occur, what outcomes would they expect, what other option of treatment existed, what length of stay in the hospital is anticipated, what will happen when they do not have the procedure or the medical management, and what kind of anesthesia should be provided. It also determined in this section whether the participants were able to ask questions, whether they were given sufficient time to sign the consent form, and the health care provider who administered the surgical informed consent, including the admitting surgeon, any doctor in the unit, or the nursing or paramedical staff.

The last section considered the issues related to patients who did not sign the informed consent form directly. These reasons were the language barrier, the lack of time, the use of difficult medical terms, cultural or traditional, education level, the improper timing of obtaining consent, and whether the patient was sufficiently informed or requested consent. Data on whether informed consent was obtained in written form was also noted.

A composite scoring procedure was used to evaluate the adequacy of informed consent in terms of seven main elements, namely provision of information about the nature of the procedure, risks involved, the anticipated benefit, alternative options, anesthesia type, the ability to pose questions, and the ability to make a decision. The participants were asked to either respond positively or not to each component, and this was scored as 1 or 0, respectively. All seven components were added together to produce a total score for every participant. Those whose total score was 7 were considered to have received adequate informed consent (1), those with a sum below 7 were considered to have inadequate informed consent (0). This method offered a standardized and objective way of assessing the completeness of the informed consent and allowed the analysis of factors that were related to the insufficient consent in the obstetrics and gynecology environment. The answers were recorded immediately to reduce recall bias, and the data collection procedure ensured that all participant information was kept confidential.

The Statistical Package of Social Sciences (SPSS) version 26 was used to enter and analyze the data. (IBM Corp., Armonk, NY). The Shapiro-Wilk test was used to determine the normality of continuous variables like age. Data with normal distribution were summarized as mean and standard deviation, and non-normally distributed data were summarized as median and interquartile range. Socio-

demographic variables, obstetric and gynecological disorders, elements of the informed consent process, and variables related to the non-self-signing of the consent form by patients were given in the form of frequencies and percentages. The relationship between the informed consent practices (e.g., informed about the nature of procedure, risks, benefits, alternatives, and type of anesthesia) and

independent variables (age group, level of education, parity, type of procedure (elective vs. emergency), and who signs the consent) were evaluated with the use of the chi-square test and fisher exact test. The effect modifiers were treated with stratification, and post-stratification chi-square analysis was conducted to adjust for potential confounding variables. A p-value ≤ 0.05 was taken to be statistically significant.

RESULTS

The participants comprising the study were 384, with an overall mean age of 31.5 years. Most of the respondents were married (around 89%), and a smaller percentage were single (11%). In terms of occupation, the majority (58%), but not all (23%), earning and unemployed persons (9%), students (8%), and retired persons (3%) were all housewives. Regarding education level, approximately 28 percent had primary education, 26% secondary education, 21% intermediate/higher education, and almost 25% were illiterate. Participants spouses (85.6%), followed by parents (6%), siblings (5.5%) and children (3%) were the most common signers of the consent form. (Table 1)

Table 1. Socio-demographic characteristics of study participants (n = 384)

Variable	Category	n (%)
Age (years)	Mean $\pm$ SD	31.47 $\pm$ 8.6
Marital status	Married	343 (89.3%)
	Single	41 (10.7%)
Occupation	Earning	87 (22.7%)
	Housewife	222 (57.8%)
	Retired	11 (2.9%)
	Student	30 (7.8%)
	Unemployed	34 (8.9%)
Educational status	Cannot read or write	95 (24.7%)
	Primary (1–5 years)	108 (28.1%)
	Secondary (6–10 years)	100 (26.0%)
	Intermediate and above (>10 years)	81 (21.1%)
Consent form signed by	Spouse	329 (85.6%)
	Parent	23 (6.0%)
	Child	11 (2.9%)
	Sibling	21 (5.5%)

The participants were mostly multiparous (58%), whereas a minority (42%) were primiparous. Over half of the respondents (56%), had a history of prior cesarean section or vaginal delivery, or gynecological surgery. In 59% of the cases, cesarean section was determined after the onset of labor. Regarding the type of surgery or medical management, slightly over half of the procedures were emergency interventions (56%), while 44% were elective. (Table 2)

Table 2. Obstetric and gynecological characteristics of respondents (n = 384)

Variable	Category	n (%)
Parity	Primiparous	163 (42.4%)
	Multiparous	221 (57.6%)
Previous C/S, vaginal delivery or gynecological surgery	Yes	213 (55.5%)
	No	171 (44.5%)
Cesarean section decided after onset of labor	Yes	217 (58.5%)
	No	167 (43.5%)
Type of surgery / medical management	Elective	170 (44.3%)
	Emergency	214 (55.7%)

Participants were aware of the important elements of informed consent in different aspects. It was found that about 49% of the respondents were educated on the nature of the surgery, and about 60% of the respondents were aware of the reasons to have surgery. Only slightly more than half (55% and 56% respectively) knew about potential complications and the anticipated hospital stay. Participants had comprehended the information on other forms of treatment (31.8%), as well as the potential complications in case the surgery or management was not carried out (58%). Only 58% of the participants stated that they were aware of the benefits to be expected of the procedure.

More than half of the participants (53%) had a chance to pose questions about their care. (Table 3)

Table 3. Awareness regarding essential components of informed consent (n = 384)

Consent component	Yes n(%)	No n(%)	Don't know n(%)
Informed about nature of surgery	189 (49.2%)	132 (34.4%)	63 (16.4%)
Informed about indication for surgery	230 (59.9%)	106 (27.6%)	48 (12.5%)
Informed about possible complications	210 (54.7%)	115 (29.9%)	59 (15.4%)
Informed about expected length of hospital stay	213 (55.5%)	116 (30.2%)	55 (14.3%)
Informed about alternative treatment options	122 (31.8%)	218 (56.8%)	44 (11.5%)
Informed about complications if surgery/management not done	221 (57.6%)	106 (27.6%)	57 (14.8%)
Informed about expected benefits	223 (58.1%)	96 (25.0%)	65 (16.9%)
Given opportunity to ask questions	202 (52.6%)	127 (33.1%)	55 (14.3%)

Other practices regarding informed consent among the participants revealed that 56% of the participants were informed of the nature of the anesthesia, 29% were not, and 15% were uncertain. Most respondents (38%) said that they were not provided with sufficient time to sign the consent form, and 62% did not. In the case of the personnel administering the surgical informed consent, any doctor in the unit (83.5%), and a nurse or paramedic (16.5%), were the responsible administrators of the consent. (Table 4)

Table 4. Additional informed consent practices (n = 384)

Variable	Category	n (%)
Informed about the type of anesthesia	Yes	216 (56.3%)
	No	112 (29.2%)
	Don't know	56 (14.6%)
Given adequate time to sign the consent	Yes	146 (38.0%)
	No	238 (62.0%)
SIC administered by	Any doctor in the unit	321 (83.5%)
	Nurse/Paramedic	63 (16.5%)

It was found that a number of factors were impediments to the signing of the informed consent by the patients themselves. The issue of language barrier was experienced by 35% of participants, and the lack of adequate time to conduct the consent process was highlighted by 42%. Medical terms were an issue to 39% of respondents, and 40% of the respondents were affected by cultural or traditional factors. Also, 39% were found to have a better educational status, 42% reported the wrong time during which the consent was taken, and 34% were not informed or even asked to give their consent. (Table 5)

Table 5. Factors associated with patients not signing informed consent themselves (n = 384)

Factor	Yes n (%)	No n (%)
Language barrier	135 (35.2%)	249 (64.8%)
Insufficient time allocated	162 (42.2%)	222 (57.8%)
Use of medical terminology	148 (38.5%)	236 (61.5%)
Cultural/traditional reasons	154 (40.1%)	230 (59.9%)
Better educational status	148 (38.5%)	236 (61.5%)
Inappropriate timing	161 (41.9%)	223 (58.1%)
Not informed or not asked	131 (34.1%)	253 (65.9%)

Among the study participants, all the participants (100%) reported that written informed consent had been obtained. However, when assessing the adequacy of the informed consent process, majority 65.1% of participants received adequate consent, whereas (34.9%) had inadequate informed consent. (Table 6)

Table 6. Status of Written and Adequacy of Informed Consent among Study Participants (n = 384)

Variable	Category	n (%)
Written informed consent taken	Yes	384 (100%)
	No	0 (0%)
Informed Consent	Adequate	250 (65.1%)
	Inadequate	134 (34.9%)

Overall, written informed consent was obtained from all study participants; however, the quality of the consent process varied substantially. While a considerable proportion of participants demonstrated adequate informed consent, more than one-third were found to have an inadequate understanding, indicating deficiencies in the depth and effectiveness of the consent process despite formal documentation. This finding highlights that the presence of a signed consent form does not necessarily reflect meaningful patient comprehension. Stratified analysis revealed no statistically significant association between adequacy of informed consent and key sociodemographic or clinical variables, including age, educational status, parity, occupational status, prior surgical history, type of procedure, or the individual signing the consent. Adequate consent practices were relatively consistent across all strata, suggesting that deficiencies in informed consent were systemic rather than confined to specific patient subgroups. Notably, adequacy was comparable between elective and emergency procedures, as well as between patients who signed consent themselves and those whose consent was obtained from relatives. (Table 7)

Table 7. Stratified analysis showing association between adequate informed consent practice and selected variables after controlling for effect modifiers (n = 384)

Effect modifier	Stratum	Adequate consent n (%)	Inadequate consent n (%)	χ ² value	p-value
Age group (years)	≤30	120 (64.9%)	65 (35.1%)	17.103	0.929
	>30	130 (65.3%)	69 (34.7%)		
Educational status	≤ Secondary education	175 (64.8%)	95 (35.2%)	1.396	0.762
	≥ Intermediate & above	75 (65.8%)	39 (34.2%)		
Parity	Primiparous	140 (64.5%)	77 (35.5%)	0.191	0.727
	Multiparous	110 (65.9%)	57 (34.1%)		
Type of procedure	Elective	110 (64.7%)	60 (35.3%)	0.152	0.738
	Emergency	140 (65.4%)	74 (34.6%)		
Person signing consent	Self	115 (63.2%)	67 (36.8%)	3.362	0.434
	Relative (parent/spouse/other)	135 (66.2%)	67 (33.8%)		
Occupation	Earning	50 (57.5%)	37 (42.5%)	4.632	0.227
	Non-earning	200 (67.2%)	97 (32.8%)		
Previous surgery history	Yes	135 (63.4%)	78 (36.6%)	1.262	0.308
	No	115 (67.3%)	56 (32.7%)		
Chi-square test applied to calculate p-values p≤ 0.05 is considered significant.					

DISCUSSION

In the present study, despite written informed consent being obtained from all participants, only 65.1% fulfilled the criteria for adequate informed consent. This finding highlights a substantial gap between formal documentation and patients' actual understanding of essential information related to their care, indicating that consent was often procedural rather than truly informed.

Similar challenges are highlighted by a number of local Pakistan studies. A cross-sectional study of tertiary care hospitals in Karachi has stated that there was optimal adherence to international informed consent requirements along with information

delivery and documentation.(21, 22) Similarly, a study at Hamdard University Hospital reported that although nearly all women had been asked for consent, a significant percentage were not aware they could refuse to give such consent, were not told about risks or choices, and that most consent forms were not signed by patients themselves but by their husbands.(23) The results are consistent with our findings, in which a high percentage of women were not given sufficient explanations, and a significant percentage of women did not sign the consent themselves, which denotes the enduring tendencies of low levels of patient autonomy and communication in the Pakistani OB-GY environments.

Low levels of patient knowledge and informed consent processes are also evidenced by comparative data from other low and middle-income countries (LMICs). In Ethiopia, fewer than half of women were found to have good knowledge of surgical informed consent, with residence, education, elective versus emergency service, and prior surgery all having an effect, with even classifications of good knowledge remaining below optimal levels.(24) Similarly, a cross-sectional study conducted in Jimma Medical Center revealed that low surgical informed consent understanding was associated with low satisfaction and poor patient-provider relationships.(25) These results indicate more general difficulties in LMICs where the quality of consent is non-proportional to educational, sociocultural, and systemic factors, which supports our high levels of insufficient consent despite documentation.

The Middle East reports are regional studies, which report both mixed findings and deficiencies. A recent Saudi Arabian cross-sectional study assessing surgical informed consent in obstetric and gynecology units indicated that there was inadequate consent in the way it was obtained and comprehended by the patients, especially in cases of emergency and elective cases, which demanded better patient communication and system-based support in consent discussions.(26) Although specific percentages varied, the motif of partial information delivery and problems with patient understanding resonates with the findings of our work.

The international literature underlines the fact that informed consent continues to be a problem even in a high-resource environment. An international survey of gynecological oncology nurses in Germany, Austria, and Switzerland found significant barriers, such as time pressure, language, and lack of resources to educate patients, among others, to affect the effective consent discussion, which are also reflected in our population.(27) Surgical systematic reviews around the world support the idea that poor understanding of consent content is a common phenomenon, regardless of documentation habits, and that measurement instruments may not be sensitive to how well patients understand the risks, benefits, and alternatives.(28) The present study found comparable inadequacies as in Ethiopia and Pakistan, indicating that failure of informed consent is not limited to resource constraint, but also to practices and systems of consent.

Other studies have studied educational aspects of informed consent between clinicians and trainees. An examination of obstetrics and gynecology resident education in Saudi Arabia identified areas of training and confidence deficiency in the domain of consent discourse, which further indicates that the

preparedness of providers might be a factor in the inconsistent quality of informed consent.(29) Likewise, the international principles focus on shared decision making as a central element of consent in obstetrics and gynecology and emphasize the necessity of a structured training in communication and standardized consent delivery methods.

Such comparisons suggest that written consent is well documented but the spirit of informed consent, understanding as well as free will is often wanting in various situations. The factors that permeate low levels of consent quality include low literacy, cultural beliefs supporting family decision-making authority, inadequate time allocation, and clinician communication behaviors, which we have found and other studies repeatedly confirm. Both local and international evidence support the idea that to enhance informed consent in obstetrics and gynecology, more than administrative compliance is needed; patients and providers must be educated, consent deliberation structured, culturally competent communication developed, and patient autonomy the focus of system wide attention.

The main limitation of this research is that it is a cross-sectional investigation which limits the possibility of linking socio-demographic, obstetric, or procedural conditions with the sufficiency of informed consent. Also, the research was done at one tertiary care hospital thus the findings might not be applicable in other healthcare settings especially in rural or primary care hospitals. Self-reported answers on understanding consent can be influenced by recall bias or social desirability bias since respondents could exaggerate their understanding in order to look knowledgeable. In addition, less than 2 percent of the participants were chosen to give sufficient consent, limiting the statistical power in identifying associations during stratified analyses. Lastly, the communication style of providers and institutional consent policies that can affect the quality of consent were not directly measured in this study.

Conclusion

The present study indicates a significant difference between written consent and the true understanding and participation of patients in obstetrics and gynecology. All participants were given written consent (100%), but 65.1% of them were given a proper informed consent, which demonstrates ongoing failures in communicating with the patients, educating them, and empowering them. Poor listening was promoted by language barriers, lack of time, use of technical medical terms, and cultural distinctions. These results help focus on the necessity of patient-centered consent approaches, improved specialist education and cultural competence to achieve the real patient autonomy. The solution to these gaps is critical to ethical and legal mandates,

patient trust and satisfaction, and overall quality of obstetric and gynecological care.

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