

# Informed Consent in Surgical Patients Current Issues and Future Perspective

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## ABSTRACT

**Objective:** Informed consent is an essential and standard procedure in medical practice. The objective of the study was to evaluate the informed consent practices of surgeons at a university teaching hospital.

**Materials and Methods:** A prospective cross sectional study was performed between the time duration of February 2022 till June 2022 at surgical and allied units of Dow University Hospital, DUHS Karachi, Pakistan

**Results:** A total of 196 patients were interviewed on their first post-operative day at their bed side. Patients were selected randomly from all surgical and allied departments of Dow university hospital, including Gynecology(36.22%), General surgery(34.18%), orthopedics(16.33%), ENT (6.12%), urology (2.55%), eye (2.55%), neurosurgery(1.53%) and maxillofacial(0.51%). 39.8% patients gave consent themselves while rest 55.1% and 5.1% consents were given by family members and parents. Only 23.47% patients or the representative who signed the consent, read the consent form before signing it

**Conclusions:** To improve the quality of communication with the informed consent, a structured conversation helps physicians establish relationships with the patients, regarding the adequacy of the information provided.

**Keywords:** Surgical Patients, informed consent, communication

## INTRODUCTION

Informed consent (IC) is a procedure by which medical professionals communicate with patients, enabling them to make a knowledgeable decision related to the treatment of their disease.<sup>1</sup> Consent is the most important principal of good medical practice as stated by the General Medical Council.<sup>2</sup> Informed consent empowers patients in their decision making capability regarding their own health, hence strengthening patient's autonomy.[3,4] Due to increased public awareness, preoperative counselling and proper documentation are very important in dealing with consequences of any procedure.

Although the significance of informed consent process is emphasized and proven in clinical research, its efficacy and viability are always a concern. Comprehension, capability, and voluntariness related issues of surgical patients are evident worldwide.<sup>1-4</sup> It is the surgeons responsibility to council patient regarding the importance of procedure, its consequences, risks and benefits and what would happen If the procedure is not done. Taking informed consent could be challenging as it can aggravate the anxiety and fear of surgery related complications. Tough it may increase the chances of refusal from surgery but it is the patients right to be educated regarding the procedure he/she would be going through.<sup>5</sup>

A large number of patients are now interested in the decision-making regarding health care provision, especially where literacy rates are high. The phenomenon behind this change has been the increased knowledge about their rights.<sup>6</sup> According to a survey at developing countries like Pakistan, challenges related to informed consent for surgery, may have larger dimensions. Unfortunately, patients and their families are mostly given very little or inadequate information regarding the nature of their disease and proposed treatment.<sup>7-8</sup>

This study was designed to evaluate the current practice of taking informed consent in preoperative emergency and elective surgical procedures in a tertiary care and teaching hospital.

## METHODS

A prospective cross sectional study was performed between the time duration of February 2022 till June 2022 at surgical and allied units of Dow University Hospital, DUHS Karachi, Pakistan, after the approval from the Institutional Review Board, IRB-2034/DUHS/Approval/2021/452.

One hundred and ninety six patients, were interviewed during this study after written and informed consent. Patients were selected from surgical and allied units of Dow university hospital, including General surgery, Orthopedics, ENT, Plastic surgery, Gynaecology and Neurosurgery. A proforma was drafted all patients who underwent any emergency or elective surgical intervention where interviewed on their first post-operative day, regarding their reviews about informed consent. Unconscious patients and mentally handicapped patients were excluded.

The STATA version 14.2 was employed to retrieve the data and carry out pertinent statistical analysis.

**Analysis:** STATA 14.2 software was used for the purpose of analysis. Categorical variables are presented as frequencies and percentages, whereas continuous variables are presented as means and standard deviations. T-test and anova tests were used to compare continuous and categorical variables, while Chi-square were used to compare two categorical variables. A P-value less than 0.05 was considered significant.

## RESULTS

A total of 196 patients were interviewed on their first post-operative day at their bed side. Written and informed consent was taken before the interview and they were clearly advised that they can refuse for interview at any time of the interview and no effect would be there on their treatment if they refuse for being the part of this study. The mean age of the participants included in this study was 40.7 ± 17.0 years. Table 1 shows 88.78% of all the patients were married. Out of 196, 57.14% were females and 42.86% were males. Patients were selected randomly from all surgical and allied departments of Dow university hospital, including Gynecology(36.22%), General surgery(34.18%), orthopedics(16.33%), ENT (6.12%), urology (2.55%), eye (2.55%), neurosurgery(1.53%) and maxillofacial(0.51%).

82.65% were elective while rest of them were emergency cases. The education level of the patients included in this study were uneducated 19.39%, primary school 27.04%, middle school 18.37% and University /college 35.2%.

When asked about informed consent 51.02% patient selected the correct answer that it is a process in which a surgeon educates a patient about the risks, benefits, and alternatives of a given procedure or intervention. Out of these 43% were educated till university/hospital, 16% till middle school, 26% till primary school and 15% patients were uneducated. 95.92% patients said

that they were consented before surgery. 46.43% patients were taken both written and verbal consent while 38.78% were taken written consent only and 14.8% verbal consent only.

39.8% patients give consent themselves while rest 55.1% and 5.1% consents were given by family members and parent (in case of patient being a child), respectively. When they were asked the reason for not giving consent themselves, most of them (31.48%) replied that their respective family member has a better understanding as compared to them. While 38.19% said that there was no particular reason for not signing the consent themselves.

Mostly (66.84%) the consent was taken one day before surgery. Most of them were taken by surgery residents (55.1%) or house officers (34.69%).

Only 23.47% patients or the representative who signed the consent, read the consent form before signing it, while 71.43% did not read the consent form they signed and 5.1% said that they could not remember whether they read it or not.

Most of the patients said that the consent form was understandable (43.88%) and was in their mother tongue (78.57%). Those who could not understand the form (16.3%), no local translator was provided to most of them (54.84%).

46.9% of patients commented that their decision regarding surgery was influenced from this informed consent activity. In fact oral information influenced most of patient's decision (60.28%) as compared to written (6.38%) or both (33.33%). Patients were satisfied that they were informed about the diagnosis (85.2%), procedure details (80.6%) and alternate treatments (34.18%).

By the end of interview session patients were asked that whether each and every detail regarding there surgical procedure must be given to you by the doctor or not? 75.51% of Patients replied that yes they must be given detailed information. As according to 76.02% of the participants it gives them more relief regarding their health and does not cause any anxiety.

In Figure 1, participant's education level was compared with their ages, which was statistically significant with a P- value <0.001. This shows older patients in uneducated category while younger patients in educated category. While there was no significant difference in Patient's gender (P = 0.160) when compared with education level, as shown in Table 2.

Table 1: patient's reviews regarding informed consent.

	N=196	%
Marital status		
Married	174	88.78
Unmarried	22	11.22
Gender		
Male	84	42.86
Female	112	57.14
Department		
Oto-rhinology	12	6.12
Ophthalmology	5	2.55
General surgery	67	34.18
Gyneacology	71	36.22
Maxillofacial surgery	1	0.51
Neurosurgery	3	1.53
Orthopedics	32	16.33
Urology	5	2.55
Education level		
Uneducated	38	19.39
Primary school	53	27.04
Middle school	36	18.37
University /college	69	35.2
Type of surgery		
Elective	162	82.65
Emergency	34	17.35
1. What is informed consent?		
a. Just an agreement between surgeon and patient.	27	13.78
b. Dialogue between patient and surgeon regarding surgical procedure.	32	16.33
c. Permission taken by a surgeon for any surgical intervention.	37	18.88
d. Process in which a surgeon educates a patient about the risks, benefits, and alternatives of a given procedure or intervention.	100	51.02
2. Was consent taken from you before surgery?		
A. Yes	188	95.92
B. No	8	4.08
3. What form of consent was taken from you?		

a. Verbal	29	14.80
b. Written	76	38.78
c. Both	91	46.43
4. Who signed the informed consent		
a. Patient	78	39.80
b. Parent (if minor)	10	5.10
c. Parents	2	1.02
d. Patient's children	17	8.67
e. Husband	25	12.76
f. Relative	49	25.00
g. Siblings	15	7.65
5. Reason for not giving consent by the patient himself.		
a. Better understanding	34	31.48
b. Patient was in pain	15	13.89
c. The patient wasn't asked or informed to sign	7	6.48
d. Advised by doctor	9	8.33
e. Mutual understanding	3	2.78
f. Her husband wanted to sign the form	1	0.93
g. The patient says they always took consent from her husband. She did not know patient gives consent themselves.	1	0.93
h. No particular reason	38	35.19
6. How long before the surgical procedure have you received the informed consent?		
a. Just before	15	7.65
b. Some hours before	50	25.51
c. The day before	131	66.84
7. Who delivered the informed consent form?		
a. Surgery resident	108	55.10
b. House officer	68	34.69
c. Operative surgeon	8	4.08
d. Medical officer	5	2.55
e. Senior registrar	3	1.53
f. Staff	3	1.53
g. Don't know designation	1	0.51
8. Did you read the informed consent form before signing it?		
a. No	140	71.43
b. Yes	46	23.47
c. Don't know	10	5.10
9. Was the informed consent form understandable?		
a. No	46	23.47
b. Yes	86	43.88
c. Don't know	64	32.65
10. Was it taken in your mother tongue?		
a. No	32	16.33
b. Yes	154	78.57
c. Don't know	10	5.10
11. If no, was local translator available to facilitate the patient in understanding the given information?		
a. No	17	8.64
b. Yes	4	2.90
c. Don't know	10	5.10
12. How much time was spent in taking consent?		
a. 5-15 minutes	50	25.51
b. < 5 minutes	145	73.98
c. > 1 hour	1	0.51
13. Was the informed consent form explained during a conversation?		
a. No	79	40.31
b. Yes	106	54.08
c. Don't know	11	5.61
14. Did informed consent form and/or oral information influence the decision to proceed to the surgical procedure?		
a. No	92	46.94
b. Yes	85	43.37
c. Don't know	19	9.69
15. If yes, which one mainly influenced your decision?		
Oral information	85	60.28
Written ic form	9	6.38
Both	47	33.33
16. Were you informed about the diagnosis?		
a. No	25	12.76
b. Yes	167	85.20
c. Don't know	4	2.04
17. Were you informed about the details of procedure?		
a. No	29	14.80
b. Yes	158	80.61
c. Don't know	9	4.59
18. Were alternate treatments discussed?		
a. No	103	52.55
b. Yes	67	34.18
c. Don't know	13.27	13.27
19. Were the risks of surgery discussed?		
a. No	73	37.24
b. Yes	101	51.53
c. Don't know	22	11.22
20. Have you had the opportunity to ask any questions		

and have you obtained exhaustive answers?		
a. No	121	61.73
b. Yes	53	27.04
c. Don't know	21	10.71
21. Do you think each and every detail regarding your procedure must be given to you by the doctor?		
a. No	34	17.35
b. Yes	148	75.51
c. Don't know	14	7.14
22. Received information caused you		
a. More relief regarding your health	149	76.02
b. More anxiety regarding your health	37	18.88
c. No difference	7	3.57
d. Don't know	3	1.53
23. Do you think detailed knowledge regarding your procedure will increase the chances of refusal from surgery?		
a. No	150	76.53
b. Yes	19	9.69
c. Don't know	27	13.78

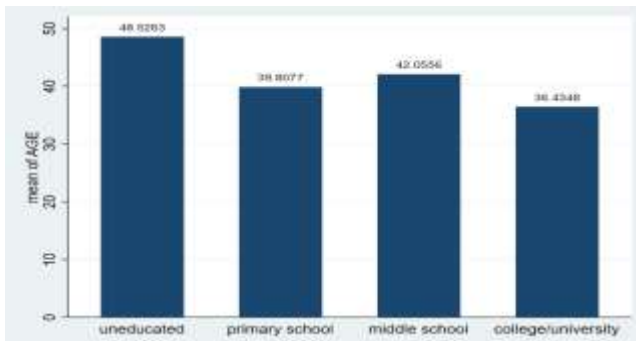


Figure 1: Graph showing comparison between education level and Patient's Ages.

Table 2: Comparison of education level with patient's Gender.

Category	N=196	Gender (n %)		p-value
		Female	Male	
Uneducated	38	21 (55.26)	17 (44.74)	0.160
Primary school	52	24 (45.28)	29 (54.72)	
Middle school	36	22 (61.11)	14 (38.89)	
College/university	69	45 (65.22)	24 (34.78)	

**DISCUSSION**

Complete information before an invasive procedure is an ethical requirement, and it is very important to involve the patient in decision-making regarding the treatment. Well-informed patients are generally more satisfied and file fewer legal claims. Conversely, patients who were not informed about the risks of surgery regretted the decision after the surgery.<sup>1</sup>

We interrogated patient's interest and concerns regarding the consent taken from them before their surgical procedure. Signing the consent form is the compulsory act before any surgical procedure. But do the patients are being informed regarding the risk and benefits of their surgery by their surgeon? Therefore, in our study the main limitation is that the patients are usually satisfied with verbal consent and don't bother to read the written informed consent.

Possible reasons for this attitude is that many patients showed minimal interest in the informed consent document, probably preferring to rely on the surgeon's expertise or they would not be able to understand.

Secondly, most of the patients received the form one day before the surgical procedure—but were not given enough time to

read and reflect on it. A probable reason for this is large patient population and shortage of time for the surgical team to explain each and every detail to the patient. Surgeons focus principally on the diagnosis and on the type of surgical procedure. A lower percentage of patients reported being informed about other aspects of the treatment, such as prognosis, consequences of a missed treatment or the possible surgical complications.

Studies has shown that detailed information increases anxiety among the pateints hence causing increased chances of refusal or surgery.<sup>9,10</sup> But our study revealed that most of the patients said that they must be given each and every detail regarding their procedure and complication. In fact it gives them more satisfaction and strengthens the trust on the surgical team.

In comparison to a previous similar study conducted at a rural tertiary care hospital that revealed 38% of the surveyed patients acknowledged that they actually understood the information imparted to them. while11% patients actually signed the consent forms themselves.<sup>7</sup> but our study showed better outcomes as 46.43% patients were taken both written and verbal consent while 38.78% were taken written consent only and 14.8% verbal consent only. While 39.8% patients gave consent themselves.

Furthermore, patients who had required intensive care or had been brought back into surgery were excluded. Therefore, the results would not be generalized to patients in more severe settings.

**CONCLUSION**

To improve the quality of communication with the informed consent, a structured conversation helps physicians establish relationships with the patients, facilitates the documentation and offers a valid legal proof for patients and physicians regarding the adequacy of the information provided.

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