

Status of Informed Consent in Surgical Patients in Hospitals of Sindh Pakistan

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ABSTRACT

Background: Informed consent (IC) is a critical step in ensuring that patients understand implications of their treatment decisions.

Materials and Methods: It is observational cross-sectional study. Non probability purposive sampling was used to collect data from different surgical units. Adult postsurgical patients were questioned using a standardized questionnaire between the first- and fifth-day following surgery in two general hospitals in Sindh province (Hyderabad and Jamshoro). Data was analyzed using SPSS and Microsoft excel.

Results: A total of 78% of individuals who claimed to have read it found informed consent to be easy to understand. Less than half of patients thought information brought them some emotional solace, while 23.2% of patients reported feeling more anxious after hearing information. This study suggests enhancing the process of obtaining consent forms by including additional information and avenues for discussion on written documents rather than relying solely on verbal communication.

Conclusion: Patients under age of sixty and patients who had completed more schooling tended to read written informed consent forms more frequently. Orally communicated pre-operative information suited patients' requirements better than written informed consent. Surgeon needs to get informed permission from patient and inform them about operation type, potential consequences and other treatment options.

Keywords: Informed consent, Medical Ethics, Surgery, Hospital, Surgeons, Health, Sindh.

INTRODUCTION

The interaction that takes place between a doctor and a patient during informed consent (IC) is what enables the patient to make an informed decision about the treatment of his or her illness.¹ The first recorded instance of an IC trial can be traced back to Germany and took place in the year 1900. In subsequent years, in 1964, the World Health Organization established the Declaration of Helsinki with 22 preconditions for research involving human subjects.² The concept of informed consent has been instrumental in empowering patients to take an active role in the decisions that pertain to their own health.³ The importance of obtaining informed consent stems from the desire to respect the patient's autonomy.⁴ Even though the significance of the informed consent process in clinical research is emphasized and has been demonstrated, there is still a concern regarding its efficiency and validity. In the international literature, questions concerning the knowledge, comprehension, and volitional involvement of research participants frequently arise.⁵ It's possible that issues surrounding informed consent have larger-scale implications in developing countries.⁶ Un-fortuitously, in the practice of hospital medicine in our system, patients and their families are typically given very little information or information that is insufficient regarding the nature of their illness and the treatment that is being proposed.⁷ In spite of these benefits, a good number of surgeons in Pakistan probably obtain consent with a feeling of unease. Since it may be difficult to satisfy all of the ethical and legal requirements for informed consent all of the time, this indicates that the required transparency principle is frequently not implemented properly.

This study's objective was to assess the present informed consent method in two tertiary care teaching hospitals in Jamshoro and Hyderabad for patients undergoing various surgical operations.

MATERIAL AND METHODS

Study setting: This study was conducted at different surgical units (General surgery, Obstetrics and Gynecology, Orthopedics and Urology) of Liaquat University Hospital (LUH) Hyderabad/Jamshoro.

Study design: Observational Cross-sectional Study

Sampling technique: Non probability purposive sampling

Sample size: For the objective of the study, sample size was calculated by using empirical formula and the largest sample size calculated was 150.

$$n = Z^2 (P) (q)$$

d2 Z value at 95% of confidence level (%) = 1.96 P = estimated prevalence = 0.89

$$q = 1 - p = 0.11$$

$$d = \text{margin of error} = 0.05$$

Inclusion criteria

- Aged > 18 years
- Surgical patients who undergone emergency and elective surgical procedure
- Patients who participated in the study by will
- Mentally alert and conscious patients

Exclusion criteria

- Patients under 18 years
- Unconscious patients
- Mentally retarded patients

Data collection procedure: The participants who fulfill the inclusion criteria were enrolled. The included study participants were educated regarding the study, its aims and objectives and they were made to sign and informed consent Performa.

Between the second and the seventh day following the surgery, all patients recruited in all surgical units of LUH Hyderabad/Jamshoro were interviewed using a standardised questionnaire created following a thorough literature search.

All patients were interviewed in a way that protected their privacy and ensured the confidentiality of their responses. A survey was conducted at a tertiary care Teaching Hospital between January 2021 and March 2022. Participants were selected from patients over the age of 18 years who had under gone elective or emergency surgery in the departments of general surgery, Obstetrics and gynecology, orthopedics and urology. Permission was obtained from the unit Head of each ward. Patients were interviewed in the immediate post-operative period, once they were deemed comfortable to answer the interviewer questions. Patients, who were unwell or uncomfortable because of pain in other immediate post-operative complications, were not interviewed. All interviews were based on structured questionnaire

Data analysis: Each and every response was screened, cleaned up, coded, and entered into the SPSS programme. Averages and

standard deviations were used to assess the quantitative variables. The tables with absolute(n) and relative(%) frequencies showed the categorization variables. The SPSS version 23.0 programme was used to facilitate the statistical analysis. For the analysis, P values less than 0.05 were deemed statistically significant.

RESULTS

A total of 150 participants; 83 male and 67 female patients participated in this study. Table 1 shows the socio-demographic characteristics of the study population with just 28% of the patients were over the age of 60 years, 63% were married and 10% had graduated, 55% of the patients were unemployed and 59% were from the low socioeconomically background.

Table 1: Sociodemographic Characteristic of Study Population

Variables	Frequency (n= 150)	Percentage (%)
Age Groups		
18-25	21	14
26-40	38	25
41-60	49	33
> 60	42	28
Sex		
Male	83	55
Female	67	45
Education		
Illiterate	42	28
Primary education (class 1 to 10)	61	41
secondary education (class 10 to 12)	32	21
Higher education (graduation)	15	10
Marital status		
Single	55	37
Married	95	63
Occupation		
Employed	68	45
Unemployed	82	55
Residence		
Jamshoro	71	47
Hyderabad	79	53
Socio Economic Status		
Low	88	59
Moderate	62	41

150 patients were recruited from 4 different surgical departments, almost 50% of the patients were from general surgery and 25% from Obs/Gyni department. Among nature of surgical procedures elective cases were about 55% (Table 2).

Table 2: Surgical Characteristics of Study Population

Variables	Frequency (n=150)	Percentage (%)
Type of Surgery		
General surgery	75	50
Orthopedic	22	15
Gyn/Obs	37	25
Urology	16	11
Nature of Surgery		
Elective	82	55
Emergency	68	45

The majority of respondents (73%) either stated that they directly received a written IC form or that it was given to a parent or a relative. The remaining 5% could not recollect receiving it, while 21% said they did not receive it. Only 27% of the patients who received the IC form reported reading it thoroughly. Of those who did read it, 78% found it to be clear, and 22% thought it was only somewhat understood. All of the patients who signed the IC form

either personally or through a parent or relative. Nobody thought it was illogical. A day before surgery, 35% of patients got the return IC form, whereas about half of them did so right away. Only 21% of patients who received written forms from the surgeon who carried out the operation did so (Table 3).

Table 3: "Modalities of acquisition of written IC (n = 150)

Modalities	Frequency (n=150)	Percentage (%)
Have you received a written IC form?		
Yes 110	73	21
I don't know / I don't remember	32	
No 8	5	
Who signed it?		
Patient	64	43
Attendant	86	57
Did you read it?		
Yes 41	27	
No, I did not want	65	43
No, due to lack of time	28	17
Partially/ Distractedly	16	11
Was it understandable?		
Yes 32/41	78	22
Partially	9/41	
No 0/41	00	
Time before the surgery		
Immediately before	53	35
Some hours before	22	15
The day before	68	45
> 1 day	03	02
They can't remember	04	03
Who delivered it?		
Operative surgeon	31	21
Other surgeon/PG	62	41
Nurse 23	15	
Anesthetist	32	21
Administration	12	08
I don't remember	22	15

Less attention was paid to the prognosis (23%), postoperative progress (15%), anaesthesia type and complications (19%), and the existence of alternative programmes (14%) than to the diagnosis, which was disclosed to (97%) of the patients, and the type of surgical technique (88%) (Table 4).

Table 4: Type of information delivered by Surgeons (n =150)

Information	Patients informed	Percentage (%)
Diagnosis	145	97
Type of surgery	132	88
Prognosis	34	23
Post-operative complications	22	15
Anesthesia type/Complications	28	19
Alternate Treatment Options	21	14

DISCUSSION

Patients who are better educated tend to report higher levels of satisfaction and make fewer legal claims.⁸ On the other hand, patients who did not get adequate information regarding the dangers associated with surgery expressed post-operative remorse.⁹⁻¹³

In this study, we investigated the four factors—delivery, signature, reading, and comprehensibility—that contribute to the appropriate usage of written IC forms. Delivering something and signing it are official and necessary requirements in order to comply with legislation. Reading and being able to understand what's being said are two of the most important steps in bringing the patient up to speed on the risks and benefits of the practical intervention. According to the findings of our research, the most significant limitation of the written IC procedure is that practically all patients were given the document and had to sign it, but only half of them read the document carefully. Possible explanations for the findings include the following: first, the

majority of patients had a low level of interest in the IC document, most likely because they preferred to rely on the knowledge of the surgeon or because they feared they would not be able to grasp it. In the course of our research, we found that patients who had completed a greater level of education were more likely to read the IC form.

Patients have stated that when giving oral instructions, surgeons tend to concentrate primarily on the diagnosis and the specific type of surgery; a lower percentage of patients reported receiving information about other treatment-related topics like the prognosis, the repercussions of skipping a treatment, or potential surgical complications. This observation is consistent with other authors' findings.^{14,15} Patients who participated in our survey claimed that during oral explanations, surgeons tended to concentrate mostly on the diagnosis and the kind of surgical treatment. There was no information provided on any defects in the institutions' specialized diagnostic tools or biological equipment that would have decreased the level of safety for the operations as a whole.

CONCLUSION

Consent form in our set up is not that much advanced that it can satisfy the patient's queries. Patients under the age of sixty and patients who had completed more schooling tended to read written informed consent forms more frequently. Orally communicated pre-operative information suited the patients' requirements better than written informed consent. The vast majority of patients in Jamshoro and Hyderabad Sindh are pleased with the treatment that they have been given and they actually do not know the meaning of consent form. The surgeon needs to get informed permission from the patient and talk to them about the type of operation, any potential consequences, and any other treatment options. Surgeons should also place a greater emphasis on the use of photographs and films that explain the process of surgery as well as other potential alternatives.

Ethical approval: This study was conducted after the approval by Research Ethics Committee LUMHS Jamshoro Letter No. LUMHS/REC/-955, Dated 30-01-2020.

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