



Original Article

Awareness of Post-Operative Patients Regarding Informed Consent Form in Public Tertiary Care Hospital of Peshawar Khyber Pakhtunkhwa: A Cross Sectional Survey

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ABSTRACT

The informed consent form is one of the components of bioethics. Written consent from the patient must be obtained prior to any medical or surgical procedure to give the patient freedom of choice. This factor has always been neglected when caring for patients in most third world countries. **Objective:** To assess postoperative patient awareness of informed consent at Peshawar KP Tertiary Public Hospital (HMC). **Methods:** This study was conducted from April 2021 to August 2021 at Hayatabad Medical Complex, a tertiary care public hospital in Peshawar. A total sample of 70 patients was drawn by consecutive selection. An adopted and pre-tested questionnaire was used for data collection. Questions were filled in by having the patient understand the question and receiving the answer from the patient. **Results:** The majority (59%) of the patients included in this study were male, while the mean age was 35 years and the majority of the patients (44%) were illiterate. Awareness of variables (2-7) was 60%, 47%, 30%, 47%, 69%, and 53%, respectively, while awareness levels from questions 8-12 were 59%, 47%, 82%, 40%, and 60%, respectively. **Conclusions:** The results of the current study indicate that the perception of informed consent among patients in tertiary care public hospitals is reasonably satisfactory, although some lack of participant knowledge of key issues has been identified and needs to be improved through education and awareness.

INTRODUCTION

Informed consent is a process that flows from the interaction between the health care provider and the patient [1]. Informed consent is an essential part of health care; it is defined as consent by the client to a proposed medical or surgical procedure, and it is the basic right of the client to get information about the relevant facts, risk and benefits of the procedure that is planned for the client. Informed consent is the due right of client as well as the patient's attendant; they need to be well informed about

what will happen after or during the surgery and any other surgical or medical procedure [2]. Giving the patient the freedom to choose is goal of informed consent. Patients can experience a lot of stress during the decision-making process, and the goal of informed consent is to help them make good decisions [3-5]. Autonomy of a client is an integral part in the health care facility [6]. A patient's informed consent is more than just signing a form. It involves the patient and the healthcare provider

exchanging information, which is necessary for medical treatment and research [7, 8]. Ever since the revelation of Nazi war crimes about half a century ago, informed consent has become an essential component of human subject research in the West. This holds true at least in theory, if not in practice. East is expected to follow the lead of the West in ethical principles and research, both being driven and lead by the western researchers [9]. Unfortunately, like other countries in the world especially the advanced, the situation is not praise worthy in Pakistan. In our healthcare setting, providers simply ask patients to sign informed consent forms for planned surgery. The consent form contains a night shift note "I am ready for surgery and all kinds of anesthesia." Nurses and doctors do not provide adequate information to patients about surgical or medical procedures, the possible benefits and risks of those procedures, and the type of anesthesia the client needs [10]. If it is evident that the patient was not properly informed, nurses must also step in. In this scenario, the nurse may inform the doctor, request additional information from the patient, or postpone a procedure until the patient is able to make decisions on their own [11-13]. Many factors contribute to the inability of patients to obtain adequate consent. One of these factors is language. Most patients admitted to the ward are illiterate and do not understand what is written on the informed consent form. A second major factor is the dominant behavior of clinicians, including physicians and surgeons. They don't want to be questioned by their patients. Patients usually don't want to hear bad news, and doctors tend to stick to the same clever explanations used in clinical practice [9]. In order to ensure that the procedures required for informed consent are carried out appropriately, it is essential for all medical professionals not just nurses to possess sufficient ethical and legal knowledge regarding informed consent, to be sensitive to the subject, and to comprehend their roles and responsibilities [14, 15]. To our knowledge, no such study has been conducted in Khyber Pakhtunkhwa to investigate patient awareness of informed consent in Peshawar public hospitals.

METHODS

A cross-sectional survey design was used to achieve the study objectives from April 2021 to August 2021. All the patients who have gone through surgical procedures in tertiary care hospitals were our study population. The sample size was calculated and estimated with a 95% confidence interval of 70 patients. Patients were selected consecutively from the surgical department of Hayatabad Medical Complex undergoing surgical intervention. Pre-design and validated questionnaires were used for data collection that was checked for validity from the experts

and a pilot test for the survey. The study objective and purpose was explained to each patient before consent. After understanding the question, I asked them to tick the options. We stayed with the patients until all questions had been answered and each questionnaire lasted at least 15 minutes for each patient. Inclusion Criteria: All patients undergoing surgical intervention were included in the study, regardless of age or gender. All patients with medical problems who were unwilling to participate in the study were excluded from the study. Data were analyzed using SPSS version 16.0. Frequencies and percentages were calculated for categorical variables and mean and standard deviation were calculated for continuous variables. A chi-square test was applied to check for associations between categorical variables.

RESULTS

In the current study the number of male patients were higher than female participants, and table 1 shows all the demographic characteristics of the study participants (table 1).

Characteristics	Numbers N=70
Gender	
Male	41(58.6)
Female	29(41.4)
Age	
Mean \pm SD	35.5 \pm 14.8
Marital Status	
Married	49(70)
Unmarried	21(30)
Qualification	
Nil	31(44.3)
Matric	12(17.1)
FA/Fsc	13(18.6)
Graduate	8(11.4)
Master & Above	6(8.6)
Socio Economic Status	
Poor	28(40)
Middle Class	33(47.1)
High Class	9(12.9)

Table 1: Demographic data of the participants

Table 2 shows the level of responses of the participants regarding informed consent, while the frequency and percentage of all the 13 items of the questionnaire were received. The knowledge level regarding variables 2, 4, 6, 8, 10 and 12 of the patients was found to be satisfactory whereas the knowledge level of the patients regarding variables 3, 5, 9 and 11 was found to be low and unsatisfactory (table 2).

S.No	Variable	Yes (%)	No (%)
1.	Have you been operated?	100(100%)	00(00%)
2.	Did your doctor give you adequate information about your operation?	42(60%)	28(40%)
3.	Were you aware of your surgeon name before operation?	34(47%)	36(53%)
4.	Were you told about the type of surgery?	49(70%)	21(30%)
5.	Did the doctor/nurse explain alternative treatments	21(30%)	49(70%)
6.	Did the doctor/nurse explain the advantages and disadvantages of this surgery?	34(47%)	36(53%)
7.	Did the Doctor/Nurse explain you the importance of this procedure?	48(69%)	22(29%)
8.	Did the doctor/nurse explain the type of anesthesia required for the surgery?	38(53%)	32(47%)
9.	Did the nurse explain the risks and complications associated with anesthesia?	40(59%)	30(41%)
10.	How many hours before surgery did the doctor/nurse tell you not to eat?	34(47%)	36(53%)
11.	Have you been informed by your doctor/nurse about the time of the surgery	59(82%)	11(18%)
12.	Did your Doctor/Nurse inform you that for how long you will be under anesthesia for this operation / Procedure?	28(40%)	42(60%)
13.	Are you satisfied with the information provided by your doctor/nurse before signing the informed consent form?	42(60%)	28(40%)

Table 2: Responses of the participants regarding informed consent

Chi-square test was applied to see an association between two categorical variables. Some of the background variables were found to be associated with the knowledge level of the study participants. For example, marital status and variable-6 (Did your Doctor/Nurse tell you how many hours you will not eat before operation?) was found to be different across the two marital groups ($p=0.045$ less than the alpha-value). Similarly, a strong association was found between qualification and awareness of surgeon name before the operation ($p=0.005$ quite less than alpha) Furthermore, an association was found between socioeconomic status and the awareness of the participants regarding duration of anesthesia during operation ($p=0.009$) (Table 3).

S.No	Row variable	Column variable	p-value
1.	Marital status	Did your Doctor/Nurse tell you how many hours you will not eat before operation?	0.045
2.	Qualification	Were you aware of the surgeon name before operation?	0.005
3.	Qualification	Did the nurse/doctor tell you about the surgery?	0.034
4.	Qualification	Did the doctor/Nurse tell you about any other treatment option?	0.041
5.	Qualification	Did the doctor/nurse explain you the importance of operation?	0.025
6.	Qualification	Did the doctor/Nurse tell you the duration of anesthesia during operation?	0.005
7.	Socioeconomic status	Were you aware of your surgeon name before operation?	0.004
8.	Socioeconomic status	Were you told about the surgery?	0.025
9.	Socioeconomic status	Did the doctor/nurse tell you the pros and cons of the operation?	0.020
10.	Socioeconomic status	Were you told about the duration of anesthesia?	0.009

Table 3: Association of informed consent with selected variables

DISCUSSION

Patients in third world countries like Pakistan come to tertiary care hospitals generally are not aware of the informed consent before any surgical procedure. The current study which addressed almost thirteen questions regarding the informed consent form, the awareness about the informed consent form was found to be low. Regarding the questions 3, 5, 9 and 11 the knowledge level of the participants was low. In the rest of the questions, the knowledge level of the participants was comparatively better. The awareness regarding the process of informed consent is low among the patients. Similarly, study was conducted by Bhurgri and Qidwai in the Aga Khan University Hospital; community health center department which shows the same results where lack of awareness among the patients regarding the informed consent was observed. The awareness was found to be only 20% among the patients [16]. Patients' decision making regarding

treatment alternatives is totally dependent upon the medical and nursing staff. Whatever the advice comes from these personnel, the patients follow them. In the current study when the patients were asked whether they were told the alternative options, only 30% said that they were told about other treatment options. A similarly study was conducted by O'Dwyer et al., in Ireland where fifty nine percent of the patients understood the alternative treatment option. In this way results of this study can be compared to the international studies [17]. Every patient whether he/she gets treatment from public or private set up, to get information about the surgical or medical procedure or even a medical treatment. In the current study, the information given to them by their doctor or nurse was not adequate. Only thirty eight percent of the patients said they had been informed well about the procedure. A similarly study was conducted by Burns et al., in Adelaide; Australia to know whether the patients get

adequate information about the surgery. Majority of the patients were not satisfied with the information provided to them before surgery [18]. Patients have the right to be given full information regarding the risks and complications of the surgical procedure. In the current study, only 40% of the patients replied that they were given information about the risks and complications of the surgical procedure before the surgery was performed. Similar study was conducted in Auckland (New Zealand) where the patients felt a need that there must be specific information regarding the surgical procedure as well as the complication should be communicated to the patients by the senior doctors who undertake the surgical procedure [19]. Ethics is considered to be the backbone of medical profession. In advanced countries the patients are fully autonomous in making their decision regarding any medical or surgical procedure. The physicians have to abide by the rules of the institutions. In the current study the results show that either there is no implementation of ethical rules or the nurses and doctors don't bother to apply these in their clinical practices. Only 54% of physicians were aware that the consent process was regulated by law. More than half of the respondents (66%) were aware that a patient rights law had been passed in Croatia. There were no differences between different specialties ($p=0.638$). Only 38% of physicians were well informed about the consent collection process [20]. Physician and surgeon he provided detailed information to the patient 33% of the time, and the anesthesiologist 16% of the time he provided detailed information to her ($p \geq 0.05$ for all questions) that contradict the findings of our study. In the current study the response of the question regarding complication whether the patients were informed, majority of the patients were not aware of the complications of the surgical procedure. Only 26% said that were told before the operation regarding the complication of the surgical procedure. A similar study was conducted by Marasini *et al.*, in Nepal to examine knowledge, attitudes, and fears associated with surgical procedures. They were also asked about complications and the importance or necessity of surgery. 60% were aware of weighing risks and benefits. This means that patients in the third world countries are somehow aware of the ethics and ethical rules while going under surgical procedures [21]. Most of our population is not literate and they are not aware of the informed consent. They take it as a necessary component of the surgical procedure. It is the right of the patients that they should know about the surgery, the importance of the surgery and the risks and complication of the surgical procedure. In the current study, patient responses indicate that surgeons and nurses did not bother to give patients all the information about the surgery. A study was conducted

among male and female general practitioners in the Hyderabad district to examine perceptions of informed her consent. Surprisingly, awareness was found in 128 people (91.4%), but unfortunately only 64 people (45.7%) were practicing it. The remaining 76 of them (54.3%) did not practice at all. This shows that practitioners are aware of this but do not want to practice it [6]. People with low literacy rates cannot understand what is written in the consent form. However, if subjects engage in such behavior, their peers, relatives, or other close people should be consulted. The language should be concise so that the contents of the consent form can be fully understood.

CONCLUSIONS

The results of the current study show that awareness regarding the informed consent among the patients in public tertiary care hospitals is somehow satisfactory among the patients but it needs to be improved through education and awareness as in several important questions, there was lacking regarding the information given to them. Qualification and socioeconomic level of the participants were found to be associated with the knowledge of the participants.

Conflicts of Interest

The authors declare no conflict of interest

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