

Informed Consent from Uninformed Patients: A Dilemma

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ABSTRACT

- Objective** To assess the amount of information provided pre-operatively by the doctors/nurses to the patients undergoing surgery and to relate understanding of this information with the educational status of the patient and their anxiety levels.
- Study design** Descriptive study.
- Place & Duration of study** Surgical Units of Jinnah Postgraduate Medical Centre, Karachi, From November 2012 to April 2013
- Methodology** A set of standardized questions were asked relating to patient's knowledge about the informed consent process, their education level and its impact on the understanding of informed consent as well as the impact of language of the consent form on the patient's interpretation of the information provided.
- Results** Out of 291 patients, 168(58.1%) patients signed the consent form themselves. Two hundred eight two (96.9%) patients were aware of the type of surgery they had to undergo. Two hundred and nine (71%) patients knew that it was their legal right to have their consent taken by the doctor before any surgery. Fifty six patients understood the consent form completely. Out of 56 patients who understood the consent form, 39 individuals had an education level of at or above matriculation. Thirty three consents were taken by operating surgeon or residents that significantly decreased the anxiety level.
- Conclusions** Most of the patients were aware of the importance of consent process as their legal right. High education level improved the understanding of the process.
- Key words** Informed consent, Surgery, Education level.

INTRODUCTION:

It is generally accepted that valid consent must be obtained before providing invasive or risky treatment.¹ The principle of informed consent embodies the legal recognition of the right of the patients to make healthcare decisions affecting their well being.² This procedure is based on the patient's right that, after listening to the explanation decide to either proceed with the treatment or withdraw.³ The aim of informed consent for an elective surgery is to provide

information about the potential risks and benefits of surgery as well as availability of any alternative treatment. This information must be fully comprehended by the patient, irrespective of language barriers or one's educational status.⁴

The aim of this study was to assess the amount of information provided by the doctors to patients undergoing elective surgery at the general surgery wards and to relate the understanding of the information provided with the educational status of the patient and their anxiety levels.

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METHODOLOGY:

A descriptive study was carried out using a standardized questionnaire-based interview technique from November 2012 to April 2013 at the general

surgical units of the Jinnah Postgraduate Medical Centre, Karachi. All interviews were conducted in Urdu or other regional languages. The patient's knowledge about the details of the procedure, anesthesia, associated risks, alternate treatments, and level of satisfaction from the pre-operative consent procedure were obtained. Whenever required patients were given a chance to further explain their experiences to get a better in-sight of the process.

All pre-operative patients were above 18 years of age and scheduled to undergo elective surgery within a day of the interview. All data analysis was performed using SPSS version 20. Frequencies and percentages were obtained for positive responses and tabulated.

RESULTS:

A total of 291 selected patients, of whom, 144(49.5%) were males and 147(50.5%) females. Out of these, 209(71%) patients knew that it was their right to have their consent taken by the doctor before any surgery was conducted on them. 168 (58.1%) patients signed the consent forms themselves whereas 122(41.9%) patients' consent forms were signed by relatives or guardians. 282 (96.9%) patients were told about their medical condition and the type of surgery they will undergo. Consent of only 33 (11.3%) patients was taken by

the operating surgeon or residents as shown in table I.

Out of the 56, 39 patients who understood the consent form completely, had an education level of matriculation or above. The level of understanding of the consent form according to the patient's education is given in table II.

DISCUSSION:

The concept of informed consent is based on the understanding of an individual to choose for him/her the best course of action so that he/she is well aware of all the proceedings.⁵ In this study, it was found that 71% individuals knew that it was their right to have their consent taken by the doctor before going for an elective surgery. The awareness level regarding their rights in terms of signing the informed consent form was high as opposed to another study conducted at a tertiary care hospital in Karachi, Pakistan, in the year 2002, where only twenty percent of the eighty patients had awareness about the process of informed consent.⁶

In this study the patients whose consent was taken by the residents or the operating surgeons experienced a decrease in their anxiety levels. The satisfaction level was high in these patients as opposed to those whose consents were taken by the paramedical staff. This decrease in anxiety level

Table I: Person taking Consent and its Effect on Level of Anxiety

Consent taken by	Decrease in anxiety level?		Total
	Yes	No	
Staff	173	85	258
Operating Surgeon	08	00	08
Junior Surgeon	21	04	25
Total	202	89	291

Table II: Level of Education and Understanding of Consent

Patient Education Level	Understanding of the Consent Form			Total
	Did not understand	Understood partially	Understood completely	
Illiterate	104	00	01	105
Below Matriculation	67	18	16	101
Matriculation	03	42	14	59
Above Matriculation	00	01	25	26
Total	174	61	56	291

appeared to be dependent upon the amount of discussion done regarding the procedure or decision making with the doctor, rather than with paramedical staff. The same was also highlighted in a survey conducted in another tertiary care setup.⁷ In this study, for 92(62.6%) out of 147 of the female patients, the consent was given by their spouse or male relatives. This practice must be seen in the background of prevalent culture in Pakistan.

The informed consent forms that were being used at the general surgery wards of this tertiary care hospital were primarily printed in English, and efforts were not made to translate them for better understanding of the patients. In the same way, as highlighted by international literature, when the doctors did not speak in the same language as that of their patients, then the main purpose of understanding what was being conveyed to and from the patients was not achieved.^{8,9} Hence, according to their ability to read as suggested by their education level, the understanding of the consent form was low among those with lower level of education. More educated patients usually had a better level of understanding.¹⁰ This was supported by the observation where 39 out of the 56 patients who understood the consent form completely had an education level of matriculation or above.

CONCLUSION:

Patients undergoing surgery have significant understanding of importance of informed consent though much more is yet to be achieved in terms its true essence.

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