

Original Article

Informed Consent for Surgery: Who is Consenting?

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Abstract

Objective: To evaluate the awareness of informed consent among patients and current consent practices in a teaching hospital.

Study Design: Cross-sectional Survey.

Place and Duration: The study was carried out at Abbas Institute of Medical Sciences attached teaching hospital of AJK Medical College Muzaffarabad from February 2011 to April 2011.

Materials and Methods: A closed ended questionnaire exploring the knowledge about informed consent was administered to the patients post-operatively to study their awareness and the practices of informed consent in the hospital.

Ethical approval: Ethical approval was taken from the hospital ethical committee. Informed consent was taken from all the subjects and their identity was kept confidential

Sample size: sample size was calculated by using WHO sample size estimator

Results: Out of ninety three respondents 59 (63.4%) were male and 34(36.6%) were female. Only 22 (23.7%) respondents gave consent of their surgery themselves for rest of 71 (76.3%) their attendants signed the consent for their patient's surgery. 17 (28.8%) males and 12 (35.2%) females thought that they should have given consent themselves.

Conclusion:

Patients, doctors and staff all are in a state of confusion that who should give consent; patient or attendants. Teaching ethics at undergraduate level will increase awareness in doctors; this will be a long term strategy. As far as short term there is a dire need of developing protocols regarding informed consent at each hospital level.

Key Words: Informed consent, Ethics, Post-operative.

Introduction

Consent is an ethical and legal requirement that must be obtained before any procedure is carried out in clinical practice. When obtained based on balanced information, it practically improves patients' satisfaction in virtually all outcomes.¹

The legally recognized concept of consent for medical care has its origins at the beginning of the 20th century. "Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an

assault for which he is liable in damages."²The legal term "informed consent" did not come into use until 1957.³

Informed consent for medical interventions must include the nature of the proposed intervention, the alternatives to it, the risk and benefits of the proposed intervention as well as the alternatives, an assessment of the patient's ability to understand the discussion, and the patient's voluntary acceptance of the proposed intervention⁴The requirement for an informed consent is well established in all decision making situations in clinical practice.⁵Patient himself may have limited awareness of the legal implications of signing or not signing consent forms⁶It is necessary that the patient understands the information provided and that the consent given is voluntary^{7, 8}. Patients have deficient knowledge about their rights and in our setup most of

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the times crucial decision making is often done by family members or is left entirely up to the attending physician.⁹

The quality of informed consent process is less than ideal in Pakistan¹⁰. We undertook this study to evaluate patient’s awareness about informed consent and the practices in our setup.

Materials and Methods

Cross-sectional Survey was carried out at Abbas Institute of Medical Sciences attached teaching hospital of AJK Medical College Muzaffarabad from February 2011 to April 2011. A closed ended questionnaire exploring the knowledge about informed consent was administered to the patients post-operatively to study their awareness and the practices of informed consent in the hospital.

All patients over the age of 18 years undergoing elective or emergency surgery were included in the study. Patients were interviewed postoperatively once

they were found comfortable to answer questions. Those patients who were uncomfortable answering questions due to any reason like pain, had developed complications were not interviewed.

Ethical approval was taken from the hospital ethical committee. Informed consent was taken from all the subjects and their identity was kept confidential. Sample size was calculated by using WHO sample size estimator, assuming anticipated population at 50% with 10% of required precision and with 95% confidence interval the sample size was calculated to be 93. Sampling technique was non probability consecutive sampling with randomization.

Results

Out of ninety three respondents 59 (63.4%) were male and 34(36.6%) were female. Maximum number of respondents 30 (32.3%) were in the age group of 18-25 years, followed by 20 (21.5%) in the age group of 36-45 years.

Table 1: Age and Gender n=93

		Gender		Total
		Male	female	
Age of patient	18-25 years	20	10	30
	26-35 years	9	8	17
	36-45 years	12	8	20
	46-55 years	8	6	14
	56-65 years	10	2	12
Total		59	34	93

Table 2: Gender * Who gave consent for your operation. Cross tabulation n=93

		Who gave consent for your operation?		Total
		My self	My attendants	
Gender	Male	15	44	59
	female	7	27	34
Total		22	71	93

Table 3: Gender * In your opinion, who should give the consent of operation. Cross tabulation(n=93)

		In your opinion, who should give the consent of operation?		Total
		Patient	Attendants	
Gender	Male	17	42	59
	Female	12	22	34
Total		29	64	93

Only 22 (23.7%) respondents gave consent of their surgery themselves for rest of 71 (76.3%) their attendants signed the consent for their patient's surgery

When patients were asked who should have given the consent for their surgeries, 29 (31.2%) thought that they should have given themselves while rest of 64 (68.8%) believed that their attendants should give consent.

15 out of 59 males (25.4%) gave consent themselves as compared to 7 out of 34 females (20.5%) giving consent themselves. 17 (28.8%) males and 12 (35.2%) females thought that they should have given consent themselves.

Discussion

Before initiating treatment we required informed consent both by law and medical ethics from our patients, this includes any surgical procedure as well. [11]Getting informed consent is an expression of active participation of the patients in the decision making process and a means of respecting individual patient's autonomy.¹²

22 (23.7%) respondents gave consent of their surgery themselves; while for 71 (76.3%) respondents consent was given by their attendants. 15 out of 59 males (25.4%) gave consent themselves as compared to 7 out of 34 females (20.5%) giving consent themselves.

Consent was valid if it is given voluntarily by an appropriately informed person who has the capacity to consent to the intervention in question; in case of this study it is the surgical procedure. Acquiescence where the person does not know what the intervention entails is not 'consent',¹³ this means that only 23.7% patients have given consent legally and ethically.

As to why rest of the patients didn't gave consent themselves and to our thinking process of consent didn't took place at all leaves us with the belief that most of our doctors and staff think that anybody can give consent for surgery may it be patient or an attendant.

In another study¹⁰ only 11 % patients signed consent themselves rest are signed by their attendants. In yet another study 29% patients signed their own consent form, the rest of them were signed by relatives.¹⁴

In all the cases consent is handwritten by the staff, there were no proper forms used to get informed consent, so there was poor documentation as well a study conducted in Karachi on participant's involved in medical research indicates that up to 61% of people believe that documentation of informed consent is

important.¹⁵ Strikingly different is a study in which 100 % patients signed consent themselves¹⁶

17 (28.8%) males and 12 (35.2%) females thought that they should have given consent themselves. It seems that more females want to give consent themselves, but this is due to the fact that there were more 20 males compared to 10 females in the age group of 18-25 years. In our study 35.2 % females want to give consent themselves, although they were not able to do so due to social reasons, in another study on consent 40% of the respondents felt it is not essential that family's permission (consent) be sought before approaching the woman for participation in research.¹⁵

Limitations of the study

Consecutive patients undergoing surgery were selected irrespective of their level of education and social status which are important factors for decision making. Patients were interviewed post-operatively; some of them had major surgical procedures done so information provided by them may have a little bias.

Conclusion

There is a strong case of getting separate consents for surgery and anaesthesia in the developed countries yet the situation regarding informed consent is far from ideal in our setup. Patients, doctors and staff all are in a state of confusion that who should give consent; patient or attendants. Both patients and doctors need to be educated about the process of consent and the ethical principles as well as protection of patient's rights and legal protection of doctors as well. Teaching ethics at undergraduate level will increase awareness in doctors; this will be a long term strategy. As far as short term there is a dire need of developing protocols regarding informed consent at each hospital level.

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