AN AUDIT OF INFORMATION PROVIDED DURING PREOPERATIVE INFORMED CONSENT

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ABSTRACT:

***Objective**:* To find out preoperative informed consent practice in a tertiary care public sector teaching hospital.

Settings: General Surgical Units of Civil Hospital Karachi

Design: Prospective observational study.

***Duration**:* January 2005 to March 2005

Patients and Methods: Patients who had undergone elective surgery were interviewed randomly during the study period under routine practice conditions. All the patients were asked a set of standard questions post operatively related to the information they were provided before the procedure as a part of standard informed consent practice. Questionnaire included the patient's knowledge about pathology, operative risks, type of anaesthesia given with its risks, alternate treatment option, results of no treatment, patient's satisfaction about the information given and whether consent form was signed.

Results: A total of 200 randomly chosen patients (121 males and 79 females) were included in the study. In 16 (8%) of patients the operative surgeons were involved in taking consent themselves. Only 90 (45%) of patients were told about the nature and purpose of procedure and 89 (44.5%) of patients knew about the possible complications of surgery. 143 (71.5%) of patients were told about the type of anesthesia required but only 30 (15%) were informed about the risks of anaesthesia. 40 (20%) of patients were allowed questions to be asked while taking consent. Interestingly, most of the patients 156 (78%) were still satisfied by the information provided to them during informed consent.

Conclusion: This study highlights the poor quality of patient knowledge about surgical procedures and the scarce information provided. The current informed consent practice which is being practiced by the doctors in a public sector teaching hospital of Karachi is below standard to international and ethical acceptability. Yet, a large number of patients were satisfied by the information provided during the informed consent process.

KEYWORDS: informed consent, preoperative, current practice.

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INTRODUCTION

Informed consent is a process of sharing information with patients that is essential to their ability to make rational choices among multiple options in their perceived best interest.[1] There is broad agreement that informed consent has become more important in medicine in the last 25 years because medical practice too has become more formalised.[2] The main purpose of informed consent before an intervention is to uphold and reinforce the concept of patient autonomy. As part of the process patients must have the opportunity to say "no" and to be presented with alternative courses

of action where they exist.[3] Standard informed consent practice is very important in answering the queries in the mind of the patients relieving anxiety and preparing them for the procedure better.

In hospital practice of our region, patients and their families are mostly given inadequate information. This study was designed to evaluate the current preoperative informed consent practice related to patients undergoing different elective general surgical procedures in a public sector teaching hospital of Karachi.

PATIENT & METHODS

A prospective observational study was carried out using a structured questionnaire-based interview technique. Patients who had undergone elective general surgery were interviewed during three months period from January to March, 2005 under routine practice conditions. All the patients were asked a set of standard questions (Appendix) post operatively related to the information they were provided before the procedure as a part of standard informed consent practice. All the interviews were conducted by interviewers who had no involvement in the delivery of health care. Interviews were conducted between one to three days postoperatively at the earliest time the patient is comfortable for such an interview to take place. However, interview conducted in postoperative period may have resulted in information given preoperatively being forgotten by the patients, but preoperatively interview carries with it the risk of interference with the process of care.

RESULTS

A total of 200 randomly chosen patients (121 males and 79 females) were interviewed postoperatively. From most of the patients 184 (92%) consent was not taken by the surgeon who will be performing the procedure, rather by a junior doctor. 143 (71.5%) patients were informed of their existing medical condition while 90 (45%) of patients were informed about the nature of proposed surgery. Complications and risks of proposed surgery were briefed to only 89 (44.5%) of patients while alternate treatment options were explained to only 41 (21.5%) of patients.

Most of the patients 143 (71.5%) were aware of the type of anaesthesia given but only 30 (15%) know the complications and risks of proposed anaesthesia. Only 40 (20%) of patients said they were allowed to ask questions during the consent. Interestingly majority 156 (78%) of patients were satisfied from the information provided. All the patients signed the consent form. (Table-I)

Appendix

Patient's Questionnaire

1. Consent taken by the operating surgeon?
2. Informed about the patient's present condition?
3. Informed about the nature and purpose of the proposed surgery?
4. Expected benefits from the surgery?
5. Approximate time of the surgery?
6. Complications or risks that may arise during or after the surgery?
7. Any alternate treatment option?
8. Type of anaesthesia required?
9. Complications and risks of anaesthesia?
10. The need for blood and blood products during or after the procedure & their risks?
11. Informed about the result of no treatment?
12. Are you satisfied with the information provided?
13. Allowed questions to be asked?
14. Consent given & signed by the patients?

DISCUSSION

Informed consent is the process whereby a mentally competent patient agrees to undergo a procedure after discussion of the indications, alternatives, potential side effects and complications.[4,5] Successful surgery depends on a relationship of trust between the patient and doctor. Surgery is technically an assault unless the patient has given express permission for this to occur.[6]

Table-I: Results of questions asked during the interview
(n = 200)

Questions	*Yes* *n (%)*	*No* *n (%)*
Consent taken by the operating surgeon	16 (8.0)	184 (92.0)
Informed about patient's present condition	143 (71.5)	58 (28.5)
Nature and purpose of surgery	90 (45.0)	110 (55.0)
Expected benefits from the surgery	107 (53.5)	93 (46.5)
Approximate time of surgery	60 (30.0)	140 (70.0)
Complications of surgery	89 (44.5)	111 (55.5)
Alternate treatment options	41 (20.5)	159 (79.5)
Type of anaesthesia	143 (71.5)	57 (28.5)
Complications of anaesthesia	30 (15.0)	170 (85.0)
Need for blood and its risks	100 (50.0)	100 (50.0)
Result of no treatment	19 (9.5)	181 (90.5)
Allowed questions to be asked	40 (20.0)	160 (80.0)
Patient satisfied about information given	156 (78.0)	44 (22.0)
Consent given & signed	200 (100.0)	0 (0.0)

The ethical validity of consent depends not on the written word, but on the nature and quality of the interaction between patient and clinician. Signatures and record keeping are just one part of the process. For consent to be valid the patient must be properly informed about risks and benefits, which requires a two way transfer of information in a meaningful and accessible form. Despite these requirements and precautions, instances still arise in which patients claim to have been inadequately provided with the information necessary to make informed decisions.[7-9]

In our study structured interviews conducted in the postoperative period were used as this was thought to best represent the perceptions the patients would take with them from the inpatient episode. It was observed that most of the patients were not properly informed about the nature and purpose of operation and the expected benefits from it. Kay R et al.[10] reported that 46% of patients received explanation about potential side effects and complications of surgery before elective abdominal procedure. McKeague M[11] in his study stressed that more specific information (including the nature of the planned operation, the alternatives and complications) to be given by the senior doctor undertaking the procedure. In our study most of the time junior doctors (house surgeons) were involved in taking the consent. It is emphasized that senior doctors should take the consent as many members of the surgical team might not have sufficient knowledge to inform the patient properly.[12]

In our study only 44.5% of patients received information regarding risks of surgical procedure and even less (15%) about risks of proposed anaesthesia. In another study it was reported that no information was received by 69.3% of patients regarding surgical risks and 75% of patients received no information on risks of anesthesia.[13]

Only 20% of our patients were given a chance to ask questions while taking consent about surgery and anaesthesia. A recent study from Scotland showed that majority of patients (67%) had no further questions at a point when so-called consent could have been obtained.[14]

Procacciante F et al. analyzed that the more information a patient has about his illness and operation risks, the more he will want to have; the less he knows the less he will want to know, and he will also have more faith in the doctors.[15] Same trend was observed in our study where very little information was provided in

informed consent but most of the patients 78% were satisfied by the information received.

CONCLUSION

This study suggests that the current preoperative informed consent practice in a large tertiary care public sector teaching hospital of Karachi is below standard to international and ethical acceptability. The quality of informed consent may be improved by increasing awareness of the ethical issues surrounding consent. More work will be require to educate doctors and health care providers to respect the patients right to know, even if they are satisfied by the very little information provided as part of preoperative informed consent process.

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