

## Awareness on consent and counselling among patients attending tertiary care hospitals : a cross-sectional study

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### Abstract

#### Introduction

Surgical consent and counselling are an integral part of medical practice and medical education. This study was done to assess how many of the surgical residents provide complete and accurate information to the patient during their training period.

#### Methods

Sixty residents from various surgical departments and 40 patients who were awaiting surgery were selected. The data was collected through interviews using two different questionnaires. The resident's questionnaire provided the information they provide to patients. The patient's questionnaire provided information on the level of their understanding from the interaction. Data were analysed using coGuide.

#### Results

Out of 60 residents, 56(92 %) reported that the side effects and consequences were explained fully. 25% of residents mentioned the name of the surgery and nearly 100% did not mention the operating surgeon's or unit in charge name. About 79% of residents felt that the patient was convinced with their way of communication, nearly 93 % of patients were convinced their disease process was explained well and 50% felt that the doctor informed the consequences of surgery well. 75% responded that doctor did not inform about the side-effects 98% were not aware of the alternative forms of treatment and, 87% of patients were not informed about the chances of recurrence of disease where ever applicable.

#### Conclusion

The majority of residents were convinced that their conveying skills are adequate for surgical counselling but they felt the need to improve. The majority of patients denied discussing

complications when occurred.

#### Introduction

Decision-making regarding patient care was predominantly vested with health care providers until recently. The primary supposition behind this was that the health care provider is superior and better-informed than the patient in directing patient's care [1]. A book on ethics written by Thomas Percival in 1803 states that all patients have a right to truth but when the physician can provide better treatment by lying or withholding information, he is advised to do as he thought best [2]. In 1905, the first litigation on informed consent in the supreme court of Minnesota raised questions about this approach. The case was of a patient who had given consent to operate on the right ear and the surgeon operated on the left ear after discovering a worse condition of the left ear. As the patient was not informed about this, the surgeon was held liable for his decision [3]. Hence a legal judgement was made, where all adults with a sound mind have the right in determining, the procedures to be undertaken on their body [4]. In the majority of countries, the problem regarding children's ability in making decisions related to their medical treatment remains unresolved. Gillick competence or the Fraser guidelines were used in Britain, in assessing children's competence. Using these guidelines, children >16 years, who can demonstrate sufficient maturity and intelligence to understand and appraise the nature and implications of the proposed treatment, including the risks and alternative courses of action are identified as having the legal capacity to consent for medical examination and treatment [5].

By definition, consent is to agree to do something or to allow someone to do something [5]. In medical terms, consent for surgery has wider meaning with its preconditions and implications. Initially, a simple consent varied from formal (signing on a form) to verbal (saying yes) and implied (nodding head) depending on the situation and seriousness. Over time, the emphasis shifted from simple consent to informed consent. Informed consent process requires voluntary authorization of patient or research subject, with full comprehension of the risk involved, for the diagnostic, investigative, or therapeutic procedure [6]. It is a process that involves complete and honest disclosure of the disease

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condition or procedure to the patient to facilitate subsequent decision-making. It is legal documentation and whereas documentation is important in satisfying the legal aspect of the consent process, initial proper counselling constitutes the most important ethical requirement [7]. In all, the patient's right to autonomy must be respected even if it leads to harm or death. Failure to obtain consent renders a physician liable for negligence and battery [8].

A typical consent form used for the surgical procedure must contain the basic information of condition and natural progression of the disease, options/alternatives, name of the procedure, side effects/ complications, extra procedures/stomas/ staged surgeries, name of the operating surgeon/in charge of the unit, trial/training/ first time surgery and second opinion/referral [9].

Counselling is a conversation between the patient and the doctor/clinician/care provider aimed at enabling the patient to make personal decisions related to their illness, cope with the disease, or social and emotional stress [10]. It involves the application of good communication skills modified by experience, providing clear, unambiguous, and honest information about the patient's illness. The concept of informed consent was introduced when the rights of the patient to his/her care were recognized. It became apparent that proper patients counselling based on knowledge of the disease, condition/procedure; consequences, risks, and availability of alternatives should precede consent. Thus, adequate counselling is a prerequisite to properly obtaining informed consent, it is even more important than the mere physical signing of the consent document.

In a medical college/hospital, it is the role of the junior residents to counsel and take informed consent from the patients during the initial days. The ideal time to learn is while his mentor is counselling some of his patients. This way they observe and absorb the key points in taking consent and also learn to balance between providing complete information and cautioning the patient about the risks, consequences at the same time. As they reach end of their training, they can individually practice counselling.

Hence, this study aimed to evaluate the efficiency of the junior residents in surgical counselling and providing complete and accurate information to the patient during his/her training period. This is a one-of-a-kind study, which has not been done in India to date.

## Methods

This was a Cross-sectional study conducted for 3 months from January 2020 to March 2020 among surgical residents and patients at a tertiary care teaching hospital. The study

consisted of two groups: one group of 60 residents from general surgery, orthopaedics, gynecology and ENT, the other group of 40 patients who underwent various surgical procedures. Both groups shared the same study setting in the same study period. We have prepared a structured questionnaire to assess whether all the key elements of the informed consent for the surgical procedure were covered in the counselling.

The questionnaire contained inquiries about the disease process, the name of the operating surgeon, the name of the operative procedure, alternative forms of treatments, risks or consequences of surgery, and complications. Some of the items were also included based on the review of existing literature [9]. The tool was validated for face validity and consensus validity by three senior-level surgeons and a public health expert.

Perceptions of the resident doctors on to what extent they have addressed these key components. The responses from the patients were also obtained on the same lines to identify the key gaps in the perception and actual implementation of the key components of informed consent. Patients were asked if residents informed them about their disease process, prognosis, treatment options, risks, chances of recurrence, complication rates, options of taking a second opinion, and referral of going to a higher centre. They were also provided with an assistant to help them mark the correct answer.

Ethical approval was obtained from the Institutional Human ethical committee of Maharajah's institute of medical science. All the study participants provided written informed consent. Confidentiality was maintained throughout the analysis and reporting of the study results. The residents were provided with structured training based on the key gaps identified in their skills following the study.

## Statistical methods:

Descriptive data were presented as frequency and proportion for all categorical variables. All statistical data were analysed using SPSS version 22 [12].

## Results

All 60 residents and 40 patients were considered for final analysis. Among the key elements to be covered in informed consent, risk and consequences of surgery were explained by 55 (91.66%) resident doctors. Natural history, disease process and prognosis were covered by 22 (36.66%), alternative treatments, name of the surgery were mentioned by 20 (33.33%) and 17 (28.33%) resident doctors respectively. The name of the operating surgeon was mentioned only by one resident. No resident informed the patient if the surgery was done for training purposes or for the

first time or for research purposes, whichever was applicable. Among the surgeons 23 (38.33%) felt as they explained fully to patients, 19 (31.66%) Patients understood the disease process well and 47 (78.33%) patients were convinced.

**Table 1.** Summary of basic details given to patients from surgeon side (N=60)

Basic details to patients from the surgeon side	Given	Not given
Name of the surgery	17 (28.33%)	43 (71.67%)
Natural history, Disease process, prognosis	22 (36.66%)	38 (63.33%)
Risks, consequences	55 (91.66%)	5 (8.33%)
Name of operating surgeon	1 (1.66%)	59 (98.33%)
Training purpose	0 (0%)	60 (100%)
Alternative treatments	20 (33.33%)	40 (66.66%)

In the majority of cases, 44(73.33 %) patient themselves give consent,16 (26.66%) were given consent by a spouse. As methods of obtaining consent for minor procedures/ local anaesthesia, 41 surgeons (68.33%) chose verbal consent and 19 (31.66%) chose written consent.

As per consent for short GA procedures, 44(73.33%) opted for verbal consent whereas 16(26.66) opted for formal consent forms.

Among the patients, 37 (92.5%) reported that they know the disease process. Inpatient population, 21 (52.5%) reported that their doctor informed them about the surgery & its complications and 10 (25%) reported that their doctor informed them about scar and open/laparoscopic options. Inpatient population 45% reported that they know the names of the surgeons. only 1 (2.5%) patients reported that they know alternative treatments. 26 (65%) said they would like to go to higher centres, 35 (87.5%) were not knowing recurrence rate.

**Table 3.** Patient knowledge level summary (N=40)

Patient knowledge	Yes	No
Do you understand the disease process	37 (92.5%)	3 (7.5%)
Has the doctor been informed about the surgery and its complications	21 (52.5%)	19 (47.5%)
Has the doctor informed about the scar, open or laparoscopic options	10 (25%)	30 (75%)
Have you taken anyone help before signing	28 (70%)	12 (30%)
Do you know alternative treatments	1 (2.5%)	39 (97.5%)
Do you know who is operating on you	18 (45%)	22 (55%)
Would you like to go to higher centers	14 (35%)	26 (65%)
Do you know about recurrences	5 (12.5%)	35 (87.5%)

**Table 2.** Summary of questioner responses from surgeon side (N=60)

Surgeon responses	Yes	No
Do you think you have explained fully	23(38.33%)	37 (61.67%)
Patient understood disease process well	19 (31.66%)	41 (68.34%)
Is the patient convinced	47 (78.33%)	13 (21.67%)
<b>Who usually gives consent</b>		
Patient	44 (73.33%)	NA
Spouse	16 (26.66%)	NA
Does the patient acknowledge complications when they occurred	15 (25%)	45 (75%)
Does the patient know if you are operating for the first time	0 (0%)	60 (100%)
Does the patient know who is operating	5 (8.33%)	55 (91.66%)
Is the information given enough	13 (21.67%)	47 (78.33%)
<b>A common way of obtaining consent for minor procedures/ local anesthesia</b>		
Verbal consent	41 (68.33%)	NA
Written consent	19 (31.66%)	NA
<b>A common way of obtaining consent for short GA procedures</b>		
Verbal consent	44 (73.33%)	NA
Formal consent form	16 (26.66%)	NA

## Discussion

Optimal outcomes in non-surgical or surgical procedures are achieved by appropriate patient counselling. Complete knowledge and course of any disease is a must before counselling a patient. The art of counselling aids in setting reasonable expectations, reviewing anticipated risks, optimizing post-operative compliance to reduce complications, and providing ongoing support for the patient's condition. Counselling is also a key factor in the process of mutual decision-making.

Consent is an essential part of counselling. The elements of valid informed consent can be summarized as follows:

Explanation and purpose of each standard procedure and those procedures that are experimental should be identified as such.

- Describing any attendant discomfort and risk that can be expected.
- Describing benefits that can reasonably be expected.
- Informing about any appropriate alternative procedures that can be advantageous to the patient.
- There should be a provision regarding his/her consent withdrawal or to discontinue treatment or participation in the project or activity at any time without prejudice to the subject.

Of all the components in IC form, explaining the course of the disease is very delicate and complex because the medical professional would like to treat a disease before it is complicated and becomes untreatable and identifying exactly who develops a particular complication and requires urgent treatment is unpredictable. Hence while explaining the course of disease doctors can advise about a particularly serious or lethal consequence of disease and suggest a form of treatment to prevent or avoid it. It takes a lot of imagination for the patient to get to the point.

Residents in medical hospitals/colleges are overburdened with their work such as case presentations, dissertations, etc. and patients are more anxious about their disease, billing, arranging donors, several referrals to other departments which they feel are of high priority, because of which both residents, as well as patients, do not consider or give time to consent and counselling.

All the doctors 60 (100%) working in the surgical units completed and returned the questionnaires in the present study. Ibingira CB OJ et al found a 52% response which was less than the current study [12]. Henley L et al found a response rate of 63% what similar to the present study [13]. With this, it can be highlighted that junior residents at a

university teaching hospital in India are compliant in responding to surveys.

Having complete knowledge of the disease and anticipation of operative surprises are the hallmarks of an experienced surgeon, who can also know what points to highlight during counselling hours. It is a good practice to accompany and observe during those sessions. This knowledge comes after following many patients over several years and by continuous updating of current changes in treatment protocols.

In this study, 38.33% of the junior residents were convinced that they had explained everything to the patient and 68.83% of the residents felt that the patients understood the explanation. This shows that there is a lack of confidence in the resident juniors in the art of counselling. Previous studies found that patients' satisfaction can be improved by making them recognise and understand their ailment and the available treatment options which can help to increase their compliance [14] [15]. This will improve the patient's psychology, mental health, tolerance power, and quality of life [16].

This study noticed that 1(2.5%) of patients said that the resident gave them the option of alternate treatments This shows that the resident doctors need to observe their seniors while conversing with patients, before taking the task themselves and 30(75%) of patients denied that residents mentioned about a particular complication. Explaining too much information within a short period as well as informing about the post-operative complications is another tough task, which the surgeon does not expect and relatives are unprepared for, unless this future problem is discussed with them before proceeding with surgery. In the emergency setting the complications can be expected due to the situation but in elective and day-care procedures it requires a lot of stability and seriousness in choosing the words for sending the information across. Any issue that is not explained before is taken as a fault of the doctor, leading to many legal and ethical controversies.

Recently the medical system has witnessed increased incidences of conflicts between doctors and patients or their attendants. The number of lawsuits against doctors and mass level agitations by doctors has increased drastically and the major reason is poor communication between doctors and patients [17]. Such incidences can be decreased if doctors endure in listening to the patients or their families and also by providing a detailed explanation about the procedure to patients [18].

In this study, we found that 16(26.66%) of the surrogate decision-makers (spouse or family members) signed the informed consent. These surrogate decision-makers

sometimes might get confused by their decision as lawyers do when faced with external pressures [19]. Surrogate decision-makers need to be reminded about the hierarchy from which the decisions should be made [19]. Patients' specific preferences from previous conversations should be reported ideally by the surrogate before making a decision rather than considering their own [19]. If a patient's preferences are unknown, the surrogates should be encouraged to make the decision, imagining themselves as patients. If nothing works the surrogate should make a decision based on medical treatment with the help of a medical team. According to individual patients' needs, some degree of variation is necessary. Through consent, the patient is guided in the right direction by dispelling any unrealistic expectations concerning the procedure. The surgeon should forge a relationship with the patient by providing good patient education during the informed consent process [21].

Culture should be considered in protecting the autonomy of human subjects, which might influence the IC process. Culture is multidimensional and includes values, beliefs, and practices of national, ethnic, religious, regional, and generational aspects that influence the complexity of IC. [22] Cultural competence needs to be developed by doctors or researchers in increasing their interpersonal skills and in their understanding and appreciation of cultural differences, which would foster in establishing and implementing informed consent procedures with cultural values. [23]

A deeper understanding of the gap between effective doctor and patient communication has come up as a major issue through this study which will help in providing vital content in training junior doctors [20]. Patients expect respect and empathy from doctors. Doctors should always be well dressed with good etiquette and be aware of their own emotions as well as the patient's emotions. Further research in this area is recommended to support the findings of the present study.

### Conclusion

Patient satisfaction and overall outcomes can be improved by incorporating patient counselling and intensified patient selection. Teaching hospitals in India are still lacking the process of mandatory written informed consent and patient documentation during surgeries. Health care professionals should keep themselves updated with different aspects of informed consent, and its importance and they should also be educated on techniques of patient counselling.

To ease the informed consent process, an informed consent template with appropriate information and room for modification needs to be developed.

### Limitations and recommendations:

This study has nominal data of one centre only. It has observation bias and Selection bias.

Even if it was done blindly and unaware of the study being conducted the results will have poor external validity. The results of the study are locally applicable and can be recommended as a Quality Improvement measure in hospitals. Due to the ongoing pandemic situation, authors were not able to cover multiple centres and hence recommend further multi-centric studies with larger sample size and including different patient categories - children, adults, educated, uneducated, emergency patients, dying, elective surgery, readily willing and self-ordained for surgery vis-a-vis reluctant and fearful to surgery.

All authors disclose no conflict of interest. The study was conducted in accordance with the ethical standards of the relevant institutional or national ethics committee and the Helsinki Declaration of 1975, as revised in 2000.

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