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Surgery

A STUDY TO ASSESS THE AWARENESS LEVEL OF DOCTORS AND PATIENTS REGARDING INFORMED DECISION MAKING

Dr (Capt) Shruti Samyal	MBBS, MD (Hosp Adm), Military Hospital Shimla.
Dr (Col) Surekha Kashyap*	Professor, Dept of Hospital Administration, AFMC, Pune. *Corresponding Author
Dr Nidhi Sharma	Resident, Dept of Hospital Administration, AFMC, Pune.

ABSTRACT Informed Consent is generally viewed as a proof of communication between a doctor and a patient, that all the relevant information regarding any planned procedure is "provided to" and "understood by" the patient. Still we face complaints against doctors and administration by the dissatisfied patients in the form of a grievance or a legal notice. Despite doing what is legally right, we fail to prevent such discontentment. What is the root cause of it? Are we viewing it wrong? Must not an Informed Consent be viewed as a "process of communication" rather than "a mere document" which is not just one sided activity of providing information but also ensuring that the information is comprehended by the receiver. Administration must reach out to doctors and patients to understand the barriers of a relevant communication starting with the assessment of their awareness level, in order to make amends in the hospital policy with a scientific evidence.

KEYWORDS : Informed Consent, Legal, Communication barriers, Scientific evidence, Root Cause, Communication process.

INTRODUCTION

Informed Consent being such a contemporary issue, lacks proper research on the applied part of the medical law. Many studies have been conducted regarding the case discussion and their landmark judgement recent being made by Disputes Redressal Commission (DSCDRC), which states that "*Merely asking patients to sign a consent form is not enough as they ought to be informed the consequences of a surgery"* (1). There are not many studies which assess the awareness level of healthcare providers and care seekers about Informed Consent in a hospital. This study endeavors to carry out an objective assessment of the awareness of surgeons and their patients about the legal and practical aspects of Informed Consent.

Importance of awareness regarding Informed Consent for patients: On the other hand, the care-seekers i.e. the patients, especially in India, have different levels of perception of their rights as far as medical care is concerned. Some believe Doctors to be equivalent to God and others believe them to be money centered. It is to balance these varied level of perceptions and "Godly" expectations from doctors which may act as "fuel" for future litigation against a doctor or hospital administration, a general awareness of law regarding 'informed consent' is essential from the seeker's end as well.

AIM

To assess the awareness regarding Informed Consent amongst surgeons and surgical patients in a tertiary care hospital.

OBJECTIVES

(i) To assess the awareness regarding informed consent amongst surgeons in a tertiary care teaching hospital. (ii) To assess the awareness regarding informed consent amongst surgical patients in a tertiary care teaching hospital. (iii) To study the impact of demographic factors on the responses of doctors and patients. (iv) To study differences in the responses of doctors and patients .

Case Study

It is Prospective and Cross-sectional study carried out in a tertiary care teaching hospital of Pune for a period of one month. The sampling technique adopted is Non probability sampling. The study population included all adult patients admitted to and doctors working in surgical wards. The study excluded the Patients and Doctors who were unable or unwilling to participate in the study. The study was carried out by using Questionnaire based analysis for the assessment of: (i) Awareness regarding informed consent amongst doctors (ii) Awareness regarding informed consent amongst patients.

The questionnaire was developed from the review of landmark cases and rulings on Informed Consent by Law,a semi-structured Questionnaire was developed which contained eleven closed ended questions regarding general awareness related to Informed Consent and one open ended question to cover the concerns of doctor and patients that cannot be covered by closed ended questions. The preliminary tool was then administered to 10 faculty members and 10 surgical ward patients to address issues like:(i) Ability to comprehend the instructions on covering letter, (ii) Understanding of Questionnaire items, (iii) The format including font and layout, (iv) Length of questionnaire (time taken to complete the question). All the comments were taken into consideration and errors were amended and the Revised Questionnaire was adopted. Validation of the Final tool was done by Senior Member of Ethical Committee of Medical Research of the teaching college. The questionnaire was self-administered by the surgeons through e-mail and for patients, the responses were received on interview basis.

Sample size: The questionnaire was distributed to a total of 52 surgeons (including residents), out of which 45 responded. The questionnaire for patients was administered amongst 75 surgical patients, which was responded by all patients.

Data Analysis:

Data was analyzed using SPSS version 20:0 statistical software. Data was analyzed for demographic differences. The responses of surgeons and their patients were compared for statistical significance by applying unpaired T-test.

DISCUSSION

What is Informed Consent? As per International Law: "An informed consent is that consent which is obtained after the patient has been adequately instructed about the ratio of risk and benefit involved in the procedure as compared to alternative procedures or no treatment at all." (2) As per Indian Law: Section 13 of The Indian Contract Act 1872 states that "two or more persons are said to consent when they agree upon the same thing in the same sense". (3) In Clinical practice informed consent is defined as the permission a patient gives a doctor to perform a test or procedure after doctor has explained all the risks and benefits of the procedure, in the language that patient understands.

Relevance of Consent

The dictum of Justice Cardozo of the supreme court of United States of America states that " 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". Consent has gained relevance with passage of time as now the law supports principal of "bodily autonomy" over the principal of "Sanctity of life". (4)

Importance of awareness regarding Informed Consent for Doctors:

The case of *Samira Kohli Vs Dr. Prabha Manchanda* is a perfect

example of need for awareness regarding Informed Consent in which the doctor could not prove that a blanket consent of both diagnostic as well as operative procedure was obtained for performing Abdominal hysterectomy with Bilateral Salpingo-oophorectomy upon discovering the positive finding on diagnostic laparoscopy. In her defence the doctor claimed that she took consent from patient's mother while patient was unconscious. The lack of evidence for consent for an operative procedure (which was not an emergency procedure) rendered the consent by 'near relative' invalid. (5)

Information about Informed Consent, on the basis of which general awareness amongst doctors and patients was assessed includes the following questions:-

1. Who should give consent? Section 11 of Indian Contract Act 1872 says that a person who is of the age of maturity and is of sound mind is competent to contract, thereby also implying that he is competent to give consent. The Indian Majority Act states that every person attains the age of majority on completing 18 years of age (6). As per IPC 1860, for child and the person of unsound mind, the consent of the guardian is sufficient (7). As per doctrine of *in loco parentis*, consent for treatment of children is to be carried out under the consent of parent or guardian (5).

2. Who should obtain consent? The duty to obtain a patient's consent for treatment rest on the patient's treating physician (8,11,12). Hospitals, nurses, surgical assistants, and referring physicians do not owe this duty to their patients (9) The treating physician's duty to obtain a patient's informed consent cannot be delegated (9) The duty is not eliminated, lessened , or spread by having the hospital nurse secure the patient's consent before surgery (9).

3. When is consent not required?In Emergency cases, the Supreme Court has observed that " every injured citizen brought for medical treatment should instantaneously be given medical aid to preserve life" and that " every doctor whether in Government hospital or otherwise has the professional obligation to extend his services with due expertise for protecting life" (10).

4. What information should be provided to patient? The law has identified certain minimum amount of information that needs to be communicated to the patient, to enable him to make an "informed decision". These include (i) The 'adequate information' to be furnished by the doctor (or a member of his team) who treats the patients, should enable the patient to make a balanced judgment as to whether he should submit himself to particular treatment or not. This means that the doctor should disclose nature and procedure of treatment and its purpose, benefits and effect; alternatives if any available; an outline of the substantial risks; and adverse consequences of refusing treatment (6). (ii) There is no need to explain remote or theoretical risks involved, which may frighten or confuse a patient and result in refusal of consent for necessary treatment (6). (iii) There is no need to explain the remote or theoretical risks of refusal to take treatment which may persuade a patient to undergo a fanciful or unnecessary treatment. (6)

RECOMMENDATIONS

1. High Priority Recommendations: (i) The hospital should employ an **Interpreter** who can speak Marathi (local language), Hindi and English to bridge the gap between doctor who is English and Hindi speaking and patient who is mainly Marathi speaking. (ii) For inpatients, a dedicated time may be allotted for **counselling** of patients and/ or relatives by the treating doctors in order to keep them well informed about planned procedures. (iii) Doctor must ask the patient if he/she wishes to be explained about the procedure in presence of a **near relative**. (iv) An informed consent must be obtained **afresh** in case the operating surgeon changes, a new risk factor is identified in the patient and the surgeon plans to perform the surgery with new procedure or new technique than previously explained.

2. Desirable Recommendations: (i) In OPDs with high workload doctors are busy and may not be available to the patients for repeated queries and doubts related to surgery. (ii) **Appointment of counsellors** can provide assistance to doctors and provide relevant information to patients whose surgery is being planned. The counsellors can be stationed in a quiet room next to waiting areas in OPDs and PA check-up rooms**.** In OPDs, fliers and educational movie clips can be provided on most common surgeries in Marathi, Hindi and English language containing relevant information regarding procedures, instructions for patients, answers to frequently asked questions (FAQs) and illustrative before and after procedure diagrams for patients review must be provided. (iii) Communication skill development. The findings of this study prove that there is a significant difference in the level of awareness regarding Informed Consent between the cohorts of varied demographics. Therefore, doctors should be trained on how to communicate with people of different age, gender and education level, so that the information is understood by them. Doctor must ask the patient to repeat the information provided to them to assess their level of understanding**.** Seminars on Legal Implications of not taking Informed Consent with examples of land mark cases should be planned for Doctors.

CONCLUSIONS

This study was taken up to assess the awareness level regarding Informed Consent amongst doctors and patients in a Tertiary Care Teaching Hospital of Pune. Demographic data was collected to study differences in the response of the study population. A semi-structured questionnaire was devised consisting of 11 closed ended questions and 01 open ended question. (a) Descriptive Analysis of closed ended questionnaire resulted in the mean awareness score for doctors (n= 45) is 95.37 % which amounts to Very Good Awareness and that for patients (n= 75) is 71.23 % which amounts to Average Awareness. (b) The findings of statistical analysis include :- (i) No significant difference in awareness level of Junior doctors (< 35 yrs.) Vs Senior doctors (> 35 yrs.) (ii) Awareness in Male patients is significantly higher than female patients. (iii) Awareness in Post Graduate level patients is significantly higher than other level patients. (iv) Awareness amongst doctors is significantly higher than patients.

Upon analysis of the open ended question it was found that main cause of communication gap between doctors and patients is language barrier and non-involvement of "near relatives" to participate in the decision making. Low literacy and high apprehension level of patient necessitates presence of an emotionally stable relative who can understand the procedure.

It is essential for healthcare provider to understand that social demographics does have an impact on comprehension of the patient. Hence, communication with patients and policy regarding it must address and bridge these communication barriers.

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