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Patient's right of informed consent: New challenge in medical practice

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Abstract
Informed consent is an ethical and as well as a legal requirement for research involving human participants and clinical treatments of human beings. It is the process where a patient or participant of a medical research is informed about all aspects of the proposed treatment, which are important for the patient to make a decision and after studying all aspects of the treatment the patient voluntarily confirms his or her willingness to participate in a particular clinical treatment sometime human participants are used in medical research. In those cases informed consent is the sine qua non for such advancement research of medical science. The concept of informed consent is embedded in the principles of Nuremberg Code in 1947, The Declaration of Helsinki in 1964 and The Belmont Report in 1978. Informed consent is an inevitable requirement prior to every research involving human being as subjects for study or prior to the every medical intervention to a patient body. This Article discusses about the basic elements of informed consent and the process to be followed while obtaining informed consent and the circumstances under which informed consent can be waived and other related issues of the informed consent.

Keywords: informed consent, doctor's obligations, rights of patients, alternative treatment procedures

1. Introduction
Consent to investigations and treatment is considered a cornerstone in the doctor-patient relationship [1]. Informed consent is a process of obtaining permission before conducting a medical intervention on the patient's body. A medical assistance provider may ask a patient to provide a prior consent to the treatment before staring the same. With the advancement of medical science, today medical practice is not simple because of various factors impinging on the doctor-patient relationship. Mutual trust forms the foundation for good relationship between doctor and patient. Mutual trust can be properly realized only when the patient has full information related to his or her treatment. Therefore, providing adequate information and educating the patient about realities and obtaining informed consent before subjecting a patient to any test or procedure or surgery is very essential. Even if the informed consent is properly obtained by the doctor or healthcare providing institution from the patient or relatives of the patient, then it can be used as a defence in legal actions against the doctor or institution for medical negligence.

2. Consent
In ordinary sense consent means a compliance or permission given voluntarily without any compulsion or force. According to Section 13 of The Indian Contract Act, 1872, two or more persons are said to consent when they agree upon the same thing in the same sense. For the purpose of medical intervention, it can be defined as an instrument of mutual communication between doctor and patient with an expression of authorization or permission to the doctor to act in a particular way.
Consent can be implied or expressed. The very act of a patient entering a doctor's chamber and expressing his problem is taken as an implied consent for general physical examination and routine investigations. The limitations of implied consent are that there is always a scope for misunderstanding between the doctor and patient on what was actually implied by the patient's actions. However, this limitation can be avoided by taking an expressed consent from the patient. An expressed consent can be written or oral. Written consents are preferable in situations involving long-term follow-up, high-risk interventions and cosmetic procedures and surgeries. Consent is also necessary for photographing a patient for scientific or educational or research purpose or for following up. Specific consent must be taken if the identity of the patient is likely to be revealed while publishing [2]. Expressed consent includes informed consent, which is the ideal form of consent because it includes all aspects of meaningful decision-making by the patient or relatives of him or her with regard to the treatment of the patient.

3. Informed consent
Ordinarily expressed consent of a patient is known as real consent or informed consent. However, there are basic differences between these two terms. Voluntariness, capacity of patient and adequate information are the three pillars of real consent. First time, the concept of informed consent was developed in Nuremberg Code in 1947. After the World War II, a criminal tribunal was set up against the war criminals at Nuremberg and it's laid down 10 codes of standard which physicians must conform when carrying out experiments on subjects. Under this code the term informed consent was define as follows:
"The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved, as to enable him to make an understanding and enlightened decision [3]."

This judgment established a new standard of ethical medical behavior for the post World War II human rights era. Amongst other requirements, this document enunciates the requirement of voluntary informed consent of the human subject. The principle of voluntary informed consent protects the right of the individual to control his own body.

Subsequently, the American Courts, while retaining the basic requirements of consent, emphasizes to the doctor's duty to disclose the necessary information to the patient to secure his consent [4]. Informed consent involves telling the patients about their condition, the nature of the proposed treatment, benefits of the proposed treatment, risks of the proposed treatment, and available alternatives to the proposed treatment along with their benefits and risks.

The basic difference between consent and informed consent is the patients' knowledge behind the consent giving process. Informed consent requires the patient to understand the procedure and outcomes of the specific medical intervention and the uncertainties about it. The patient should have the information regarding the available alternative treatment options and their advantages, disadvantages and probable outcomes. The quantity of information required to make consent informed may vary depending on complexity and risks of treatment as well as the patient's capability to understand it and weigh up the options [5]. Therefore, accurate, adequate and relevant information must be provided truthfully in a form and language that the patient can understand [6]. It cannot be a patient's signature on a dotted line obtained routinely by a staff of the hospital. Unfortunately in India, this is the most prominent practice in the healthcare institutions.

4. Pre-requisites of Informed Consent:

The following five elements can be ascertained as pre-requisites of informed consent: (i) disclosure (ii) comprehension (iii) voluntariness (iv) competence and (v) consent. It can be summarized as that one can give an informed consent to a medical intervention if one receives a through disclosure about it, comprehends the disclosure, acts voluntarily, is competent to act and one consents to the intervention. There is no obligation on the part of the patient to accept the treatment without knowing its consequence and the doctor has no right to treat a patient without his consent.

Patient should be competent to give consent i.e. patient must be an adult and of sound mind. The soundness of mind can be judged by judging the ability of the person to comprehend the nature and consequences of the act that he is consenting to proposed treatment [7]. In case of minor or unsound mind patients, consent must be obtained from parent or legal guardian [8]. In case of incapacitated persons, close family members or legal guardians can give consent [9]. Patient means a reasonable or average patient. It is not easy to ascertain the quantity of information required for considering patient's consent as informed one. To decide whether adequate information has been given, Courts usually rely on "Prudent Patient Test" [10]. There is always a degree to which informed consent must be assumed or inferred based upon observation knowledge or legal reliance [11].

In this respect American scenario is different from India. In America, patients use to get a list of patient's rights from the hospital authorities and in that list the patient's right to make the decision about the process and consequences of medical intervention. Thus, the right of the patients has been pleased at highest pedestal in American medical system. In India, the scenario is quite different than US. Infact, there is a presumption that whenever the patient takes his first step towards the doctor's chamber, he has given his implied consent to the medical treatment. However, with the growing complexity in the modern medical treatment procedure the bigger clinics and hospitals made their patients to sign written forms of consent even for clinical examination and investigative procedures.

Patient's' perception of risk of a medical intervention is also highly individualistic, variable and unpredictable. The information provided to a patient should include all material risks of the proposed treatment. However, the list of risks and side effects cannot be exhaustive to the level of absurdity and impracticality. So, what is expected is that the doctor should provide necessary information so that a prudent or reasonable patient would expect to make a reasonable decision about the course of action to be taken. Moreover, doctor must inform about the possible alternatives available to the patient. Voluntariness is the most important component of informed consent and a patient cannot be said to be truly willing unless he is in a position to choose freely, and freedom of choice predicates the full knowledge of the circumstances on which the exercise of choice is conditioned [12].

5. Exceptions to the right of Informed Consent:

a) Doctor's privilege

If a doctor is of the opinion that certain information can seriously harm a patient's health whether physical, mental or emotional, then he has the privilege to withhold such information. However, it should be shared with close relatives of the patient.

B) Placebo [13]

Use of placebos in certain self-limiting conditions or to patients with high psychological overlay or to those who insist for some form of medication is justified as there are high chances of benefit to the patient with negligible risk. Revealing the truth to the patient takes away the very purpose of administration of placebo.

c) Emergency situation:

An emergency situation is also an exception to the general rule of informed consent. The delivery of medical services is rendered lawful in such circumstances either on the ground that the doctor has implied consent from the patient to give emergency aid or, more accurately, on the ground that the doctor is privileged by reason of necessity in giving the aid and cannot be held liable for doing so. On either basis, in an emergency, the law sets aside the requirement of consent on the assumption that the patient, as a reasonable person, would want emergency aid to be rendered if he or she was capable of giving consent.

6. Documentation

It is important to record the process of consent taking for future evidence. It should be prepared in duplicate and a copy should be handed over to the patient or to his or her relatives. It should be dated and signed by the patient or guardian, the doctor and an independent witnesses and it should be preserved for atleast three years.

The Indian legal system relies mainly on documentary evidences in a situation where medical negligence is alleged by the patient or the relatives of him or her. Medical records are considered useful evidence by the Courts as it is accepted that documentation of fact during the course of treatment of a patient is usually genuine and unbiased. In an accusation of negligence, these documents are often the most important evidence that decides the fate of the case [14].

7. Effect of failure to secure consent

Treating a patient without consent can result three different consequences under civil law, criminal law and professional regulation [15]. A patient can either claim compensation under law of torts [16] or move to the Consumer Forum for appropriate remedy. If the physician fails to obtain consent before treatment, it may result in commission of the offence of battery or assault, for which the patient can also take criminal action against the doctor. Even he can file a case against the doctor for using criminal force under Section 350 of Indian Penal Code, 1860 [17]. Moreover, a doctor cannot carry out a medical treatment which requires consent of the patient [18].

However, mere failure to inform the risks of the procedure of treatment or the prognosis is not a valid ground for legal action. In general, there is a perception that the patient, who goes to a doctor, himself permits to examination by the physician. However, the concept of compulsory informed consent arises where the proposed treatment requires administration of drug, subjecting a patient to investigative procedures or surgical interventions. Failure to inform the risks involved in any of the above procedures may constitute the grounds for legal action against the doctor or hospital authority. To prove the complaint against a doctor on the ground of lack of informed consent, a patient or his relatives must show the followings: (i) an undisclosed risk has materialized, (ii) the undisclosed risk has caused harm to the patient, and (iii) if the risk has been disclosed, the patient would have refused treatment. The probability and magnitude of those risks may be matters of medical judgement and beyond the knowledge of the lay person. Medical expert testimony must also be introduced to establish the case of lack of informed consent that should have been disclosed to support the plaintiff's claim [19].

In an emergency situation, a doctor may have to operate even in the absence of consent, to save the life of the patient. It is possible that even with such an intervention, the patient may not survive. Assuming that the doctor is competent and has exercised due care and diligence, doctor cannot be held responsible for patient's death, as he has acted in good faith and in the best interest of the patient. This protection is given under Section 88 of Indian Penal Code, 1860 [20].

8. Informed refusal

Patient has got the right of self-determination. Self-determination also encompasses the right to refuse the medical intervention and this right can properly be utilized only when patient has a clear idea about the pros and cons of a specific medical treatment. Even patient has also a right to choose between two available medical treatment procedures. Even patient can reject a specific procedure even though that has been preferred by a medical practitioner. Regardless the doctor's opinion, it is the patient who has right to make the final decision whether to undergo the treatment or not. Doctor's duty is to explain the probable consequences of non-treatment and benefits of treatment and leave the patient to decide the further action. Such informed refusals must be recorded as documentary evidence. If a propose treatment is refused by the patient his or her decision must be respected by the Doctors and legal relatives as far as possible.

9. Conclusion

In case of medical practice except the emergency situation the real key to take the decision regarding the treatment procedure is held by the patient itself. Doctor may suggest the treatment procedure but can only perform such treatment with the informed consent of the patient. Obtaining consent is not only an ethical obligation, but also a legal compulsion. The level of disclosure has to be case-specific. There cannot be anything called a standard consent form as it totally dependent upon various complex issues related to patient like social status, education, economic capacity etc.

No doctor can avoid the legal obligation of informed consent and cannot avoid the legal consequences arise out of the failure of taking informed consent. In the present situation doctors are going through a controversial phrase that how to fulfill the legal obligation of the informed consent and what are the proper procedure to comply with such obligation.

It is suggested that doctors must take adequate precaution and diligence before starting the treatment. Maintaining a good relationship with patient often smoothen the function of the doctors.

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17. Section 350 of Indian Penal Code, 1860 states as: Whoever intentionally uses force to any person, without that person's consent, in order to the committing of any offence, or intending by the use of such force to cause, or knowing it to be likely that by the use of such force he will cause injury, fear or annoyance to the person to whom the force is used, is said to use criminal force to that other.
18. Andrew Grubb (ed.). Principles of Medical Law, (2nd Ed. Oxford University Press, New York), 2004, at p. 133.
19. Kannan K. Medicine and Law, (2nd Ed. Oxford University Press, Lucknow), 2010; at p. 191.
20. Section 88 of Indian Penal Code, 1860 as follows: Act not intended to cause death, done by consent in good faith for person's benefit.—Nothing which is not intended to cause death, is an offence by reason of any harm which it may cause, or be intended by the doer to cause, or be known by the doer to be likely to cause, to any person for whose benefit it is done in good faith, and who has given a consent, whether express or implied, to suffer that harm, or to take the risk of that harm. Illustration A, a surgeon, knowing that a particular operation is likely to cause the death of Z, who suffers under a painful complaint, but not intending to cause Z's death and intending in good faith, Z's benefit performs that operation on Z, with Z's consent. A has committed no offence.