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Are We Taking a Legally Valid Consent?

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ABSTRACT

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The practice of modern medicine has expanded over years to command so much influence in increasing the life span and quality of life of patients to a great extent. The increasing financial implications and the complex social settings of these decisions raise new ethical questions regarding what is good and what is right in the behaviour of doctors and patients. Respect for the wishes of the patient is a duty which becomes even stronger when the patient is vulnerable. Every human being of adult years and of sound mind has the right to determine what shall be done with his body and a surgeon who performs an operation without the patient's consent commits an insult for which he is liable to damages.

Medical treatment has become a joint venture combining the doctor and the patient. The purpose of the informed consent principle is to empower the patient to make correct autonomous decisions. Informed consent is an educational process with both ethical and legal implications, whereby a person is said to have given consent based upon a clear appreciation and understanding of the facts, implications and future consequences of an action. Awareness among the patients with respect to their rights, has forced the medical community to be more vigilant when dealing with patient care. Informed consent is a prerequisite and is mandatory for participation in scientific research and in clinical teaching.

Keywords: Consent, Informed Consent, Doctrine of Disclosure, Informed Consent and Indian Law, Implied Consent, Express Oral and Written Consent, Proxy Consent, Blanket Consent, Informed Refusal

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Good communication makes for good medicine; and Good records are essential for the defense of the doctor - David Bogod[1]

INTRODUCTION

The ever increasing power of modem medicine, and the complex sociological and financial settings in which it is practiced, raise new ethical questions concerning what is good and what is right in the behaviour of doctors and patients. Respect for the values and wishes of the patient, is a duty which becomes even stronger if the patient becomes vulnerable. Every human being of adult years and sound mind has a right to determine what shall be done with his body; and a surgeon who performs an operation without the patient's consent commits an assault for which he is liable to damages.[2]

Medical treatment has become a joint venture combining the doctor and the patient. The purpose of the Informed consent principle is to maximise the ability of the patient to make substantially autonomous decisions.[3] The proper use of this principle diminishes the possibilities of errors, negligence, coercion and deception. But the main purpose is to assert the patient's autonomy and to protect his status as a self-respecting human being, as enshrined within Article 21 of the Indian Constitution.

NEED FOR AN INFORMED CONSENT

In formed Consent concept has been recognized in all patient care fields. It is an educational process with both ethical and legal implications, whereby a person is said to have given consent based upon a clear appreciation and understanding of the facts, implications, and future consequences of an action. Awareness among the patients with respect to their rights, has forced the medical fraternity to be more vigilant while dealing with patient care. The clinician should negotiate rather than dictate what is in the best interest of the patient. An important aspect of several Medical Consumer litigations is improper consent and withholding of complete information from the patient.[4] If a medical practitioner attempts to treat a person without valid consent, then he will be liable under both tort and criminal law. Tort is a civil wrong for which the aggrieved party may seek compensation. In certain cases, there is a possibility of criminal prosecution for assault or battery. Battery is an act that either intentionally or negligently directly causes some physical contact with another person without that person's consent.[5] The apex court in India, recently ruled that however broad the consent might be for diagnostic procedure, it cannot be used for therapeutic surgery.

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Furthermore, the court observed that the consent by the patient for a particular operative surgery, cannot be treated as consent for an unauthorized additional procedure involving removal of an organ only on the ground that it is beneficial to the patient or is likely to prevent some danger developing in the future, where there is no imminent danger to the life or health of the patient.[6] This proposition puts a restraint on the rol & of the "paternal doctor" in the Indian scenario. It is therefore contended that it is not only informed consent which is imperative now, but the same shall be "prior informed consent", unless there is imminent threat to the patient's life.

Hence it is of paramount importance for a doctor to have a legally valid consent from his patients and in order to be fully legal, the patient's consent must be "informed".

Components of informed consent

The modem informed consent is an interaction between the patient and his doctor and has 7 com ponents:[3] Decision making capacity, Voluntariness, Disclosure, Recommendation, Understanding, Decision to consent or refuse, and finally Autonomous Authorisation.

Persons who have attained the age of 18 years are generally considered to have attained the age of maturity and are competent to give consent. The law thus presumes capacity, rationality, autonomy, and freedom if the person has attained the age of so called maturity. For minors parental consent is required. In most instances, it is for the doctor treating the patient to decide whether the patient is competent or not, to make a decision. This decision should be taken by the patient after understanding all the information disclosed by the doctor. The doctor can recommend treatment options but the decision should be made by the patient voluntarily and the informed consent process finally concludes with the patient intentionally authorising the doctor to perform the specific procedure. The contents and wordings of the informed consent are still being debated and experimented.

Doctrine of disclosure

The "informed consent" doctrine is American in origin and relates to the amount of information that a patient should be provided with, to avoid any probable action in negligence. Informed consent from the American sense is often described from the viewpoint of a prudent patient, popularly known as the prudent patient test. The doctor will keep in mind the patient and disclose all such information which is required to be given7, m contrast to this, the English approach is doctor centric, which is known as the prudent doctor test. Here, the doctor, endowed with greater prudence to protect the right interest of the patient, is bestowed with the final right to decide how much information shall be divulged to the patient considering the circumstances8.

A medical practitioner in India also has a duty to provide all the necessary information to the patient in a language that is understandable to him. Regarding the quantum of information, there are no clear parameters laid down by the courts. The amount and the nature of information that must be disclosed to the patient should, as far as possible, be determined by the question: "what would this patient need to know and understand in order to make an informed decision".[9]

This standard is most challenging to integrate into practice, since it requires tailoring information to each patient. Patients should be given the opportunity to ask questions and honest unbiased answers should be provided. The Doctor is legally bound-to pass on every detail regarding the disease condition, nature of the proposed treatment, any alternative treatment, prognosis if the treatment is not taken, possible risks and benefits of the procedure. All the relevant information must be explained in comprehensible non-medical terms preferably in local language. This should be documented along with the name of the treating doctor and the health care provider taking the informed consent. Exceptions to the obligation to disclosure include patients who choose not to be informed, emergencies in which a valid consent form cannot be obtained and situations of "therapeutic privilege".[3] Doctors can choose to withhold information if they feel disclosure would cause psychological harm to the patient or may deter the patient from making a rational decision. In such instances, full disclosure should be made to the relative.

Informed consent and Indian law

Section 13 of the Indian Contract Act defines "Consent" as: "Two or more persons are said to consent when they agree upon the same thing in the same sense." This Act also provides under Section 11 that only those persons who are of and above 18 years of age are competent to enter into a contract and section 14 states that "consent would not be a free consent if it is caused by coercion, undue influence, fraud, misrepresentation and mistake." Self-defense of body (IPC sections 96 to 102, 104, 106) provides right to the protection of bodily integrity against invasion

by other. All medical procedures, including examinations, diagnostic procedures and medical research on patients are potential acts of bodily trespass or assault (IPC 351), in the absence of consent or statutory sanction.[10] Treatment and diagnosis cannot be forced upon anyone who does not wish to receive them except in statutory sanction.

When a patient comes to a doctor. Implied or tacit consent is assumed and the doctor can perform inspection, palpation, percussion and auscultation. Express oral consent is obtained for relatively minor examinations or therapeutic procedures, preferably in the presence of a disinterested third party. Express written consent is to be obtained for all major diagnostic procedures, general anesthesia, surgical operations, intimate examinations, examination for determining age, potency, virginity, and in medico- legal cases. There is no mandate that a doctor should always obtain written consent and failure of which would hold him liable. However, if there is a written consent, the medical practitioner would have greater ease in proving consent in case of litigation, but if the health care provider does not make the necessary disclosures and does not receive the patient's "informed consent", he or she is exposed to liability for malpractice. It should also be borne in mind that merely signing the consent form does not exclude a doctor's responsibility if he is negligent in performing his duties.

When the patient is unable to give consent himself, there are no clear regulations or principles developed in India. If such a situation exists, the medical practitioner may proceed with treatment by taking the-Proxy Consent of any relative or authorised guardian of the patient-or even an attendant.

If it is determined that the patient is legally competent and he/she still cannot be convinced to undergo the recommended care, the. patient's "Informed refusal" must be obtained and documented. The doctor must respect the patient's wishes, no matter how misguided he believes the patient to be. The doctor who ignores the patient's informed refusal of consent risks a claim for battery.[10]

When a patient is unconscious with an imminent danger to his /her life and no relative is present then the law presumes that consent has been deemed to be given". A doctor is duty-bound to treat a patient in the case of a life saving emergency, without waiting for any formalities including consent. Hypothetically, if a competent patient in an emergency resists taking treatment, what shall be the way out? Indian courts are not very clear on that. It would be prudent for the doctor to document an informed refusal and if deemed necessary, save the patient's life with a proxy consent.

The Blanket Consent usually taken in some Indian hospitals at the time of patient's admission does not have a legal validity.[4] Informed consent should be patient and procedure specific. The informed consent doctrine has been elaborated primarily for medical treatment. In the context of a clinical trial it obtains additional importance. Informed consent is a prerequisite and is mandatory for participation in scientific research and in clinical teaching.

CONCLUSION

In India, legal cases concerning absence of consent are rare at present, but such cases will increase in the coming years as medical techniques become more advanced, medical care becomes more widespread and the level of patient awareness increases. Unlike the west, the Doctor-Patient relationship in India is governed more by trust wherein the doctor is the authoritative figure. Illiterate population which is less aware about the consumer rights and an already overburdened health service with lack of time for communication, are few of the factors responsible for loss of the basic essence of informed consent.[4] However, it should be remembered that an Informed consent is a patient's right and a physician 's duty and even though our patients trust us to do the right thing, clear documentation formalises the process, demonstrates respect for the patient's right, and may provide us with added legal protection.

END NOTE

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