

Informed Consent: A Legal Formality or a Mandate

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ABSTRACT

Doctor patient relationship which in olden days was a highly revered one has undergone considerable change due to the greater awareness among patients regarding their rights and easy access to litigation process. The profession which was considered the most humble one has transformed into a service and falls under the purview of Consumer Protection act. Informed consent is a concept which gives the person right to pick and choose from the different types of treatment modalities, right to voluntarily suffer any harm which may occur during treatment thereby also decreasing the burden of responsibility which falls upon the doctor's shoulders to pick the best treatment modality for his patient and to bear the brunt of patient and his relatives if something goes wrong. Thus informed consent is not just a legal formality but a mandate which guarantees not only the best treatment for the patient as per his choice but also safeguards a doctor against unnecessary litigations.

Keywords: Consent, Doctor-Patient relationship, Right to choose, Litigation

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INTRODUCTION

Every person has a right to have his/her body integrity protected against invasion by others. Consent is the ethical precept that allows the patient to make invasion lawful – whether that invasion is into their body or their confidential information.¹ Concept of consent is embodied in the Roman maxim “Volenti nonfit injuria,” that is, he who consents cannot complain of it. In the case of *Murphy vs Steeplechase Amusement Co.*, in 1929, the judge ruled that “one who takes part in such sport accepts the dangers so far that they are obvious and necessary just as a fencer accepts the risks of a thrust by his antagonist or a spectator at a ball game the chance of contact with the ball.” Patients’ right to autonomy in medical decision-making is embodied in the words of Judge Cardozo as “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 patient’s consent commits an assault for which he is liable in damages.”² The earliest expression of this fundamental principle, based on autonomy, is found in the Nuremberg Code of 1947. The Nuremberg Code was adopted immediately after World War II in response to medical and experimental atrocities committed by the German Nazi regime. The code makes it mandatory to obtain voluntary and informed consent of human subjects.³ Similarly, the Declaration of Helsinki adopted by the World Medical Association in 1964 emphasizes the importance of obtaining freely given informed consent for medical research by adequately informing the subjects of the aims, methods, anticipated benefits, potential hazards, and discomforts that the study may entail.⁴

WHAT IS CONSENT

Consent is defined as voluntary agreement, compliance, or permission given for a specified act or purpose.⁵ 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.” It consists of four separate but correlated elements: Voluntariness, capacity, knowledge, and decision-making. Voluntariness suggests willingness of the patient to undergo treatment. Capacity means a degree of ability of the patient to understand the nature and consequences of the treatment offered. Knowledge means that sufficient amount of information about the nature and consequence of the treatment has been disclosed to the patient. Decision-making means the ability to take decisions regarding consent. To be legally valid, all these elements must be present in the consent. In tort law, usage of force against any human body, without proper justification, is actionable irrespective of the quantum of force. If a medical practitioner attempts to treat a patient without obtaining proper consent, he will be held guilty under tort law.

TYPES

Consent may be implied or expressed. An implied consent is not written, but it is legally effective and is the most common variety of consent. It involves consent to medical examination pertaining to inspection, palpation, emergency procedures, comatose patient requiring immediate treatment, and a mentally incompetent patient

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requiring treatment when legal guardian is unavailable. An expressed consent may be oral or written. It should be stated in a language, i.e., easily understood by the patient and should preferably be taken in the presence of a disinterested witness. Oral consent is taken for majority of minor examinations or therapeutic procedures. Oral consent where properly witnessed is as valid as written consent, but the latter has the advantage of permanent form and easy proof. Consent obtained in written format after explaining the nature and consequences of the treatment procedure being contemplated is a valid form of consent.

INFORMED CONSENT

The term was first used in 1957 by a California Appellate court in *Salgo vs Leland Stanford Jr. University Board of Trustees Case*, where the patient consented to an aortogram without being advised allegedly of the risk posed by the use of contrast medium. The patient suffered damage and filed a suit against the doctor. The court asserted, "a physician violates his duty to the patient and subjects himself to liability if he withholds any fact that is necessary to form the basis of an intelligent consent by the patient to the proposed treatment." Traditional doctor-patient relationship was one in which the doctor and the patient were unequal bargaining partners in a contract for services, with the doctors' special knowledge creating the advantage. Informed consent is meant to force the doctor to give the patient the knowledge that will make him or her an equal bargaining partner. Thus, informed consent is meant to transform the essence of the doctor-patient relationship to a contractual one as contractual relationships are thought to promote individual autonomy and freedom of choice.⁶

WHO SHOULD TAKE CONSENT?

Informed consent is an ongoing process rather than a form signed once and for all, never to be discussed. It is a two-way communication whereby the doctor is ready to listen and discuss anything that the patient may fear as a risk, a side effect, or a concern about the proposed treatment. It is the duty of the patient's attending doctor at the time in question to take consent. The nurse or substitute doctor covering for the patient's original doctor may only supplement or complement the doctor's specific information required to make an informed choice. For those practicing in a private hospital setting, under the dictum of "respondent superior," an employer hospital could be held jointly liable with an employee doctor whose failure to obtain consent caused injury and damage to a patient. So, a hospital policy must govern the procedure by which consents are obtained and any deviation from such a policy may be admissible evidence.

REQUIREMENTS OF VALID CONSENT

A medical practitioner in India 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. Therefore, any information that a doctor deems fit considering best practices is reasonable information. Considering the knowledge gap in this regard, the professional regulatory body for medicine can play an important role in establishing standards.

The common law application of consent is not fully developed in India, although the Indian courts have often referred to these principles. In such situations, obviously one has to refer to the principles of the Indian Contract Act and the Indian Penal Code (IPC). The relationship between a medical professional and his patient is a contract by parties competent to contract, giving rise to contractual obligations. Parties are generally competent (in accordance with the Indian Majority Act) (i) if they have attained the age of 18, (ii) if they are of sound mind, (iii) if they are capable of comprehending the information provided by the doctor, (iv) if they are not under any fear of injury or threat, (v) if they are not intoxicated, and (vi) if they are not under false conception or misinterpretation of facts.

As per the IPC, 12 years is the age for giving consent. Section 88 and Section 90 of the IPC suggest that the age for giving valid consent for any medical procedure is 12 years. Hence, a doctor taking consent for medical or surgical treatment from a person aged 12 years or more can be legally said to have taken a valid consent and cannot be held criminally liable on this account. However, Sections 87 IPC mention 18 years as the age for giving consent for acts not intended and not known to be likely to cause death or grievous hurt. However, these acts are not necessarily for the benefit of the person. Hence, Section 87 IPC is not applicable to the medical profession as here the acts are done for the person's benefit.

BLANKET CONSENT

This type of consent is not taken for specific procedure but is broad or open and vague. Recently, the apex court gave an impacting judgment in the area wherein the court observed that "where a surgeon is consulted by a patient and consent of the patient is taken for diagnostic procedure/surgery, such consent can not be considered as authorization or permission to perform therapeutic surgery either conservative or radical (except in a life-threatening emergent situation)."⁷ Furthermore, the court observed that "where the consent by the patient is for a particular operative surgery it can not 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.”

PROXY CONSENT

It is the type of consent not given by the patient himself but given by some other person on his behalf. In the UK, there are several ethical issues raised regarding the proxy consent on behalf of such persons. Irrespective of age, for a person who is incompetent due to unsoundness of mind, consent will be obtained from the guardian of the patient. In India, the court has not come across borderline cases of an adult refusing treatment leading to emergency and leaving the doctor in a dilemma, unlike in the West.

DOCTRINE OF LOCOPARENTIS

In an emergency situation involving children, when parents are not available or legal guardians are not available, consent from the person in charge of that child can be taken. For example, if a child is ill and needs operation, the school teacher can give consent in the absence of the parents of the child.

DOCTRINE OF EXTENSION AND PROPORTIONALITY

When a patient consents to medical therapy or for the performance of a procedure or surgical operation, the scope of the consent is limited to whatever parameters were expressed before the medical intervention. However, an extension of the scope of the consent is permissible to save the life of a patient. The doctrine of proportionality advocates that artificial life support (in the form of respirator, intravenous fluids, nasogastric feeding, etc.) needs to be maintained as long as it provides benefit to the patient and outweighs the burden to the attendant.

According to the judgment given by the Apex court in the case of *Samira Kohli vs Dr Prabha Manchanda & Anr*, consent should include

- The nature, purpose, and procedure of treatment with its benefits and effects
- Alternatives (if any available)
- An outline of the substantial risks
- Adverse consequences of refusing treatment.

EXCEPTIONS TO MATERIAL DISCLOSURE

- Under certain circumstances, the doctor may withhold information from the patient on the basis of the opinion that the information might seriously harm the patient or make him/her resort to rash action.

- A competent patient may specifically ask not to be informed.
- A doctor is privileged not to advise the patient of the matters that are of common knowledge or of the matters of which the patient has actual knowledge, especially on the basis of past experience.
- No duty to inform arises in an emergency in which the patient is unconscious or otherwise incapable of giving valid consent and harm from failure to treat is imminent.

CONCLUSION

Dr Mark E Battista’s premise “Document it. If you have not documented it, you did not do it” holds true in all aspects. Written documentation of the informed consent is of prime importance for both the parties should litigation occur later on. Lack of communication and empathy often acts as precipitating factors for negligent suits. To standardize the practice, the Medical Council of India (MCI) has laid down guidelines that are issued as regulations in which consent is required to be taken in writing before performing an operation.⁸ The MCI guidelines are applicable to operations and do not cover other treatments. For other treatments, the following may be noted as general guidelines:

- For routine types of treatment, implied consent would suffice.
- For detailed types of treatment, ideally express oral consent may be needed.
- For complex types of treatment, express written consent is required.

Consent should be individual and case specific and be taken just before the procedure. Consent should be open for discussion and potentially retractable at any time during the course of treatment.

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