

How to Avoid Litigations in Medical Practice

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“Everything U should know about a Valid Informed Consent”

Important Guidelines laid by Supreme Court for Valid Consent

- (i) A doctor has to **seek and secure the consent of the patient before commencing a “Treatment”**. The consent so obtained should be real and valid, which means that: the patient should have the capacity and competence to consent; his consent should be voluntary; and his consent should be on the basis of adequate information concerning the nature of the treatment procedure, so that he knows what is consenting to.
- (ii) The **'adequate information' to be furnished** by the doctor, should enable the patient to make a balanced judgment as to whether he should submit himself to the particular treatment or not. This means that the Doctor should disclose
 - (a) Nature and procedure of the treatment and its purpose, benefits and effect;
 - (b) Alternatives if any available;
 - (c) an outline, of the substantial risks; and
 - (d) Adverse consequences of refusing treatment.
- (iii) Consent given only for a diagnostic procedure cannot be considered as consent for therapeutic treatment. Consent given for a specific treatment procedure will not be valid for conducting some other treatment procedure, unless the additional procedure is necessary to save the life of the patient.
- (iv) There can be a common consent for diagnostic

and operative procedures where they are planned together. There can also be a common consent for a particular surgical procedure and an additional or further procedure that may become necessary during the course of surgery.

- (v) The nature and extent of information to be furnished by the doctor to the patient to secure the consent need not be of the stringent and high degree but should be of the extent which is accepted as normal and proper by a body of medical men skilled and experienced in the particular field...

Stages in the consent process

- Ensure competence (ensure that the patient can take in, analyze and express his/her view).
- Check details (correct patient).
- Make sure that the patient understands who you are and what your role is.
- Discuss the treatment plan and sensible alternatives.
- Discuss possible risks and complications (especially those specific to the patient).
- Discuss the type of anesthetic proposed.
- Give the patient time and space to make the final decision.

- Check that the patient understands and has no more questions.
- Such informed consent must be obtained in the presence of a witness, who should affix his or her signature to state so, prior to every procedure.

Invalid Consent

The following situations will make the consent invalid;

- If it was obtained by fraud, by misrepresentation as to the nature of the procedure or by undue influence or by threat of violence.
- The consent was obtained when the patient was under sedation.
- If there is failure in giving proper information and sufficient disclosure regarding the procedure
- If the consent is given by a minor since he is not legally competent to give it
- If the consent is given by a person of unsound mind or mentally handicapped
- **If the procedure performed by a doctor is substantially different from the one for which consent was given or the procedure performed exceeds the scope of consent**
- **If the different physician than the one to whom consent was given, carries out the procedure.**

Types of Consent

- Informed consent:** The entitlement of a **conscious patient of sound mind** to decide whether or not to submit to a particular course of treatment proposed by the doctor is the foundation of doctrine of informed consent. In medical practice, anything beyond the routine would require this type of consent.
- Implied consent:** It is the consent given **automatically by the patient by virtue of his action.** When a patient approaches a doctor for

consultation, it implies his or her willingness to be examined by the doctor. For example when the patient rolls up his/her sleeves for allowing a blood sample to be taken, it implies consent for undergoing blood test.

- Blanket consent:** The consent obtained to the effect that the patient is willing to undergo any type of treatment including surgeries **without mentioning any particular procedure**, is termed as blanket consent. Such consent, however, have no legal validity
- Third party consent:** This is legal, when an adult, responsible person gives consent for a patient who is unable to give consent. This is so in the case of legal guardian, who on behalf of a minor or a close relative in unconscious patient, gives consent. But such consent is totally invalid if the patient is an adult of sound mind and is in the position to give consent.

Consent in Emergencies

- Things are different in emergency situations. The patient being in shock or under sedation may not have the capacity to understand the emergency situation and give the consent. A doctor can lawfully operate under such circumstances without consent, since it would be life-saving surgery. Medical and not the legal considerations are of greater importance in life-threatening situations.
- However, such emergency treatment or surgery should be restricted only to the procedures absolutely necessary. Anything else that could be performed later on electively should be deferred.
- Please do take a written opinion from an expert colleague stating necessity of the emergency surgery without consent.
- In unconscious patient, if time permits, attempt should be made to obtain signature of the next of kin. If no relative or responsible person is available, permission of the in-charge of the hospital, police or judicial officer can be obtained.

Valid age for consent

Any person of sound mind above the age of 18 years can legally give the consent. Section 90 of the Indian Penal Code says the consent given by a child under 12 years of age as it is invalid. A patient belonging to the age group between 12 and 18 years and who has sufficient understanding, can give an effective consent. In case of litigation the court will determine the "level of understanding".

However, the pregnancy of minor woman cannot be terminated except with consent in writing of her legal guardian..

Refusal of Consent/Treatment

- The patient has a right to control his own body. A competent adult is entitled to reject a specific treatment or all treatment or to select an alternative form of treatment even if the decision may entail risks as serious as even death.
- The doctor who takes the defense that consent was not given must prove the absence of consent.
- If the refusal involves the welfare of a minor or an unborn baby, the court can override the refusal of parents.
- In situation where there is a refusal to treatment, the consequences should be explained to the patient in the presence of witnesses and they should sign a refusal document. If the patients or relatives refuse to sign also, neutral witness's signature may be obtained.
- The doctor can even refer the patient elsewhere if he refuses or withdraws his consent.

Some points to remember

- Absences of a valid consent form along with

improper documentation are the commonest causes of doctors losing court cases.

- Consent has to be procedure specific and person specific.
- You need a separate consent for Blood transfusion
- Do not forget to obtain signature of spouse in addition to the patient's consent, before performing sterilization operation. Even though legally it is not required, it is highly desirable.
- It is advisable to ask the person giving consent to write in his own handwriting so that the validity of the consent cannot be questioned later on.
- Do not to delegate the job of obtaining consent to junior staff or others.
- When two or more procedures are planned, it is necessary to have consent for each. If a change is made in the planned procedure it must be explained to the patient and a new form should be completed, signed and witnessed.
- It is important to keep the consent forms along with the patient's case records in safe custody.
- In absence of valid consent a doctor still can be held liable even if procedure went fine and patient actually benefitted from it.
- The medical practitioners who violate the essential criteria of the informed consent are liable to be removed from the rolls of the Medical Council. Even the Indian Penal Code makes the offence punishable with a fine and or imprisonment.
- And finally, a legal valid consent doesn't offer immunity from medical negligence, so be careful.