

Consent and the Indian medical practitioner

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ABSTRACT

Consent is a legal requirement of medical practice and not a procedural formality. Getting a mere signature on a form is no consent. If a patient is rushed into signing consent, without giving sufficient information, the consent may be invalid, despite the signature. Often medical professionals either ignore or are ignorant of the requirements of a valid consent and its legal implications. Instances where either consent was not taken or when an invalid consent was obtained have been a subject matter of judicial scrutiny in several medical malpractice cases. This article highlights the essential principles of consent and the Indian law related to it along with some citations, so that medical practitioners are not only able to safeguard themselves against litigations and unnecessary harassment but can act rightfully.

Key words: Doctor-patient relationship, Indian law, informed consent

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INTRODUCTION

Legally, two or more persons are said to consent when they agree upon the same thing in the same sense.^[1] Consent must be obtained prior to conducting any medical procedure on a patient. It may be expressed or implied by patient's demeanour. A patient who comes to a doctor for treatment implies that he is agreeable to general physical (not intimate) examination.^[2] Express consent (verbal/written) is specifically stated by the patient. Express verbal consent may be obtained for relatively minor examinations or procedures, in the presence of a witness.^[3] Express written consent must be obtained for all major diagnostic, anaesthesia and surgical procedures as it is the most undisputable form of consent.

ESSENTIAL PRINCIPLES OF A VALID CONSENT AND THE INDIAN LAW

A doctor must take the consent of the patient before commencing a treatment/procedure

Except in emergencies, informed consent should be obtained sometime prior to the procedure so that the patient does not feel pressurised or rushed to sign. On the day of surgery, the patient may be under extreme

mental stress or under influence of pre-medication drugs which may hamper his decision-making ability. Consent remains valid for an indefinite period, provided there is no change in patient condition or proposed intervention.^[4] It should be confirmed at the time of surgery.^[4]

Consent must be taken from the patient himself

The doctor before performing any procedure must obtain patient's consent.^[5] No one can consent on behalf of a competent adult. In Dr. Ramcharan Thiagarajan Facs versus Medical Council of India case,^[6] disciplinary action was awarded to the surgeon for not taking a proper informed consent for the entire procedure of kidney and pancreas transplant surgery from the patient. In some situations, beside patient consent, it is desirable to take additional consent of spouse. In sterilisation procedures, according to the Ministry of Health and Family Welfare, Government of India guidelines, consent of spouse is not required.^[7] The Medical Council of India (clause 7.16) however states that in case an operation carries the risk of sterility, the consent of both husband and wife is needed.^[8] It is advisable to take consent of spouse when the treatment or procedure may adversely

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affect or limit sex functions, or result in death of an unborn child.^[9] In case of minor, consent of person with parental responsibility should be taken.^[10] In an emergency, the person in charge of the child at that time can consent in absence of parents or guardians (*loco parentis*).^[11] In a medical emergency, life-saving treatment can be given even in absence of consent.

Refusing treatment in life-threatening situations due to non-availability of consent may hold the doctor guilty, unless there is a documented refusal to treatment by the patient. In *Dr. TT Thomas versus Smt. Elisa and Ors* case,^[12] the doctor was held guilty of negligence for not operating on a patient with life-threatening emergency condition, as there was no documented refusal to treatment.

The patient should have the capacity and competence to consent

A person is competent to contract^[13] if (i) he has attained the age of majority,^[14] (ii) is of sound mind^[15] and (iii) is not disqualified from contracting by any law to which he is subject. The legal age for giving a valid consent in India is 18 years.^[14] A child >12 years can give a valid consent for physical/medical examination (Indian Penal Code, section 89).^[3] Prior to performing any procedure on a child <18 years, it is advisable to take consent of a person with parental responsibility so that its validity is not questioned. If patient is incompetent, then consent can be taken from a surrogate/proxy decision maker who is the next of kin (spouse/adult child/parent/sibling/lawful guardian).^[11]

Consent should be free and voluntary

Consent is said to be free^[16] when it is not caused by coercion,^[17] undue influence,^[18] fraud,^[19] misrepresentation,^[20] or mistake.^[21-23]

Consent should be informed

Consent should be on the basis of adequate information concerning the nature of the treatment procedure.^[5] Consent should be informed and based on intelligent understanding. The doctor must disclose information regarding patient condition, prognosis, treatment benefits, adverse effects, available alternatives, risk of refusing treatment and the approximate treatment cost. He should encourage questions and answer all queries.^[2]

If the possibility of a risk, including the risk of death, due to performance of a procedure or its

refusal is remote or only theoretical, it need not be explained.^[5] Exceptions to physician's duty to disclose include^[24]: (i) Patient refusal to be informed; this should be documented. (ii) If the doctor feels that providing information to a patient who is anxious or disturbed would not be processed rationally by him and is likely to psychologically harm him, the information may be withheld from him (therapeutic privilege); he should then communicate with patient's close relative, family doctor or both.

The "adequate information" must be furnished by the doctor (or a member of his team) who treats the patient.^[5]

Information imparted should enable the patient to make a balanced judgment as to whether he should submit himself to the particular treatment or not.^[5]

Consent should be procedure specific

Consent given only for a diagnostic procedure, cannot be considered as consent for the therapeutic treatment.^[5] Consent given for a specific treatment procedure will not be valid for conducting some other procedure.^[5] In *Samira Kohli versus Dr. Prabha Manchanda and Anr* case,^[5] the doctor was held negligent for performing an additional procedure on the patient without taking her prior consent. An additional procedure may be performed without consent only if it is necessary to save the life or preserve the health of the patient and it would be unreasonable to delay, until patient regains consciousness and takes a decision.^[5]

A common consent for diagnostic and operative procedures may be taken where they are contemplated.^[5]

Consent obtained during the course of surgery is not acceptable

In *Dr. Janaki S Kumar and Anr versus Mrs. Sarafunnisa* case,^[25] in an allegation of performing sterilisation without consent, it was contended that consent was obtained during the course of surgery. The commission held that the patient under anaesthesia could neither understand the risk involved nor could she give a valid consent.

Consent for blood transfusion

When blood transfusion is anticipated, a specific written consent should be taken,^[24] exception being an emergency situation where blood transfusion is needed to save life and consent cannot be attempted.^[26] In *M. Chinnaiyan versus Sri. Gokulam Hospital and Anr*

case,^[27] court awarded compensation as patient was transfused blood in the absence of specific consent for blood transfusion.

Consent for examining or observing a patient for educational purpose

Prior to examining or observing patients for educational purpose, their consent must be taken.^[28]

Blanket consent is not valid

Consent should be procedure specific. An all-encompassing consent to the effect 'I authorize so and so to carry out any test/procedure/surgery in the course of my treatment' is not valid.^[29]

Fresh consent should be taken for a repeat procedure

A fresh written informed consent must be obtained prior to every surgical procedure that includes re-exploration procedure. In Dr. Shailesh Shah versus Aphraim Jayanand Rathod case,^[30] the surgeon was found deficient in service and was liable for compensation as he had performed a re-exploration surgery without a written consent from the patient.

Surgical consent is not sufficient to cover anaesthesia care

The surgeons are incapable to discuss the risks associated with anaesthesia. Informed consent for anaesthesia must be taken by the anaesthesia provider as only he can impart anaesthesia related necessary information and explain the risks involved. It may be documented by the anaesthesiologist on the surgical consent form by a handwritten note, or on a separate anaesthesia consent form.^[31]

Patient has the right to refuse treatment

Competent patients have the legal and moral right to refuse treatment, even in life-threatening emergency situations.^[31] In such cases informed refusal must be obtained and documented, over the patient's witnessed signature.^[32] It may be advisable that two doctors document the reason for non-performance of life-saving surgery or treatment as express refusal by the patient or the authorised representative and inform the hospital administrator about the same.

To detain an adult patient against his will in a hospital is unlawful.^[9] If a patient demands discharge from hospital against medical advice, this should be recorded, and his signature obtained.^[9]

Unilaterally executed consents are void

Consent signed only by the patient and not by the doctor is not valid.^[33]

Witnessed consents are legally more dependable

The role of a witness is even more important in instances when the patient is illiterate, and one needs to take his/her thumb impression.^[34]

Consent should be properly documented

Video-recording of the informed consent process may also be done but with a prior consent for the same. This should be documented. It is commonly done for organ transplant procedures. If consent form is not signed by the patient or is amended without his signed authorisation, it can be claimed that the procedure was not consented to.^[10]

Patient is free to withdraw his consent anytime

When consent is withdrawn during the performance of a procedure, the procedure should be stopped. The doctor may address to patient's concerns and may continue the treatment only if the patient agrees. If stopping a procedure at that point puts patient's life in danger, the doctor may continue with the procedure till such a risk no longer exists.^[10]

Consent for illegal procedures is invalid

There can be no valid consent for operations or procedures which are illegal.^[24] Consent for an illegal act such as criminal abortion is invalid.^[9]

Consent is no defence in cases of professional negligence.^[9]

HOW TO OBTAIN A VALID CONSENT AND CONSENT FORMAT

Always maintain good communication with your patient and provide adequate information to enable him make a rational decision.^[35] It is preferable to take consent in patient's vernacular language. It may be better to make him write down his consent in the presence of a witness.^[34] It is desirable to use short and simple sentences and non-medical terminology that is written/typed legibly.^[36] Patient information sheets (PIS) depicting procedure related information, including pre-operative and post-operative pre-cautions in patient's understandable local language with pictorial representation may facilitate the informed consent process. These may help in providing consistently accurate information to the patients.^[35] PIS should be handed over to the patients

Patient's name.....Age/Gender.....

Medical record number.....Address.....

Proposed surgical procedure.....

I hereby give my free and voluntary consent in a fully alert state of mind to the administration of general and/or regional anaesthesia with or without sedation/local anaesthesia with or without sedation/sedation only, for the performance ofprocedure on me/my patient. I agree to be supplemented or administered any other mode of anaesthesia during the course of the procedure/surgery, if necessary.

I have been explained in a language that I understand the procedure involved in the administration of various types of anaesthesia, together with the expected benefits and the associated risks including the risks that are specific to me. I have had an opportunity, to discuss and clarify any concerns and ask questions regarding the anaesthesia procedure and alternative methods and the same have been satisfactorily answered.

I have been given patient information sheets/information material on CD regarding the proposed anaesthetic technique which I have fully understood.

I have been explained the risks associated with undergoing/not undergoing blood transfusion and am willing/not willing to undergo transfusion if required during the perioperative period (if applicable).

I have been explained the additional/high risk of anaesthesia due to emergency nature/inadequate fasting period/difficult airway/co-existing or co-morbid conditions such as (if applicable).

I have been explained the risk of dental trauma and subsequent morbidity (if applicable).

I have been explained the need of post-operative ventilation and Intensive Care Unit following my/my patient's surgery (if applicable).

Patient's signature/Proxy decision maker's name and signature.....

Relationship to patient in case of proxy decision maker.....

Place.....Date.....Time.....

I have explained verbally to the patient in detail about the anaesthesia technique and procedure, related risks, advantages and disadvantages. I have given the patient opportunity to ask any questions and have satisfactorily answered them.

Anaesthesiologist name and Signature.....

Place, Date and Time.....

Witness Name and Signature.....Address.....

Place, Date and Time.....

Figure 1: Anaesthesia informed consent form

after explaining the contents. Even videos may be used as an aid in increasing patient understanding.^[37]

Though there is no standard consent format, it may include the following [e.g., Figure 1]:^[38]

- Date and time
- Patient related: Name, age and signature of the patient/proxy decision maker
- Doctor related: Name, registration number and signature of the doctor
- Witness: Name and signature of witness
- Disease-related: Diagnosis along with co-morbidities if any
- Surgical procedure related: Type of surgery (elective/emergency), nature of surgery with antecedent risks and benefits, alternative treatment available, adverse consequences of refusing treatment
- Anaesthesia related: Type of anaesthesia (general and/or regional, local anaesthesia, sedation) including risks
- Blood transfusion: Requirement and related risks
- Special risks: Need for post-operative ventilation, intensive care, etc
- Document the fact that patient and relatives were allowed to ask questions, and their queries were answered to their satisfaction.

CONSENT IN RELATION TO PUBLICATION

A registered medical practitioner is not permitted to publish photographs or case reports of his/her patients without their consent, in any medical or another journal in a manner by which their identity could be revealed. However, in case the identity is not disclosed, consent is not needed (clause 7.17).^[8]

CONSENT IN RELATION TO MEDICAL RESEARCH

Consent taken from the patient for the drug trial or research should be as per the Indian Council of Medical Research guidelines^[39]; otherwise it shall be construed as misconduct (clause 7.22).^[8]

COMMON FALLACIES IN THE CONSENT PROCESS

The anaesthesiologist must ensure that consent is given maximum importance, and all the legal formalities are followed before agreeing to provide the services. Following are some frequent mistakes and omissions that can cost him/her dearly in the event of a mishap:

- Procedure is considered trivial, and consent is not taken
- Consent of relative is taken instead of the patient, even when patient is a competent adult.
- Consenting person is minor, intoxicated or of unsound mind
- Blanket consent is taken.
- It is not procedure specific
- Consent for blood transfusion is not obtained.
- Fresh consent is not taken for a repeat procedure
- Procedure related necessary information is not given
- Even if the information given, it is not documented
- Consent lacks the signature of the treating doctor
- Consent is not witnessed
- Alterations or additions are made in the consent form without patient's signed authorisation.

SUMMARY

It is not only ethical to impart correct and necessary information to a patient prior to conducting any medical procedure, but it is also important legally. This communication should be documented. Even professional indemnity insurance may not cover for lapses in obtaining a valid consent, considering it to be an intentional assault.

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