

Consent in Clinical Practice: A Review

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Abstract

Consent is an ethical principle. Medical treatment can only be administered with consent of a competent patient. Giving the treatment without consent is failure to respect patient's autonomy; violating an individual's right to self-determination. Any medical treatment given without consent is an action for trespass where damages are payable. The core idea of autonomy is one's action and decisions are one's own. Therefore every patient has the right to know what happens to his body. It is the moral and legal duty of a physician to inform the patient about all the aspects of his illness and help him by advising so that he is able to make a logical and intelligent decision about his treatment. Examining or treating a patient without his consent amounts to battery and assault and may invite legal liabilities for a physician.

Keywords: Consent; Clinical Practice; Medico-Legal.

Introduction

The word consent is from the French word 'consente' and the Latin word 'consentire', which means co 'together' + sentire 'feel' [1]. The concept of consent comes from the ethical issue of respect for autonomy, individual integrity and self determination.

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.' Judge Cardozo (1914). With these words Judge Cardozo, expressed patient's right to autonomy in making informed decision pertaining to his medical treatment [2]. The term consent means voluntary agreement, compliance, or permission. Section 13 of the Indian Contract Act lays down that two or more persons are said to consent when they agree upon the same thing in the same sense (meeting of the minds) [3]. In modern

days, the doctor is no longer held in high esteem. The faith in the healer has been slowly waning. The gentleman's agreement no longer holds true and every agreement is now in black and white. Today the doctor is viewed with suspicion and the doctor too safeguarding himself or herself prefers to have consent for everything.

Consent and Its Validity

It becomes legally valid, when it is given only after understanding: What it is given for? The risks involved in consequence. Fulfills the rules of consent. Consent from a patient to a doctor is a must for examining or treating especially when the law demands it for any reason.

Types of Consent

Implied Consent

An implied consent is not written, that is, its existence is not expressly asserted but nonetheless, it is legally effective. It is provided by the demeanor of the patient. It implies consent to medical examination in a general sense i.e. when a patient approaches the doctor for treatment; it is presumed that there is consent for routine physical examination.

Expressed Consent

Anything other than the implied consent described above is expressed consent. An expressed

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consent is one the terms of which are stated in distinct and explicit language. It may be oral or written. For the majority of relatively minor examinations or therapeutic procedures, oral consent is employed but this should preferably be obtained in the presence of a disinterested party. However, a person closely related/associated with the patient is not ideal for the purpose [5].

Informed Consent

In medical practice, anything beyond the routine would require this type of consent. The concept of informed consent has come to the force in recent years and patients who allege that they did not understand the nature of the medical procedure to which they gave consent have brought many actions. This is essential in medical practice, when diagnosing or treating is beyond the routine methods, wherein risks are involved. Thus, the doctor should explain all relevant details to the patient. This is called rule of full disclosure. All information should be explained in comprehensive, non-medical terms preferably in patient's own language about the, Nature of the illness, Nature of the proposed treatment or procedure, Alternative procedure, Risks and benefits involved in both the proposed and alternative procedure, Potential risks of not receiving the treatment and Relative chances of success or failure of both procedures [5,6].

Blanket Consent

Consent taken on a printed form that covers (like a blanket) almost everything a doctor or a hospital might do to a patient, without mentioning anything specifically. Blanket consent is legally inadequate for any procedure that has risks or alternatives. The informed consent when expressed by the patient in writing is termed as "informed expressed written consent". This is a must in all surgeries, administration of anesthesia and all complicated therapeutic and diagnostic procedures [7].

Rules of consent are though rigid in their legal implications, certain deviations are usually allowed and they are:

Doctrine of Therapeutic Privilege

At times it may not be possible to explain everything to the patient. Accordingly under such circumstances doctor can reveal the details to any one of the close relatives of the patient. This is called doctrine of therapeutic privilege [8].

Doctrine of Emergency

According to this, a doctor can provide the treatment without taking prior consent from a patient who is gravely sick, critically ill, unconscious or not able to understand the suggestions or when mentally ill (Section 92, IPC).

Doctrine of Loco-Parentis

In emergency situations involving children, when their parents/ guardian are not available, according to this doctrine, consent can be obtained from the person accompanying [9].

Consent and Age

Minimum age for giving valid consent for physical/medical examination is 12 years (Section 89, IPC). Accordingly, for medical examination of a child below the age of 12 years, the consent is to be obtained from the parent/ guardian of the child. A person who is above 18 years age can give valid consent to suffer any harm which may result from an act in good faith and which is not intended or known to cause grievous hurt or death (Section: 88, IPC) [10].

Consent in Relation to Medico-legal Purposes

In medico-legal cases where the law requests an examination, consent must be obtained whether it is victim or accused/ assailant to be examined. Without consent examination amounts to assault [11]. Examination findings when used in process of investigation can damages the party examined. If later on the party is proved innocent, damages sustained cannot be undone. This is why the right to deny consent for examination is generally given to the party [12].

Marriage and Conjugal Obligations

Regarding consent in relation to these matters, such as sterilization, artificial insemination, etc. consent of both the partners must be obtained.

Sexual Intercourse

In India sexual intercourse with a consenting woman amounts to the legal offence of rape if she is below the age of 18 years and this is called as statutory Rape.

Examination of Rape Victim

In the examination of a victim of alleged rape to confirm the allegation, the doctor should obtain prior

consent observing all formalities. The consent must necessarily be after telling her that the findings of clinical examination shall be revealed in a court of law. Consent must be obtained from her relatives if the victim is a child or minor.

Consent and Negligence Charges

In medical negligence charges against a doctor, consent is not a valid defense.

Consent in Drunkenness and Intoxicated Cases

Consent obtained from a person who is drunk/ under the influence of alcohol is invalid. However, in such events, examination of the case may be done and findings may be revealed only after obtaining the consent at a later period when the person becomes sober.

Consent in Examining Criminal Cases

Here no consent is necessary, provided the requisition is from a police officer who is not below the rank of Sub-Inspector of Police, and the examination is done in the presence of disinterested witness (Section: 53, Cr. P.C). However, a doctor as a routine formally may obtain consent, and according to this section if the criminal is not willing to get examined, examination may be done with mild degree of force. When the criminal is a female, examination should be done only by or under the supervision of a lady medical officer [13].

Consent in Unconscious

Victims/assailants/any patient: Examination findings can be divulged to police only after the patient regains consciousness and gives consent for disclosure.

Consent in Relation to Autopsy Examination

It is improper and illegal to perform autopsy without consent or authorization. Consent differs with type of autopsy to be performed:

- Consent is not required if it is a medico legal autopsy. Here autopsy is done only with an authorization.
- Consent is a must from spouse or relatives for clinical or pathological autopsy. Failure to get consent here is a ground for charges of mutilation of deceased and emotional hurt by legal heirs [14].

Consent in Relation to Remove and Retain Parts of the Body

Specific consent must be obtained for this purpose. However, no civil action has so far been reported for the removal of tissues from the body at autopsy even without specific consent [15]. Perhaps it may be justifiable to remove certain tissues for demonstration, even without consent during bonafide autopsies, done without visible mutilation of the body.

Consent in Relation to Organ Transplantation

In living: A person can donate voluntarily his/her organs, tissues, etc. to another person for therapeutic purposes. However, in India the consent given for such purposes becomes legally valid only if the donor is above the age of 18 years [16]. Informed witnessed consent under Human Organ Transplantation Act, 3.22 It states that a living person should give his/her consent in writing to donate kidney, for the transplantation purposes, in presence of two or more witnesses, at least one of them should be a near relative of the person consenting.

In dead: Consent should be given earlier by the person in writing in the form of a Written Will when he was alive. However, this consent or will made by the deceased when he/she was alive becomes null and void after his/her death and to remove organs from the dead body; consent must be obtained from legal possessors of the dead body. No law of the land can procure organs from the dead body if the legal possessor of the deceased refuses to give his/her consent to donate the organs or tissues [16].

Consent in Emergencies

Emergencies require a quick response. Law clearly mandates that during emergencies the doctors must put all efforts in providing the requisite care rather than completing medical records or taking consent. However, once the emergency is over, the doctor must specifically ensure that all the procedural requirements have been completed.

Consent: Surgical Interventions, Procedure

During pre-surgery counseling, the patient must be specifically informed about the choice of anesthesia, the alternatives if any that may have to be attempted and the risks involved in each type. Take separate consent for surgery and anesthesia.

The patient must be disclosed the name of the principal anesthetist and the principal surgeon and

the same must be duly recorded in the consent. A doctor or Hospital need not voluntarily disclose the name of each member of the surgical team to the patient but if the patient specifically seeks this information there can be no valid reason to withhold the same. Special care must be taken if there is a possibility of damage or removal of an organ. The patient must be counseled and an elaborate written consent must be taken [17].

Consent: In Medical Termination of Pregnancy

It is mandatory to take written consent in termination of pregnancy, even if the patient may have volunteered for the same. An elaborate procedure is laid down for terminating pregnancy under Medical Termination of Pregnancy Act, 1971 and rules made there under, which must be religiously followed. Only when the pregnancy involves extreme risk to the life of the pregnant woman, the doctor may terminate pregnancy without consent. A per MTP Act, to carry out medical termination of pregnancy, consent of mother alone is sufficient if she is or claims to be more than 18 years of age. Otherwise consent of nearest relatives or guardian is required. A procedure involving sterilization or one that limits sexual functions of the spouse, consent of both the partners is required [18].

Consent: Blood Transfusion

Before any surgery, procedure, contemplate whether blood transfusion would be required or not. If there is any possibility, even bleak, take specific, separate and written consent of the patient for blood transfusion and keep blood ready rather than requisitioning blood at the last minute.

Consent: Refusal, Compulsory Treatment

It is advisable in case the patient refuses to consent to any life-saving procedure or treatment, withdrawing from the patient should be seriously considered. Any kind of delay, refusal in giving consent for a treatment, procedure, hospitalization must be clearly and specifically be recorded in the patient's medical records.

Consent: General Precautions

- Give all the requisite information in the language known to the patient explain the content of the document in a language known to the patient before taking the patients signature or thumb impression and also get this fact attested by the

independent witnesses.

- Any pressure, compulsion or coercion on the patient to give consent is per se illegal and impermissible.
- Recording of the correct, specific medical name of the procedure, surgery, treatment in the consent is a must. General declaration in the consent form cannot be a substitute for providing legally mandatory specific information.
- Taking consent on a printed sheet having standard clauses without recording any requisite particulars is negligence. Courts are increasingly commenting adversely against hospitals, doctors for taking consent in such a routine manner.
- It is advisable to ensure that documents like consent form, information sheets, medical records should be written by a single person and with the same pen without changing ink, as such documents are usually kept with the hospital and not given to the patient, but it bears patients signature. Hence preferably be written by single person with same pen without changing ink.
- Do not avoid taking patients written consent if a written and specific consent is the legal requisite. Even if the patient volunteers or suggest a particular course and if a written and specific consent is the legal requisite, a written consent must be taken. Recording the fact that the patient had volunteered for that particular course in the patient's medical record cannot be a substitute for a written consent.
- Possible complication and side effects must be explained by the doctor to the patient and in case the consequences are grave, the aforesaid information must be given in writing, either in the consent form, prescription or discharge card.
- No consent is required to put the patient on the ventilator
- Do not reduce the consent to mere formality. It is rather a process of communication 'requiring the fulfillment of certain established elements like competence, sufficient disclosure, understanding and volunteering.
- The patient must be duly informed about the advantages and disadvantages, risks and complications associated with a procedure, surgery, treatment in terms that can be comprehended by the patient.
- When any procedure has been made compulsory by law e.g. Vaccination, consent is not necessary.
- Prisoner can be treated without their consent.

- No patient can be detained in hospital without his consent. If the patient wants discharge against medical advice (DAMA), he or she may be discharged after taking his signature, undertaking on the case papers for the same.

Conclusion

Thus valid consent is an important ingredient of our medical practice today. Examination of a patient for diagnosis, therapeutic intervention, treatment and surgery, consent should be obtained to safe guard oneself from future medical litigation. We must adhere to aim in medicine "do no harm". By helping in healing we must not harm the patient.

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