

INTRODUCTION

“There are three factors in the practice of medicine: the disease, the patient, and the physician. The physician is the servant of science, and the patient must do what he can to fight the disease with the assistance of the physician.”

— Hippocrates, *The Epidemics*, Book I

The concept of consent comes from the ethical issue of respect for autonomy, individual integrity and self determination. 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)¹. In law, the tort of battery is defined as ‘Application of force to the person of another without lawful justification’ and therein lies the essence of requirement of consent for any medical treatment². “Every human being of adult years and sound mind has a right to determine what should be done with his body and the surgeon who performs operation without his patient’s consent commits assault for which he is liable in damages”³. This principle is applicable not only to surgical operations but also to all forms of medical treatment and to diagnostic procedures that involve intentional interference with the person.

Types of Consent

Depending upon the circumstances, in each case, consent may be implied, expressed or informed.

Implied Consent

Much of physicians work is done on the basis of consent, which is implied either by the words or

behavior of the patient or by the circumstances under which treatment is given, e.g. it is common for a patient to arrange an appointment with a Doctor, to keep the appointment, to volunteer the history, to answer question relating to the history and to submit without objection to physical examination. In these circumstances consent for the examination is clearly implied. An implied consent is a consent which is not written, that is, its existence is not expressly asserted, but nonetheless, it is legally effective. It is provided by the demeanour of the patient and is by far the most common variety of consent in both general sense but not to procedures more complex than inspection, palpation, percussion, and auscultation.

Expressed Consent

An express 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. Oral consent, where properly witnessed, is as valid as written consent, but the latter has the advantage of easy proof and permanent form. It should be obtained when the treatment is likely to be more than mildly painful, when it carries appreciable risk, or when it will result in diminishing of a bodily function. Consent may be confirmed and validated adequately by means of a suitable contemporaneous notation by the treating physician in the patient’s record. Expressed consent in written form should be obtained for surgical operations and invasive investigative procedures. It is prudent to obtain written consent, also where never analgesic, narcotic or anesthetic agents will significantly affect the patient’s level of consciousness during the treatment.⁴

Informed Consent as a Right

Informed consent is the legal embodiment of the concept that each individual has the right to make decisions affecting his or her well-being. It is generally accepted that individuals should consider the risks and potential benefits flowing from their decisions. To do so, decision-makers must have knowledge of those risks and potential benefits. The law protects the individual's right to give informed consent by requiring the disclosure of information by the party to whom consent is given. In the case of the doctor-patient relationship the onus of disclosure of information lies with the doctor and the right to decide the manner in which his/her body will be treated lies with the patient. Hence, it is the duty of the doctor to disclose information on the risks emanating from the treatment to the patient⁵.

Informed Consent

Therefore all information should be explained in comprehensive, non-medical terms preferably in patient's own language about the:

- i. Nature of the illness
- ii. Nature of the proposed treatment or procedure
- iii. Alternative procedure
- iv. Risks and benefits involved in both the proposed and alternative procedure
- v. Potential risks of not receiving the treatment
- vi. Relative chances of success or failure of both procedures⁴. Yet, in practice this is not always so simple. Because in certain situations the patient may be in dire need of treatment, but revealing the risks involved (the law of full disclosure) may frighten him to refusal. The doctor may not reveal the risks involved, if—
 - a. Patient prefers not to be informed
 - b. When complications are trivial
 - c. When revealing complications is likely to have a gross impact on psychology of the patient (a close relative of the patient can be informed of the complications and a colleague should be consulted, preferably patient's family physician for the treatment of the patient). This is known as "Therapeutic privilege"¹. But the doctor should note his decision and reasons for the same in patient's case record⁶.

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 an esthesia and all complicated therapeutic and diagnostic procedures.

Physician's failure to provide the patient with information necessary to make an informed and intelligent choice, is a breach in standard of disclosure, which, if found to be the cause of alleged injury, makes a prima facie case for negligence on part of the physician.

Role of hospital: A question that may creep, particularly for those practicing in a hospital setting, is, "Does the hospital have a responsibility to ensure that the patient received adequate disclosure?" Under the theory of "Respondent Superior", an employer (hospital) could be held jointly liable with an employee (doctor) whose failure to obtain informed consent could be shown to have caused injury and damage to a patient. A hospital policy must govern the procedure by which consents are obtained.

A patient can withdraw consent after signing a consent form. Though this is the rule, but there are practical limitations. In such cases, if patient is admitted in a hospital, it is the obligation of the hospital to make sure that no member of the hospital staff performs the refused procedure.

Legally Valid Consent¹

Legally valid consent for medical examination, interventional procedure and treatment is one that is⁷:

- i. Given by the person himself, if above 12 years of age (Sec. 88 IPC), conscious and mentally sound or given by the parent, guardian or close relative, if the patient is less than 12 years of age or is insane or is unconscious. In such circumstances consent give by parent, guardian or close relative is known as "substitute or proxy consent".
- ii. Informed expressed written consent.
- iii. Given before actually doing the procedure.
- iv. Given in the present of two witnesses.
- v. Given freely, voluntarily and directly.
- vi. Given without fear, fraud or force.
- vii. Signed by the doctor, patient (or guardian) and witnesses. Should be written in patient's own handwriting

VALID CONSENT

Consent consists of three related aspects:

1. Voluntariness
2. Capacity
3. Knowledge

1. Voluntariness

Patients should give consent completely voluntarily without any duress either from the Doctor or any third party (e.g. relatives). Consent obtained with compulsion either by the action or words of the doctor or others is no consent at all. Especially in our country we need to keep in mind that initiative to the treatment may not be of the patient herself and she may be coerced by relatives into giving consent. Here the Doctors have to ensure voluntariness of the consent.

2. Capacity to Consent

The patient should be in a position to understand the nature and implication of the proposed treatment, including its consequences. In this regard the law requires following special considerations.

a. Age of Consent

In our country only a person who is a major by law i.e. above the age of 18 can give valid consent for the treatment. Hence any person who is a minor, cannot legally give consent.

The concept of a “mature minor” i.e. a minor who is mature enough to understand the implications of his or her treatment though well established in some western countries is not routinely recognized in our country. It is also important for a Doctor to remember that even though a minor may represent himself/herself as a major even then the onus of finding out whether the patient is minor or not is on the physician.

b. Mental Incapacity

It is well accepted that a person should be mentally capable to give consent for his or her own treatment. This implies that patients who are mentally retarded or mentally incapable due to any diseases, process may not be capable of giving their own consent. In such cases consent from the legal guardian is essential.

Patients under the influence of alcohol or drugs as well as patients suffering from extreme pain form a separate category; validity of consent in such situations is liable to be questioned.

3. Knowledge Forms the Crux of the Matter Regarding the Consent

It includes:

- Nature of the diagnosis
- Nature of treatment planned

- Forceable risk involved in the treatment
- Prognosis if treatment is not carried out
- Any alternative therapy available.

It is duty of a Doctor to disclose all these points to the patients so that patients may exercise his right to self determination about the proposed course of the treatment.

When questioned specifically by a patient about the risk involved in a particular treatment proposed the doctor’s duty is to answer both truthfully and as fully as the questioner requires.⁸

Consent in Emergency

Generally it is essential to obtain consent before any treatment is administered. However, there is an important exception to the rule. In cases of emergency a patient may be unable to give consent, in such cases a substitute decision maker, if readily available, should be approached. If however such a person is not on the scene, then it is the duty of the Doctor to do what is essential to save life even without consent.

For the doctor to declare any clinical situation an emergency, for which consent is not required there should be demonstrable immanent threat to the life or health of the patient.

There must be an undoubted necessity to proceed at that time. Under such emergency situations, the treatment should be limited to those steps which are necessary to deal with, imminent threat to life, limb or health.

When in emergency, it is imperative to proceed without valid consent from the patient it is correct to keep contemporaneous record explaining such circumstances, which forced the Doctor to act likewise.

If the circumstances are such that the urgency might be questioned later, arranging a second medical opinion would be prudent, if it is possible to do so.

Consent for extend treatment, sometimes during an operation, it becomes essential to extend the surgery in the interest of the patient’s health.

If this is important to carry out at that particular moment then at least substitute decision maker should be informed and validity of urgency of such a step should be well documented.

Entirely unrelated surgery should not be undertaken unless it is essential to save the life of the patient.

In Ram Biharilal’s case—the surgeon did not explain the hazards of chloroform anesthesia before taking consent of the patient for operation of appendicitis⁹.

On finding the appendix to be normal, he proceeded to remove the gallbladder without consent and risking the ill effects of the patient under chloroform.

In this case the surgeon was held negligent.

Blanket Consent

It is a 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 alternatives¹⁰.

Refusal of Treatment

The patient has a right to control his or her body. Hence any treatment without consent of the patient is actionable.

Any competent adult is entitled to reject any specific treatment offered to him, even if the decision may entail risk, as serious as death, and may appear wrong in the eyes of the medical profession. This concept has been rigorously followed by the western law courts in recent times. However, in our country the interest of the state in protecting and preserving the lives and health of its citizens has also been importance in some rare situations¹¹.

Proxy Consent (Substitute Consent)

All the above types of consent can take the shape of *proxy consent*, e.g., parent for child, close relative for eventually unsound/unconscious patient, consent given by *loco parentis*, etc.

Informed Refusal

The doctor is duty-bound to disclose appropriately and adequately to the patient/attendants the risk and possible consequences of not undertaking the treatment/diagnostic procedures/blood transfusion. After understanding all the facts, the patient can refuse to submit to treatment.

Doctors are advised to avoid paternalism. *Paternalism* is an abuse of medical knowledge in such a way that the patient is deprived of his ability to make rational choice.

Situations Where Consent May not be Obtained

- **Medical Emergencies:** The well being of the patient is paramount and medical rather than the legal considerations come first. It may not be necessary to

obtain a consent where life saving procedures are to be undertaken for example:

- In an accident case;
- In a major surgery or post-surgery where additional emergency procedures are required, as for example, doing a tracheostomy to ease breathing.
- In case of person suffering from a notifiable disease. In case of AIDS/HIV positive patients, the position in India regarding its being a notifiable disease or not is not yet clear. However, the Supreme Court in *Mr. X v. Hospital Z* has held that wherever there is a danger of transmitting HIV infection to the 'would be spouse', the doctor/hospital would be under a duty to inform the 'would be spouse', of the danger. Rather, not doing so would make the doctor/hospital *participiens criminis* under sections 269 and 270 of IPC. In England, the Public Health (Infections Diseases) Regulations, 1998 extends the provisions of notifiable diseases to AIDS patients but not to persons who are HIV positive.
- Immigrants
- Members of Armed Forces
- New admissions to prisons
- In case of a person where a court may order for psychiatric examination or treatment.
- Under section 53(1) of the Code of Criminal Procedures, a person can be examined at request of the police, by use of force. Section 53(2) lays that whenever a female is to be examined, it shall be made only by, or under the supervision of a female doctor.

ROLE OF CONSENT IN CIRCUMSTANCES OTHER THAN MEDICAL EXAMINATION AND TREATMENT¹²

1. A female of more than 16 years can give valid consent for sexual intercourse (Sec. 375 IPC). Therefore sexual intercourse by a man with a woman of less than 16 years even with her consent amounts to rape⁴.
2. A person below 18 years cannot give valid consent to suffer any harm which can result from an act not known or intended to cause grievous hurt or death (Sec. 87 IPC). A person above 18 years can participate in rough sports like rugby, boxing, wrestling etc³.
3. The nature of illness of a patient should not be disclosed to a third party without his consent. But a doctor can disclose a secret without consent (even if patient refuses consent) if it is "Privileged communication"¹³.

4. It is improper to disclose the illness of a patient to a third party without his consent or concerned authorization.
5. Removal of organ for transplantation:
 - From a living person: 1section 3 of “The Transplantation of Human organs Act, 1994” defines authorizes the removal of any of his/her organs for therapeutic purposes. Therefore, it is illegal to remove of organs from the body of a person of less than 18 years even with his/her consent. If the person is above 18 years, conscious and of sound mental health his/her own consent is required for removal of organs from his/her body.
 - From a dead body: 1. no organ can be removed, it in request is to be carried out on the dead body. 2. To remove organs from the body, there must exist an oral or written consent of the deceased that have been obtained at any time in the presence of two or more witness, during his last illness. Even if the consent was given by the deceased during life, permission must be obtained from the person in possession of the body.
 - I. For video and audio recording: doctor should in from the patient before recording (except in situations in which consent may be understood from patient’s cooperation with a procedure e.g. radiographic investigation) and obtain his consent. But doctor may record without consent in exceptional circumstances, such as when it is believed that child has been victim of abuse. If a recording has been made in the course of investigation or treatment of a patient but the doctor now wishes to use it for another purpose e.g. Publication in textbook, journals, etc., the patient’s consent must be obtained.
 - II. For research¹⁴: before obtaining consent from the potential subject the doctor must inform about:
 - a. Purpose of the study.
 - b. How the research relates to the subject’s underlying condition and the impact on his well being.

- c. Procedure of the study.
- d. What risks and benefits the person can expect.
- e. Alternative treatments available.

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 one self from future medical litigation. We must adhere to aim in medicine “do no harm”. By helping in healing we must not harm the patient.

“The meaning of good or bad, of better or worse is simply helping and hurting”.

— Ralph Waldo Emerson

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