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# **ROLE OF CONSENT IN MEDICAL NEGLIGENCE**

AUTHORED BY - SHUBHAVI MALHOTRA<sup>1</sup>

## **ABSTRACT-**

Consent plays a pivotal role in medical jurisprudence, serving as a fundamental principle that safeguards patient autonomy while delineating the boundaries of lawful medical intervention. In cases of medical negligence, the presence or absence of informed consent significantly impacts liability and ethical considerations. This paper explores the legal and ethical dimensions of consent in medical negligence, analyzing its role in distinguishing between permissible medical procedures and actionable malpractice. It examines the doctrine of informed consent, emphasizing the duty of healthcare providers to disclose risks, alternatives, and potential consequences of treatment. Furthermore, the paper evaluates judicial precedents and statutory frameworks governing medical consent, highlighting instances where inadequate disclosure has led to negligence claims. The study also addresses exceptions to consent, such as emergencies and therapeutic privilege, assessing their implications on liability. By critically analyzing legal principles and case laws, this research underscores the necessity of robust consent practices to mitigate legal risks and uphold patient rights in medical practice.

## **Introduction-**

The term 'consent' is defined thus- when two or more persons agree upon the same thing in the sense they are said to consent as per the definition of 'consent' given in Section 13 of the Indian Contract Act.

Consent for the purpose of medical treatment means: the granting of permission by the patient for another person to perform an act<sup>2</sup>.

Consent in context of a doctor-patient relationship, means the grant of permission by the patient for an act to be carried out by the doctor, such as diagnostic, surgical or therapeutic procedure. Consent can be implied in some circumstances from the action of the patient, such as when a patient enters a dentist's clinic and sits in the dental chair, his consent is implied for

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<sup>1</sup> LLM Student, Amity University Noida

<sup>2</sup> Taber's Cyclopedic Medical Dictionary, 20<sup>th</sup> edn, 2001.

examination, diagnosis and consultation.

Consent must be voluntary, competent and informed. Voluntary means that, when the patient gives consent, he or she is free from extreme duress and is not intoxicated or under the influence of medication and that the doctor has not coerced the patient into giving consent<sup>3</sup>.

Consent is “not a ‘one-off’ event of signatures on paper” and not a submission of the patient to a particular treatment but rather a process of communication. It is then perceived as a proactive process empowering the patient to consciously decide on what he/she considers best. Thus, consent is “a process of communication requiring the fulfilment of certain established elements, like competence, sufficient disclosure, understanding and volunteering<sup>4</sup>.”

Apart from the requirement of consent being there under law of torts and various laws of the country, there is now a specific provision under the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 through Regulation No. 7.6 which states that before performing an operation, the physician should obtain in writing the consent from the husband or wife, parent or guardian in the case of minor, or the patient himself, as the case maybe. In an operation which may result in sterility the consent of both husband and wife is needed.

A duty is cast upon the medical practitioner to prove that he did not use any undue influence in order to get a legally valid consent from a patient and he has at no point of time utilised his dominant and superior position in obtaining the consent from the patient who is always practically in a precarious needy and difficult position.

In case the consent is not obtained, that will give rise to cause of action for seeking the remedy criminally for making any invasive procedure without consent of patient amounting to assault, with criminal force under Section 350 of the Indian Penal Code and can also seek a civil remedy for compensation for the injury occurred to the patient in accordance with law of torts.

According to law of torts, the doctor does not seek a legally valid consent; and even if there is no damage in form of negligence, the patients can sue the doctor for the injury upon his personal

<sup>3</sup> West's Encyclopedia of American Law, 2<sup>nd</sup> edn, 2008.

<sup>4</sup> C. Jayapal Reddy v. G.S Rao, Managing Director, Yashoda Group of Hospitals, 2014(1)CPJ271(NCDRC)

or private rights encroached upon which has been endowed upon him by legislative enactments. The principle of requiring consent applies in all cases except in certain circumstances in which doctor may be entitled to proceed without his consent, firstly, when the patient's balance of mind is disturbed; secondly, when the patient is incapable of giving consent by reason of unconsciousness; and finally when the patient is a minor<sup>5</sup>.

A medical practitioner cannot examine, treat or operate upon a patient, without the patient's consent except by committing a trespass or assault. This consent, which may be implied, amounts to an agreement on part of the patient to permit the treatment in question and is sufficient consideration for an implied promise to exercise proper skill and care<sup>6</sup>.

It's noteworthy to notice that the legislation does not mandate written consent; rather, it only requires simple consent. The necessity of written consent is really decided by the medical practice itself. Ideally, written agreement would be useful in cases when the patient is given anaesthesia (either local or general) or is in excruciating pain while the therapy is being administered. A doctor is not required to always get written consent; if he does not, he might be held accountable. However, in the event of litigation, the medical professional would find it easier to prove permission if it was in writing.

The element of consent is one of the critical issues in medical treatment. The patient has a legal right to autonomy and self determination enshrined within Article 21 of the Indian constitution. He can refuse treatment except in an emergency situation where the doctor need not get concerned for the treatment. The consent obtained should be legally valid. A doctor who treats without valid consent will be liable under the torts and criminal laws as well as Consumer Protection Act. The law presumes that the doctor to be in a dominating position, hence the consent should be obtained after proving all necessary information<sup>7</sup>.

Express written consent is to be obtained for: (i) all major diagnostic procedures; (ii) general anaesthesia; (iii) surgical operations; (iv) intimate examinations; (v) examination for determining age, potency and virginity; and (vi) in medico legal cases. Informed consent for high risk in writing has to be obtained either from the patient or from her close relatives and if

<sup>5</sup> Punjabi Nursing Home v. Kailash Marodia, 2003 (2) CPJ 194 (MP SCDRC)

<sup>6</sup> Charlesworth & Percy on Negligence, 11<sup>th</sup> Edn, 2006, p.108

<sup>7</sup> Omprakash v. Nandimath: Consent and Medical Treatment: The Legal Paradigm in India.



that is not taken and if the patient becomes paralyzed or dies, then certainly there are chances that the patient's relatives would allege negligence on part of the treating surgeons and the hospital. Hence informed consent is very essential<sup>8</sup>.

It is possible to give explicit or implicit consent for treatment. It may be argued that the patient's voluntary entry into the consultation rooms constitutes his agreement for the clinical diagnosis to be made. When a patient generally complies with a doctor's directions during a clinical diagnostic, consent may be assumed. This is a great illustration of implicit permission.

A vaginal examination or other intimate examination of the patient may be required during the clinical evaluation. The doctor should ideally get another consent for this type of examination by asking the patient verbally. Additionally, it is desirable to get the patient's written agreement before doing any intrusive examinations, such as making an incision or taking samples of bodily fluids.

### **Who can give consent?**

For the purpose of clinical examination, diagnosis and treatment, consent can be given by any person who is conscious, mentally sound and is of and above 12 years of age as provided under Sections 88 and 90 of the IPC.

Consent is defined under section 13 of the Indian contract act. This act also provides under section 11 that only those persons who are of and above 18 years of age are competent to enter into a contract. Since doctor patient relationship amounts to entering into a contract, it is advisable that consent should be obtained, especially written consent, from parents or guardian of a patient who is below 18 years so that validity of the contract is not challengeable.

### **When consent is not valid?**

Consent given under fear, fraud or misrepresentation of facts or by a person who is mentally unsound, not fully conscious, intoxicated or who is ignorant of the implications of the consent, or who is under 18 years of age is invalid.

A signed consent form by itself does not constitute consent; it simply serves as evidence of

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<sup>8</sup> H.S Tuli v. Post Graduate Institute of Medical Education and Research, 2008 (1) CPJ 392 (NCDRC)

consent. The consent form will be valid only if it has the following 3 essential components-

- (i) the patient gives it voluntarily without any conversion
- (ii) the patient has the capacity and competence to give consent
- (iii) the patient has an adequate level of information about the nature of the procedure to which he is consenting.

The consent should be a free consent as seen under section 10 of the Indian contract act in context of medical negligence. A duty is cast upon the medical practitioner to prove that he did not use any undue influence in order to get a legally valid consent from a patient and he has at no point of time utilised his dominant and superior position in obtaining consent from the patient who is always practically in a precarious, needy and difficult position<sup>9</sup>.

### **Capacity and Competence to give consent-**

The law presumes that an adult is competent, but competency may be an issue in numerous instances. Competence is typically only challenged when a patient disagrees with a doctor's recommended treatment or refuses treatment altogether. If an individual understands the information presented regarding treatment, she or he is competent to consent to or refuse treatment<sup>10</sup>.

There are three aspects to competence: first, comprehending and retaining treatment information, second, believing it and, third, weighing it in the balance to arrive at a choice.

When patients lack the competence to make a decision about treatment, substitute decision makers must be sought. Hence, the determination of whether patients are competent is critical in striking a proper balance between respecting the autonomy of patients who are capable of making informed decisions and protecting those with cognitive impairments<sup>11</sup>.

Although incompetence denotes a legal status that in principle should be determined by a court, resorting to judicial review in every case of suspected impairment of capacity would probably bring both the medical and legal system to a halt. The sun more situations there is good reason to continue the traditional practice of having physicians determine patients' capacity to decide

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<sup>9</sup> Punjabi Nursing Home v. Kailash Marodia, 2003 (2) CPJ 194 (MP SCDRC)

<sup>10</sup> West's Encyclopaedia of American Law, 2<sup>nd</sup> edn, 2008

<sup>11</sup> Assessment of Patients' Competence to Consent to Treatment, Paul S Appelbaum, MD N Engl J Med 2007; 357:1834-1840

when to seek substituted consent<sup>12</sup>.

In addition, since consent obtained from an incompetent person is invalid, physicians who do not obtain a substituted decision may be subject to claims of having treated the person without informed consent.

### **Advance directive or living will for medical intervention-**

Advanced medical directives are documents that are made at a time when a person has full decision making capabilities and are used to direct medical care in the future when this capacity is lost. Many statutes are narrowly drawn and specify that they apply only to illnesses when death is eminent rather than illnesses requiring long term life support, such as in end-state lung, heart or kidney failure; multiple sclerosis; paraplegia and persistent vegetative state.

Patient sometimes use living wills to direct future medical care. Most commonly, living wills specify steps a patient does not want taken in cases of life threatening illness, but they may be used to specify that a patient wants aggressive resuscitation measures used.

Studies have shown that living wills often are not honoured, despite the fact that federal law requires all hospitals, nursing homes, and other medical aid providers to ask patients on admission whether they have executed an advanced directive. Some of the reasons living wills are not honoured are medical persons fear of liability; the patient's failure to communicate his or her wishes or misunderstanding or mismanagement by hospital personnel.

Another way individuals attempt to direct medical care is through a durable power of attorney. A durable power of attorney is a written document to where in the person designates and other person to perform certain acts or make certain decisions on his behalf. It is called durable because power continues to be effective even after the person becomes incompetent or it may only take effect after the person becomes incompetent. A durable power of attorney may be used by itself or conjunction with a living will.

When advanced medical directives function as intended and are honoured by physicians, they

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<sup>12</sup> Assessment of Patients' Competence to Consent to Treatment, Paul S Appelbaum, MD N Engl J Med 2007; 357:1834-1840

free family members from making extremely difficult decisions. They may also protect physicians. Standard medical care typically requires that doctor provides maximum care. In essence, a living will can change the standard of care upon which the physician will be judged and may protect the physician from legal or professional repercussions for withholding or withdrawing care<sup>13</sup>.

### **Implied consent-**

It means basically non-verbal consent suggested by the actions by the patient, as when he or she enters the dental office and sits in the dental chair. This suggests that the patient seeks examination, diagnosis and consultation<sup>14</sup>.

This is by far the most common variety of consent in both general practice and hospital practice. The fact that a patient comes to a doctor for an ailment implies that he is agreeable to medical examination in the general sense. Consent is implied when a person holds out his arm for an injection. This however does not imply consent to procedures more complex than inspection palpitation, percussion and routine sonography. For other examinations notably rectal and vaginal examination and withdrawal of blood for diagnostic purpose express consent should be obtained.

### **Express consent-**

Express consent is anything other than implied consent. This may either be oral or written. Express oral consent is obtained for relatively minor examinations or therapeutic procedures, preferably in the presence of a disinterested 3rd party.

Express consent is to be obtained for:

- all major diagnostic procedures
- general anesthesia
- for surgical operations
- intimate examinations etc.

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<sup>13</sup> <http://legal-dictionary.thefreedictionary.com/patient+rights>

<sup>14</sup> <http://legal-dictionary.thefreedictionary.com/patient+rights>

### **Informed consent-**

Indian Saint means of voluntary agreement made by a well advised and mentally competent patient to be treated. The healthcare provider should provide full disclosure of information regarding the material risks, benefits of the proposed treatment, alternatives, and consequences of no treatment, so that the patient can make an intelligent and informed choice<sup>15</sup>.

The concept of informed consent has come into force in recent years and many actions have been brought by patients who alleged that they did not understand the nature of the medical procedure to which they gave consent.

All information must be explained in comprehensible non medical terms preferably in the local language about the:

- diagnosis;
- nature of treatment;
- alternative methods of treatment;
- risks and benefits involved in both proposed and alternative procedure;
- the relative chances of success or failure of both procedures so that the patient has option to accept or reject the treatment.

### **Proxy consent-**

Proxy consent has been defined as: “A decision made with or on behalf of a person who lacks full legal capacity to consent to or refuse medical treatment. In the case of children under the age of 16 years who are not competent because they are deemed insufficiently mature or understanding of their situation people with parental responsibility is usually asked to take a proxy decision about their care. However parents can only consent to or refuse treatment on behalf of their children in so far as they are considered to be acting in the child's best interest. For adults, a person previously nominated by the patient while he or she had capacity can be granted a lasting power of attorney and may make healthcare decisions on the patient's behalf. The decision itself may be based on either a judgement of the patients best interest or a judgment as to what he or she would wish in the circumstances<sup>16</sup>.”

<sup>15</sup> Taber's Cyclopedic Medical Dictionary, 20<sup>th</sup> edn, 2001.

<sup>16</sup> Oxford Concise Medical Dictionary, 8<sup>th</sup> edn, 2010



Proxy consent is valid in the following circumstances:

- in emergency/accident cases where parents/guardians or near relatives are not available
- in case of unconscious patient/ patient under anaesthesia requiring emergency treatment/operation
- in case of mentally unsound patient
- in the case of minor where consent may be given by parent/close relative.

Regarding proxy consent, when the patient is unable to give consent himself, there are no clear regulations or principles developed in India. If such a situation exists the medical practitioner may proceed with treatment by taking the consent of any relative of the patient or even an attendant.

In one case, the wife of the patient informed the hospital authorities in unambiguous terms that she had no objection to her husband undergoing bypass surgery, her consent was deemed sufficient for the purpose of any formalities with which the hospital was required to comply<sup>17</sup>.

### **Blanket Consent-**

Many doctors or hospitals adopt the practice of obtaining “blanket consent” when the patient, at the time of consultation or admission is asked to put his or her signatures on a printed form in which it is stated that he or she gives consent to all the types of treatment and even surgery without mentioning the nature of treatment or surgery. Such a consent is termed as a blanket consent. Such signing of consent form does not amount to simple or informed consent and is not valid in the eyes of law.

The worst solution to documenting informed consent is the form that blankets all possibilities. The typical blanket form recites that the physician and his or her designates may do what they think is necessary. These forms usually contain language about how the physician has discussed their treatment with the patient under the patient has had an opportunity to ask questions. Such a form may protect the physician from acquisitions of battery. As the soul records of consent, these forms are worthless<sup>18</sup>.

The concept of written, witnessed or expressed consent in hospitals, has assumed great

<sup>17</sup> CA Muthu Krishnan v. Rajyalakshmi, AIR 1999 AP 311

<sup>18</sup> <http://biotch.law.lsu.edu/books/lbb/x292.htm>

importance because it is not possible to cover by implied consent the vastly increased number of diagnostic and therapeutic procedures, being carried out regularly and the consent is valid only for a specific procedure. The usual blanket consent form used by medical institutions in which the patient consents and authorises the doctor to do whatever he thinks best for the patient under the circumstances may turn out to be of no value in court<sup>19</sup>.



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<sup>19</sup> Article on informed consent by Late Lt. Gen. NR Krishnan