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Informed Consent in Medical Decision Making In India

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Abstract

Consent is one of the key elements for protection of welfare of patients or research participants. The physician has a legal and ethical responsibility to provide adequate information to the patient so that he or she is able to process the information and make appropriate decisions. The patient's consent must be voluntary and competent. In order to meet the requirements for effective, informed decision making, a physician must disclose material facts, which are relevant to decision making, including the patient's diagnosis, proposed treatment, risks and benefits of the treatment, alternative treatments along with their risks and benefits, and the risks of refusal. A physician must answer truthfully about the number of similar procedures or cases performed, and disclose success rates, and any financial conflict(s) of interest. The physician must advise patients of all personnel involved in their care and their respective roles, including residents, students, and equipment representatives.

Keywords: *Medical consent, Indian medical ethics*

INTRODUCTION

The medical profession is endowed with ethical, morale and contractual obligation to give treatment to the patients. The patients no longer could be driven under paternalistic umbrella of medical practitioners rather a doctor is under obligation to divulge all information to patients in a comprehensible manner so that the patients can take decisions. Consent is defined as " the agreement to what other person has proposed [1].

The earliest expression of this fundamental principle, based on autonomy, is found in the Nuremberg Code of 1947 [2]. The first was Nuremberg code adopted after World War II to safeguard interests of human subjects in clinical experiments. Similarly, the Declaration of Helsinki adopted by the World Medical Association in 1964 emphasizes the importance of obtaining freely informed consent for medical research by adequately informing the subjects objectives, benefits and side effects of the study [3]. Several international conventions and declarations have similarly ratified the importance of obtaining consent from patients it is of utmost importance that physicians are aware of their legal obligations in obtaining consent from patients.

CONSENT AND ITS TYPE

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) [4].

According to the law of tort - battery is defined as 'Application of force to the person of another without lawful justification'. Therefore in absence of proper consent battery would be committed [5].

Implied Consent
This type of consent which is although not written but legally binding is seen in day to day practice either by the words or behavior of the patient or by the circumstances under which treatment is given.

Expressed Consent
An expressed consent is the one for which the terms are stated in distinct and explicit language. It may be oral or written. Oral consent is employed for minor examinations or therapeutic procedures but this should preferably be obtained in the presence of a witness. Oral consent is as valid as written consent [6]. It should be obtained when the treatment is likely to be more than mildly painful, or when it carries appreciable risk, or when it will result in diminishing of a bodily function. It is better to take consent for invasive procedures, surgery and even for narcotics or analgesics during the treatment. Written consent guarantees active and explicit consent, thus offer the highest guarantee to the participant. It is most appropriate in studies that contain some level of risk, but also in many studies with no risk above those of daily life, when participants disclose personal or sensitive information, or when they are exposed to deception, or any experimental treatment. Experiments and in-depth interviews in particular should consider written consent.

Oral consent is also a valid option for participants that are uncomfortable reading and writing. In that case, the researcher should record the reading of a consent statement, and the clear answers of the participants indicating willingness to participate. The recording verifies informed oral consent [7]. It is useful in situations where active consent is essential but the discomfort or risk are too greater to make written consent valid, for e.g consent from criminals, immigrants, homeless people or where research is pertaining to behavior or where research is pertaining to behavior or attitudes bearing senses.

Informed Consent
It is necessary that all information is explained in comprehensive, non-medical terminology preferably in patient's own language, information pertaining to:

- Nature of the illness
- Nature of the proposed treatment or procedure and alternatives
- Potential risks of not receiving the treatment

Active consent & Passive consent
Active consent is recommended for research where participants indicate their willingness to participate by agreeing to a specific statement prior to inclusion in the study.
In passive consent participants are informed of the study, and are considered to agree to participate unless they specifically decline to be included in the study. This is often seen in schools that send forms to parents asking them to allow their students to participate in various studies or activities. Although it yields high participation rates, it should be limited to completely innocuous research (typically not involving minors) where participants are only observed without giving any drugs or intervention.

Blanket Consent
It refers to consent taken to cover everything done to patient without specific mentioning the procedure. Blanket consent is legally inadequate for any procedure that has risks or alternatives[8].

Proxy Consent (Substitute Consent)
All the above types of consent can take the shape of proxy consent, when the participant is minor or an adult incapacitated to give valid consent e.g., parent for child, close relative for mentally unsound/unconscious patient, consent given by loco parentis, etc.

INDIAN SCENARIO

The doctors in India take a paternalistic view 'The doctor knows the best', for their patients decisions due to widespread illiteracy among population.

The principle of autonomy is enshrined within Art 21 of the Indian Constitution, which deals with the 'right to life and personal liberty'. The expression of personal liberty under article 21 of the constitution is of the widest amplitude and covers a wide variety of rights, including the right to live [9]. Thus, every human being has a right to determine what shall be done with his or her own body. A Surgeon who performs an operation without the patient's consent commits an assault for which he is liable. In India the common law doctrine is not fully developed and courts seek Indian Contract act and Indian penal code for cases falling in gambit of consent.

The paradigm shifts toward patient autonomy away from physician's paternalism makes patient consent more relevant in present context. Parties are generally competent (in accordance with the Indian Majority Act) [10]

- If they have attained the age of 18,
- Are of sound mind, and
- Are not disqualified by any law to which they are subject to.

The General Medical council in England states that a young person can be treated as an adult and can be presumed to have the capacity to decide if he/ she have attained 16 years of age [11]. The first Indian case that emphasized the importance of informed consent was Ram Bihari Lal v Dr J N Srivastava [12].

The patient was suspected to have appendicitis. She was operated after taking her consent. During operation it was found that her appendix was normal without inflammation. To protect the interest of the patient, the doctor removed her gangrenous gall bladder. The doctor was held liable as he was operating without consent. The doctor acted as per traditional paternalistic notion acts like a parent of the patient and starts deciding on behalf of the patient himself but unfortunately, the law does not accept this notion. The foremost concern is patient's autonomy, had the doctor acted accordingly he should have stopped after finding a normal appendix rather than operating the gall bladder, failing to do so the doctor was culpable of trespass. When he proceeded in removing her gall bladder, he was acting *sans* valid consent, which was an extreme case of professional paternalism and gross disobedience to the right of the patient's autonomy and held liable as he operated without patient's consent.

The important question is now is that whether the hospitals have responsibility to inadequate information disclosure towards patients as per theory of respondent superior? A hospital policy must govern the procedure by which consents are obtained. Consent been a continuous process can be revoked back by patient and in such scenario it is duty of hospital to ensure that the procedure or intervention is not taken by any of the hospital personnel on the patient.

THE STATUTORY SECTIONS RELATED TO INFORMED CONSENT

Indian Penal Code, 1860 Section 53(1) CrPC: In criminal cases when examination of an arrested person can lead to vital evidence related with the commission of crime, he can be examined by the doctor without his consent and even using force, if the application for examination is from a person not below the rank of sub Inspector [13].

- Section 54 CrPC: An arrested person can also request to be examined by a doctor to detect any evidence which he feels is good for him.
- Section 87. Act not intended and not known to be likely to cause Death or Grievous Hurt, done by consent.

- Section 89 Act done in Good Faith for Benefit of Child or Insane Person, by or by Consent of Guardian.
- Section 90 IPC: Consent given by an insane person or given under fear of injury, death etc. or due to misconception of a fact is invalid [14].
- Section 92. Act done in Good Faith for Benefit of a Person without Consent.
- Section 202. Intentional omission to give information of offence by person bound to inform is punishable by law.
- Indian Contract Act14, 1872- Every person is competent to contract who is of the age of majority according to the law to which he is subject and who is of sound mind, and is not disqualified from contracting by any law to which he is subject[15].
- The Indian Majority Act15, 1875- The legal age for giving a competent consent in India is 18 years as per the Indian Majority Act. Whereas in children between 12 and 18 years consent for physical examination and treatment [16].

WHO CAN GIVE CONSENT?

Guardian, parents, or person in whose legal custody the patient (age < 12 years) is present. The treatment of children is mainly under the consent of parent or guardian or under the doctrine of in loco parentis, where the consent is given by a third party in place of patient [17]. In case of emergency where parents or guardian are not available the consent can be taken from person in charge of child to give consent for treating child, who become sick during picnic away from the home town or the consent of the principal of a residential school. There are other situations like legally separated parents or sole custody authorized to one parent or unmarried mothers, where the consent could be obtained from the mother or who is legally entitled. It is desirable that the doctor himself takes consent from patients. Local guardian can give consent on behalf of a person only if the treatment is an emergency one.

COMPONENTS OF INFORMED CONSENT

Informed consent is a requires that consent obtained from a person meets certain minimum standard in medical field referring to information furnished by doctor so that patient is aware of risks and benefits of treatment.

This doctrine is based on the following components:

Right of seeking Information

By the patient before giving consent for treatment that includes nature of disease, it's course, testing requirements, treatment options, consequences of non treatment, risks and benefits of treatment, expected outcome, cost of treatment and follow up requirement [18, 19].

Competency of patient for giving valid consent. He / she should have

- Sound disposing mind.
- legally competent
- Understanding of implications of his consent.

Understanding of the nature and content of the physicians' disclosure should be such that an ordinary person could easily understand it [20].

- **Voluntary** Consent to treatment free from any undue pressure or coercion [21].
- **Decision:** A patient must communicate his decision freely without being biased from any corner as to undergo for treatment.

Emergency

In case of Medical Emergency failure to take consent from patient for treatment will not amount to battery and medical practitioner are provided immunity under section 92 IPC-1860 [22]. In the case of *Bailey vs. Belinfante* the doctor was charged of battery, liable for civil action

for damages for performing procedure without consent [23, 24].

JUDICIAL PRONOUNCEMENTS

'The Bolam' test (Reasonable Doctor test) In 1954, John Hector Bolam underwent electroconvulsive therapy (ECT) for clinical depression. At that time, medical opinion differed on how best to minimize the risk of injuries possible from convulsions induced by ECT. In this case the manual restraint was ineffective causing fracture of pelvis [24]. The plaintiff argued that the doctor and the hospital were negligent in providing standard of care to the patient. The case established the test for the standard of care in law, required of a doctor which states that *[a doctor] is not guilty of negligence if he has acted in accordance with the practice accepted as proper by a responsible body of medical men skilled in that particular art ...Putting it the other way round, a man is not negligent, if he is acting in accordance with such a practice, merely because there is a body of opinion who would take a contrary view.*

Thus if the medical practice is supported by reasonable peers, Bolam's test is fulfilled and hence no medical negligence.

In **Canterbury v Spence (reasonable patient test, transatlantic test)** the US court emphasized on patient's right to know all material risks and is obligation on doctor to disclose the risks associated with treatment as in this case the risk of paralysis after spinal surgery. The failure on the part of doctor amounts to negligence [25].

In **Reibl v Hughes** and **Rogers's v Whittaker** cases the doctor failed to disclose material risk to patient. Mr Reibl suffered a massive stroke after carotid artery surgery, but was not warned of this possible risk, the Canadian Supreme Court held the doctor negligent in disclosure of material risk to patient. Dr Whittaker, an ophthalmic surgeon, was held to be negligent in failing to warn Mrs Rogers that surgery to her right eye could lead to a risk of loss of sight in her left eye (through the process of sympathetic ophthalmia) [25, 26]. The High Court of Australia emphasized that the court, and not the medical profession, set the standard of care of disclosure [27, 28].

In **Smith v Tunbridge Wells** case, a young man had not been warned of a risk of impotence and bladder dysfunction after rectal prolapse surgery. Justice Morland concluded that material risk although remote but failure to disclose it made the later liable for negligence [29].

In **Chester v Afshar** Mr Afshar, an eminent neurosurgeon carried operation for removal of prolapsed lumbar intervertebral discs, the patient Ms Chester suffered nerve damage leading to paralysis. Mr Afshar failed to warn her of the risk of paralysis and failure of disclosure of material risk he was held liable [30]. The case reinforced that consent been a process and a cooling period is beneficial to both the patient and surgeon rather than obtaining consent in a single consultation, one should allow patient to ponder over the pros cones of surgery before reaching on to a decision.

Sidaway v Board of Governors of the Bethlem Royal Hospital

Sidaway case is an important house of court case in English law pertaining to the duty of surgeon to inform the patient before any surgical procedure. Here the plaintiff suffered from neck pain post a cervical decompression surgery. The neurosurgeon did not explain the remote side effect of paraplegia due to cervical compression. The patient developed paraplegia after spinal surgery.

The court rejected the claim for damages and held that consent did not need detailed explanation of all side effects. However,

Lord Scarman in dissent said that Bolam test should not be applied to the issue of informed consent and the doctor is under duty to explain all material risks.

Dr.T.T.Thomas vs. Smt. Elisa

In this case the question was the liability of a doctor for not performing an emergency operation for want of patient's consent and consequent death of patient. The patient with severe abdominal pain after admission in hospital was diagnosed with acute appendicitis, he needed surgery but it was not done on the same day due to refusal of patient to give consent for operation. There was no mention of consent refusal in case sheet of the patient and Kerala high court held doctor negligent for failure to perform emergency operation [30].

Samira Kohli Appellant versus Dr Prabha Manchanda and others

The Supreme Court held that consent given for diagnostic procedure is not valid for therapeutic one. The addition of clause like "laporotomy if needed" does not amount to consent for a total hysterectomy with bilateral salpingo opherectomy [31]. The appellant was a competent adult neither a minor nor mentally challenged or incapacitated with no question of someone else giving consent on her behalf, she was temporarily unconscious under anesthesia and as there was no emergency therefore the respondent should have waited until the appellant regained consciousness and gave proper consent. In absence of emergency the consent given by her mother is not a valid or real consent. Although the decision to remove reproductive organs as part of surgical treatment was correct but the doctor was caught in caveat of performing surgery without adequately informed consent amounting to invasion and interference with bodily integrity and autonomy of patient. The respondent was awarded compensation of Rs 25,000/INR

Montgomery v/s Lanarkshire Health Board (Scotland)

The law of consent has changed subsequently to Montgomery case decided by UK court. It reaffirms right to autonomy to woman who unfortunately had shoulder dystocia in labor. Mrs Montgomery, a lady was not informed by her obstetrician of chances of shoulder dystocia although she had expressed concerns about vaginal delivery; the doctor did not explain the risk of dystocia as the risk was negligible.

It brings English law and Scottish law on the same platform with US law and stress that it is no longer appropriate and sufficient to standard reasonable medical professional test instead the standard is whether the patient attach significance to it or not. The court ruled that Mrs Montgomery should have been informed of the risk of shoulder dystocia and given the option of a caesarean section. The index case hammers final nail in coffin of medical paternalism.

CONCLUSION

In order to meet the requirements for effective, informed decision making, a physician must disclose material facts, which are relevant to decision making, including the patient's diagnosis, proposed treatment, risks and benefits of the treatment, alternative treatments along with their risks and benefits, and the risks of refusal. A physician must answer truthfully about the number of similar procedures or cases performed, and disclose success rates, and any financial conflict(s) of interest. The physician must advise patients of all personnel involved in their care and their respective roles, including residents, students, and equipment representatives. The following mnemonic is useful for guiding and documenting discussion with the patient: **A**lternative therapies available, **B**enefits of the therapy proposed, **C**ommon but not devastating risks, **D**evastating but not

common risks and **E**xtra considerations specific to the patient in question.

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