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Medical consent in india - Ethical and legal issues

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Abstract

In India in recent years there has been an increase in the number of malpractice suits that have arisen because of lack of consent or inadequate consent from the patients for various procedures. Many clinicians are unaware of the legal and ethical requirements and clinical aspects of consent in Medicine in India. Unlike many other countries, the Indian Statute Book does not contain separate legislation regarding age for consent to medical treatment. This paper discusses the ethical, legal and clinical aspects of informed consent. For effective legal protection, suggestions have been given for taking proper informed consent in various scenarios. There is a need to frame guidelines for signing consent forms. Need for legislation with regard to age for consent for medical treatment has also been highlighted.

Keywords

Informed consent, Presumed Consent, Third-Party Consent, Parental Consent, age for consent, ethical and legal issues .

Introduction

Over the last few decades we have moved from a paternalistic view of medicine in which the doctor decided what was best for the patient to a discussion about whether in some cases full disclosure might harm the patient. Traditional doctor-patient relationship was one in which the doctor and the patient were unequal bargaining partners in a contract for services with the doctors special knowledge creating the advantage. Informed consent is meant to force the doctor to give the patient the knowledge that will make him or her an equal bargaining partner. Thus informed consent is meant to transform the essence of the doctor-patient relationship to a contractual one as contractual relationships are thought to promote individual autonomy and freedom of choice.[1]

In psychiatric practice one sometimes deals with patients whose judgment may be impaired at times due to mental illness. Doctors may also be privy to many intimate details of their patients, involving their personal, emotional and social life. Hence role of consent in psychiatry (especially the ethical and legal aspects) becomes very important.

Consent

Consent means an agreement, compliance or permission given voluntarily without any compulsion.[2] Section 13 of *The Indian Contract Act* states that 'two or more persons are said to consent when they agree upon the same thing in the same sense'. Common meaning of consent is permission whereas the law perceives it as a contract i.e. an agreement enforceable by law. In consent there are four separate but correlated elements that are: voluntary ness, capacity, knowledge and decision-making. Voluntary ness suggests willingness of patient to undergo treatment. Capacity means a degree of ability of the patient to understand the nature and consequences of the treatment offered. Knowledge means that sufficient amount of information about the nature and consequence of the treatment has been disclosed to the patient. Decision-making means the ability to take decisions regarding consent. To be legally valid all these elements must be present in the consent.

Consent can be implied, expressed or presumed. When a patient comes to a doctor an implied consent is there for taking history, general physical examination etc. The limitations of implied consent are that there is always a scope for misunderstanding between the doctor and patient on what was actually implied by the patient's actions. An expressed consent can be written or oral. This is taken if

there is no implied consent or when any material risk is involved. Expressed consent includes informed consent, which is the ideal form of consent because it includes all aspects of meaningful decision-making. Informed consent involves telling the patients about the nature of their condition, the nature of the proposed treatment, benefits of the proposed treatment, risks of the proposed treatment, and available alternatives to the proposed treatment along with their benefits and risks. Presumed consent is important in cases of emergency when consent cannot be taken. Another example of presumed consent as practiced in some countries (U.S.A., Spain, France) is in postmortem cases where unless there is a pre-recorded objection or an intimation of objection from the next of kin of deceased prior to death, corneas can be removed for transplantation.[3,4] (In India there is a proposed amendment in the Human Organ Transplantation Act along these lines). Presumed consent allows the removal of organs, unless the decedent has opted out or the family objects i.e. unless there is a pre-recorded objection or an intimation of objection from the next of the kin of the deceased.[3,4] Tacit consent describes consent that is expressed silently or passively by omission.

Ethical and Legal Issues Involved

1. First and foremost is the age at which valid consent can be given in India.
2. Relative importance of written and verbal consent.
3. When and how the consent should be taken. Who should sign the forms?
4. Circumstances in which full disclosure of medical facts can be dispensed with.
5. Role of proxy consent.
6. Consent in Medical Emergencies.
7. Problems and dilemmas faced when taking consent in Psychiatric Practice.

Ethical, Legal and Clinical Principles of Informed Consent

1. Consent is said to be free when it is not caused by coercion, undue influence, fraud, misinterpretation or mistake. The consent must be to do a lawful act and it must not disobey any provision of the law.

Consent by intoxicated person, person of unsound mind or a person below twelve years of age is invalid {Section 90 IPC(Indian Penal Code)}.

2. Many countries have legislated age for giving valid consent for medical examination and procedures. In England sixteen years is the age for giving valid consent for medical examination and procedures. But unfortunately the Indian Statue Book does not contain

separate legislation regarding consent to medical treatment nor do the various acts relating to majority, minority and guardianship throw any light on the subject. As a result, the laws for consent in general are also being applied to the medical profession.

According to Section 90 IPC a child less than twelve years of age or insane person cannot give valid consent.

By implication from Section 90 IPC, one can say that in general a boy or girl can consent to medical or surgical treatment if he or she is above twelve years of age provided the treatment is intended for his or her benefit and is undertaken in good faith.

Section 88 and Section 90 of the IPC suggest that the age for giving valid consent for any medical procedure is twelve years. Hence a doctor taking consent for medical or surgical treatment from a person aged twelve years or more can be legally said to have taken a valid consent and cannot be held criminally liable on this account.

However Sections 87 IPC mentions eighteen years as the age for giving consent for acts not intended and not known to be likely to cause death or grievous hurt. These acts are not necessarily for the benefit of the person . Hence Section 87 IPC is not applicable to the medical profession as here (in Section 87 IPC), the acts are NOT done for the person's benefit.

Another school of thought however feels that valid consent can only be given at or above eighteen years of age.[5] They feel that consent is a contract between two parties and as the Indian Contract Act states that to enter into a contract both parties must be at least eighteen years of age, this should be the age for giving valid consent in medicine. However it should be noted that the Indian Contract Act is for conditions like marriages, financial agreements etc. and is not specific for the medical profession.

Further, even though consent is said to be a contract (under Indian Contract Act), various Acts do not override the Indian Penal Code.

Those doctors who do consider consent to be a contract take the consent of the parent or guardian for medical procedures in which death or grievous injury can occur when the age of

What is already known on this topic

- i) As per the Indian Penal Code twelve years is the age for giving consent. Section 88 and Section 90 of the IPC suggest that the age for giving valid consent for any medical procedure is twelve years.

the patient is less than eighteen years. They feel this will be of benefit in cases involving civil liability.

All this has led to ethical and legal dilemmas in the minds of the doctors in many cases. A sixteen- year- old girl coming for gynecological examination and asking for a pregnancy test is one such example. Is the consent of the parents required in this case or is the girl's consent valid (if she refuses the involvement of her parents)? There is also the need to respect the confidentiality between the patient and the doctor. A seventeen-year-old boy desiring an operation which his parents are refusing is another.

In practice in the absence of clear-cut legal provisions most doctors consider the consent of a person less than eighteen years sufficient for medical examination only and for any other medical procedure ask for the consent of the parents. All this highlights the need for specific legislation for age for giving valid consent for medical procedures.

3. Oral consent is legally valid when taken for some specific procedures like injecting medication, drawing blood for pathological examination, gynecological examinations etc. Oral consent can be proved in court if it was taken in the presence of witnesses or if the doctor records in the case record of the patient that oral consent was taken. For major procedures and surgery, written consent should be taken but if for some reason only oral consent is possible then the doctor should enter it into the case record of the patient.

The value of signed written consent is important for those cases that go to court as a written consent will be of great value for the doctor when he defends himself. According to the Indian

Hence a doctor taking consent for medical or surgical treatment from a person aged twelve years or more can be legally said to have taken a valid consent and cannot be held criminally liable on this account. However Sections 87 IPC mentions eighteen years as the age for giving consent for acts not intended and not known to be likely to cause death or grievous hurt. However these acts are not necessarily for the benefit of the person. Hence Section 87 IPC is not applicable to the medical profession as here the acts are done for the person's benefit.

ii) The general practice is that the patient or parent/guardian sign the consent form. Doctors do not sign it.

iii) In many cases verbal consent is considered adequate and written consent dispensed with.

What this paper adds

- i) Article highlights the ethical and legal dilemmas faced by doctors due to absence of legislation regarding age for giving valid consent for medical examination and procedures in India. A section of the medical fraternity (who take consent to be a contract) feel eighteen years is the age for giving medical consent, while another section (who follow the IPC) consider twelve years as the age for giving consent. In the absence of clear cut legislation in this regard majority of doctors consider the consent of a person above twelve and less than eighteen years valid for medical examination only and for medical procedures prefer to take the consent of the parents/guardians. They feel this will be of benefit in cases involving civil liability. To resolve this matter legislation should be passed specifying age for giving valid medical consent ,as has been done in other countries, so that arbitrariness can be done away with and legal problems

Medical Council (Professional Conduct and Ethics) Regulations 2002, before performing an operation written consent should be obtained. Those doctors who take consent to be legal contracts between two parties feel that both the doctor and patient should sign the consent form as this is the basic requirement of a contract, otherwise it becomes null and void. Two witnesses who are uninterested third parties should preferably also sign it.[5] The Consent form used in All India Institute of Medical Sciences, New Delhi (our country's premier medical institute) also requires the form to be countersigned by the treating doctor who certifies that informed consent has been taken.[6]

avoided.

ii) Importance of written consent has also not been given its due. As far as court cases are concerned written consent is of paramount importance in legal matters as verbal consent can be denied and is difficult to prove in court.

iii) If consent is taken as a legal contract between two parties than both the doctor and the patient should sign the consent form, a practice rarely followed. On this point again, clear-cut legislation or guidelines from the MCI should be there.

Consent should be individual and procedure specific. It should be taken before the procedure as blanket consents are not acceptable.

4. Full disclosure must be there for consent to be legally valid. There should not be any suppression of facts. All relevant information of the disease and treatment, material risks involved, other alternative treatment, must be given by the doctor himself to the patient as it is a contract between the patient and the doctor. Legal standards may require physicians to disclose information that a reasonable practitioner in a similar situation would disclose ('professional standard of disclosure'), or information that a reasonable patient would find material to his or her decision ('materiality standard'). Exceptions to disclosure requirements are:

a. Emergencies : When the time required for disclosure would create a substantial risk of harm to the patient or third parties, full disclosure requirements may not apply.

b. Waiver : Patients may waive their rights to receive information. This should be a knowledgeable waiver, i.e. patients should be made aware that they have a right to receive the information, to designate a surrogate to receive the information, or to be informed at a later date.

c. Therapeutic privilege : Information can be withheld, when disclosure per se would be likely to cause harm to patients (e.g. when a

patient with an unstable cardiac arrhythmia would have his or her situation exacerbated by the anxiety attendant on full disclosure of the risk of treatment). In emotionally disturbed patients the doctor should request a specialist consultation to establish that the patient is emotionally disturbed. The doctor should also note his decision in the patient's records explaining his intentions and the reasons for it.

d. Incompetence : Incompetent patients may not, as a matter of law, give an informed consent. State law generally provides alternative mechanisms by which consent can be obtained, and requires disclosure to a substitute decision-maker.

e. Involuntary treatment : Many states allow psychiatric treatment to occur without patients' informed consent. This occurs most commonly when patients' refusals of treatment are specifically overridden following clinical, administrative, or judicial review.

5. Proxy consent or Surrogate decision maker. When a person is incapable of giving expressed consent a substituted consent can be taken from the next of kin. Generally accepted order is spouse, adult child, parents, siblings, and lawful guardian.

6. In medical emergencies consent need not be obtained if circumstances are such that it is impossible for that person to give consent (Section 92 IPC). Locoparentis: In an emergency involving children when their parents or guardians are not available, consent is taken from the person in charge of the child e.g. school teacher.

7. With regard to any person charged with criminal acts who has not been arrested, ethical considerations preclude forensic evaluation prior to access to, or availability of legal counsel. The only exception is an examination for the purpose of rendering emergency medical care and treatment.

8. It is important to appreciate that in a particular situation such as court ordered evaluations for competency to stand trial, consent is not required. In such a case a psychiatrist should inform the subject and explain that the evaluation is legally required and if the subject refuses to participate in the evaluation this fact will be included in any report or testimony.

9. Consent of an intoxicated person is invalid (Section 90 IPC).

10. An arrested person can be examined without consent if requested to do so by a police officer not below the rank of a Sub-Inspector (Section 53 IPC).

11. A prisoner can be treated without consent in the interest of society.

12. Consent of one spouse is not necessary for an operation (including MTP) or treatment of another. For contraceptive sterilization consent of both husband and wife should be taken.

Informed Consent in Psychiatry

In its ethical dimension informed consent encourages respect for individual autonomy in medical decision-making. There are however conditions and circumstances that limit autonomy and therefore also autonomous choice. People with a learning disability or a mental or physical illness may be temporarily incapacitated to make autonomous choices due to their condition. In these cases the concepts of capacity and competence become paramount in determining the extent to which a person's autonomy is restricted. Competence is a legal term, and courts decide on the competence of a person based on the inputs provided to it by the doctors who give an opinion on the capacity of the patient to comprehend facts and make independent decisions. Capacity in contrast is a medical term and doctors determine a person's capacity to make certain choices.[7] It is worth noting that this distinction often breaks down in practice. When clinicians determine that a patient lacks decision making capacity the practical consequences may be the same as those attending a legal determination of incompetence.

Two basic preconditions have to be met to render a person incapable of managing his or her own affairs. Firstly, there needs to be an objective cognitive deficit that impairs problem solving and decision-making. Secondly, there must be an incapability to sensibly delegate responsibility to someone else.

Some authors have suggested a 'sliding scale' of ability to take into account that different decisions require different levels of understanding. Thus decisions of most potential risk, such as death, demand greater levels of capacity than decisions of minor potential

risk.[8] Hence if the consequences for welfare are grave our need to be able to certify that the patient possesses the requisite capacity increases, but if little in the way of welfare is at stake, we can lower the level of capacity required for decision making. Every effort should be made to minimize the time taken to determine a patients' capacity.[9]

Some psychiatric disorders can impair decision-making functions to some extent, but not to the point where patients would be considered legally incompetent. In such cases, clinicians can make disclosure in a manner that takes patients' limitations into account. This may include simplifying elements of the disclosure, offering information in smaller amounts stretched out over time, and repeating disclosure several times. The implication of these accommodations to patients' impairments is that some patients may be asked to consent to treatment (when it needs to be implemented promptly) before having received a disclosure comparable to that offered to non-impaired persons.

Some psychiatric patients may manifest impairments of decision-making capacities that are likely to resolve quickly, especially if effective treatment can be implemented. In such cases short term treatment of the patient can be initiated, even in the absence of a fully adequate consent, obtaining such consent as soon as the patients' condition permits it. This practice is acceptable when recovery of decision-making capacities is likely to occur.

Psychotherapy and other psychiatric records may contain sensitive and deeply personal information about patients. These records should not be released without patient consent. Patients should understand to whom the information will be disclosed, what information will be discussed, how the information will be used and what the potential consequences might occur.[10]

Conclusions

Twelve years is the age for giving valid consent. However this is true as far as criminal liability is concerned. For cases involving civil liability eighteen years is the age for taking valid consent (taking into account the Indian Contract Act). In view of this ambiguous position t here is an urgent need for legislation in India regarding age of consent for medical treatment. This will go a long way in removing ethical and legal dilemmas being faced by the doctors in this regard.

It is always advisable to take written consent. Whether both the patient and doctor should sign the consent form is another point for which no clear-cut guidelines exist. The Medical Council of India or the lawmakers should issue clear-cut guidelines in this regard. Consent should be individual and case specific and be taken just before the procedure. Consent should be open for discussion and potentially retractable at any time during the course of treatment.

In an emergency it is sometimes impossible to know the patients will in which case it is practical and justifiable to act in the patients' best interest. The ethical rather then the legal consideration should prevail.

Full disclosure is necessary before taking informed consent. The legal exceptions to this are important for doctors to understand as they are often called upon to treat patients in emergency situations, to treat patients who lack capacity to make decisions and to treat patients whose disorders influence their ability to tolerate detailed explanations. Legal reasons restricting choice can also be there as in case of prisoners.

The right of patients to consent or refuse consent to medical treatment is an important right incorporated into the legal framework. In psychiatry important exceptions to this rule exist because of ethical, legal and practical reasons. Some persons do not have the mental capacity to make an informed choice in which case it is ethical to consider acting in their best interest. Concept of therapeutic privilege allows physicians to modify only the degree of disclosure- the ensuring basic treatment must still be explained to the patient. In psychotic conditions therapeutic privilege can be invoked and details regarding long-term side effects can be temporarily postponed. Such cases should be carefully documented and full disclosure should take place once the patient's conditions have improved. Careful documentation, ongoing education and provision of opportunities for collaborative decision-making in such cases may be more effective and can provide effective legal protection.

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