



Informed Consent- A Must In Medical/Dental Practice

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Abstract

A doctor should always obtain consent before any medical examination. Any such examination without prior consent, amounts to an assault on the patient. Consent may be implied, expressed or informed depending upon the circumstances. A well recorded consent serves as a good defence for a physician in cases of medical negligence. Any kind of research work which involves potential subjects, patient's examination or any invasive procedure or using patient's data for publication requires informed consent. This article is an effort to showcase the vital issues related to informed consent.

Keywords: Dentist; Indian Penal Code; Lawsuit; Negligence; Patient; Physician

Introduction

Medico-legal consent is one of the critical issues in the arena of medical treatment. Consent is defined as "two or more persons are said to consent when they agree to the same thing in the same sense ^[1]." One of the duties of a doctor towards his patients is to obtain consent before any medical examination. Any such examination without prior consent amounts to an assault on the patient. However, the consent of the patient is not required in situations like medical emergency, for vaccination etc. If the patient is not medically or legally competent to give consent, the consent of the parents or guardians or any person present at the time with the patient can be taken. The fundamental ethical principal of autonomy and the right of self-determination gave rise to the concept of informed consent ^[2]. The autonomy says that an individual's action and decision are his/her own. Thus, it is the legal and moral duty of the doctor that all aspects of the illness should be explained to the patient, so that he could make appropriate decisions for his treatment.

Consent is essential in all cases where a patient comes or is brought for examination or treatment. The type of consent varies from case to case relating to the planned treatment. If a patient refuses to give consent, then he cannot be examined nor can be treated ^[3]. Informed consent is necessary where the examination and treatment involves beyond routine medical examination. Consent is mandatory for blood transfusion, organ transplantation, artificial insemination (of both the spouses), sterilization, medical termination of pregnancy (of the woman if she is above 18 years of age, parent or legal guardian if she is less than 18 years), dental procedures and all other forms of invasive diagnostic and therapeutic procedures ^[4]. Consent of spouse is required if the operation or instrument involves danger to the life or impairment of sexual functions. For cadaveric transplantation, the next of kin, who is in possession of the dead body provides the consent. It is mandatory to take written informed consent from the subjects who are participating in a biomedical research programme and again during publication of patient's record or data or photographs, in articles or

journals, it is necessary to take consent from them with the assurance of protection of their identity^[5].

In case of emergency, consent is taken from the patient if he is conscious, oriented, competent and able to freely express his willingness to accept the treatment. However, if the person is unconscious and there is no one who can give consent on his/her behalf, consent can be taken from the Assistant Medical Officer (AMO) on duty or rather the situation gives consent for treatment (Emergency Doctrine) immunity from prosecution by sec 93 of Indian Penal Code (IPC) Act done in good faith for benefit of a person without his consent.

History

The principle of consent is a not relatively new. In fact, there are documents already in the Egyptian, Greek and Roman civilisation which show how the doctor's intervention had, in some way, first to be approved by the patient^[6]. The Hippocratic physician respected a principle of professional responsibility which was more religious and of a moral type. The conviction with which the physician acted, in the interest of his patient's well-being, has been passed down over the centuries.

Rationale Of Consent

The basic aim of informed consent is to give sufficient information to a patient so that he can take a knowledgeable and informed decision about the drug, device or procedure proposed for him in the course of treatment after having him explained about all the known possible and foreseeable risks associated with it. The doctrine of informed consent also gives a patient the right to refuse the proposed treatment.

Types Of Consent^[7]

1. Implied Consent

This is the most common form of consent seen in medical practice. In implied consent, the patient's behaviour indicates his consent, e.g., when a patient puts forth his arm for intramuscular injection. Though it is not expressed, it is legally effective. However, such type of consent is generally restricted to common procedures of medical examination beyond which you need to take a full expressed informed consent.

2. Expressed Consent

In expressed consent, a patient specifically expresses his free consent to a physician to undertake diagnostic or therapeutic treatment. He may express either verbally or in writing after being informed about all the aspects of the diagnostic and therapeutic procedure. Both the forms of expressed consent are acceptable in the court of law, but it is the written expressed consent, which has more value, as it is a permanent record.

3. Blanket Consent

It is a consent taken on a printed form that covers almost everything that a doctor or hospital might do to a patient, without mentioning specifically. Blanket consent is legally inadequate for any procedure that has risks and alternatives.

4. Proxy Consent

Eg. Parent giving consent for child.

Elements Of Informed Consent

1. Disclosure Of Information

A doctor should explain to his patient the exact nature of the disease, the need for the treatment, along with the likely chances it's success. The patient should be made aware of any alternative forms of treatment if available along with the benefits and risks involved in both the proposed and alternative procedure. The patient should have the right to choose between proposed and alternative procedure and also the right to refuse all of them and the medicolegal consequences of such refusal.

2. Free And Voluntary Decision

The patient's consent must be voluntary and free from coercion, force and misrepresentation of facts. Consent to be legally valid must be intelligent, informed and voluntary and should be taken freely and exclusively by the patient. Nobody is authorized to give consent on behalf of the patient (with few exception).

3. Capacity To Decide

This forms the most important aspect of informed consent. A competent person should be legally competent to do so, should be of sound disposing mind and should have proper reasoning for his decision. He should be at least 12 years of age and be able to understand the implications of his consent.

Criteria For Legal Valid Of Consent ^[8]

The person giving the consent should be of sound disposing mind and should be giving it voluntarily, without any fear, force, fraud, undue duress, coercion, misrepresentation of facts and threats of physical violence, death etc. The consent needs to be free, fair, uninhibited, clear, direct and personal and should be well informed. It should be taken prior to the procedure (therapeutic or diagnostic) and should be complete and specific. It should be given by a person who is of sufficient maturity to understand the nature and consequence of the act to which he has given consent in front of a third uninterested party as a witness.

Dental Procedures Requiring Informed Consent

Most diagnostic procedures such as general clinical examination, periodontal probing and radiographs do not require formal consent. All procedures, from a simple buccal pit restoration to the removal of a complicated impacted third molar, can produce an irreversible change to the body with the risk of some type of complication. Even minor occlusal adjustments can affect the surrounding dentition, masticatory function or temporomandibular joint stability. These need to be presented to the patient and documented in writing. Dental treatment provided to patients who travel across international borders for the purpose of receiving dental care comes under dental tourism. Patients partaking in this dental tourism should be informed of its potential problems.

Sections Of IPC And Crpc Related To Consent ^[9]

Sec 87 IPC – A person above 18 years of age can give valid consent to suffer any harm, which may result from an act not intended or not known to cause death or grievous hurt.

Sec 88 IPC - A person can give valid consent to suffer any harm that may result from an act, not intended or not known to cause death, done in good faith and for its benefit.

Sec 89 IPC - Act done in good faith for benefit of child or insane person, by or by consent of guardian.

Sec 90 IPC - Consent to be given under fear or misconception.

Sec 92 IPC - Act done in good faith for benefit of a person without consent.

Sec 53 CrPC - Examination of accused by medical practitioner at the request of police officer.

Sec 54 CrPC - Examination of arrested person by medical practitioner at the request of the arrested person.

Some Documented Legal Cases

Dr. TT Thomas versus Smt. Elisa and Ors case- Refusing treatment in life-threatening situations due to non-availability of consent may hold the doctor guilty, unless there is a documented refusal to treatment by the patient ^[10].

Dr. Ramcharan Thiagarajan Facs versus Medical Council of India case- disciplinary action was awarded to the surgeon for not taking a proper informed consent for the entire procedure of kidney and pancreas transplant surgery from the patient ^[11].

Dr. Prabha Manchanda and Anr versus Samira Kohli case- Consent given only for a diagnostic procedure, cannot be considered as consent for the therapeutic treatment. Consent given for a specific treatment procedure will not be valid for conducting some other procedure ^[12].

Dr. Janaki S Kumar and Anr versus Mrs. Sarafunnisa case- Consent obtained during the course of surgery is not acceptable as the patient under anaesthesia could neither understand the risk involved nor could she give a valid consent ^[13].

M. Chinnaiyan versus Sri. Gokulam Hospital and Anr case- Court awarded compensation as patient was transfused blood in the absence of specific consent ^[14].

Dr Jayesh Dube vs Saroj Cheda October 2015, Mumbai- Dr Dube was charged with negligence in tooth extraction and faulty bridge (fixed denture) construction ^[15].

Dr Naveen Ram vs Abhiram May 11, 2017, Kolar- The dentist treated the patient for ear ache which ultimately led to his death ^[16].

Dr Mohan Dhawan vs Mrs. Gertrude D'souza, August 2017, Chandigarh- The court observed that Gertrude D'Souza was allured to get dental implants fixed in India at competitive rates and that Dhawan performed a surgery without her consent. He was charged under IPC sections 420 (cheating), 467, 468 and 471 (forgery) ^[17].

Conclusion

It is not only ethical to impart correct and necessary information to a patient prior to conducting any medical procedure, but it is also important legally. This communication should be documented. This documented consent is mandatory for all diagnostic and therapeutic procedures that have risk or adverse effects or complications.

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