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## Informed Consent – A Moral Obligation

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### Abstract

*Informed consent is a vital legal tool for any practicing doctor , which not only acts as a tool to safeguard the doctor from legal implication but is also a moral obligation as this shows that the doctor is respecting the patients autonomy. A well informed and written informed consent is mandatory from the very first day the patient enters the clinic and should carry forward till the time the patient leaves the clinic after completion of his treatment. This present article helps us to understand the concept of informed consent in detail. It highlights the situations where the nature and form of consent can be modified keeping in mind the need of the hour. It also focuses on various types of consent and methods to help doctors improve their skills in obtaining a legally and ethically valid informed consent.*

**Key words:** *consent, patient autonomy, legal tool*

### INTRODUCTION

Law in the sphere of medicine is an established concept in developed countries, but remains in its infancy in developing countries. Knowledge of law is power and helps self realization. Many developing countries have an emergent need to

generate awareness of rights so that people live in consonance with the true dictates of democracy and rules of law. So why wait for the time to fall prey rightfully or wrongfully to an ever evolving legal framework. We as professionals should not be ignorant towards law as we have a moral and

ethical obligation to protect our consumers and society.

Informed consent is one legal aspect in our profession, which can safeguard us against much legal litigation. It represents the patients right to take part in the clinical decision making concerning their treatment. It does not mean putting a signature on the consent form but it is a dialogue between the patient and the dentist which continues throughout the course of the treatment.

### DOCTOR PATIENT RELATIONSHIP

A doctor patient relationship is special and is based upon the foundation of trust, that the doctor will perform his duties keeping in mind the patient's best interest. There are various ethical principles which help the dentist to perform his duty towards the patient but sometimes the commercial element overrides the ethical element and the patient feels that the doctor has not performed his duty in the best interest of the patient. Some people worry that medicine has lost its way and has eschewed the virtues of professionalism, thereby changing from a health care profession to a for profit enterprise<sup>(6)</sup>. Thus the patient is either dissatisfied with the treatment or he feels that certain unwanted treatment has been done on him or her or he might feel that he was not informed about the nature of the treatment and the consequences of undergoing the treatment. In this case there arises a need for furnishing information to the patient regarding the treatment regimen and thus obtaining a informed consent from him before starting the treatment.

### CONCEPT OF INFORMED CONSENT

The concept of informed consent was evident already in the Hippocratic Oath, which clearly illustrates the notion that respect is an integral part of relationship between patients and health care professionals<sup>(5)</sup>. During the 20<sup>th</sup> century, numerous experiments were conducted on soldiers and civilians without their consent, not for the purpose of directly helping people but to test different medical hypothesis<sup>(9)</sup>. This resulted in the development of the Belmont report from the national commission for the protection of human subjects of biomedical and behavior research<sup>(10)</sup>. But the actual concept of voluntary consent developed from one of the darkest episodes in the history of medical research, the horrific experiments carried out by doctors on concentration camp victims in Nazi Germany – was exposed at the Nuremberg trials of 1947. Emerging from the Nuremberg trials was a code of ethics setting out 'standards to which physicians must conform when carrying out experiments on human subjects'. The Nuremberg code includes such principles as informed consent and absence of coercion; properly formulated scientific experimentation; and beneficence towards experiment participants<sup>(1)</sup>. Later the original declaration of Helsinki was developed and is seen as having its roots in the Nuremberg Code. Both the Nuremberg code and the declarartion of Helsinki stated that the voluntary consent of human research subjects is absolutely necessary and the consent should be based on sufficient knowledge and understanding<sup>(1)</sup>

Informed Consent is based on two ethical principles- autonomy and beneficence<sup>(11)</sup>

Autonomy;- the predominant model in the past still adhered to by many health care professionals is the concept of paternalism. This concept implies that the doctor is knowledgeable and skilled, therefore the best person to make judgments without involving the patient when deciding a therapeutic regimen. A shift in attitude has taken place after world war 2 with the Nuremberg trials resulting in the Nuremberg code and the declaration of Helsinki which stated that the voluntary consent of human research subject is absolutely essential and the consent should be based on sufficient knowledge and understanding. From these regulations was derived the concept of patient autonomy in health care. Thus autonomy is defined as a person's ability to decide and act on the basis of rational thought and deliberation. This is reflected by obtaining a voluntary and informed consent from the patient or guardian before clinical intervention.

Beneficence: - is a moral obligation to act in the interest of others. All health care providers have a duty to care for the patient and all health care actions performed should be done with the best interest of the patient in mind.

A conflict in the autonomy and beneficence can occur when both patient and clinician differ in what they both consider as "the patient's best interest". In such a situation decision should be based on the attitude of the patient and the dentist's technical judgment.

## INFORMED CONSENT IN THE LEGAL CONTEXT

The Indian civil law defines informed consent as 'which considers a doctor –patient relationship to be contractual and legal agreement for professional service.'

Section 13 of this law defines consent as- when two or more person agree on the same thing in the same sense

Section 14 of this law defines consent as 'one given without coercion, under influence, fraud, misrepresentation or mistake'

### WHO CAN GIVE CONSENT?

The age of consent is bound by legal definitions and within the context of the Indian law there are two schools of thought.

**SECTION.90** of the Indian Penal Code of 1860- states that "Consent by intoxicated person, person of unsound mind or a person below twelve years of age is invalid." This therefore implies that a person above 12 years of age can consent to medical/surgical/dental treatment if it is intended for their benefit and undertaken in good faith.

**SEC. 11 OF THE INDIAN CONTRACT ACT OF 1872** - a competent person of sound mind who has attained the age of majority of 18 years (according to the Indian Majority Act of 1875) can legally enter into a contract.

In the absence of clear cut legislation, the majority of doctors/dentists in India consider the consent of a person above twelve and less than eighteen years of age valid for medical/dental examination

only, but for dental interventions prefer to take the consent of the parents/guardians. This is a definite safeguard against civil liability<sup>(8)</sup>

### **CONDITION WHERE THE CONSENT IS HELD VALID**

1. Patient is competent to give consent
2. Full information of risks, benefits, alternatives and costs has been provided
3. Consent is freely given, and
4. Consent is specific to the procedure.

### **CONDITIONS WHERE THE CONSENT CANNOT BE HELD AS VALID**

As stated in IPC 1860, Sec 90, consent is considered invalid if

1. A person who is under 12 years of age
2. Consent given under fear, fraud or misrepresentation of facts,
3. Persons under the influence of alcohol,
4. Or by a person who is ignorant of the connotations of the consent,

### **SITUATIONS WHERE CONSENT MAY NOT BE OBTAINED:**<sup>(12)</sup>

Though consent is an essential aspect in a doctor-patient relationship it need not be obtained in the following situations:

1. In the event of Medical Emergencies.
2. In case of a person suffering from notifiable diseases
3. Immigrants.
4. Members of Armed Forces.
5. Handlers of food and dairymen.
6. New admission to Prisons.

7. In case of a court order or request of the police

### **FOR HOW LONG IS CONSENT VALID?**<sup>(8)</sup>

(ACT Health Procedure Consent to treatment, 2008) Though there is no legally defined time period for consent to be valid, it can be considered valid until the patient withdraws it or there is a change in the patient's circumstances, which may include:

1. Improvement/deterioration in the patient's condition
2. Availability of new treatment options since consent was given.
3. Due to disease progression the treatment choice has changed from cure to palliation.

### **TYPES OF CONSENT**<sup>(2) (8)</sup>

Broadly consent can be classified into 2 types

1. **IMPLICIT**-.- the patient voluntarily comes to the dentist's office and the dentist is performing a simple examination or non-invasive procedure that poses no risk of harm to the patient. Is implied when the patient indicates a willingness to undergo a certain treatment or procedure by his behavior such as in case of dental examination the patient sits on the dental chair and shows his willingness to undergo treatment by opening his/her mouth without any verbal conformation.
2. **EXPLICIT** – any treatment is required that poses a potential risk to the patient, even if the likelihood for potential complications is low. This includes any

procedure from something such as a simple filling to more complex procedures such as oral surgery, extraction or prosthetic rehabilitation. The patient is fully informed regarding the procedure, the duration of the procedure, the number of appointments required, the kind of material to be used etc. Apart from this the patient is also informed of any other available treatment options so that he or she can choose form amongst them. This kind of consent is given orally or in writing. It is preferable that in this case a disinterested third party acts as a witness to this kind of consent.

3. **PROXY CONSENT (Substitute consent):** patient is unable to give consent because he/she is a minor or mentally unsound/unconscious.
4. **LOCO PARENTIS :** In an emergency situation in case of children, when parents / guardians are not available, consent can be obtained from the person bringing the child for dental examination or treatment (For example: school teacher, warden, etc
5. **OPEN/BROAD/BLANKET CONSENT -** is usually consent signed at the time of hospital admission, to cover any subsequent procedures. This type of consent implies that there are no restrictions to the scope and duration of the consent, and does not inform patients adequately about risks.
6. **VERBAL CONSENT:** Verbal consent is where a patient states their consent to a

procedure verbally but does not complete a written consent form.

### **CONSEQUENCES OF FAILING TO OBTAIN INFORMED CONSENT**

Giving treatment without consent is failure to respect patient's autonomy. This disrespect can be classified as

1. **ASSAULT** (threat of using force)
2. **BATTERY**(actual usage of force)
3. **NEGLIGENCE**

Assault- is covered under Section 351-358 of the Indian Penal Code (The Indian Penal Code 1860). Whoever makes any gesture, or any preparation intending or knowing it to be likely that such gesture or preparation will cause any person present to apprehend that he who makes that gesture or preparation is about to use criminal force to that person, is said to commit as assault.

Battery- is an intentional physical contact with a person without his or her consent that results in bodily harm or harmful or offensive touching of another or is offensive to a reasonable sense of dignity.

Negligence- Failure to furnish full information about procedure and risks.

The dentist can be held accountable for this breach of duty of care under the Consumer Protection Act (CPA) 1986. This act provides for a three-tier quasi judiciary system (district, state and national level) to settle consumer disputes.

## POSSIBLE CONSEQUENCES OF NOT OBTAINING CONSENT FOR TREATMENT

If invasive treatment is provided without patient consent to the general nature of the procedure, then a practitioner may be sued for the tort of battery, and damages claimed for trespass to person - unless the failure to obtain consent is justified by necessity: for example, in an emergency. However, the role of the law of trespass in the area of 'informed consent' is limited. Consent to a procedure is not usually negated by being obtained without disclosure of associated risks and possible alternative treatments.

The most applicable sanction for failure to disclose this sort of information lies in the tort of negligence<sup>(3)</sup>. It is accepted that a practitioner's general duty to act reasonably includes a duty to provide adequate information, particularly in relation to risks or hazards. If something goes wrong then the practitioner may be exposed to liability for damages in negligence. A negligent act is usually found or alleged to have occurred in the procedure itself. However, a failure to provide information about the procedure and associated risks may also amount to negligence. For action in negligence on the latter score to succeed, two points must be established:

- a) that failure to disclose the information was unreasonable; and
- b) that this failure was a cause of harm to the patient.

The measure of reasonableness in relation to information-giving is akin to the standard of care required in relation to diagnosis and treatment,

viz. that of an 'ordinary careful and competent practitioner of the class to which the practitioner belongs'. To satisfy the second element (causation), the patient must establish both that he or she would not have consented to the treatment had proper disclosure been made and that injury was suffered due to the treatment.

At present it is not easy for the plaintiff/patient to establish any, let alone all of these things, especially causation. Actions in negligence are often unsuccessful. The mere fact of treatment without consent will not be regarded as compensatable injury. However, this may undergo change as the law in medical negligence evolves further, particularly in the areas of:

- I. determining the weight that is to be accorded evidence derived from standard practice; and
- II. assessing whether risk was material, that is, whether it would have influenced a reasonable person in the position of the patient in deciding whether to accept the procedure in question.

## METHODS OF IMPROVING INFORMED CONSENT<sup>(8)</sup>

1. Replace complex words with simpler words.
2. Change compound sentences (multiple thoughts connected with "and", "but", "so", "because") into two or more short sentences.



3. Change passive voice to active voice (change “a sample will be drawn” changed to “We will take a sample”).
4. Use simple declarative statements where possible.
5. The level of understanding in the primary language may be greater, so the consent form should be preferably be made in the local language.
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