Informed Consent in Clinical Practice - An Overview
Maneesh Godbole

Since time immemorial, doctor-patient relationship has been based on trust and was almost paternalistic in nature. It was a much simpler relationship where the patient reposed complete faith in the doctor, believed that the doctor had his/her best interests at heart and followed the advice of the doctor without any hesitation and questioning. However, with changing times, because of several factors, there has been a change in this equation and the relationship has become much more complex. Recent changes in the health care delivery system and the complex sociological settings in which it is practiced, have resulted in an increase in judicial activity and medical negligence lawsuits for physicians. In this setting, Informed Consent becomes a sociolegal obligation for the medical profession. However, the procedure of obtaining informed consent from the patient is not taken seriously by the doctors who consider it a waste of time and an unnecessary activity. Moreover, the doctrine of Informed Consent is addressed only superficially in the medical curriculum. As long as everything goes well there is no problem. However, in case of any complication, the same patient who professed to have complete faith in the doctor is incited by people to file a lawsuit against the doctor. If the correct procedure for informed consent has not been followed, the doctor faces a lot of trouble.

Consent of the patient has an immense practical importance to the clinicians. Doctors may do nothing to or for a patient without valid consent. This principle is applicable not only to surgical operations but also to all forms of medical treatment and to diagnostic procedures that involve intentional interference with the person. Informed consent is recognized as the most important instrument that protects both the patient’s autonomy and professional autonomy of the doctor.

Presently in India, the doctrine of informed consent is not in routine practice. This type of consent may take roots in the Indian medical practice soon, since advancement in technology and information is taking place very fast leading to an increase in consumer awareness. In this context, this article tries to highlight certain important aspects of obtaining informed consent.

Background
The fundamentals of today’s practice of Informed Consent gained more structure at the beginning of 20th century, especially after the development of anesthesia and more invasive surgery. After the Second World War, there was a strong public reaction to the cruelties committed by Nazi concentration camp “doctors” who performed horrible tests on “patients” without prior information or approval. A code was written as a direct result of the Nuremberg trials. This “Nuremberg Code” was an important step in the development of the Informed Consent process in trials. It consisted of ten preconditions any human research study had to fulfill.

What is Informed Consent
As there is no simple and well defined idea regarding what constitutes consent in medicine, one has to depend upon legal use of the term. It is described as “voluntary authorization, by a patient or research subject, with full comprehension of the risks involved, for diagnostic or investigative procedures, and for medical and surgical treatment”.

It is based on the basic bioethical principles of
• Autonomy
• Beneficence
• Non-maleficence and
• Justice, professional declarations and the legal considerations

Consent means free, voluntary agreement or compliance. In consent, there are three separate but correlated elements - voluntariness, capacity and knowledge.

• Voluntariness suggests willingness of patient to undergo treatment.
• Capacity means a degree of ability of the patient to understand the nature and consequences of treatment offered.
• Knowledge means that sufficient amount of information about the nature and consequence of treatment has been disclosed to the patient.

These three elements must be present in the consent, only then it is legally valid. Therefore, for consent to be valid it must be:
• given by someone who is competent (has legal capacity)

1Department of Community Medicine, KIMS, Hubli
Correspondence to Dr Maneesh Godbole (maneeshag65@gmail.com)
• sufficiently informed
• freely given

Section 90 of the Indian Penal Code (IPC) defines consent in negative terms. As per this section, any consent given under the following circumstances will not be true consent:
1. By a person under fear of injury
2. By a person who is under misconception of the facts and person who obtains consent knows or has reason to believe that consent was given in consequence of such fear / misconception.
3. By intoxicated person
4. By a person who is of unsound mind or, unable to understand the nature and consequences of that to which he gives consent.
5. By a person who is below the age of 12 yrs.

Informed consent, as opposed to just consent, is when the patient gives consent after he/she has been provided with adequate, correct and relevant information, in a form and language that the patient can understand. It should not be that the patient signs over the dotted line as a routine, which is what happens most of the times.

Pre-requisites for informed consent

Informed consent is a process requiring a competent doctor, adequate transfer of information, and consent of the patient.

Basic elements of Informed Consent are
• Preconditions
• Information and
• Consent

Consent is an opportunity for the medical fraternity to guide the patient to the right decision for himself/herself, and also dispel any unrealistic expectations concerning the procedure. Ultimately it is an opportunity to create a relationship of openness and trust between doctor and patient, which may help if procedural complications are encountered. With high health-care expectations, a poorer than expected outcome may make the patient dissatisfied, and subsequently lead to anger. Good patient education during the informed consent process is the doctor’s chance to establish a rapport with the patient and make sure that the patient’s expectations are realistic.

Types of Consent

Implied consent is one, which is not written but is legally effective. When a patient comes to a doctor’s consulting room or hospital and waits for the doctor, implied consent is presumed. Such implied consent only applies to history taking and ordinary medical examination like inspection, palpation and auscultation; it does not cover the consent for examination of private parts of the patient or matters such as vein punctures or injections or any major intervention.

The express or specific consent may be oral or written. An oral consent is legally valid, but it is preferred to obtain a written consent for major procedures because there is risk involved that the patient, in the case of oral consent, may at later stage deny that any oral consent was given by him. If, for whatever reason, only oral consent is possible, it is appropriate to make an entry in the patient’s clinical record which may be of use in future if any action is brought on this count and this entry in the clinical record may afford corroborative evidence to support the defense taken by the medical practitioner concerned.

Procedure of Informed Consent

Who should obtain informed consent?

Informed consent for elective surgery is often obtained by junior medical staff, during pre-assessment clinics, or on the day of surgery. Current guidance states that the person obtaining consent must either
1) be capable of performing the procedure themselves; or
2) have received specialist training in advising patients about the procedure.

Junior medical staff may be placed in a position where they fail to fulfill either of the above two criteria. Certain specialist procedures, such as cataract surgery or elective angiography, have very specific risks, which may not be adequately covered in undergraduate education. A thorough understanding is required to be able to appropriately advise the patient. Instruction in obtaining informed consent is therefore vital.

What should be the timing of informed consent?

For consent to be valid the patient must
1. be competent to take the particular decision
2. have received sufficient information to make a decision and
3. not be acting under duress.

The third criterion is not fulfilled if consent is obtained upon the day of surgery. Most patients will have firmly decided to proceed before attending for surgery. However, a minority may develop doubts upon learning about the procedure in more detail, during the consent process. If these doubts arise on the day of surgery the patient may feel under duress to proceed, as all the arrangements have been made. Therefore it would be wiser to obtain informed consent at the time of listing in clinic, when the risks and benefits are often explained. The patient will feel under less pressure to proceed, and hence will not be acting under duress.
Informed consent remains valid for an indefinite period, allowing advance consent to be sought, providing that the patient’s condition has not changed, and/or new information concerning the proposed intervention or alternative treatments have not come to light in the intervening period. It is good practice, if consent was obtained in advance, to confirm consent at the time of surgery.

**Explanation of the procedure**

Consent should begin with a brief explanation of the planned operation, including the type of anaesthesia involved. It is wise to describe what the patient may expect to experience during surgery, if under a local anaesthetic. The explanation should be in a layman’s language, avoiding medical jargon, as this can interfere with clear understanding. Sufficient information to make a decision should also include an explanation of

1. the risks and benefits involved
2. any alternative treatments
3. the risks and benefits if nothing is done.

**Explanation of potential risks**

The consent form should have specific sections for documentation of the intended benefits and serious or frequently occurring risks. It is a debatable issue as to how much to mention. One of the opinions is that the patient should know everything, while some other groups oppose this stating that this would only serve to confuse the patient. So, the issue of how much to explain to a patient is debatable, with the following quotation highlighting the dilemma faced by many doctors:

Ultimately, the decision of what to mention lies with the consulting surgeon. In general, it is thought that a doctor:

1. Should explain to the patient if there is any risk of serious adverse consequences;
2. Should mention significant risk that would affect the decision of a reasonable patient;
3. Is under a clear and legal obligation to tell the truth if asked a direct question.

In practice, a complication that is likely to occur more than 1% of the time is often mentioned, but certain less frequent complications may be so grave that the doctor feels it wise to mention them. For example, permanent loss of vision following routine cataract surgery occurs in approximately 4 in 1000 cases and should be routinely mentioned. Some complications are so extremely rare that they need not be routinely mentioned; however, if asked a direct question concerning the possible occurrence of such a complication, the doctor must answer truthfully. An important point to remember is that the doctor has a responsibility to inform a patient of ‘a significant risk which would affect the judgement of a reasonable patient’ (i.e. cause the patient to decline surgery). This does not mean that the doctor is liable every time a complication occurs which he or she has not mentioned: it only applies to complications that may cause a reasonable patient to decline surgery, had they known about them. In practice this includes serious or frequently occurring risks which may tip the risk/benefit balance, in that patient’s mind, in favour of declining surgery. As all patients are different it is the doctor’s duty to highlight patients who are unsure, and give them more discussion time to reach an appropriate decision.

The aim is to inform the patient well enough to allow them to make a balanced decision. Too little information fails to inform, while too much information may be counter-productive and only lead to confusion. In practice, listing potential surgical complications may be meaningless to many patients, unless they are readily described in a manner easily understandable to a lay person (e.g. infection instead of endophthalmitis).

Some patients may wish to know little or nothing about the risks, but this should not be assumed. One must presume that all patients wish to be well informed about benefits and risks, and paternalistic assumptions are not acceptable. If the converse is true, however, then one should abide by the patient’s wishes and document this to be the case.

Providing patients with an idea of the frequency of complications helps put a certain degree of proportion into the patient’s mind. It is clearer to express risk in terms of proportions (1 in 100, 4 in 1000) as opposed to percentages, which may not be understood.

**Explanation of potential benefits**

After explaining the risks it is sensible to remind the patient of the potential benefits of undergoing the procedure. The frequency of success can be balanced against the frequency of risk. Appreciation of this balance underpins the concept of informed consent.

**Explanation of alternative treatments**

Any alternative options should be briefly explained, putting them in context by highlighting the pros and cons compared to the current procedure.

**Explanation of the outcome if surgery was not performed**

This is particularly important in elective surgery, where the immediate result of no surgery is status quo. The long term possibility
of spontaneous resolution or worsening of the condition and the way surgery may influence this is worth highlighting.

**Use of additional media**

Use of audio visual information and leaflets can be useful, and indeed are recommended. However, it is not sufficient to discharge the duty of explaining risks by simply giving out a leaflet. Additional information should be supplemental to, not a replacement, for verbal consent. The use of diagrams, models, handouts, and language appropriate to the patient’s education or ethnic background can heighten the ability of the patient to understand.

**Prerequisites for giving consent**

The patient should be an adult, of sound mind and competent to give consent. In case of children, consent of the parent should be obtained and in case of incapacitated persons, close family members or legal guardians can give consent. The term prudent patient is used to refer to a patient who can reason.

Prudent patient means a reasonable or average patient. To decide whether adequate information has been given, courts rely on this “Prudent Patient Test”. It is not easy to answer the question, How much information is “adequate”? A netizen may expect and demand detailed information. On the other hand, an illiterate may say that “I do not understand anything, doctor, you decide what is best for me!” If a patient knowingly prefers not to get full information that attitude also needs to be respected as a part of patient’s right to autonomy.

Patients’ perception of risk of a medical intervention is also highly individualistic, variable and unpredictable. The information provided to a patient should include all material risks. But, the list of risks and side effects cannot be exhaustive to the level of absurdity and impracticality. For example, hardly any patient can go through the product information leaflet included in any drug pack and if somebody does, it is unlikely that the drug is consumed. So, what is expected is that the doctor should provide information that a prudent or reasonable patient would expect to make a knowledgeable decision about the course of action to be taken in the presence of alternatives.

**Conditions in which the patient’s ability to give informed consent may be affected**

Many situations commonly arise around the time of surgery, in which a patient’s ability to make health care decisions may be, rightfully or wrongfully, called into question. Some of them include:

- the premedicated patient
- the patient in labor
- the patient under stress
- the patient with known mental illness
- the patient with organic brain disease
- the immature patient (i.e. patient who is minor in age, or who has immature mental capacity, such as some forms of mental handicap)

The first rule of informed consent is: If it isn’t documented it didn’t happen. Although a piece of paper cannot prevent a lawsuit, documented evidence that a conversation between a patient and the physician occurred is critical.

**Consent in paediatric age group:**

Parents and physicians should not exclude children and adolescents from decision-making without persuasive reasons. Informed consent has only limited direct application in pediatrics. Only patients who have appropriate decisional capacity and legal empowerment can give their informed consent to medical care. In all other situations, parents or other surrogates provide informed permission for diagnosis and treatment of children with the assent of the child whenever appropriate. This is called “proxy consent”.

**Consent taking process in India—some studies**

It is commonly believed that patients in India do not need to be told about their operations as they are unable to understand the complexities and forget the salient facts soon afterwards. Obtaining informed consent is therefore considered to be an unnecessary ritual.

In a study undertaken at the All India Institute of Medical Sciences, 100 consecutive patients undergoing elective major abdominal operations were studied in which 5 days after their operations, they were asked to recall certain details about the procedure which had been explained to them preoperatively. Seventy per cent of the patients recalled the relevant data. The ability was the same in males and females (67% and 69%) but the older, less educated and poorer patients performed worse than the others. Ninety-eight per cent of the patients appreciated being given the information as it reduced their anxiety about the operation. Indian patients are able to comprehend and should be informed about the details of their operation. Particular care should be taken during explanation to the old, poor and illiterate. In these informed consent should be a continuous process rather than a single event and the information should also be given to a younger and more educated relative.
A statutory legal obligation in India specifies that surgeons should explain to a patient the nature, purpose, risks and benefits of a proposed operation as well as alternatives to the surgical procedure. However, the process of obtaining consent for operation is usually treated as a ritual in which patients are presented with complex information that they cannot understand and duly sign or place their thumb prints on the dotted line. This is particularly true in developing countries like India where many patients are poor and illiterate and put themselves entirely in the hands of their doctors whom they consider to be next to God.

While the MOHFW has made available guidelines on the consent taking process, these guidelines have been poorly implemented in India. In March 2005 the Supreme Court, in response to a public interest litigation in Ramakant Rai vs. Union of India, observed that there was no uniformity in the standards and procedures being followed in conducting sterilisations across states, and laid down the following directions:

• that state governments should set up a panel of approved doctors, who have at least five years experience in gynaecology, to conduct sterilisations;
• that the states should maintain a checklist with details of the client’s age, health status and number of children, to be filled up by the doctor before performing the procedure;
• that a uniform proforma should be used to obtain consent from the client before performing the surgery;
• and that details of persons undergoing sterilisation and the number of deaths that occur during or after sterilisation should be registered.

It also empowered state governments to hold inquiries into any breach of the guidelines and to take punitive action against doctors and organisations that were not adhering to the guidelines. The Supreme Court expressed concern over deaths caused by unregulated sterilisations in the country; it ordered that a compensation of Rs. 1 lakh be paid to the next of kin in the case of death following sterilisation and Rs. 30,000 in case of incapacity or post-operative complications, to be effective till a uniform insurance policy was introduced. In fact, by the end of 2005, the MOHFW had brought out an insurance scheme for failure, death and medical complications arising out of sterilisation and an indemnity cover for the doctor/health facility performing the sterilisation procedure (MOHFW, 2005). In addition, the MOHFW has provided for the setting up of a Quality Assurance Committee (QAC) at the state and district levels to monitor and evaluate that the family planning services are being provided in accordance with the guidelines issued by Government of India (MOHFW, 2005).

As noted, little is known about the consent taking process in India; what is known comes from studies of quality of care in reproductive health.

According to the National Family Health Survey–2 (NFHS–2), while nationally, 19 percent of currently married women who were current users of modern family planning methods were informed about other methods of family planning by a public sector provider and 28 percent by a provider in a private facility, in Tamil Nadu 7 percent and 22 percent of women respectively were similarly informed.

Legal aspects of Informed Consent Sections 87 to 91 of Indian penal code deal with consent. Consent is perhaps the only principle that runs through all aspects of health care provisions today. It also represents the legal and ethical expression of the basic right to have one’s autonomy and self-determination. If a medical practitioner attempts to treat a person without valid consent, then he will be liable under both tort and criminal law. Tort is a civil wrong for which the aggrieved party may seek compensation from the wrong doer. The consequences would be payment of compensation (in civil) and imprisonment (in criminal). To commence, the patient may sue the medical practitioner in tort for trespass to person. Alternatively, the health professional may be sued for negligence. In certain extreme cases, there is a theoretical possibility of criminal prosecution for assault or battery.

In tort law, usage of force against any human body, without proper justification, is actionable irrespective of the quantum of force. If the medical practitioner attempts to treat a patient without obtaining proper consent, he will be held guilty under tort law. Consent for treatment may be expressed or implied. The patient entering the consultation chambers by his own volition may be considered to have given consent for a clinical diagnosis to be carried out. Consent may be inferred from the general submission by a patient to orders given by a doctor during clinical diagnosis. This is an excellent example of implied consent. During the clinical examination, there might arise the need for an intimate examination of the pa
tient, such as a vaginal examination. For such an examination, the medical practitioner must ideally obtain another consent by asking the patient’s permission orally. Furthermore, if there is a need to undergo an invasive examination, such as an incision or drawing of samples of body fluids, a written consent of the patient is ideally required.7

All medical procedures, including examinations, diagnostic procedures and medical research on patients potentially acts of bodily trespass or assault (IPC 351), in the absence of consent or statutory sanction. Treatment and diagnosis cannot be forced upon anyone who does not wish to receive them except in statutory sanction.

The age for consent for medical treatment is not officially laid down. There are obscure provisions made in Indian penal code section (IPC87 and 88), which refers to the validity of consent, which may occur from any act done in good faith and for individual benefit. Perhaps, these provisions are not specifically directed at medical treatment. When both the IPC (Sections 87 & 88) are combined, one can conclude that there is an implication that parental consent is necessary for medical treatment or surgical procedures on the minor. No one can give consent for any treatment on behalf of adult, but it is advisable to be on the safer side that the doctor should take the consent of the next of kin of the patient. Local guardian can give consent on behalf of a person only if the treatment is an emergency one. Unconscious / Unknown patient when admitted in hospital, the medical superintendent / In charge of hospital can give consent for treatment. Pathological autopsy should not be carried out without the consent of next of kin of the deceased. In case of consent for donation of organ after death the will of the deceased is enough. Not taking consent is considered as deficiency in medical services under the section 21 of the Consumer Protection Act. Consent of ones spouse is not necessary for the treatment of other. Husband or wife has no right to refuse consent to any operation, which is required to safeguard the health of the partner. Consent in medical emergencies

In India, the entire gamut of laws on consent turns into complex propositions if an emergency medical situation arises. In a few of the milestone decisions, the apex court ruled that a medical practitioner has a duty to treat a patient in an emergency. Failure on the part of a government hospital to provide timely medical treatment to a person in need of such treatment results in the violation of his right to life guaranteed under Art. 21.8 Proceeding in the same direction, the court emphasized further that every doctor whether at a Government hospital or otherwise has the professional obligation to extend his services with due expertise for protecting life. No law or state action can intervene to avoid or delay the discharge of the paramount obligation cast upon members of the medical profession. The obligation of a doctor is total, absolute, and paramount. A doctor is duty-bound to treat a patient in the case of an emergency, without waiting for any formalities. There are several statutes (like medical institutions regulation acts in various states) imposing this duty upon medical establishments to treat emergency patients, especially accident victims.

So, let us all be a little more careful in our practice to avoid unnecessary complication in our professional lives.

References

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