PATIENT RIGHTS: CONSENT AND INFORMED CONSENT:
A LEGAL STUDY

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ABSTRACT

With the idea of a welfare state, it is imperative on the governments to make such rules and legislations that protect the rights of its citizens. The issue of informed consent aims at highlighting the right of the patients of self-determination and their autonomy in decision-making. Although informed consent is an important process, its effectiveness and validity is still a concern.

This paper analyses the concept of informed consent through its history, global significance and various judicial pronouncements such as the Bolam Test which helped shape the judicial decisions. Also, various issues involving the implementation of the informed consent process have been discussed along with some suggestions that can help improvise the implementation of this concept.

Keywords: consent, informed consent, Indian laws, doctor-patient relationship, medical emergency
Introduction

The issue of consent in medical practices has become one of the major areas of interest in the present times. With people becoming more are more educated and aware of their rights, the right of the patients to be informed about the medical treatment is of greater importance. While the need of the client participation in healthcare decision making has been acknowledged, its implementation has been varied and individualistic.

With the idea of a welfare state, it is imperative on the governments to make such rules and legislations that protect the rights of its citizens. Every patient has an inherent right be informed about the medical treatment along with the possible risks and benefits and if he/she feels right so to do, he/she can even refuse for their treatment even though the said treatment will save their life. Thus, informed consent process provides the potential participants with the necessary trial information that eventually aids and empowers them to make an informed and a rational decision about their participation.

The principle of consent has been very well analysed by Justice Cardozo in a case as, “Every human being of adult years and sound mind has a right to determine what should be done with his body; and a surgeon who performs the operation without his patient's consent, commits an assault for which he is liable in damages”\(^1\).

Therefore, consent in medical practice is a legal requirement and not a mere procedural formality. Thus, for a consent to be legally acknowledged it must be a valid informed consent. Legally consent has been defined in the Indian Contract Act, 1872 as ‘consensus ad idem’ i.e. agreeing on the same thing in the same sense. The consent must be taken prior to the medical procedures and must be given by a person capable of giving his/her consent. For the consent to be informed consent, the patient must be informed about all the material details prior to his treatment.

The evolution of the idea of consent in medical practice

Historically, the Indian system of medicine, namely Ayurveda, siddha and unani imposed responsibility on the physician without giving patients any right of decision-making. It was all based on the concept of fiduciary relationship between the physician and the patients. Similarly,

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\(^1\) Schoendorff vs. Society of New York Hospital, (1914) 211 NY 125
in the Ancient Greece, the physicians were paternalistic in attitude and consent from patients was more of defensive medical practice and deemed unnecessary.

After the advent of the 20th century which led to the growth of natural rights, importance started to be given to the fundamental human rights. It was after the medical and experimental atrocities committed by the German Nazi Regime during the World War II that shook the entire world awake that the Nuremberg Code of 1947 came into existence. The code was the first documents of its kind that made it mandatory to obtain the voluntary and informed consent of the participants. The code consists of 10 principles, among which the longest is on the informed consent. The set of 10 research principles under the Nuremberg Code\textsuperscript{2} are as such:

- absolute necessity of obtaining a voluntary consent from the human subjects before including them in studies
- conducting only those studies which are good for the society
- developed on the results of animal experiments
- avoid physical and mental suffering and injury
- refraining from research if there is a reason to believe that death or disabling injury will occur
- assess the degree of risk involved in research in comparison to the anticipated benefits
- taking appropriate steps to avoid any untoward incidence
- performed by scientifically qualified persons
- right to withdraw from the study at any stage by participants
- Termination of the trial at any stage if the researcher believes there are obvious reasons for human harm, was proposed for the first time.

Thereafter, the Declaration of Helsinki\textsuperscript{3} was adopted by the World Medical Association in 1964 which stated about the importance of having an ethics committee in order to review a research proposal, which consisted of patient information sheet and an informed consent form. It further highlighted that the consent should be an informed consent after the patients has been apprised with the relevant information regarding the aim, procedure, benefits, potential risks and discomforts that may arise.

\textsuperscript{2} Nuremberg Military Tribunal, \textit{The Nuremberg code.} JAMA 1996;276:1691
\textsuperscript{3} Declaration of Helsinki, 1964
While the Nuremberg Code was in place, US issued the Belmont Report in 1979 which highlighted three main ethical principles while the research is conducted which are, respect for persons, beneficence and justice. Following this, the Indian Medical Council of Medical research (ICMR) released its first guidelines on ethics in 1980 as, “policy statement on ethical considerations involved in research on human participants.” Under the topic of informed consent it was stated, “the best way of obtaining informed consent is one that is difficult and one in which the norms and forms used in other countries are really not fully relevant to the conditions prevailing in this country.” However, according to a revised version in 2006, more emphasis was given to the community participation and permission from culturally appropriate authority on account of increasing number of community-based studies in India.

Consent and Informed Consent

Consent is the basic principle of asking the permission. Consent has been defined under the Indian contract Act, 1872 as agreeing on the same thing in the same sense, but, informed consent goes a step further and refers to the consent given by a patient after receiving the relevant information. The British journal of Medical Practitioners refers to the difference between consent and informed consent as being “the patient’s knowledge behind the consent decision.”

'Informed consent' as defined in Taber's Cyclopedic Medical Dictionary is stated as "Consent that is given by a person after receipt of the following information: the nature and purpose of the proposed procedure or treatment; the expected outcome and the likelihood of success; the risks; the alternatives to the procedure and supporting information regarding those alternatives; and the effect of no treatment or procedure, including the effect on the prognosis and the material risks associated with no treatment. Also included are instructions concerning what should be done if the procedure turns out to be harmful or unsuccessful."

The difference between the consent and informed consent is the additional word “informed”, which means that making sure patients are given enough information about the risks and benefits of all reasonable treatment options before the treatment starts. According to the British
Journal of Medical Practitioners, informed consent “requires the ability to understand and weigh up information.”

Informed consent is a legal obligation in India according to which a doctor must inform the patient about the nature, purpose, risks and benefits of any proposed medical procedure along with alternatives that may be available. Thus, consent without necessary information is no consent at all.

The process of informed consent helps the patients to better understand and visualise the risks involved. Consent is one of the basic rights of autonomy and self-determination. Consent can be express as well as implied consent. The general submission by a patient to the orders by a doctor can be regarded as implied consent. However, in certain other cases a standard form of written contract is signed by the patient thus giving their express consent for the diagnosis. The doctor need not tell the patient about the remote risks involved. Only where there is a recognised risk, rather than a rare complication is the surgeon under a duty to inform and warn the patient.

The requirement of the law in India is mere consent and not written consent. However, in certain sensitive case, written consent is preferred. To this effect, the Medical Council of India has laid down certain guidelines where consent has to be in writing before performing any operation. The MCI guidelines are applicable to operations and do not cover other treatments. For other treatments, the following may be noted as general guidelines:

1. For routine types of treatment, implied consent would suffice.
2. For detailed types of treatment, ideally express oral consent may be needed.
3. For complex types of treatment, written express consent is required.

Who is competent to give the consent

A valid consent can ideally be given by the patient only after he had been informed about the relevant facts. The consent will be considered as real when the patient is given sufficient information to understand the nature of the operation, its likely effects, and any complications

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6 Regulation 7.16, of Medical Council of India (Professional Conduct, Etiquette and Ethics) Regulations, 2002
which may arise and which the patient must be made aware of. The competency of a patient is guided by the idea that the patient should be capable of understanding the risks and benefits involved. One way of adjudging the competency of the patients is the test of majority. A person who has attained the age of majority and has a sound mind is considered to be competent to give his consent.

The law presumes capacity, rationality, autonomy and freedom once the person reaches the age of maturity. However, in exceptional cases where the patient is incompetent to give his consent owing to factors like old age, extreme health condition etc. then consent may be attained through any competent family member.

**Consent in medical emergency**

India being a welfare state, imposes the highest degree of importance on the lives of its citizens, thus in cases of emergency a medical practitioner is duty bound to treat a patient even without obtaining consent. The obligation of a doctor is total, absolute and paramount.

In cases 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. According to sec. 92, Act done in Good Faith for Benefit of a Person without Consent are not actionable.

In the case of Dr. T.T. Thomas vs. Elisa⁸, the patient was diagnosed as a case of perforated appendix with peritonitis requiring an operation. But, unfortunately no operation was done as the doctor claimed that the patient did not consent for the surgery. Therefore, other measures were taken to ameliorate the condition of the patient, which grew worse by the next day. Although the patient was then willing to undergo the operation, his condition did not permit it. Ultimately, the patient died. Although, there was no mention of consent refusal in case sheet of the patient. The court in this case held the doctor liable for not performing an emergency operation for want of patient’s consent and consequent death of patient. The court observed that,

“*The consent factor may be important very often in cases of selective operations, which may not be imminently necessary to save the patient's life. But there can be instances where a*  

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⁸ AIR 1987 Ker. 52
surgeon is not expected to say that ‘I did not operate on him because, I did not get his consent’. Such cases very often include emergency operations where a doctor cannot wait for the consent of his patient or where the patient is not in a fit state of mind to give or not to give a conscious answer regarding consent. Even if he is in a fit condition to give a voluntary answer, the surgeon has a duty to inform him of the dangers ahead of the risks involved by going without an operation at the earliest time possible”.

Legal Liability

The process of obtaining a voluntary informed consent is not an option rather it a mandatory legal formality failing which a medical practitioner will be liable under both tort and criminal law. In case any act is performed on the body of the patient without his/her prior approval it amounts for trespass to person. Additionally, the doctor can be made liable for negligence. Furthermore, in certain extreme situations, the case of assault or battery can also be made out.

Under the tort law, unjustified use of force against a human body is an actionable wrong irrespective of the quantum of force used. Thus, if any medical practitioner attempts to treat any patient without his consent, then the doctor can be made liable under torts.

Judicial evolution of the concept of consent

‘The Bolam’ test (Reasonable Doctor test)9 in 1954, John Hector Bolam underwent electroconvulsive therapy (ECT) for clinical depression. During those times, medical opinion varied on what would be the best method to minimize the risk of injuries possible from convulsions induced by ECT. In this case the manual restraint was ineffective causing fracture of pelvis. The plaintiff further argued that there was negligence by the doctor and the hospital in providing standard of care to the patient. The case established the test for the standard of care in law, to be maintained by a doctor. It observed that,

"(i) A doctor is not negligent, if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art. Putting it the other way round, a doctor is not negligent, if he is acting in accordance with such a practice, merely because there is a body of opinion that takes a contrary view……In order to recover damages

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9 Bolam v. Friern Hospital Management Committee, (1957) 2 All.E.R. 118
for failure to give warning the plaintiff must show not only that the failure was negligent but also that if he had been warned he would not have consented to the treatment.”

Following the Bolam test, In Canterbury v Spence\(^\text{10}\) (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.

In India, Bolam test has been accepted as a general rule. In Achutrao Haribhau Khodwa vs. State of Maharastra,\(^\text{11}\) the apex court held that,

“The skill of medical practitioners differs from doctor to doctor. The nature of the profession is such that there may be more than one course of treatment which may be advisable for treating a patient. ……..Medical opinion may differ with regard to the course of action to be taken by a doctor treating a patient…..doctor acts in a manner which is acceptable to the medical profession……..attended the patient with due care skill and diligence and if the patient still does not survive or suffers a permanent ailment, it would be difficult to hold the doctor to be guilty of negligence. In cases where the doctors act carelessly and in a manner which is not expected of a medical practitioner, then in such a case an action in torts would be maintainable”.

In Smith v Tunbridge Wells\(^\text{12}\) 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.

**Indian law on consent**

Article 21 of the Constitution of India talks about the right to life and personal liberty according to which every individual has autonomy over his body. He has every right over his body and no one can touch it without prior permission. Thus, this right gives the power of self – determination to the individuals and in case any injury, harm etc. is done to any individual by any involuntary act by another, the other person can be made liable for the same.

\(^\text{10}\) Canterbury v. Spence, 464 F.2d 772, 782 (C.A.D.C. 1972)

\(^\text{11}\) 1996 (2) SCC 634

The consent law in India is guided by the Indian Contract Act and the Indian Penal Code. The relationship between the doctors and the patients is generally formalised through written contracts entered into by competent parties. The competency of the parties is checked by three factors which are: attainment of the age of majority, their sane mind and if they are disqualified by any law to which they are subject. Furthermore, it is imperative that the Contract Act specifically mentions that any consent obtained by fraud, coercion, misrepresentation, mistake, undue influence is no consent at all.

Thus, once the consent is obtained it is relevant for that purpose only and if the doctor goes beyond the area consented to, then he does so at his own risk as there is no consent for the same. A doctor who went ahead in treating a patient, to protect the patient's own interest, was held liable as he was operating without consent.\textsuperscript{13}

One of the earliest Indian judgement on the informed consent is of Ram Bihari Lal v Dr J N Srivastava,\textsuperscript{14} in this case 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.

In case of proxy consent, where the patient is incompetent to give consent himself, there are no clear regulations or principles developed in India. In such situations, the medical practitioner may proceed with treatment by taking the consent of any relative of the patient or even an attendant. In another case, the wife of a patient informed the hospital authorities in unambiguous terms that she had no objection to her husband undergoing bypass surgery, her

\textsuperscript{13} Maneka Gandhi v Union of India, AIR 1978 SC 597
\textsuperscript{14} AIR 1985 MP 150
consent was deemed sufficient for the purpose of any formalities with which the hospital was required to comply.

In one case, the relationship between the patient and his wife were strained. A patient was operated on for sterilization. While giving consent he deposed that he is married and has two baby girls. In fact, he was undergoing an operation only for getting the money as incentive. After the operation, his father contended that the patient was of unstable mind and was not competent to give consent. The court held that if there are no circumstances for a doctor to sense foul play or doubt about the capacity of the patient, he is protected.\(^\text{15}\)

Also, in the case of Samira Kohli vs. Dr. Prabha Manchanda & Anr\(^\text{16}\), the court referred to the case of Salgo vs. Leland Stanford\(^\text{17}\) where it was held that a physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment.

Also, the Code of Medical Ethics (approved by the central government under section 33 of Indian Medical Council Act, 1956) there is a chapter relating to the disciplinary action which enumerates a list of responsibilities, violation of which will be a professional misconduct.

Clause 13\(^\text{18}\) of the said chapter states the following responsibility on a doctor:

"13. Before performing an operation, the physician should obtain in writing the consent from the husband or wife, parent or guardian in the case of a minor, or the patient himself as the case may be". In an operation which may result in sterility the consent of both husband and wife is needed.\(^\text{19}\)

**Issues in informed consent**

In developing countries like India, the process of informed consent is treated as more of a meaningless ritual and an unnecessary legal procedure rather than a way to actually make the patients aware about the treatment procedures. The major reason for this is that majority of the patients in India are illiterate and poor and put themselves absolutely in the hands of the

\(^{15}\) C A Muthu Krishnan v M. Rajyalakshmi, AIR 1999 AP 311

\(^{16}\) Case No.: Appeal (civil) 1949 of 2004, decided on 16/01/2008.

\(^{17}\) 154 Cal. App. 2d.560 (1957)

\(^{18}\) The Indian Medical Council (Professional Conduct, Ethics & Etiquettes) Regulations-2002

\(^{19}\) Yadav M, Thakur PS, Rastogi P. “Role of Informed Consent in India; Past, Present and Future Trends”. 36 *Indian Acad Forensic Med* 411-420 (2014)
doctors. This ultimately leads back to the paternalistic approach of the doctors under which they regard the process of informed consent as something that wastes their valuable time and energy and in fact sometimes scares the patients enough that it results in them refusing for any medical procedure which might be lifesaving. Also, the rigid legal outlook towards the consent process is one reason why medical practitioners are reluctant to start the process.

It is also assumed that since the patients in India are illiterate, they tend to lack even the basic knowledge about the medical procedures and hence it becomes difficult for them to recall the information passed by the doctors to them after few days only. Further, the complex medical terminologies, complex languages and the lengthy consent documents make the patients less willing to participate. Also, sometimes the patients feel pressured or frightened to give their consent. They are struck with anxiety and fear of the new procedures. Often after the patients get scared of the procedures, they tend to deny the disease state by hiding true facts and try to convince the doctors that they feel or more stable.

Moreover, in India, there is a further issue with the relationship of doctor’s vis-à-vis a female patients. India being a patriarchal society, often the decisions are taken typically by the male member of the family, thus, the female members are often expected to be acquiescent, allowing the senior most male family member to do the necessary talking. This thereby tends to create the impression that the patients’ knowledge is not worth taking into consideration. They further state that as patients are seen as lacking in capacity to fully understand the information provided, trying to communicate to them is often seen as a futile exercise.

According to a qualitative study carried out in a private hospital in Tamil Nadu, for most of the patients’, informed consent was merely an unfamiliar phase which meant nothing more than signing a document. According to one of the patients, she had never paid attention to any of the words of the documents and had always left it entirely in her mother to deal with it. While to some other patients, this document was merely a document for the defence of the hospital in case of any mishap.


Also, in many cases in order to avoid the risk of patients refusing for the treatment, the doctors occasionally try to sublime the medical procedures by saying that “everything will be fine.” Many a times the language barrier also acts as the void between the communication of the doctors and the patients. A brief analysis of the process of informed consent can be explained through the following fig:\textsuperscript{22}:

![Fig. : Informed consent: conceptual framework](image)

**Suggestions**

In a country like India where there are diverse patients of different socio-economic backgrounds, it is necessary that the consent forms should be made available in various languages which are understood by the patients. Also, new methods should be developed to make the consent forms accessible to people with audio-visual aids.

\textsuperscript{22} Ibid.
Also, since the doctors usually have scarce time to explain each and every fact to every patient, social workers should be trained in this process so that they can talk to the patients and explain in detail about their illness and the procedure which can be adopted. Also, the language of the consent forms should be simplified to the 8th grade reading level since the complex medical jargons are often not understood by the patients.

Perhaps since mostly the patients prefer the verbal mode of information thus, they often tend to ignore reading the consent forms. Hence, there should be more use of structured visual aids such as charts, diagrams, videos that can help the patients better understand the purpose and value of the treatment. Also, the information process should be a continuous process rather than a single event.

Also, for better medical treatments, there should be free flow of communications between the doctors and the patients. Thus, a participatory relationship should follow where patients feel free to air their concerns and doctors recognize patient’s views.

The Association of American Medical Colleges has put forth certain strategies23 which can increase the readability of the consent forms, few of which are listed as such:

- Simplify language using short, familiar, concrete and simple words
- Use adequate spacing and white spaces to make content inviting to read
- Avoid crowding of words and letters
- Use headings/subtitles. These reduce content density and serve as road signs
- Use list rather than paragraphs when possible
- Avoid medical terminology whenever possible
- Keep sentence length below 12 words
- Keep paragraph length below 7 lines
- Use clean, easy to read print type
- Ensure each paragraph conveys only one idea
- Spell out abbreviated terms
- Consider using simple illustrations and examples

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These strategies should be put into use while creating the consent forms. These will benefit the patients for better understanding of the medical procedures and will help doctors in conveying in better terms all the relevant information.

**Conclusion**

The doctor-patient relationship has always been acknowledged as a very important factor which influences the health outcomes of a patient. Thus, the individual’s right about making informed choice should be given much importance. The process of informed consent should be treated as a continuous dynamic process rather than an isolated event. The consent should be taken at a prior stage from the patient himself after he has been informed about the necessary information. It should be borne in mind that the patient has the right to refuse treatment and no involuntary procedure can be carried on him against his will. Despite, several ethical codes and legislations, the idea of informed consent is more of words than practice. Hence, more effort should be put in through national and international bodies to improve the situation and create awareness about this issue.