CONSENT IN MEDICAL NEGLIGENCE CASES IN INDIA

Written by ***Prahalad Sriram***

5th Year B.A. LL.B. Student, School of Law, CHRIST (Deemed to be University), Bengaluru, India

ABSTRACT

Consent is an essential ingredient for valid agreements and contracts. It is also at the core of most medical negligence cases. The concept has undergone changes in the last half-century, especially in the medical field, with the legal systems beginning to shift towards a standard that places a higher standard of disclosure requirements on medical practitioners. The informed consent standard is a test that has been adopted by the courts in U.K. which promises more autonomy to the patients, and thus a more favourable stance for plaintiffs. A landmark judgement in 2008 in India observed that India is not yet ready for this standard and sought to fall back to the one existing in *status quo*. While 12 years have elapsed since this judgement, the author believes its time the standards of consent are revisited. The argument to place greater reliance on patient autonomy is made after describing the various nuances and intricacies involved in the concept, laws, and case laws relating to medical consent. The analysis plainly suggests that a share of the onus shifting on to medical practitioners would ease both the experience in courts for potential plaintiffs, as well shift the burden to the party most competent and at a better position to understand and convey medical information. India's unique socio-economic situation has to be kept in mind and the author posits that policy relating to shifting of the prevailing standard of medical consent be researched upon and slowly introduced. This would allow for better protection of plaintiffs, while also reducing instances of medical negligence in the first place.

***Keywords*:** Medical, Negligence, Consent, Informed, Express, Implied, Samira Kohli,

INTRODUCTION

Consent is a well-known essential within the medico-legal fraternity, acting as a foundation upon which contracts and agreements are built upon. It is also one of the critical issues surrounding medical negligence cases. The principles of consent, specifically in the context of medicine can be traced back to the Nuremberg Code[i] that was drafted after the Second World War, mostly to curb medical experiments and atrocities committed by the Axis Powers. This code imposes a mandate to obtain voluntary, free, and informed consent of the human subject. Similarly, the Declaration of Helsinki adopted by the World Medical Association in 1964 also highlights the sacred nature of obtaining informed consent freely, for medical purposes.[ii] Similarly, many other international conferences, declaration and conventions have ratified the importance of obtaining consent from patients before their treatment. This paper discusses the concept of consent itself, its types, its objectives, and most importantly, its implications on cases of alleged medical negligence under the scope of the Consumer Protection Act, 1986.

WHAT IS CONSENT?

The Black's Law Dictionary defines consent as "concurrence of wills".[iii] What this means is essentially a meeting of minds of two individuals when it comes to a certain topic. This meeting of minds can be with regard to a certain act, commission, or omission thereof which both parties are seeking as an end result of this will of theirs. As defined by Section 13 of The Indian Contract Act, 1872, 'consent' refers to- "two or more persons are said to be consented when they agree upon the same thing in the same sense."[iv] This also embodies within itself, the maxim of *consensus ad idem,* or 'meeting of the minds'. It is essential to note that both these definitions stress upon a certain concurrence or meeting of minds or 'same sense'. In practice, this is when there exists no ambiguity or asymmetry between the parties when it comes to the exact nature, terms, and consequences of the contact they are consenting to.

WHY IS CONSENT IMPORTANT?

Consent embodies a basic legal standard and ethical mandate of the basic right to protect one's own autonomy.[v] Thus, it is essential to uphold the sanctity of this concept to ensure that no moral or ethical lines are crossed, especially in the field of medical negligence. Failure to adhere to this concept would be violating an individual's right to personal liberty, enshrined under Art. 21 of the Indian Constitution[vi], and would also open up the possibility for civil and criminal suits to be proceeded against the offending medical practitioner. Apart from the Constitution, it is a well settled principle of natural justice and has even been embodied in several international declarations and conventions that have been ratified by various countries. For example, the United Nations Declaration of Human Rights, under Article 3, says "Everyone has a right to life, liberty, and security of person."[vii] An act or omission that goes against a person's wishes or expectations, or imposing consequences that a person does not fully understand leads to a violation of this basic tenant of human rights.[viii] Thus, consent plays a significant role in all aspects of one's life. Within the medical realm, every person has a primary right over their own body and any infringement would be going against the principles of natural justice. Thus, common law has embodied this concept into various provisions which can hold parties indulging in such infringements liable to be subject to these provisions. A doctor that indulges in treating his patient without the patients' consent would be committing the torts of battery and assault, and would also be liable for criminal prosecution for the same offences.[ix] A medical practitioner is not above the law, and violating these cardinal principles would subject them to the same consequences as any other man. However, the law does allow doctors some leeway when it comes to emergency situations or situations wherein valid consent cannot be obtained, subject to certain conditions, but that is beyond the scope of this paper.

TYPES OF CONSENT

In the medical field, consent of three main types:

i) Implied Consent
ii) Express Consent
iii) Informed Consent

These vary primarily depending on circumstances.

Implied Consent – This kind of consent is implied by way of acts or behaviour of the parties or by circumstances under which the treatment is given. The demeanour or actions of the parties plays a vital role in this type of consent.[x] This type of consent is not expressly asserted nor documented, but nonetheless is still legally valid. For instance, when a patient upon fixing a medical appointment volunteers to share his medical history and answer questions pertaining to it, he submits himself without any objections for physical examination by way of an implied consent.

Expressed Consent – Where the terms of agreement or consent are stated in an explicit and distinct manner. It could be either in a written or oral form. In majority of treatments and procedures that are considered minor in nature, a express consent is obtained ideally from a disinterested party.[xi] This consent should ideally be obtained in writing whenever invasive or investigative procedures are done that might cause significant pain to the patient, or when drugs, narcotics or analgesics are used which might significantly alter the patient's level of consciousness.[xii]

Informed Consent – This type of consent is a manifestation of the principle that every person is entitled to form his own decisions based on what affects his well-being.[xiii] Individuals should be allowed to make their own cost benefit analysis for which they must be informed of the pros and cons; benefits and risks of the procedure. The law is made to protect the patient's right to formulate an informed decision by necessitating the complete disclosure of every information pertaining to the treatment by the doctor in order to ensure room for informed consent. The onus is therefore on the doctor to disclose all information and the right to decide how his body will be treated lies with the patient.[xiv] Thus, all relevant information regarding the treatment or procedure must be enunciated in explicit, comprehensive and preferably using simple instead of technical medical terms and in a language that the patient understands. This consent, when received in writing is called as an "informed, express written consent" and should be ideally obtained in surgery and other serious procedures, and all serious and complicated diagnostic and therapeutic procedures.

APPLICABILITY

It is pertinent to note that the law itself does not mandatorily impose the necessity to obtain written consent, but instead insists merely on consent. Therefore, medical practitioners themselves have determined the need for written consent and impose this practise of obtaining written consent on them. A practitioner may not obtain the written consent at all times and therefore, the failure of this task would not result in him being made liable for the same. However, it is common knowledge that if a written consent is obtained, the doctor can use it as a defence in case of any civil dispute arising out of alleged medical negligence where the petitioner may claim otherwise. Since there exists no rules regarding this, the Medical Council of India (MCI) has put forth certain guidelines for regulating 'consent' which is mandated to be obtained in express form before the surgery is performed.[xv] These regulations are applicable only to operations. For other treatments, these are generally accepted as general rules:

a) For routine treatment, implied consent is sufficient;
b) For detailed treatment, express or oral consent is ideally required;
c) For complicated treatment, written express consent is needed.[xvi]

LAWS ON CONSENT

Article 21 enshrined under The Indian Constitution includes the right to 'self-determination and autonomy' under the right to life and personal liberty. The term personal liberty is to be read with the widest scope and covers within its ambit a wide array of rights which includes the right to dignity along with all other rights that can be clubbed with it.[xvii] In India, although the courts have often mentioned these principles, they are not fully developed.[xviii] In such cases the Indian Penal Code, 1860 and the Indian Contract Act, 1872 may be referred to as they lay down principles for consent. The doctor-patient relationship is a contractual one between parties that are competent to enter into such contractual obligations. The criteria laid down under the Indian Majority Act, 1875, Indian Contract Act, 1872 and the Indian Penal Code, 1860 are supposed to be fulfilled in order to be a competent party. These include being of sound mind, being above the age of majority, being able to understand the consequences of consenting, and not being disqualified by law. Consent when obtained, is supposed to have

clear parameters of operation based on the relevant information obtained. This acts a sort of protection for the medical doctor/practitioner. However, if the practitioner acts outside the ambit of the parameters agreed upon by the parties, he would be treating the patient at his own risk as it is considered the same as not obtaining consent as all.[xix] These principles are enunciated in various case laws.

STUDY OF CASE LAWS ON CONSENT

A patient suffering from appendicitis was subjected to an operation by her doctor after obtaining due consent for the same. During the surgery, however, the doctor discovered that the appendix was not inflamed and was normal. He found the patient's gall bladder was gangrenous and keeping her best interest in mind, removed it to prevent further complications. It was later discovered that her kidney was affected by the surgery. The court held the doctor liable for operating without consent and stated that, even though a medical practitioner might be acting in the best interests of the patient, the law upholds the individual's dignity and autonomy and their right to make a decision on what will happen to their body above everything else.[xx]

The Court in *Satishchandra Shukla*,[xxi] held that where a surgeon obtains consent from a patient for a diagnostic procedure, the consent obtained will be considered invalid for performing a therapeutic surgery except in cases where the patient's life is threatened in an emergency scenario.[xxii]

In the land mark judgment of *Samira Kohli v. Dr. Prabha Manchanda and Anr.*,[xxiii] an unmarried woman was advised to undergo a medical procedure called a laparoscopy by her doctor. The consent form which she signed was for admission and for this particular operation for which the signature was obtained. During the operation, the patient's mother was consulted for obtaining consent to perform hysterectomy since the patient was unconscious at the time. This was a proxy consent and hence, the court held in favour of the patient and stated that removing her reproductive organ was done without her 'real consent' and the doctor was held liable for the same.[xxiv]

Ever since the landmark judgment of *Indian Medical Association v. Shantha,*[xxv] wherein it was held by the apex court that as per section 2(1)(o) of the consumer protection Act, 1986, the term 'service' included within its ambit every medical services, there has been a slew of cases in the District fora, the National Commission and the State Commissions wherein medical practitioners have been alleged to have been exhibiting deficiency in their service and thus committing medical negligence as per the Consumer Protection Act, 1986. Although the burden of proof on the Complainant is relatively high, many doctors use the defence of having taken a valid consent from the complainant or the patient signifying that they cannot be held liable except in circumstances of gross negligence or where the doctrine of *res ipsa loquitur* applies.[xxvi] This has prompted many medical practitioners to draft and use a wide range of consent forms that individually seek consent for every single medical procedure that is considered detailed or complicated and might result in serious consequences for the patient. So far, the use of such consent forms is merely a formality as seen by the patients and the practitioners and it is not until something goes wrong that the parties realise the importance of the forms that are being summarily signed. A problem emerges when private practitioners who rely primarily on oral or implied consent are being sued for negligence when they cannot prove that the patient's consent has been obtained. Also, doctors, who are experts in their own fields, cannot be expected to draft a legal document asking for consent that would hold water especially when being critically examined by a quasi-judicial body such as the ones set up by the Consumer Protection Act, 1986. Large hospital enterprises, however, are prone to a large amount of litigation considering the scale and volume of patients that they treat even on a daily bases, and thus have vast and extensive consent forms for every procedure to ensure that it does not give cause of action for a suit against them. The law in the country itself does not place any mandate on the doctors or medical practitioners to obtain written or express consent, but merely asks for the consent to be obtained and personal autonomy and dignity to be respected. Further, bodies such as the MCI do have guidelines, but are just that, and do not actually have model consent forms or any binding rules regarding taking consent from their patients.

DOES CONSENT WAIVE LIABILITY?

When a patient consents to an operation, he does not waive all rights to sue the doctor in certain cases. When consent is obtained, the patient only loses the right to sue on the ground that his individual autonomy was violated and that he was not prepared to face the outcomes of the surgery, as he had already signed a form stating exactly that. However, signing a consent form does not waive off the right to sue the practitioner for gross medical negligence, especially in cases where the doctrine of *res ipsa loquitur* would apply. The doctor is allowed to errors of judgment, but is not allowed to stoop below a certain degree of care that is imposed upon him by law. Also, as seen in the *Samira Kohli*[xxvii] judgment, consent for one procedure cannot be considered valid consent for another. But the alternative is quite severe. Not obtaining consent for a procedure would easily fall under the ambit of medical negligence and if proven, the Commissions would not hesitate to hold the doctor liable.

CONSENT IN THE UNITED KINGDOM

It is generally seen as fair when a consumer or customer is informed of all the risks associated with a certain procedure, especially when it affects the person's life or body. In the U.K, two major case laws reigned supreme when it came to the question of consent and what a doctor is supposed to disclose to a patient before he performs a particular surgery. The case *Bolam v. Friern Hospital Management Committee,*[xxviii] widely popular for the famous Bolam's test, also talks about consent. In this judgment, the doctors were allowed to rely on their professional judgement to disclose information according to what they felt would be sufficient to obtain consent. There was no necessity to disclose certain side effects or complications that may arise if it was in the doctor's opinion, too remote a possibility. This 1954 case was later affirmed in *Sidaway v. Board of Governors of The Bethlem Royal Hospital and The Maudsley Hospital*[xxix] which is again a land mark judgment in itself wherein the court holds that when a patient does not ask for the risks involved during the procedure, according to Justice Diplock, disclosing the risks may affect the patient's mind and can dissuade him from undergoing the procedure which otherwise would have been in the patient's best interest according to the medical expert. Thus, these judgments really constricted the possibility of suits in cases where the patients'

alleged consent was not being based on full disclosure and understanding of all risks involved with the procedure.

A recent case, however, has overturned these old principles. In the 2015 case of *Montgomery v. Lanarkshire Health Board*[xxx], the United Kingdom Supreme Court showed that personal autonomy and self-determination were at the core and cannot be ignored. This case held that the doctor would need to give the fullest possible information or all possible options that would be necessary for making a sound and informed decision by a reasonable person with respect to every information in possession of the doctor prescribing the treatment. The patient in this case was not informed of a 9-10% risk associated with the delivery of her child due to her condition because the doctor assumed that she thought that the risk of problems for the baby arising from the condition was very small. She stated that she believed that if the condition was mentioned, all women would request a caesarean section. This judgment shows the new approach to the age-old principle of consent by the UK in that the court believe that consent should be informed and not just a mere formality.

WHERE DOES INDIA STAND?

In the landmark cases filed under the Consumer Protection Act, that talk about consent in medical negligence cases are those such as the *Samira Kohli vs. Dr. Prabha Manchanda and Anr,*[xxxi] case wherein the Supreme Court considers two main approaches to patient consent that is prevalent in the world. First is the concept of 'real consent' that was laid down in *Bolam's* case and was further discussed in *Siadaway's* case wherein it was not necessary for the doctor to disclose every piece of information, but rather, just to ensure that the consent is obtained without coercion, and that the patient is competent enough to give the consent. The third approach chosen was to find out whether the patient had adequate information about the procedure. This is prevalent in most common law countries, including the UK. The other is the concept of 'informed consent' that was laid down in the case of *Canterbury v. Spence*[xxxii] where the United States court highlighted the importance of doctors being required to disclose as much information as is possible about any and all of the risks involved in a treatment, as well as other options available to the patients. This, of course, places a much higher burden on the

doctor to fulfil while obtaining consent, as he has to make sure, every single aspect of the treatment is addressed for obtaining valid consent.

Now, the British view has changed, as rightly predicted in the *Samira Kohli* judgment,[xxxiii] as the *Montgomery* case has increased the disclosure requirements of doctors, thus leading to the scenario wherein 'informed consent' is what prevails over the UK.

Further, other countries such as Canada and Australia have also shifted to the requirement of high degrees of disclosure of informed consent, thus leaving India behind. The Supreme Court has addressed this issue in the same judgment where it balances the costs and benefits of both these types of consent and reached a view wherein the court opined that:

> "*We have however, consciously preferred the 'real consent' concept evolved in Bolam and Sidaway in preference to the 'reasonably prudent patient test' in Canterbury, having regard to the ground realities in medical and health-care in India. But if medical practitioners and private hospitals become more and more commercialized, and if there is a corresponding increase in the awareness of patient's rights among the public, inevitably, a day may come when we may have to move towards Canterbury. But not for the present."* [xxxiv]

CONCLUSION

This leaves the field open for the future where the court can decide that the time has come to shift to a more ideal disclosure standards that informed consent requires, but the question is when? The *Samira Kohli* judgment came out in 2008 and already a period of 12 years has elapsed. In this period, the United Kingdom, the model that we had followed till date regarding the consent standards, has also shifted to 'informed consent'. Like the court had stated in the judgment, many issues that were unique to India which resulted in the judgment favouring 'real consent', but has the times not changed enough for the Indian courts to adopt a change in the way doctors disclose information to patients? India faces many problems that pose a challenge such as illiteracy and language barriers do not allow for the same level of disclosure norms that countries like the United States, and recently, the United Kingdom enjoy. However, considering the sharp increase in the number of cases that are filed due to medical negligence,

and the fact that many of these cases would not have arisen if there were mandatory or a higher burden on the doctors to disclose information regarding the treatment to the patients, it would arguably be in the best interest of the consumers for the courts to shift their ideal for consent in medical practice. Further, this would help place the consumer on a more equal pedestal as compared to doctors who now enjoy more freedom considering the high burden placed on the complainant in these cases. This warrants further policy research into the field of medical consent to ascertain whether the country is ready to adopt a standard that is more beneficial to the patient.

ENDNOTES

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[xvii] Kharak Singh v. State of Uttar Pradesh 1963 AIR 1295, 1964 SCR (1) 332.
[xviii] *Id.*
[xix] *supra* note at 16.
[xx] Ram Bihari Lal v. Dr. J. N. Srivastava, AIR 1985 MP 150.
[xxi] Satishchandra Shukla vs Union of India, 1 (1986) ACC 46.
[xxii] *Id.*
[xxiii] 2008, (1) SCALE 442.
[xxiv] Samira Kohli v. Dr. Prabha Manchanda and Anr., 2008, (1) SCALE 442.
[xxv] 1995 (6) SCC 651.
[xxvi] Janice v. St. Anthony's Medical Center, SC 88948.
[xxvii] *supra* note at 23.

[xxviii] (1957) 1 WLR 582, (1957) 2 All ER 118.
[xxix] [1985] 1 All ER 643, [1985] 2 WLR 480.
[xxx] [2015] UKSC 11.
[xxxi] *supra* note at 23.
[xxxii] 1972 [464] Federal Reporter 2d. 772.
[xxxiii] *supra* note at 23.
[xxxiv] *Id.* at para 33.