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ORIGINAL ARTICLE

INFORMED CONSENT TO MEDICAL TREATMENT WITH SPECIALREFERENCE TO THE INDIAN PERSPECTIVE

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Abstract:

A doctor should not only obtain the consent of a patient but also his informed consent before administering any treatment or performance of medical procedure. The rationale behind this proposition is that every medical procedure is beset with inherent risk. No doubt a doctor performs the procedure for the benefit of his patient. But sometimes the risks may outweigh the benefit. Therefore risks associated with the procedure must be divulged to a patient along with relevant information regarding diagnosis to enable him to arrive at a decision whether to undergo the treatment or not. The underlying notion is that a human body is inviolate. It is a reflection of the principle of bodily autonomy, which confers an exclusive right of self-determination to a patient. Hence the presumption is that an adult of sound mind knows what shall be and shall not be done with his body. Therefore it is necessary to involve a patient in the medical decision making process that he should have his own share of information. In this article an attempt is made to examine the doctrine of informed consent from the Indian perspective with reference to the doctrine as interpreted in the USA, as it is a doctrine which was invented there and English law on the subject which is applied by the Indian courts.

KEY WORDS:

Medical Treatment , Perspective , Administering .

INTRODUCTION

MEANING & OBJECT OF INFORMED CONSENT:

It signifies consent obtained after divulging the material risks associated with a medical procedure and alternative modes of treatment with their relative merits and risks so as to enable a patient to arrive at a rational conclusion as to whether to submit himself to the treatment of a doctor or not.

It is an ethical concept. Accordingly it's roots can be located in the right of self-determination which is an off-spring of the principle of bodily autonomy, to treat the patient justly by supplying his share of information, truthfulness, to do good and not to harm the patient.Components of the doctrine:

a)Disclosure of Information: A certain amount of information needs to be disclosed to the patient. The nature and extent of disclosure depends upon the knowledge and experience of a patient. Hence it varies from one patient to another patient.

b)Competency: There is a legal presumption that a patient is competent to understand the information

furnished by the doctor.

c)Understanding: In addition to that there is a further presumption that a patient understands the information divulged by his doctor. Accordingly the duty of a doctor ends with the disclosure. He is under no obligation to ascertain whether the patient has comprehended the information furnished or not.

d)Voluntary decision: On disclosure of information, a patient has to take a decision from his free volition as to whether to undergo the treatment or not. If it is extracted by way of coercion undue influence, misrepresentation or fraud it will have a vitiating effect on the consent.

AMERICAN PERSPECTIVE:

The doctrine of informed consent is a trans-atlantic doctrine. It owes it's origin to the USA, where it was profounded first. It owes its genesis to the decision in Salgo v Leland Stanford Jr. University Board of Trustees. In this case it was held that when a doctor failed to disclose the real facts to a patient, the consent so obtained ceased to be an intelligent one. Accordingly the doctor was held liable for trespass and not for negligence.

The above decision was harsh towards the doctors. Generally non-consensual medical treatment only invites liability for trespass. But the above proposition of a law was laid down at a point of time, when the law pertaining to informed consent was at a rudimentary stage. Further examined in the light of subsequent development recognising the legal presumption of competency and understanding of the information on the part of a patient the notion of lack of intelligent consent was dispensed with. The inevitable conclusion of such presumptions is that the consent for treatment is intelligent one that it's genuineness cannot be questioned.

The decision in Natanson v. Kline, made a significant departure from Salgo to do away with the injustice done to the doctors. In this case a patient was suffering from breast cancer. After mastectomy she was subjected to cobalt therapy, in order to prevent its spreading to the other parts of the body. As a result of the therapy, she received burn injuries. She brought an action against the radiologist for his failure to inform the inherent risk in the procedure. A verdict was recorded in favour of the patient. Accordingly the radiologist was held liable for negligence (unlike in Salgo) and not for trespass. It was held that a doctor was under an obligation to make a reasonable disclosure of the risks and danger involved in any procedure. The court (as in Salgo) further observed that what risks ought be disclosed was a matter of medical judgement. It follows that extent and standard of disclosure need to be regulated by the reasonable doctor test.

The decision in Natanson stands significant for the reasons that lack of informed consent invites liability for negligence (not for trespass) and the substitution of the obligation of reasonable disclosure for intelligent consent.

It is the decision in Canterbury v. Spence, which brought a radical change in the concept of informed consent by incorporating novel contents. In this case the patient who underwent a laminectomy procedure suffered paralysis as a result of it. He sued the doctor for his failure to divulge the risk associated with the procedure. Allowing the action, the court observed.

“Respect for the patients' right of self-determination on a particular therapy demands a standard set by law for physion rather than one which physicians or may not impose upon themselves”.

It is evident from the above decision that the extent and standard of disclosure must be determined by law. It cannot be left to the medical profession. The reason is that medical profession may show a bias towards their own members by not exposing them to legal liability.

Accordingly it was held that a doctor should disclose all the material risks associated with the medical procedures what a prudent patient placed in the position of a patient would consider them as material. In this regard the court observed.

“A risk is thus material when a reasonable person what the physian knows or should know to be in patient's position would be likely to attach significance to the risk in determining whether or not to forgo the proposed therapy”.

It follows from the above observation that the court rejecting the reasonable doctor test substituted the prudent patient test. Accordingly the risks what ought to be disclosed are not one what reasonable doctor would have disclosed, but what a prudent patient placed in the position of patient would expect the doctor to disclose. Therefore a material risk is one to which a prudent patient would attach significance to decide whether to undergo the treatment or not and not one what a reasonable doctor would consider. In effect a doctor is not permitted to step into the shoes of a patient.

The judicial rejection of reasonable doctor test is based on the following reasons:

a.The determination of material risk does not warrant any medical evidence. A layman without any scrupple, would come to the conclusion that risk of death, brain injury, cardiac arrest, paralysis, loss of limb etc. are material risks, which if divulged may deter a patient from submitting to the medical procedure.
b.The medical profession may use the professional practice from which emanates the reasonable doctor criteria as a shield to protect its members from legal liability.

The legal position is divided between the professional practice and prudent patient tests. In spite of the rejection of the former in Canterbury, in many jurisdictions, courts apply it. Accordingly, the burden falls on a doctor to prove that professional practice is in favour of non-disclosure. However in many other jurisdictions, Canterbury has garnered sufficient judicial support as laying down the binding principle with respect to the extent and standard of disclosure.

In Cobbs v. Grant, a hybrid test was laid down applying prudent patient test with respect to material risks and reasonable doctor test regarding the additional information what a patient may demand from a doctor.Position under English Law:

The genesis of the doctrine of informed consent in England can be inferred from the decision in Chatterton v. Gerson, which recognised a positive obligation of disclosure of risks on the part of a doctor, which is something akin to the doctrine of informed consent. In the above case a patient underwent a hernia operation, as a result of which suffered from pain and suffering. Subsequently two more operations were performed to set right the injury, but in vain, only to witness permanent loss of sensation in his right thigh. The patient initiated an action against the doctor on the ground that there was a lapse on the part of the latter in not disclosing the risks associated with the procedure. The doctor contended that it was his general practice to inform the risks inherent with a procedure and could not recall whether he had done so. Even though the action was not allowed, the court recognised a positive duty of disclosure. It was held that if a procedure was beset with any real risk of misfortune, a doctor was under an obligation to divulge what he intended to do and it's implication on the patient, like what a careful and responsible doctor placed in similar circumstances would have done.

The English law applies the Bolam principle to determine the negligence of a doctor, as laid in Bolam v. Friern Hospital Management Committee. Accordingly, a doctor is not guilty of negligence if he has acted in accordance with a practice which is accepted as proper by a responsible and respectable body of medical opinion.

It follows that the content and standard of disclosure depend upon the practice accepted as proper by a responsible and respectable body of medical opinion. Accordingly the extent and standard of disclosure depends upon the professional judgement. Therefore the test is what a reasonable doctor would or not have disclosed. The court in Sidaway v. Board of Governors of Bethlem Royal & Maudsley Hospital, refused to split the comprehensive duty of a doctor for application of different tests one for diagnosis, medical advice, administration of treatment, performance of medical procedure and the other for disclosure obligation. In effect, the Bolam principle could retain it's favour with the court.

The above decisions reflect the paternalistic altitude of courts towards the medical profession culminating in medical paternalism. A reasonable degree of medical paternalism is essential Law needs to be protective of medical profession. But it should not be extended to its illogical extent to hold that a doctor can tell a lie in the interest of the patient.

The recent trend manifests a shift from pro-doctor to pro-patient approach. In Chester v. Afsar, it was held that a surgery performed without informed consent was unlawful. It was observed, in modern law paternalism no longer rules. The court made a very consequential observation that informed consent was a basic human right of a patient which protected the dignity and autonomy of the patient and any lapse on the part of a doctor to divulge the risk was itself an injury.

The above decision made a radical departure from the earlier restricted view by upholding the primacy of patient's right of self-determination. It has further diluted the rigid causation requirement in favour of a patient. In effect, now it is suffice, if a patient merely proves that a doctor did not adhere to the duty of disclosure of risk. A patient needs to prove only the materialisation of risk. The reasonable doctor test has lost its foothold as the professional organizations for the medical practitioners insist them to obtain informed consent by divulging the risk inherent in the medical procedure. In effect there is a drift towards the prudent patient test, which earlier could not cut ice with the court in Sidaway. It is further suggested that doctor – patient relationship being a fiduciary in nature, imposes a duty of disclosure on a doctor. This is indeed a novel approach of looking at the doctrine of informed consent.

INDIAN PERSPECTIVE:

Medical profession has been bought under the fold of the Consumer Protection Act. Accordingly a doctor for any deficiency in his service can be held liable under the Act. The substantive law relating to negligence remains the same. Any deficiency in service under the above Act is determined on the basis of negligence. The definition of deficiency in service contemplated in the above Act is wide enough to cover the instances of lack of informed consent. There is no tort law relating to informed consent. Courts have been reluctant to insists the disclosure requirement. Vinitha Ashok v. Laxsmy Hospital, could have been an apt case, in which the seed of doctrine of informed consent could have been sown. But it did not happen so. In this case a patient who had cervical pregnancy was subjected to lameneria tent method for the dilation of cervix. There was another method viz. dilapan. The patient's contention was that the method used by the doctor culminated in removal of her uterus. The National Commission rejecting the contention held that the doctor was not negligent.

In the above case neither the patient invoked the doctrine nor the court adverted its mind to it. The reason can be certainly gathered from the fact that medical law then was in just a take-off stage and the then prevailing position was not ripe for the application of doctrine of informed consent.

The above view can be obviously deciphered from the following observation of Supreme Court in Indian Medical Association v. V.P. Shantha. “In India majority of citizens requiring medical care and treatment fall below the poverty line. Most of them are either illiterate or semi literate. They cannot comprehend medical terms, concepts and treatment procedures. For them any treatment with reference to rough and ready diagnosis based on their outward symptoms and doctor's experience or institution is acceptable and welcome so long as it is free or cheap and whatever the doctor decides as being in their interest is usually unquestionably accepted. They are a passive, ignorant and uninvolved in treatment procedures. The stark reality is that for a vast majority in the country, the concept of informed consent or any form of consent and choice in treatment have no meaning or relevance. The position of doctors in government and charitable hospitals who treat them is also unenviable. They are overworked, understaffed with little or no diagnostics or surgical facilities and limited choice of medicines and treatment procedures. What choice of treatment can these doctors give to the poor patient? What informed consent can they take from them”.

Subsequently there has been a movement towards the application of the doctrine of informed consent. In Ramgopal Varshney v. Lasor India Sight Ltd, a doctor failed to divulge the risk associated with a cataract operation. He became blind after that operation. The National Commission held the failure to obtain informed consent amounted to deficiency in service. In this regard, it observed,

“The concept of informed consent has come to the fore in recent of years and many actions have been brought by patients who alleged that they did not understand the nature of the medical procedure to which they give consent. All information's must be explained in comprensible non-medical terms preferably in local language about the (i) diagnosis, (ii) nature of treatment, (iii) risks involved, (iv) prospects of success, (v) prognosis of the procedure if not performed and (vi) alternative methods of treatment. The three important components of such consent are information, voluntariness and capacity”.

It is evident from the above observation that the patients allege that they do not understand the information given by the doctors. The inability of the patients to understand the information is not a justification for any doctor to dispense with the disclosure requirement. The court in unequivocal language made it very obvious that the doctors should explain all the information contemplated above in a local language, i.e language understandable to the patient.

The Supreme Court had an occasion to delve upon the obligation of disclosure in Samira Kohli v. Dr. Prabha Manchanda. In this case an unmarried woman aged 44 years had complained prolonged menstrual bleeding for nine days. She was advised to undergo a ultra sound test. Subsequently she was subjected to laparoscopy. The consent form filled by the doctor showed consent for diagnostic and operative laparoscopy. Further it stated, laparoscopy if needed. One Dr. L. came out from operation theatre and took the consent of patient's mother for performing hysterectomy, when the patient was still under anaesthesia. Thereafter the respondent doctor performed an abdominal hysterectomy (removal of ovaries and fallopian tubes). The patient brought an action against the doctor for want of consent and informed consent for performance of the procedures, for which she had not given consent. The National Commission dismissed the complaint. On appeal the S.C. allowed the appeal in part and directed the respondent to pay a compensation of Rs. 25000. It was further observed that the patient should have been furnished a minimum level of information.

The Supreme Court in the above case laid down the following propositions:

(a) A doctor should disclose (i) nature and procedure of the treatment, its purpose, benefits and effect (ii) alternatives if any available (iii) an outline of substantial risks and (iv) adverse consequences of refusing treatment.
(b) There is no need to disclose remote or theoretical risks which might confuse a patient and result in refusal of consent for the necessary treatment or which might compel a patient to undergo a forceful or unwarranted treatment.
(c) The nature and extent of disclosure is governed by Bolam principle as laid down in Bolam v. Friern Hospital Management Committee. Accordingly the nature and extent of disclosure is governed by professional practice. In effect, a doctor invites liability for medical negligence for want of informed consent if a responsible and respectable body of medical opinion is in favour of disclosure of the information which ought to be disclosed as contemplated above. It follows that the prudent patient test as laid down in Canterbury did not find favour of the honourable Supreme Court. At the same time the honourable supreme court is not oblivions of the enormous commercialization of medical profession which might justifiably warrant the rejection of the Bolam principle in the sphere of informed consent in favour of a highly demanding requirement of informed consent. In this regard the court observed, "if medical practitioners and private hospitals become more and more commercialised and if there is a corresponding awareness of patient's right among the public, inevitable a day may come, when we have to move towards Canterbury, but not for the present".

CONCLUSION

The above discussion reveals that doctor invites liability for negligence for want of informed consent. In the USA, prudent patient test is applied to ascertain the negligence of a doctor which is more of demanding nature than the standard and extent of disclosure as contemplated in the Bolam principle which is the hub around in which the medical lawyer revolve England as well as India.

The Canterbury decision gave currency to the prudent patient test as the yardstick of the standard and the extent of disclosure to be made by a doctor regarding the information connected with administration of treatment and performance of medical procedure. In effect, the professional practice test as contemplated in the Bolam case has been rejected as laying down the standard and extent of disclosure. The Bolam principle in the realm of disclosure requirement has been rejected for the reasons discussed above. In addition to that it should be noted that it is doubtful whether in matters relating to disclosure requirement always the interest of the patients looms large in the eyes of the doctors. The doctors may devour the disclosure of information for the fear of losing a patient. But the circumstances under which doctors can withheld the disclosure are delineated by the courts, which fall into the following exceptions of therapeutic privilege of a doctor, emergency and waiver on the part of a patient. In effect, if follows that the doctrine of informed consent is not an absolute doctrine. It confers the doctors the required professional discretion.

The professional practice test may take into consideration only medical considerations while laying down the standard of disclosure. But it should be noted that certain non-medical considerations enter into the decision to undergo a medical procedure examined from the point of view of a patient. For eg. A patient may be suffering from heart ailment for which doctors may conclude the necessity of a by-pass surgery with an inherent risk of death. If the patient is the only bread earner of the family, the risk is divulged, he may refuse to undergo the treatment. He may think that it is a waste of expenditure and as such it aggravates and adds to the already existing misery. Therefore he may decide to support his family opting out from the medical procedure as for as possible. Moreover performance of certain medical procedure involves huge expenditure. Commercialization of medical profession has enhanced the dimension of financial constraints. In the light of above discussion it is submitted that in the sphere of disclosure as contemplated in Canterbury, the professional practice test must give way to the prudent patient test.

It is evident from the perusal of English decisions with respect to disclosure requirement that a wind of change is blowing moving away from the earlier stance of paternalistic attitude towards the medical profession. The English law in Afsar gave currency the Canterbury principle. It is land able that the Canterbury principle could further cut ice with English courts resulting in recognition of a full pledged doctrine of informed consent. However known for its earlier support for medical paternalism, the moot question how for the English law would continue with the changed attitude towards medical profession needs to be placed under wait and watch policy.

The discussion on informed consent from the Indian perspective manifests that the Indian law also has recognised the doctrine of informed consent in the realm of disclosure requirement, as medical law here has moved for from the take-off stage. The medical law in India relating to medical negligence stands on the

edifice of the principles laid down under the English law. Accordingly, as the legal position stands now the standard and extent of disclosure is governed under the Bolam principle. The time is not ripe for the application of Canterbury principle which warrants the application of a more demanding doctrine of informed consent. The ground reality is that in India, medical profession has been already commercialised. It is commendable that taking cognizance of this naked truth, the supreme court in Samira Kohli, adumbrated in its warning that if commercialization of medical profession continues unabated, Canterbury principle would certainly come to the fore replacing the Bolman principle in the realm of the application of the doctrine of informed consent. To conclude, as the position stands now the days are not for ahead for the realization of the above prophecy.

END NOTES

[1]Natanson v. Kline, 186 Kan 393, 350 p. 2d 1093 (1960), Canterbury v. Spence, 464 F. 2d 772 at 780 (D.C. cir. 1972)
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[3]Airedale NHS Trust v. Bland, (1993) AC 789 (hl) Scholendorff v. Society of New York Hospital (1914)
[4]Brain Brom Berger, Patient participation in Medical Decision – making: Are the courts, The Answer UNSWLJI (1983)
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[14] See supra n. 1
[15] Ibid
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[20]Id at p. 157
[21] 502 p. 2d I (1972)
[22](1957) 2 All ER 118
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[24] Hatcher v. Black, The Times, 2 July 1954
[25] (2004) UKHL41
[26]M. Stauch, 'Causation and Confusion in respect of Medical Non-Disclosure: Chester v. Afsar, 14 Nottingham L T. 66 (2005)
[27] Indian Medical Association V.V.P Shantha, 1995 (6) SCC 651
[28] Ibid
[29] See the definition of deficiency in service as contemplated in the Consumer Protection Act, 1986
[30] 2001 (8) SCC 731
[31] See supra n. 27 at p. 666
[32] (2009) (PJ 23 (NC) 2009 J.M.C. 83 (N.C)
[33] Id at p. 87-88
[34] (2008) 2 SCC 1
[35] See supra n. 22
[36] See supra n. 34 at p. 30
[37] See Canterbury v Spence, supra n. 1; Reibel v. Hughes, [1980] 114 DLR 1; Nishi v. Hartwell, 473 p. 2d 116 (1970)
[38] Crouch v. Most, 432 P. 2d 254, 1967
[39] See supra n. 37