Review Research Paper

Role of Informed Consent in India Past, Present and Future Trends

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Abstract

There is a need to keep the cost of treatment within affordable limits. Bringing in the American concepts and standards of treatment procedures and disclosure of risks, consequences and choices will inevitably bring in higher cost-structure of treatment. Patients in India cannot afford them. People in India still have great regard and respect for Doctors. The Members of medical profession have also, by and large, shown care and concern for the patients. There is an atmosphere of trust and implicit faith in the advice given by the Doctor. Apex Court observed that "What choice do these poor patients have? Any treatment of whatever degree is a boon or a favour, for them. The stark reality is that for a vast majority in the country, the concepts of informed consent or any form of consent, and choice in treatment, have no meaning or relevance."

This paper deals with the applicability of concept of **'informed consent'** in past, present and future scenario in India, based on the critical review of recent decisions of Hon'ble Supreme Court of India and National Consumer Dispute Redressal Commission, New Delhi.

Key Words: Consent, Real Consent, Informed Consent, Oral Consent, Deficiency of Service

Introduction:

An increasingly important risk area for all doctors is the question of consent. No-one may lay hands on another against their will without running the risk of criminal prosecution for assault and, if injury results, a civil action for damages for trespass or negligence. In the case of a doctor, consent to any physical interference will readily be implied; a woman must be assumed to consent to a normal physical examination if she consults a gynecologist, in the absence of clear evidence of her refusal or restriction of such examination.

The problems arise when the gynecologist's intervention results in unfortunate side effects or permanent interference with a function, whether or not any part of the body is removed.

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For example, if the gynaecologist agrees with the patient to perform a hysterectomy and removes the ovaries without her specific consent, that will be a trespass and an act of negligence.

The only available defense will be that it was necessary for the life of the patient to proceed at once to remove the ovaries because of some perceived pathology in them. [1, 7]

Indian Scenario:

In India, majority of citizens, requiring medical care and treatment fall below the poverty line. Most of them are illiterate or semi-literate. They cannot comprehend medical terms, concepts, and treatment procedures.

They cannot understand the functions of various organs or the effect of removal of such organs. They do not have access to effective but costly diagnostic procedures. Poor patients lying in the corridors of hospitals after admission for want of beds or patients waiting for days on the roadside for an admission or a mere examination is a common sight. [7]

For them, any treatment with reference to rough and ready diagnosis based on their outward symptoms and doctor's experience or intuition is acceptable and welcome so long as it is free or cheap; and whatever the doctor decides as being in their interest, is usually unquestioningly accepted. They are a passive, ignorant and uninvolved in treatment procedures. The poor and needy face a hostile

medical environment - inadequacy in the number of hospitals and beds, non-availability of adequate treatment facilities, utter lack of qualitative treatment, corruption, callousness and apathy. Many poor patients with serious ailments (e.g. heart patients and cancer patients) have to wait for months for their turn even for diagnosis, and due to limited treatment facilities, many die even before their turn comes for treatment. [7]

Is Concepts of Informed Consent having No Meaning or Relevance in present scenario?

What choice do these poor patients have? Any treatment of whatever degree is a boon or a favour, for them. The stark reality is that for a vast majority in the country, the concepts of informed consent or any form of consent, and choice in treatment, have no meaning or relevance. [7]

Position of Doctors in Government and Charitable hospitals:

The position of doctors in Government and charitable hospitals, which treat them, is also unenviable. They are overworked, understaffed, with little or no diagnostic or surgical facilities and limited choice of medicines and treatment procedures. They have to improvise with virtual non-existent facilities and limited dubious medicines.

They are required to be committed, service oriented and non-commercial in outlook. What choice of treatment can these doctors give to the poor patients? What informed consent they can take from them? [7]

Indian Middle Class Public Psyche about Medical Private Commercial Sector:

The private hospitals and doctors prescribe avoidable costly diagnostic procedures and medicines, and subject them to unwanted surgical procedures, for financial gain.

The public feel that many doctors who have spent a crore or more for becoming a specialist, or nursing homes which have invested several crores on diagnostic and infrastructure facilities, would necessarily operate with a purely commercial and not service motive; that such doctors and hospitals would advise extensive costly treatment procedures and surgeries, where conservative or simple treatment may meet the need; and that what used to be a noble service oriented profession is slowly but steadily converting into a purely business. [7]

But unfortunately not all doctors in government hospitals are paragons of service, nor fortunately, all private hospitals / doctors are commercial minded. There are many doctors in government hospitals that do not care about patients and unscrupulously insist upon 'unofficial' payment for free treatment or insist upon private consultations. [7]

On the other hand, many private hospitals and Doctors give the best of treatment without exploitation, at a reasonable cost, charging a fee, which is reasonable recompense for the service rendered. [7]

Who is Responsible for Bad Reputation of Noble Profession?

Some doctors, both in private practice or in government service, look at patients not as persons who should be relieved from pain and suffering by prompt and proper treatment at an affordable cost, but as potential income-providers / customers who can be exploited by prolonged or radical diagnostic and treatment procedures. It is this minority who bring a bad name to the entire profession. [7]

Era of Specialists and Super Specialists:

The proliferation of specialists and super specialists, have exhausted many a patient both financially and physically, by having to move from doctor to doctor, in search of the appropriate specialist who can identify the problem and provide treatment. What used to be competent treatment by one General Practitioner has now become multi-pronged treatment by several specialists.

Factors for Higher Cost of Treatment: Defensive Practice:

Law stepping in to provide remedy for negligence or deficiency in service by medical practitioners, has its own twin adverse effects.

Firstly more and more private doctors and hospitals have, of necessity, started playing it safe, by subjecting or requiring the patients to undergo various costly diagnostic procedures and tests to avoid any allegations of negligence, even though they might have already identified the ailment with reference to the symptoms and medical history with 90% certainly, by their knowledge and experience. [7]

Secondly more and more doctors particularly surgeons in private practice are forced to cover themselves by taking out insurance, the cost of which is also ultimately passed on to the patient, by way of a higher fee. [7] As a consequence, it is now common that a comparatively simple ailment, which earlier used

to be treated at the cost of a few rupees by consulting a single doctor, requires an expense of several hundred or thousands on account of four factors:

i. Commercialization of medical treatment;
ii. Increase in specialists as contrasted from general practitioners and the need for consulting more than one doctor;
iii. Varied diagnostic and treatment procedures at high cost; and
iv. Need for doctors to have insurance cover.

Answer to Prohibitive Cost of treatment:

The obvious, may be novae, answer to unwarranted diagnostic procedures and treatment and prohibitive cost of treatment, is an increase in the participation of health care by the state and charitable institutions. [7]

Doctors themselves could make a Difference:

An enlightened and committed medical profession can also provide a better alternative. Be that as it may. We are not trying to intrude on matters of policy, nor are we against proper diagnosis or specialization. We are only worried about the enormous hardship and expense to which the common man is subjected, and are merely voicing the concern of those who are not able to fend for themselves. We will be too happy if what we have observed is an overstatement, but our intuition tells us that it is an under statement. [7]

What is meant by Consent?

The term **'informed consent'** is often used, but there is **no such concept in English law**. The consent must be real: that is to say, the patient must have been given sufficient information for her to understand the nature of the operation, its likely effects, and any complications which may arise and which the surgeon in the exercise of his duty to the patient considers she should be made aware of; only then can she reach a proper decision.

But the surgeon need not warn the patient of remote risks, any more than an anaesthetist need warn the patient that a certain small number of those anaesthetized will suffer cardiac arrest or never recover consciousness. Only where there is a recognized risk, rather than a rare complication, is the surgeon under an obligation to warn the patient of that risk.

He is not under a duty to warn the patient of the possible results of hypothetical negligent surgery.

In advising an operation, therefore, the doctor must do so in the way in which a competent gynaecologist exercising reasonable skill and care in similar circumstances would have done. In doing this he will take into account the personality of the patient and the importance of the operation to her future well being. It may be good practice not to warn a very nervous patient of any possible complications if she requires immediate surgery for, say, a malignant condition.

The doctor must decide how much to say to her taking into account his assessment of her personality, the questions she asks and his view of how much she understands.

If the patient asks a direct question, she must be given a truthful answer. To take the example of hysterectomy: although the surgeon will tell the patient that it is proposed to remove her uterus and perhaps her ovaries, and describe what that will mean for her future well being (sterility, premature menopause), she will not be warned of the possibility of damage to the ureter, vesicovaginal fistula, fatal haemorrhage or anaesthetic death." [1, 7]

Consent in the Context of a Doctor-Patient Relationship:

Consent in the context of a doctor-patient relationship, means: the grant of permission by the patient for an act to be carried out by the doctor, such as a diagnostic, surgical or therapeutic procedure.

Consent can be **implied** in some circumstances from the action of the patient. For example, when a patient enters a Dentist's clinic and sits in the Dental chair, his consent is implied for examination, diagnosis and consultation. Except where consent can be clearly and obviously implied, there should be **express consent**.

Global Scenario:

There is, however, a significant difference in the nature of **express consent** of the patient, known as **'real consent'** in **UK** and as **'informed consent'** in **America**.

Concept of ‘valid’ and 'real' consent in UK:

In UK, the elements of consent are defined with reference to the patient and consent is considered to be valid and 'real' when:

i. The patient gives it voluntarily without any coercion;
ii. The patient has the capacity and competence to give consent; and
iii. The patient has the minimum of adequate level of information about the nature of the procedure to which he is consenting to.

Concept of 'informed consent' developed by American Courts:

On the other hand, the concept of 'informed consent' developed by American courts, while retaining the basic requirements consent, shifts the emphasis to the doctor's duty to disclose the necessary information to the patient to secure his consent.

'Informed consent' is defined in Taber's Cyclopedic Medical Dictionary thus:

"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."

Doctor's Duty to Inform:

The United States Courts of Appeals, District of Columbia Circuit, emphasized the element of Doctor's duty in 'informed consent' thus:

"It is well established that the physician must seek and secure his patient's consent before commencing an operation or other course of treatment. It is also clear that the consent, to be efficacious, must be free from imposition upon the patient.

It is the settled rule that therapy not authorized by the patient may amount to a tort - a common law battery - by the physician.

And it is evident that it is normally impossible to obtain consent worthy of the name unless the physician first elucidates the options and the perils for the patient's edification. Thus the physician has long borne a duty, on pain of liability for unauthorized treatment, to make adequate disclosure to the patient." [**Emphasis supplied**] [1]

The Basic Principle in Regard to Patient's Consent in USA:

The basic principle in regard to patient's consent may be traced to the following classic statement by **Justice Cardozo** in a case, [2]:

“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”.

Fundamental Principle on Consent in English Law:

This principle has been accepted by **English Court** also. In a case, [3] the **House of Lords** while dealing with a case of sterilization of a mental patient reiterated **the fundamental principle** that every person's body is inviolate and performance of a medical operation on a person without his or her consent is unlawful.

The **English law** on this aspect is **summarized** thus:

"Any intentional touching of a person is unlawful and amounts to the tort of battery unless it is justified by consent or other lawful authority. In medical law, this means that a doctor may only carry out a medical treatment or procedure which involves contact with a patient if there exists a valid consent by the patient (or another person authorized by law to consent on his behalf) or if the touching is permitted notwithstanding the absence of consent." [4]

The next question is whether in an action for negligence / battery for performance of an unauthorized surgical procedure, the Doctor can put forth as defense the consent given for a particular operative procedure, as consent for any additional or further operative procedures performed in the interests of the patient.

The Supreme Court of BC, Canada, [6] was considering a claim for battery by a patient who underwent a caesarian section. During the course of caesarian section, the doctor found fibroid tumors in the patient's uterus. Being of the view that such tumors would be a danger in case of future pregnancy, he performed a sterilization operation. The court upheld the claim for damages for battery.

It held that sterilization could not be justified under the principle of necessity, as there was no immediate threat or danger to the patient's health or life and it would not have been unreasonable to postpone the operation to secure the patient's consent. The fact that the doctor found it convenient to perform the sterilization operation without consent as the patient was already under general anaesthetic, was held to be not a valid defense.

A somewhat similar view was expressed by Courts of Appeal in England in a case [3] it was held that the additional or further treatment which can be given (outside the consented procedure) should be confined to only such treatment as is necessary to meet the emergency, and as such needs to be carried out at once and before the patient is likely to be in a position to make a decision for himself. [Para 16]

Lord Goff observed:

"Where, for example, a surgeon performs an operation without his consent on a patient temporarily rendered unconscious in an accident, he should do no more than is reasonably required, in the best interests of the patient, before he recovers consciousness. I can see no practical difficulty arising from this requirement, which derives from the fact that the patient is expected before long to regain consciousness and can then be consulted about longer term measures."

Exception to the Rule:

The decision in a case, [6] decided by the Supreme Court of NS, Canada, illustrates the exception to the rule, that an unauthorized procedure may be justified if the patient's medical condition brooks no delay and warrants immediate action without waiting for the patient to regain consciousness and take a decision for himself. [Para 16]

In that case the doctor discovered a grossly diseased testicle while performing a hernia operation. As the doctor considered it to be gangrenous, posing a threat to patient's life and health, the doctor removed it without consent, as a part of the hernia operation. An action for battery was brought on the ground that the consent was for a hernia operation and removal of testicle was not consent. The claim was consent of the patient where it is necessary to save the life or preserve the health of the patient. [6]

The Principle of Necessity:

Thus, the principle of necessity by which the doctor is permitted to perform further or additional procedure (unauthorized) is restricted to cases where the patient is temporarily incompetent (being unconscious), to permit the procedure delaying of which would be unreasonable because of the imminent danger to the life or health of the patient.

Practical or Convenient Reasons, Not Relevant:

It is quite possible that if the patient been conscious, and informed about the need for the additional procedure, the patient might have agreed to it. It may be that the additional procedure is beneficial and in the interests of the patient. It may be that postponement of the additional procedure (say removal of an organ) may require another surgery, whereas removal of the affected organ during the initial diagnostic or exploratory surgery would save the patient from the pain and cost of a second operation. Howsoever, practical or convenient the reasons may be, they are not relevant.

What is Relevant?

What is relevant and of importance is the inviolable nature of the patient's right in regard to his body and his right to decide whether he should undergo the particular treatment or surgery or not.

Therefore at the risk of repetition, we may add that unless the unauthorized additional or further procedure is necessary in order to save the life or preserve the health of the patient and it would be unreasonable (as contrasted from being merely inconvenient) to delay the further procedure until the patient regains consciousness and takes a decision, a doctor cannot perform such procedure without the consent of the patient. [7]

Code of Medical Ethics, Professional Misconduct and Consent:

We may also refer to the Code of Medical Ethics laid down by the Medical Council of India (approved by the Central Government under section 33 of Indian Medical Council Act, 1956). It contains a chapter relating to disciplinary action which enumerates a list of responsibilities, violation of which will be professional misconduct. Clause 13 of the said chapter places 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. [8]

Guidelines of GMC of U.K.:

"S.C also refers to the following guidelines to doctors, issued by the General Medical Council of U.K. in seeking consent of the patient for investigation and treatment: "Patients have a right to information about their condition and the treatment options available to them. The amount of information you give each patient will vary, according to factors such as the nature of the condition, the complexity of the treatment, the risks associated with the treatment or procedure, and the patient's own wishes.

For example, patients may need more information to make an informed decision about the procedure which carries a high risk of failure or adverse side effects; or about an investigation for a condition which, if present, could have serious implications for the patient's employment, social or personal life. x x x x x

You should raise with patients the possibility of additional problems coming to light

during a procedure when the patient is unconscious or otherwise unable to make a decision. You should seek consent to treat any problems which you think may arise and ascertain whether there are any procedures to which the patient would object, or prefer to give further thought before you proceed."

The Consent form for Hospital admission and medical treatment presumed to constitute the contract between the parties.

The Consent form for Hospital admission and medical treatment, to which appellant's signature was obtained by the respondent on 10.5.1995, which can safely be presumed to constitute the contract between the parties, specifically states:

"(A) It is customary, except in emergency or extraordinary circumstances, that no substantial procedures are performed upon a patient unless and until he or she has had an opportunity to discuss them with the physician or other health professional to the patient's satisfaction.

(B) Each patient has right to consent, or to refuse consent, to any proposed procedure of therapeutic course."

Nature of Information that is required to be furnished by a Doctor:

The Apex Court next considers the nature of information that is required to be furnished by a Doctor to secure a valid or real consent. In a case, [9] **Scott L.J.** observed: "A man cannot be said to be truly **'willing'** unless he is in a position to choose freely, and freedom of choice predicates, not only full knowledge of the circumstances on which the exercise of choice is conditioned, so that he may be able to choose wisely, but the absence from his mind of any feeling of constraint so that nothing shall interfere with the freedom of his will." [7

Duty and Liability of Doctor for Providing Information:

In another case, [10] 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. [7]

Rationale of a Doctor's Duty to Reasonably Inform a Patient:

Canterbury [1] explored the rationale of a Doctor's duty to reasonably inform a patient as to the treatment alternatives available and the risk incidental to them, as also the scope of the disclosure requirement and the physician's privileges not to disclose. It laid down the 'reasonably prudent patient test' which required the doctor to disclose all material risks to a patient, to show an 'informed consent'.

It was held: "True consent to what happens to one's self is the informed exercise of a choice, and that entails an opportunity to evaluate knowledgeably the options available and the risks attendant upon each. The average patient has little or no understanding of the medical arts, and ordinarily has only his physician to whom he can look for enlightenment with which to reach an intelligent decision.

From these almost axiomatic considerations springs the need, and in turn the requirement, of a reasonable divulgence by physician to patient to make such a decision possible. Just as plainly, due care normally demands that the physician warn the patient of any risks to his well being which contemplated therapy may involve. The context in which the duty of risk-disclosure arises is invariably the occasion for decision as to whether a particular treatment procedure is to be undertaken.

To the physician, whose training enables a self-satisfying evaluation, the answer may seem clear, but it is the prerogative of the patient, not the physician, to determine for himself the direction in which his interests seem to lie. To enable the patient to chart his course understandably, some familiarity with the therapeutic alternatives and their hazards becomes essential a reasonable revelation in these respects is not only a necessity but, as we see it, is as much a matter of the physician's duty. It is a duty to warn of the dangers lurking in the proposed treatment, and that is surely a facet of due care.

It is, too, a duty to impart information which the patient has every right to expect. The patient's reliance upon the physician is a trust of the kind which traditionally has exacted obligations beyond those associated with arms length transactions.

His dependence upon the physician for information affecting his well-being, in terms of contemplated treatment, is well-nigh abject. We ourselves have found “in the fiducial qualities of (the physician-patient) relationship the physician's duty to reveal to the patient that which in his best interests it is important that he should know”. We now find, as a part of the physician's overall obligation to the patient, a similar duty of reasonable disclosure of the choices with respect to proposed therapy and the dangers inherently and potentially involve.

In our view, the patient's right of self-decision shapes the boundaries of the duty to reveal. That right can be effectively exercised

only if the patient possesses enough information to enable an intelligent choice.

The scope of the physician's communications to the patient, then, must be measured by the patient's need, and that need is the information material to the decision. Thus the test for determining whether a particular peril must be divulged is its materially to the patient's decision: all risks potentially affecting the decision must be unmasked.

"It was further held that a risk is material 'when a reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to forego the proposed therapy'. The doctor, therefore, is required to communicate all inherent and potential hazards of the proposed treatment, the alternatives to that treatment, if any, and the likely effect if the patient remained untreated. [1, 7]

This stringent standard of disclosure was subjected to only two exceptions:

(i) Where there was a genuine emergency, e.g. the patient was unconscious; and
(ii) Where the information would be harmful to the patient, e.g. where it might cause psychological damage, or where the patient would become so emotionally distraught as to prevent a rational decision.

It, however, appears that several States in USA have chosen to avoid the decision in Canterbury [1] by enacting legislation which severely curtails operation of the doctrine of informed consent. [1, 7]

Stringent Standards Not Accepted in the English Courts:

The stringent standards regarding disclosure laid down in Canterbury [1], as necessary to secure an informed consent of the patient, was not accepted in the English courts. In England, standard applicable is popularly known as the **Bolam Test**. [11]

McNair J., in a trial relating to negligence of a medical practitioner, while instructing the **Jury**, stated thus:

"(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. At the same time, that does not mean that a medical man can obstinately and pig-headedly carry on with some old technique if it has been proved to be contrary to what is really substantially the whole of informed medical opinion. [7, 11]

(ii) When a doctor dealing with a sick man strongly believed that the only hope of cure was submission to a particular therapy, he could not be criticized if, believing the danger involved in the treatment to be minimal, did not stress them to the patient. [7, 11]

(iii) In order to recover damages 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. [7, 11]

A **Scottish case [12]** is also worth noticing. In that decision, **Lord President Clyde** held: "In the realm of diagnosis and treatment there is ample scope for genuine difference of opinion and one man clearly is not negligent merely because his conclusion differs from that of other professional men, nor because he has displayed less skill or knowledge than others would have shown.

The true test for establishing negligence in diagnosis or treatment on the part of a doctor is whether he has been proved to be guilty of such failure as no doctor of ordinary skill would be guilty of if acting with ordinary care". [12. 1]

What is the Need of a patient?

He also laid down the following requirements to be established by a patient to fasten liability on the ground of want of care or negligence on the part of the doctor:

"To establish liability by a doctor where deviation from normal practice is alleged, three facts require to be established.

First of all it must be proved that there is a usual and normal practice;

Secondly it must be proved that the defender has not adopted that practice; and

Thirdly (and this is **of crucial importance**) it must be established that the course the doctor adopted is one which no professional man of ordinary skill would have taken if he had been acting with ordinary care". [12, 1]

In a case, the House of Lords, per majority, adopted the Bolam test, as the measure of doctor's duty to disclose information about the potential consequences and risks of proposed medical treatment.

In that case [13] the defendant, a surgeon, warned the plaintiff of the possibility of disturbing a nerve root while advising an operation on the spinal column to relieve shoulder and neck pain. He did not, however, mention the possibility of damage to the spinal cord. Though the operation was performed

without negligence, the plaintiff sustained damage to spinal cord resulting in partial paralysis. The plaintiff alleged that defendant was negligent in failing to inform her about the said risk and that had she known the true position, she would not have accepted the treatment.

The Trial Judge and Court of Appeal applied the **Bolam test** and concluded that the defendant had acted in accordance with a practice accepted as proper by a responsible body of medical opinion, in not informing the plaintiff of the risk of damage to spinal cord.

Consequently, the claim for damages was rejected. The House of Lords upheld the decision of the Court of Appeal that the doctrine of informed consent based on full disclosure of all the facts to the patient, was not the appropriate test of liability for negligence, under English law. The majority were of the view that the test of liability in respect of a doctor's duty to warn his patient of risks inherent in treatment recommended by him was the same as the test applicable to diagnosis and treatment, namely, that the doctor was required to act in accordance with the practice accepted at the time as proper by a responsible body of medical opinion.

Lord Diplock stated: "In English jurisprudence the doctor's relationship with his patient which gives rise to the normal duty of care to exercise his skill and judgment to improve the patient's health in any particular respect in which the patient has sought his aid has hitherto been treated as a single comprehensive duty covering all the ways in which a doctor is called on to exercise his skill and judgment in the improvement of the physical or mental condition of the patient for which his services either as a general practitioner or as a specialist have been engaged.

This general duty is not subject to dissection into a number of component parts to which different criteria of what satisfy the duty of care apply, such as diagnosis, treatment and advice (including warning of any risks of something going wrong however skillfully the treatment advised is carried out).

The Bolam case itself embraced failure to advise the patient of the risk involved in the electric shock treatment as one of the allegations of negligence against the surgeon as well as negligence in the actual carrying out of treatment in which that risk did result in injury to the patient. The same criteria were applied to both these aspects of the surgeon's duty of care.

In modern medicine and surgery such dissection of the various things a doctor has to do in the exercise of his whole duty of care owed to his patient is neither legally meaningful nor medically practicable.

To decide what risks the existence of which a patient should be voluntarily warned and the terms in which such warning, if any, should be given, having regard to the effect that the warning may have, is as much an exercise of professional skill and judgment as any other part of the doctor's comprehensive duty of care to the individual patient, and expert medical evidence on this matter should be treated in just the same way. The **Bolam test** should be applied". [13, 7]

Lord Bridge stated:

"I recognize the logical force of the Canterbury doctrine, proceeding from the premise that the patient's right to make his own decision must at all costs be safeguarded against the kind of medical paternalism which assumes that 'doctor knows best'. But, with all respect, I regard the doctrine as quite impractical in application for three principal reasons.

First, it gives insufficient weight to the realities of the doctor / patient relationship. A very wide variety of factors must enter into a doctor's clinical judgment not only as to what treatment is appropriate for a particular patient, but also as to how best to communicate to the patient the significant factors necessary to enable the patient to make an informed decision whether to undergo the treatment.

The doctor cannot set out to educate the patient to his own standard of medical knowledge of all the relevant factors involved. He may take the view, certainly with some patients that the very fact of his volunteering, without being asked, information of some remote risk involved in the treatment proposed, even though he described it as remote, may lead to that risk assuming an **undue significance in the patient's calculations**. [13, 7]

Second, it would seem to me quite unrealistic in any medical negligence action to confine the expert medical evidence to an explanation of the primary medical factors involved and to deny the court the benefit of evidence of medical opinion and practice on the particular issue of disclosure which is under consideration. [13, 7]

Third, the objective test which Canterbury propounds seems to me to be so imprecise as to be almost meaningless. If it is to be left to individual judges to decide for themselves what: "a reasonable person in the patient's position' would consider a risk of sufficient significance that he should be told about it, the outcome of litigation in this field is likely to be quite unpredictable". . [13, 7]

The doctor's duty is to answer truthfully and as fully as the questioner requires:

Lord Bridge however **made it clear** that when questioned specifically by the patient about the risks involved in a particular treatment proposed, the doctor's duty is to answer truthfully and as fully as the questioner requires.

He further held that remote risk of damage (referred to as risk at 1 or 2%) need not be disclosed but if the risk of damage is substantial (referred to as 10% risk), it may have to be disclosed. Lord Scarman, in minority, was inclined to adopt the more stringent test laid down in Canterbury. [13, 7]

Applicability and Acceptance of 'Bolam Test' in India:

In **India, Bolam test** has broadly been accepted as the general rule. We may refer three cases of this Court. In one case, [14] Apex Court held:

"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. Courts would indeed be slow in attributing negligence on the part of a doctor if he has performed his duties to the best of his ability and with due care and caution.

Medical opinion may differ with regard to the course of action to be taken by a doctor treating a patient, but as long as a doctor acts in a manner which is acceptable to the medical profession and the Court finds that he has 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 another case, [15] this Court after referring to Bolam, [11] Sidaway, [13] and Achutrao, [14] clarified:

"A doctor will be liable for negligence in respect of diagnosis and treatment in spite of a body of professional opinion approving his conduct where it has not been established to the court's satisfaction that such opinion relied on is reasonable or responsible.

If it can be demonstrated that the professional opinion is not capable of withstanding the logical analysis, the court would be entitled to hold that the body of opinion is not reasonable or responsible.

In another case, [16], this Court held:

"The approach of the courts is to require that professional men should possess a certain minimum degree of competence and that they should exercise reasonable care in the discharge of their duties. In general, a professional man owes to his client a duty in tort as well as in contract to exercise reasonable care in giving advice or performing services".

Neither Achutrao [14] nor Vinitha Ashok [15] referred to the American view expressed in Canterbury. [7]

Apex Courts' Concern:

We are concerned with doctors in private practice and hospitals and nursing homes run commercially, where the relationship of doctors and patients are contractual in origin, the service is in consideration of a fee paid by the patient, where the contract implies that the professional men possessing a minimum degree of competence would exercise reasonable care in the discharge of their duties while giving advice or treatment. [7]

'Bolam Test' Versus the 'Reasonably Prudential Patient' Test:

Having regard to the conditions obtaining in India, as also the settled and recognized practices of medical fraternity in India, we are of the view that to nurture the doctor-patient relationship on the basis of trust, the extent and nature of information required to be given by doctors should continue to be governed by the Bolam test rather than the 'reasonably prudential patient' test evolved in Canterbury. [7]

Doctors' discretion is important:

It is for the doctor to decide, with reference to the condition of the patient, nature of illness, and the prevailing established practices, how much information regarding risks and consequences should be given to the patients, and how they should be couched, having the best interests of the patient. [7]

Summary and Conclusions:

Global scenario and Trends are shifting from 'real consent' concept evolved in Bolam and Sidaway to the 'reasonably prudent patient test' in Canterbury.

We may note here that courts in Canada and Australia have moved towards Canterbury standard of disclosure and informed consent - vide Reibl v. Hughes (1980) [17] decided by the Canadian Supreme Court and Rogers v. Whittaker - 1992 [18] decided by the High Court of Australia.

Even in England there is a tendency to make the doctor's duty to inform more stringent than Bolam's test adopted in Sidaway. [13]

Lord Scarman's minority view in Sidaway [13] favouring Canterbury, in course of time, may ultimately become the law in England. A beginning has been made in Bolitho v. City and Hackney HA – 1998 [19] and Pearce v. United Bristol Healthcare NHS Trust 1998 [20].

We have however, consciously preferred the 'real consent' concept evolved in Bolam [11] and Sidaway [13] in preference to the 'reasonably prudent patient test' in Canterbury, having regard to the ground realities in medical and health-care in India.

Need of the Hour:

Remarkable developments in the field of medicine might have revolutionized health care. But they cannot be afforded by the common man. The woes of non-affording patients have in no way decreased. Gone are the days when any patient could go to a neighbourhood general practitioner or a family doctor and get affordable treatment at a very reasonable cost, with affection, care and concern. Their noble tribe is dwindling. [7]

Health care (like education) can thrive in the hands of charitable institutions. It also requires more serious attention from the State.

In a developing country like India where teeming millions of poor, downtrodden and illiterate cry out for health-care, there is a desperate need for making health-care easily accessible and affordable. [7]

Many papers published on the issue of consent have given insight into the problem of consent, age of consent [23] and informed consent [24, 25] in Indian context.

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