Informed consent - legal and ethical aspects

A review of the case law

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Patient autonomy is an accepted principle in medical ethics, In actual practice, this important principle is usually either ignored or only partially accepted, particularly in the Indian context. Informed consent is probably the most important concept flowing from the doctrine of autonomy. In the Indian context, informed consent was practically nonexistent till the Consumer Protection Act was made applicable to the medical profession. Now, both doctors and patients are becoming more aware about this concept, and patients are better informed of their rights.

This increasing patient awareness seems to have created confusion and panic in the medical profession, and has also made the medical profession more defensive. Informed consent is seen more as a legal requirement than an ethical obligation. A review of the various legal issues and the case law may remove the confusion.

An adult patient has complete autonomy over his body when he can consent to any form of' medical treatment without fear of being vetoed by someone else. Any procedure done without consent would amount to battery and assault. However, complete patient autonomy gets restricted in certain circumstances. For example, despite accepting the notion. of complete patient autonomy, courts all over the world are reluctant to legally accept active euthanasia.

Valid consent is necessary before any medical treatment. Such consent can bc implied, as in the case of a general physician's treatment involving physical examination and administering injections. The consent practiced in Indian hospitals particularly in public hospitals — in which patients being admitted are asked to sign a form stating that they are willing for any form of treatment, is a blanket consent of questionable legal validity. To give informed consent to treatment of any nature, the patient must have the required information.

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True and informed consent

Courts in India and other Commonwealth countries have long differentiated between true and informed consent.The concept of true consent was enunciated by British courts in Sidway v Board of Governers of the Royal Bethleham Hospital.(1985)2 WLR 840. A patient operated upon for back pain suffered paralysis due to spinal cord injury and sued the hospital and surgeon for not informing her of the risk before surgery. The court held that the risk was agreed to be less than one per cent and since there was a responsible body of medical opinion who would have informed the patient in similar terms as those used by the surgeon, the latter was not negligent.

In Blythe v Bloomsbury Health Authority (1993) 4 Med L.Rev. 15 1, the patient complained that the doctor had not disclosed all the risks of Depo Provera.The court held that the doctor is not obliged to explain all possible risks of a treatment in responding to a general inquiry from the patient. As in Sidway, the courts held that the general test of medical negligence — as explained in Hunter v Hanley by Lord President Clyde and later in Bolam v Friern Hospital by Macnair J (1957) — would apply to the legal question about consent.

The Indian courts have' followed the same principle over the years. This is evident from L.B.Joshi v T.R.Godbole SC AIR p 183-187 and Ram Bhiharital v Dr.Srivatsava AIR 1985 MP pp 157- 158. However. American and Canadian courts have taken a more liberal 'patient oriented' view compared to the 'doctor oriented' approach of British and Indian courts. In Canterbury v Spence (1972) 464 F(sd)772 the court gave more importance to the 'reasonable' patient than to the 'reasonable ' doctor. In this case the patient had suffered temporary paralysis following surgery for back pain.The court held that all possible risks should be explained to the patient.

In fact in Hatcher v Black, Lord Denning cautioned British courts against the dangers of following the American concept of informed consent. In this case a singer was operated for a thyroid nodule and suffered a temporary change in voice. She sued the doctor for nondisclosure of all the facts. In Arato v Aveon (1994) 6 Med L Rev 230, the Supreme Court of California held that the concept of informed consent required disclosure of all material facts.

Today, courts in some commonwealth countries have started accepting the American concept of informed consent.In Roger v Whitaker (1992),an Australian court held the doctor guilty for not disclosing the risk of symphathetic opthalmitis in the normal eye after surgery on a diseased eye.

Can a doctor conduct a procedure or operate in the absence of consent in the best interests of the patient'? Again on this point there is diversity of opinion between American and Canadian courts on the one hand and British and Indian courts on the other. In the Canadian case of Malette v Shulman (1 99 1) 2 Med L.Rev 162., a road accident victim required a blood transfusion. The doctors were

informed that her belongings contained a Jehovah 's Witness card requesting that no blood products be used in her treatment. However, in view of the patient's deteriorating condition, the doctor went ahead with the blood transfusion.The Ontario Court of Appeal held that the doctor was guilty of trespass. In Thor v Supreme Court (1994) Med L Rev 220 the Supreme Court of California held that a prisoner who was quadriplegic but mentally competent cannot be kept by force on a life support system.

lack of consent not always a constraint

On the other hand, in India, Dr Thomas v Smt. Elisa, AIR 1987, the court held that the doctor was guilty of' negligence for not operating on a patient with life-threatening peritoni tis following a perforated appendix only because the patient was not in a conditon to give consent and the relatives were not available. The court held that it is the doctor's ethical and legal duty to treat the patient to best of his ability; lack of valid consent is not a constraint in life-threatening situations.This view was reiterated by the Indian Supreme Court in Paramanand Katara v Union of India.

British courts have adopted a flexible approach to the question of patient's unfettered autonomy. For example in Re F(1989) 2 WLR 1025, a 36-year-old female patient in a institute for the mentally handicapped formed a sexual relationship with a male inmate.The court allowed the institute to do a tubectomy with the view that the patient was incapable of managing 0ther forms of contraception or of handling the consequences 01' pregnancy and childbirth. In many cases the courts have allowed the hospital and doctors to stop life-support systems in patients of Permanent Vegetative Status (PVS).

It is obvious from the cases quoted here that the case law on informed consent remains inconclusive, with a wide diversity of opinion amongst various courts. This is more so in the Indian context, as we have various disciplines of medicine. Many disciplines like Ayurveda have very few standardised therapeutic systems. Therefore, informed consent even with good intentions becomes a practically difficult proposition.

As a result of the confusion and panic on informed consent doctors are scurrying to prepare various 'legally foolproof' consent forms. A signed consent form of any nature neither guarantees a doctor protection against legal action nor ensures patient satisfaction. It merely demonstrates that some process to exchange information was followed. Wrangling about consent forms does little to advance the debate about the ethical aspect of informed consent. The medical professiona's paranoia about medico-legal cases has given birth to ethically questionable notions such as the Informed Request: a patient has to request the doctor for the treatment or surgery — and this is supposed to remove the necessity of informed consent!

Fully informed consent is probably never attainable. A sick person by the very nature of his or her illness has lost some measure of autonomy. The immense complexi ties of modern medical technology and drugs and their many possible side effects can never be explained to the nonmedical person: many are not even known to the medical profession. Intraoperative and postoperative pain is difficult to predict, as there are various determinants like the patient's pain threshold, state of' his illness, age, cultural background and psychological status. There are no precise words to communicate the extent and 'quantum of pain. Pain remains beyond communication.

Communication forms the soul of the concept on informed consent. However, communication is something which is not taught to medical students. A study in Australia found that 66 per cent of complaints of medical negligence arise following poor or improper communication. The majority of complaints received by consumer associations in India are following such a communication breakdown between doctor and patient. Modern medical science and prognosis of various diseases are based on probabilities. A patient of' diabetic foot gangrene can be told that he has a 20 per cent chance of l imb salvage following revascularisation. What the patient really wants to know is whether he is likely to be in that lucky 20 per cent. Modern science cannot guarantee this and this usually forms the nucleus for a breakdown in communication.The patient's expectation is natural. Therefore, improving medical graduates' communication skills should form the basis of better informed consent.A 'biohumane' rather than a 'biopositivist' medical profession is the need of the hour. Communication is an art as well as a science.

The concept can be abused

It is also necessary for patients and consumer groups to realise that every illness or disease has a 'price'. No treatment is without side effects.The benefit-risk ratio of every treatment is important. A patient with a fractured neck femur, in spite of excellent treatment with ultra modern implants, is likely have some restriction of hip joint movements. This cannot and should not form the basis for non-disclosure of risk and lack of informed consent. Abuse of the concept of informed consent is detrimental to the long-term interest of the country's healthcare system. Therefore patient education should form part of strategies followed by consumer groups.

The debate about informed consent needs to move away from the legal aspect to the domain of ethics where it really belongs. Unless ethical standards in the profession are enforced, medicolegal aspects of informed consent will continue to haunt doctors.