INFORMED CONSENT : ETHICAL AND LEGAL CONSIDERATION

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ABSTRACT

In health care, there are a number of pertinent issues, which have no "right or wrong" answers. These are in the "grey areas" of a medical ethic where religious belief and cultural background play a prominent role in deciding which is the best answer which might not be accepted as unchallengeable right. Growing public awareness with regard to advances in medical science has increased the need for patients to be given more information before they submit to any medical treatment. Informed consent, thus, has been of current interest to the community as patients claim greater participation in medical decision-making. In allowing this to occur, the law has much difficulty in balancing the rights of the patient on one hand, and the rights of the doctor, on the other. We believe that much of the negative reaction to informed consent stems from some fundamental misunderstandings about what informed consent requires. How much must the patient be told of the risks involved in a recommended operation or course of treatment? By what standard is the medical practitioner's duty of disclosure judged and what are the legal consequences attendants upon failure to obtain informed consent? This article endeavors to provide some answers to these questions in the light of the approach taken by the courts in various countries.

WHAT IS "INFORMED CONSENT"?

The doctrine of informed consent embodies the general principle that a person has a right to determine whether or not to undergo any medical procedure. A doctor should give the patient sufficient information for him to understand the nature of any proposed treatment, its implications and risks and the consequences of not taking the treatment. If a doctor touches any part of the patient's body with or without instruments during treatment, without authority, he may be prosecuted criminally or sued for damages in civil action. The rationale behind the development of the doctrine of informed consent is to encourage rational decision-making by ensuring that the patient is given sufficient information to make a good decision. As such, it is the patient who makes the final decision about whether to take a chance with the treatment or operation recommended by the doctor or risk the consequences.

DEVELOPMENT OF INFORMED CONSENT

The doctrine of informed consent originates from the United States of America through the assertion of an eminent American jurist, Justice Benjamin Cardozo, in ***Schloendorff v. Society of New York Hospital 211 NY 125 (1914)***, where His Honour stated that "every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault for which he is liable in damages". Implicitly, the statement above embodies the general principle of the patient's right to self-determination, which is central to the doctrine of informed consent.

The Nuremberg Code which was drafted by a committee of the AMA as a guide for the Nuremberg tribunal in trying the Nazi criminals also adopted this doctrine [1947]. It reads, "*The voluntary consent of the human subject is absolutely essential. The person must have a legal capacity to give consent, should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit and duress, and should have sufficient knowledge and comprehension of the elements of the subject-matter involved as to enable him to make an understanding and enlightened decision*".

The development of Informed Consent can be traced back to the Hippocratic Oath which declares, "*the health of my patient will be my first consideration*". Similarly both **Article 7** of the UN Convention on Civil and Political Rights and **Article 3** of European Convention contain a ban on inhuman and degrading treatment or punishment. In addition, the UN Convention says, "*no one shall be subjected without his free consent to medical or scientific experimentation*". The individual is therefore given unconditional legal

protection and there may be no balancing of interests of science and society against the interests of the individual human being (Kjonstad 1986: 12).

The World Medical Association has passed guidelines concerning biomedical research involving human beings. These guidelines were embodied in the World Medical Association, Declaration of Helsinki which were made at Finland on June, 1964. Similarly, International Code of Medical Ethics adopted the same view. It declares that, *"A physician shall act only in the patient's interest when providing medical care which might have the effect of weakening of physical and mental condition of the patient".*

Malaysian Code of Professional Conduct also recognized the concept of "informed consent". **Section 29(1.5.1) of Medical Act** clearly states that, *"in any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entails. He or she should be informed that he or she is at liberty to abstain".* The same section under **clause 3.3.1** further states, *"the practitioner shall not provide any premises, instruments, substances or knowledge to facilitate the practice of torture or other forms of cruel, inhuman or degrading treatment or to diminish the ability of the victim to resist such treatment"* Not only that, **Patient's Charter** under **Part iv** also endorsed similar view. Among others, it declares that, *"A patient shall have the right to information regarding all aspects of medication. A patient's consent shall be required before any procedure is carried out and in the case of a minor; the consent shall first obtained from the parent or guardian. A patient's consent shall be required for the inclusion of a patient in any research. The patient shall be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail."* Further, *"the patient shall be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time."*

From the above discussion, it can be concluded that the performance of an operation or medical research by a doctor other than the one expected and consented, is recognized by the medical profession as unethical and constitutes a battery. In addition to potential liability for battery, the involved doctors risk the imposition of discipline by the Board of Medical Ethics. As such, doctors have both an ethical and statutory duty to secure appropriate consent to surgery or any other invasive procedure.

WHAT STANDARD IS USED TO MEASURE THE SCOPE OF DISCLOSURE IN THE PROCUREMENT OF INFORMED CONSENT?

The doctrine of informed consent is basically to promote individual autonomy. A person should not be exposed to a risk of damage unless he has agreed to the risk. Although this proposition would probably meet with wide approval, there are differences of opinion as to the extent of the duty to disclose risks. The more paternalistic approach is to countenance the non-disclosure of a considerable amount of information if the doctor thinks it would not be in the patient's interest to be told. This view is generally known as "therapeutic privilege". An alternative school of thought holds that, given a rational patient, the doctor must reveal all the relevant facts as to what he intends to do. It is not for him to determine what the patient should or should not hear. This second approach is best known as "prudent patient" approach. However, it should be noted that even though the second approach most fully satisfies the requirements of self-determination, the doctor could criticize it on the grounds that it leaves little scope for the exercise of clinical judgment.

While most jurisdictions hold that disclosure is required, there are many varied interpretation of what disclosure should include. To enable the patient to make an intelligent and informed decision about the proposed treatment, the basic elements of disclosure should include 1) the type of procedure or treatment proposed; 2) the complication of that procedure or treatment; 3) any alternatives to the procedure or treatment; 4) benefits that will hopefully be derived; and 5) the probable outcome if the procedure or treatment is not carried out.
In the United States for example, there are some jurisdictions in which the full disclosure rule applies and others in which the professional standard has been accepted. Within the Commonwealth, there are decisions ranging from the endorsement of the professional standard to the extreme patient-oriented approach which emphasizes complete disclosure of risk (Mason 1987: 152).

In the American case of ***Salgo v. Leland Stanford Jr. University Board of Trustees 317 P. 2d 1093 (1960),*** the doctor failed to warn his patient of the risk of paralysis inherent in the performance of a translumbar aortography, and as result of the operation the patient suffered severe paralysis of the lower limbs. The

patient claimed that the doctor was negligent in failing to warn of the risk of paralysis. The court held that " *a physician would violate 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...full disclosure of facts is necessary to an informed consent*". However, the court further added that the content of the disclosure was a matter for professional medical judgment. Similarly in the case of ***Bolam v. Friern Hospital Management Committee [1957] 2 All ER 118,*** the court expressed the view that the doctor was entitled to proceed without explanation of the risks in the light of the patient's condition. This case concerned the administration of electro-convulsive therapy without an anaesthetic as was common at that time, to a mentally ill patient to whom the risk of fracture in such a procedure had not been explained. House of Lords in this case has formulated the rule that a doctor is not negligent if he acts in accordance with a practice accepted at the time as proper by a responsible body of medical opinion even though other doctors adopt a different practice. In other words, medical practitioners need only to tell their patients what other doctors think they should be told. The standard of disclosure is to be based on medical judgment. The decision in ***Bolam*** has been applied in case of ***Whitehouse v. Jordon (1981) 1 All ER 267*** and ***Maynard v. West Midlands Regional Health Authority (1985) 1 All ER 635.***

In ***Sidaway v. Board Governors of Bethlem Royal Hospital and Maudsley Hospital [1985] 1 AC 871,*** the English court was given the opportunity to discuss the doctrine of informed consent in greater detail. The plaintiff in this case underwent an operation on her spine to relieve pressure on one of the nerve roots. Unfortunately, during the operation, her spinal cord was damaged leaving her disabled. The neurosurgeon had told her about the risk of damage to the nerve root (a risk of about 2%) but had not told her about damage to the spinal cord (a risk of 1%). There was no evidence that the operation had been carried out negligently. However the plaintiff argued that the defendant had been negligent in not telling her of the risk of damage to the spinal cord. The court held that it was a matter for the doctor's clinical judgment which risks should be disclosed to enable the patient to make a rational decision. Thus the plaintiff's claim failed.

On the other hand, in the case of ***Canterbury v. Spence 464 F. 2d 772 (D.C.Cir. 1972),*** the plaintiff suffered paralysis as a result of undergoing a laminectomy. He claimed that the doctor was negligent in failing to warn him of the risk of paralysis. In determining the scope of the doctor's duty to disclose such information, Robinson J. said that *"respect for the patient's right of self-determination on a particular therapy demands a standard set by law for a physician rather than one which physicians may or may not impose upon themselves."* The court at this juncture felt that to permit the physician to determine what information need to be disclosed by reference either to his own personal standards or to the medical profession would in any ways undercut the patient's right to have the available information he might need to make a decision for himself. Hence, it was decided that the standard of disclosure based on medical judgment was merely a façade and to determine what risks a person regards, as material should be determined without the aid of medical science. Clearly the decision in ***Canterbury*** reflects a shift in the law towards greater respect for patient autonomy. Before ***Canterbury,*** what is "material" would be a matter of medical judgment but in ***Canterbury,*** the question is to be determined by the *"prudent patient"* test. A risk is thus 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 determining whether or not to forego the proposed therapy. All this however, subject to the doctor's "therapeutic privilege" to withhold information as to the risk from the patient if that is shown to have posed a serious threat of psychological detriment to the patient. Similarly in the case of ***Bolitho v. City of Hackeney Health*** **Authority [1997] 4 All ER 771,** in applying the professional standard, the House of Lords held that a doctor could be liable for negligence in diagnosis or treatment despite a body of professional opinion sanctioning his conduct where it had not been demonstrated to the judges' satisfaction that the body of opinion relied on was responsible, reasonable and respectable.

The Australian courts have been very authoritative on the issue of informed consent compared to England. ***Canterbury*** was closely followed in judgment of the Supreme Court of South Australia in ***F v. R (1983) 33 SASR 189*** where the court firmly rejected the standard of disclosure based on medical judgment. In ***F v. R,*** a married woman who had no desire to have any more children was advised to have a tubal ligation operation. She was told that the operation would ensure that she will not have any more children in the future but she was not told that there was a 1% failure rate of the operation being reversible. The operation was performed competently but unfortunately, the procedure given reversed itself and she became pregnant. She brought an action against the doctor for failing to inform her of the 1% risk that the operation might reverse itself. Evidence was shown that what the doctor did was in conformity with a responsible body of medical opinion. Although the Supreme Court found the defendant not to have been negligent, opinions of medical witnesses on the standard of disclosure are not decisive. Therefore, it was held that: ***"The ultimate***

question, however, is not whether the defendant's conduct accords with the practices of his profession or some part of it, but whether it conforms to the standard of reasonable care demanded by the law. That is a question for the Court, and the duty of deciding it cannot be delegated to any professional group in the community". Similar stand was adopted by the High Court of Australia in ***Rogers v. Whitaker (1992) 175 C.L.R. 479***, where the court also rejected the professional test as standard for the disclosure of information by a doctor to a patient. The High Court concluded that, with regard to negligence, the scope of a doctor's duty of disclosure is; ***"...to warn a patient of a material risk inherent in the proposed treatment, a risk is material if, in the circumstances of a particular case, a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it or if the medical practitioner is or should reasonably be aware that a particular patient, if warned of the risk, would be likely to attach significance to it or if the medical practitioner is or should reasonably be aware that the particular patient, if warned the risk, would be likely to attach significance to it. This is subject to therapeutic privilege."*** In determining what information is "material" for a given patient, the needs of each patient must be taken into account. The doctor must consider all that he knows about the patient, in order to decide, in the light of those circumstances, what risks the patient would be likely to consider significant. Thus, the High Court felt that opinions of medical witnesses should not be decisive. It was for the courts, having regard to the "paramount consideration" that a person is entitled to make decisions about his own life, to set the appropriate standard of care.

In Malaysia, the duty of the doctor to disclose the "material risk" to the patient, in undergoing a treatment, has been accepted on the lines of English law. In ***Liew Sin Kiong v. Dr Sharon OM Paulraj [1996] 5 MLJ 193,*** following ***Sidaway,*** it was considered to be common ground that there is in law a duty on a doctor to warn the patient of any material risk in undergoing or foregoing a treatment. However, this duty of disclosure was measurable according to the standard set up by the opinion of a responsible group of doctors. In the instant case, it was proved on evidence that the defendant doctor had explained to the plaintiff the risk of infection in the eye which underwent surgery. Although the doctor had failed to disclose to the patient, the risk of danger to the patient's spinal cord, such non-disclosure was considered to accord with the practice accepted as proper by a reasonable body of neurosurgical opinion. Further, the court held that if a doctor was of the view that a patient was in need of an operation, then such benefit outweighed a remote risk, the doctor should be allowed the "therapeutic privilege" in deciding whether or not to disclose the risk.

The main problem for patients in Malaysia hospital is that their consent has rarely been "informed" in nature. They are usually asked to sign consent forms before any operation but in reality, they do not really understand what they are signing. They are rarely informed about the risks inherent in any proposed treatment. This issue has been highlighted in case of ***Tan Ah Kau v. Government of Malaysia [1997] 2 AMR 1382.*** On this issue, the court held that no consent was actually given by the plaintiff, as the content of such consent had not been fully and comprehensively explained to the plaintiff. The plaintiff was not given the opportunity to opt out of the operation. He was a man of 40 years with a wife and eight children and was diagnosed as having slow growth cancer. Thus, it is illogical that a man would opt for an operation that is subjected to a risk of instant paralysis instead of thinking about his ability to provide for his family first, even if it meant to be able to provide for only 20 years.

The Malaysian Courts appear to be contented with the Professional standard as enunciated in the ***Bolam*** case, in relation to the requirement of the informed consent. This is evident from the decision of the Court of Appeal, in the case of ***Dr. Soo Fook Mun v. Foo Fio Na & Anor [2001] 2 CLJ 4575.*** In allowing the appellant appeal, Gopal Sri Ram JCA, considered the Bolam test appropriate for Malaysia for the present. The Court of Appeal ought not to alter the approach for two reasons. Firstly, as a matter of precedent, it is not open to the Court of Appeal as an intermediate court of appeal to alter the law as that is a function that is reserved for the apex court. Secondly, as a matter of practical justice, the Bolam test places a fairly high threshold for a plaintiff to cross in an action for medical negligence and it is right that it be so. If the law played too interventionist a role in the field of medical negligence, it will lead to the practice of defensive medicine. For the time being, the Bolam test maintains a fair balance between law and medicine.

CONCLUSION

In conclusion, it is submitted that the patient should have the right to make an informed choice. The decision to undergo a proposed treatment should not be left solely to the discretion of the doctor. Instead, it should be a combined decision between the doctor and the patient, but the patient's views should be given outmost consideration. Some countries have said that informed consent is impossible to achieve while

others have pointed out the doctor's dilemma where if he tells the patient too little, he will hold himself open to liability for assault or annoyance if he performs the operation, and if he tells the patient every risk, whether real or remote, attendant upon the operation, the patient may be frightened off, having the operation which may clearly be in his interests. Admittedly, there are difficulties inherent in the concept of voluntary informed consent, but surely, the answer lies not in rejecting the concept but establishing and improving a true relationship of confidence between director and patient, as even though the need for a proper informed consent, but it would certainly reduce the chance that its validity would be tested in court.

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