MORAL STATUS OF "INFORMED CONSENT" IN MEDICAL PRACTICE

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"Informed consent" is recognised as the most important instrument that protects both the patient's autonomy and professional autonomy of the doctor. As there is no simple and well defined idea regarding what constitutes consent in medicine, one has to depend upon legal use of the term. However, the legal doctrine seems to be inadequate to account for the implicit meanings that medical practice attaches to the term. The present paper attempts to understand the unique nature of "informed consent" in the context of doctor-patient relationship.

I

Consent in legal terminology means 'voluntary agreement, complinace or permission'. Section 13 of the *Indian Contract Act* lays down that two or more persons are said to consent when they agree upon the same thing in the same sense. Basically there are two types of eonsents: implied or expressed. Implied consent is a consent although not written (that is, its existence is not expressly asserted) is legally valid. Express consent is a consent that is written or oral and expressed in a distinct language. The more specific concept (and focus of attention in medical practice) is *informed consent* as consent which has specific implications to the bioethical problems. Informed consent has a rather complex and at times *naive* meaning, but assumes significance in the context of the *doctrine of informed consent.*

The doctrine of informed consent was introduced with a view to delineating physicians' duties to inform the patients of the benefits and risks of treatment or of non-treatment of disease the patient is suffering from; and obtaing permission of the patient to proceed with the treatment. The objective of the doctrine was to

Indian Philosophical Quarterly XXVIII No 2
April 2001

protect patients' rights and ensure that the patients are not exploited by the physicians. Although the doctrine has been in force for almost half a century, there has been lot of confusion in the legal circles regarding the implications of such a doctrine. Besides, in practice, there has been little or no compliance of the doctrine, except in the case of surgery on the patient.

The legal doctrine, *ab initio* seems to go against the rights of the physicians. Even the *Oath of Hippocrates* never envisaged that the patients be informed about their illness. Instead, physicians were debarred from informing or showing any signs of the type of illness or symptoms or mode of treatment to the patients, Hippocrates had ordered the physicians to "Perform (these duties) calmly and adroitly, concealing most things from the parient while ... attending to him. Give necessary orders with cheerfulness and serenity, turning his attention away from what is being done to him; sometimes reprove sharply and emphatically, and sometimes comfort with solicitude and attention, revealing nothing of the patient's future or present condition."[1]

Even other codes promulgated by the association of medical practitioners have never envisaged the need for complete disclosure. In the case of reserach, there has been indications that consent of the patients be obtained and that the patients be fully aware of the implications of the treatment sought to be administered. But in the case of mere therapy, there has been no statement from any authority that makes it mandatory that the patient be informed and informed consent obtained before any medical intervention is carried out.

Scholars of the subject have pointed out that in many cases the legal doctrine of informed consent is bogged down in rhetorics and common place cliches that often do not have legal interpretation and binding. Some even conclude that "informed consent" is a creature of law and not of medical practice, and that the judges ruling in many cases are not aware of the medical tradition right from Hippocrates to contemporary medical codes. Even when judegs took up legal matters in relation to 'informed consent' there were no precedents to fall back upon nor there were theoretical and practical guidance from the medical profession that the judges could follow. In due course of time, more specific guidelines were developed within the context of tort law. If the medical profession had voluntarily

been more open to patients' desires and concerns as a matter of its own practice, then the judges and legislators would not have intervened. Medical practitioners would not have been advised by lawyers and judges as to what should be their attitute to patients. It is the reluctance on the part of physicians to critically evaluate their acts of negligence (what has come to be known as the "conspiracy of silence") which is primarily responsible for the governmental interference and frustration among patients, and has led to 'judicial activism'.

The question whether there was negligence on the part of the physician is to be decided legally on the basis of information supplied to the patient regarding the extent of disease, type of medical intervention and plausible consequences of the same. One of the important questions in tort law is whether the patient is competent to understand the information given to him and consent to the medical intervention proposed by the physician. Legal doctrine has laid down certain criteria to judge the *competence* to consent. Individuals under stress and strain due to pain and suffering or due to reactions to a particular drug have reduced capacity to understand and make decisions. Persons with marginal capacities to understand and make decisions are, in practice, treated as competent to consent. Competence or capacity to consent should be assessed individually in terms of the situation and judges do take into account specific conditions while deciding whether there is negligence or not on the part of the physician.

Legal doctrine also lays down certain criterion for judging what level of disclosure is deemed adequate. Disclosure may be of *professional standard* ("is limited to those disclosures which a reasonable medical practitioner would make under the same or similar circumstances"), *reasonable person standard* ("average reasonable person" could deem relevant or material to the decision at hand), and *subjective standatd* (takes into account "idiosyncratic views and character of the individual patient in determining disclosure").[2]

H. T. Engelhardt, Jr. while summarising the complex justification for informed consent points out that informed consent (1) "respects the freedom of the individual involved and provides authority for common endeavours; (2) it recognises that individuals are often the best judge of their own best interest; (3) even if they are not the best judges it acknowledges that the satisfaction of choosing

freely is often preferred over having the correct choice imposed by others; and (4) it reflects the circumstance that the physician-patient relationship may often be such as to bring about a special fiduciary relationship that creates an obligation to disclose information. One can thus give a justification for the practice of free and informed consent on the basis of the principle of autonomy and beneficence."[3] The seemingly clear cut guidelines seem to lead to many problems as individuals do not necessarily choose according to their best interests. And in case of proxy consent, some guardians do not act with moral authority or their actions cannot be deemed to be extensions of individual's freedom.[4]

The *principle of patient* autonomy though envisaged as a positive contibution to patient's well-being, its origin must have had a negative basis as there were threats to physician's freedom in medical practice. The purpose of 'informed consent' in physician-patient relationship is often seen in negative terms. It is viewed as measure of control on the actions of physicians and enabling and empowering a patient population that has been mute and powerless in the face of medical practice and authority. In Stephen Wear's terms: "(It) is the cutting edge of the patient autonomy movement".[5] It is in this sense that there is insistence on the part of legislators and controlling authorities that consent is a prerequistie to all medical interventions, particularly when they are of serious nature.

In legal terms, informed consent involves information regarding (a) "diagnosis for which future investigation or intervention is proposed", (b) information regarding "the recommended intervention coupled with the significant benefits and risks attendant to it", (c) information regarding "the result or prognosis if no intervention is attempted" and (d) information "regarding any significant alternative modalities with the attendant risks and benefits".[6]

This information, however, is to be provided only under certain conditions and informed consent be obtained. In other words there are situations in which the informed consent cannot or need not be obtained. For example, under emergency conditions when immediate medical intervention has to be taken the physician under *emergency exception* may act without the informed consent. Similarly, when the patient gives up the right to be informed i.e. *waiver exception* and the physician is permitted to take all necessary steps on behalf of the patient.

Again, in *therapeutic privilege exection,* the physician may not seek informed consent as he is convinced that disclosure may cause physical or psychological harm to the patient.

II

There are however areas of informed consent that have positive contribution to make to the physician-patient relationship. Informed consent does improve the care of patients. It performs this task "by facilitating autonomy through the provision of choice, and by increasing the patient's participation in his own care."[7] To see the issue as a threat to paternalism is a misconstrued notion.

The information supplied by the physician concerning the patient's state of health must be such that the patient understands in his *own way* the implications of the diseased state and the implications of the course of treatment prescribed and plausible functional disabilities that may result while fighting the disease. Understanding in one's *'own way'* implies that the patient must not be kept in the dark about the painful truth of risks or suffering, nor should every detail of risk and hazards be given to the patient. The patient must know only those risks and hazards that any rational human being, can in the same position, take in, without unnecessary psychological tension.

Informed consent presupposes patient's capacity to know the subtle problems regarding disease and general presuppositions of medicine. In the general understanding of medical practice, informed consent cannot be deemed to medical education, wherein patients are taught to recognise the seriousness of disease, the risk involved, what medicine can do and what it cannot do, the ethics of medical profession etc. Physicians, and more particularly, specialists tend to exercise 'dismissal' of patient's right to information not on theoretical grounds or justification of paternalism, but because of their own inability to communicate with patients whose level of medical education makes it impossible to understand the presuppositions of medical practice. In fact, the most important problem faced by physicians dealing with more serious disease is that patients (and relations of patients) do not understand that medicine is not a science as physics and that decision regarding medicine is primarily a

science of competing probabilities. And like science has paradigm shifts[8], medicine does undergo shifts in interpretation of disease and symptoms of disease.

Is it possible to have 'informed consent' on the part of the patient who is both physically and emotionally disturbed due to fear and uncertainty? Although legal definition of consent may make it mandatory on the part of the patient to give informed consent, it is questionable whether the consent is morally valid. The pain and suffering, the distress and anxiety, past experiences regarding disease may cloud the patient's rational abilities and hamper an objectively evaluated consent that is in his best interest. In the case of consent on behalf of someone else (proxy consent) the problem gets more compounded and decisions regarding the course of medical intervention become uncertain and ambiguous. Such a situation compels medical practitioners assert their right to determine the type of medical action deemed right.

III

The nature of medicine as a science has a very serious implication for the informed consent. As mentioned earlier, medicine is not like physics and the casuistic approach to disease is not based upon laws of nature that are deemed absolute. Medicine is statistical in the sense that the law like statements in the medical discussions are based upon data collected by medical practitioners in their interaction with patients. In fact, even when a new drug is approved for marketing, the clinical trials are statistically calculated. When a patient is expected to give his consent on the basis of information provided to him, his attention may be focused on the negative percentage. In other words, the patient who is emotionally affected by the disease and is frightened of being disabled, will not 'see' that there are 90% chances for his recovery, but notice that there are 10% chances of being disabled for life or the disease may prove fatal. There may be greater harm in informing the risk of small statistical probability, which may be seen as a large threat to life.

The basic concern of medical practice was to protect the patient and promote his well-being regardless of all implications. The paternalism based upon beneficence was commonly practised by the medical practitioners. It is only in the current 'over treating' scenario that medical practice seems to recognise patients and physicians as moral strangers. Physician is not necessarily seen as wise and beneficent as in the past. This is because medicine is today an enterprise pursued by physicians who

develop only transient and temporary relationship with the patient. It is in this context that patient autonomy and informed consent are seen as 'antidotes' to arrogant physicians and necessary mechanisms for protecting the rights and freedom of the patients.

While it is always argued that patients have freedom to seek or reject medical intervention, the question whether this freedom is respected in the medical practice has been debated. Besides, freedom is not freedom to choose medical help or not, but freedom to decide to what extent the medical intervention and care should be accepted or restricted. Under the influence of paternalism, this freedom in health care has been threatened and therefore patients are compelled to assert the freedom as freedom from interference, legitimised by informed consent. The assertion of freedom in this sense was partly due to the legal battles fought in Karen Ann Quinlan case and others.

Theoretically a patient suffers from dual deprivation of freedom in a diseased state. First, he is deprived of his freedom to function normally due to illness and secondly, under the influence of paternalism, the physicians deprive the patient of his freedom to choose the type of treatment etc. The defenders of paternalism cannot *a priori* assume that the patient has either lost the abilities to understand, evaluate and make choices or the same have been diminished due to fear, stress, pain, confusion etc. [9]

Clinical decisions involve value judgements regarding the risk, benefits, price, societal cost, etc. Informed consent could or should be used to decide what course of action the physician should take as the decision will have to depend upon the value of the patient. This is pre-eminently important in the context of secular and pluralistic societies where the value system of the patients and physicians do not necessarily coincide.

Stephen Wear has a dissent even while clarifying and defending informed consent. While agreeing that paternalism in contemporary 'assembly-line' medical practice may have lost justification, and alternatively, it may not necessarily involve 'across-the board' provision of informed consent, Wear argues that the need for understanding the risky interventions, etc. is not to decide 'to treat or not to treat' "but to appreciate and adapt to the threatened or actual changes in ... (the

life) circumstances."[10]

There is another aspect of informed consent that needs to be understood. The moral and legal justification for informed consent seems to come from extraordinary cases, either involving terminal illness or involving extraordinary medical interventions. In majority of cases, neither the patients want to know the details of their illness nor want to get the expert and specialised knowledge that physicians use in clinical decisions. Even the most educated patients seem to have disinclination to understnad the various details about their illness. They (the patients) seem to be content with the physician's understanading of the problem and the course of medical intervention he prescribed. Majority of the patients seem to have 'faith' in the ability of the physician and the physician's implicit concerns for the health of the patient. In other words, the principle of beneficence seems to be still widely accepted, to the extent that any negative implications of the treatment are seen as mistakes or 'hand of God'.

Due to the problems discussed above, physicians and moral philosophers began to suspect the character of informed consent. One wonders whether informed consent comes in the way of the healing process as it interferes in the unique physicain-patient relationship and also creates a mental burden to the patient during a period of tension and anxiety. In other words, the question is whether informed consent is a myth and a harmful one for health care.

Alan Meisel and Mark Kuczewski[11] identified eight 'myths' about informed consent. There is insistence that a patient/guardian sign a consent form, which is treated as informed consent. It is true that physicians medical administrators feel secure when signature is appended on such a form (often labelled as informed consent form), but it does not follow that merely signing a form is 'informed consent' as the form even if it contains some details of sickness, risk, etc., the same may not stand scrutiny of law. In other words, it does not follow that the patient really understood or was made to understand all the implications of medical intervention for which he has given sanction. It is, therefore, a myth to assume that the physician can conclusively argue that the patient, just because he signed the form, gave informed consent.

Another myth is to assume that informed consent is obtained just because

a consent form is signed-it is possible that the signature may have been obtained on the ground that a medical Miranda warning was given, and not that the patient was told about the therapeutic options and varied consequences of these options. It is necessary that the risk of treatment be informed to the patient, but this is not sufficient to claim that the consent is informed consent.

The third myth, called 'medical cafeteria' myth by Alan Meisel and Mark Kuczewski assumes that merely informing the patient all the therapeutic options and leaving it to the patient to make the choice, implies informed consent. Informed consent involves "shared or collaborative decision making ..." (and) "in selecting and revising treatment goals, physician and patients need to form a partnership".[12]

The fourth myth is regarding the quantum of information to be supplied to the patient. It is a myth to assume that all the information regarding the treatment should be given to the patient. What is mandatory is that reasonable amount of information should be given and not information à la Physicians' Desk Reference.

Fifth myth is regarding the time of disclosure of information. The term informed consent unfortunately turns out to be information after consent. In other words, most of the time, information regarding the consequences of treatment is given to the patient only when he or she refuses or questions the nature of treatment. It may be noted that physicians are expected to obtain not only informed consent but also informed refusal.

The sixth myth is regarding complexity of information and the capacity to understand the same on the part of the patient. There are two extreme positions taken in the understanding of informed consent. It is either claimed that patients are frightened by the complex and difficult information provided and consequently no information should be provided ; or, that all information should be provided and the patients' choice should be respected without suspicion regarding his capacity to understand. To assume either of the two exclusively is a myth.

Again it is a myth that patients must be given information whether they want it or not. Both legally and morally, a patient may opt for waiver regarding information consent and therefore to compel patients to receive information and make decisions would amount to disrespecting their dignity. Further, to waive

the right to decide does not imply waiver to right to information.

Finally, it is a myth to assume that the physician can deny information if he believes that the patient will undermine the goals of informed consent. This is unacceptable as physicians have no right to withhold information on the ground that the patients will refuse the recommended treatment. Physicians can withhold information only if such disclosure would upset a patient and would incapacitate him or her from discussing the treatment options.

Theoretical studies in the area of informed consent do not reflect the actual reality of how informed consent is obtained and the mode of communication between the physician and patient. It is necessary that we understand the problem from the actual hospital situation and medical practice involving both simple and complex medical interventions.

There are number of studies showing how patients do not seem to take informed consent seriously. It is also observed that most people do not read the consent form seriously. Most of the patients felt that the form had to be signed to protect the physician. Besides, the consent forms contained details about legal clauses, mostly in fine print that patients or guardians did not have the inclination to read in the anxiety situation that they found themselves. Typically, the form is pressed into the hand of the patient and he is aksed to sign the form in a most hurried maneer, thereby even casual attempt to read what is printed may seem to be case of lack of faith in the physician present.[13]

There are on the other hand studies[14] that seem to indicate contrary to the above. Wear quotes studies that found patients deeply interested to know and be informed about their illness and willing to participate in the decision-making. It was noted with regret that physicians underestimated the patients' desires and capacity to understand the implications of the directions of treatment.

It is very important that we distinguish between medical practice in hospital context and private practice where the relation between patient and physician is direct and without bureaucratic involvement. In the former case, the hospital rules and regulations to a large extent interfere in the physician-patient relationship thereby undermining the informed consent requirement. It is too often that consent

forms are procured after providing minimal information and with the sole objective of protecting the physician to some extent and the hospital administrators to a greater extent. Most of the times, there is no involvement of the patient in the decision-making process. Whereas in the case of private practitioners, there may be the physician's concern for the legal system and his own desire to keep him away from any future legal liability. However, there is patient involvement, in the decision-making on the basis of *reasonable* information and understanding, since in such a practice there is no procedural and bureaucratic mediation.

It is ironic that the problem of informed consent arose in the context of malpractice in the medical profession, particularly exploitation of patients by physicians. But the undermining of implied consent takes place in the hospital context and public health system, where physicians do not have the profit motive to trigger such actions. It is again ironic that the 'physician arrogance' is more expressed in the public health care system than in the private physician-patient interaction.

Physicians should not be averse to both informed consent and patient autonomy. Medical practitioners should realise that it is patients who are responsible for their health, and it is they who can make decisions about the treatment they should get. This is justifiable even within the principle of beneficence as informed consent must be obtained in the best interest of the patient. Besides, informed consent brings about a healthy relationship between the physician and the patient who cease to be 'moral strangers'. The physician tries to understand the patient, determine whether he is competent to give consent and also remove the fears and anxieties the patient faces.

Conclusion

The proponents of informed consent argue that the procedure if followed helps the patients to cope with the disease, adapt to the changing environmental conditions and one's interaction with it, helps to reduce the pain and anxiety associated with the disease, and enhances the acceptance of treatment. In spite of the difficulties expressed by critics that there cannot be informed consent as the

patient can never be expected to fully understand the nature of risks involved in the treatment, it may be argued that some degree of understanding is better than none at all.

The opponents of the informed consent argue that such a procedure will not be effective and at best marginal. Besides, a patient suffering from illness is prone to fear, stress and anxiety, and many other factors that will diminish the patient's ability to understand, evaluate and decide. There are also factors that are part of the treatment procedures such as drugs, diagnostic procedures, etc. that will make it difficult for the patient to apply his mind to give informed consent. Asking for informed consent from a patient suffering from a serious illness may be construed as adding to the psychological tension of the patient.

Which side does balance tilt in judging the protagonists and critics of 'informed consent'? There are normal situations in medical practice that do not seem to require any instruction of informed consent, and at best such mediations can have negative impact on the physician-patient relationship. Again, at times in 'normal' situations, both physicians and patients may find informed consent as redundant and waste of time. To claim that the patient should praticipate in the decision-making in the cases where the risks are insignificant, such demands are exaggerated claims. However, there are some abnormal, extraordinary and grey areas in medical practice that may involve alternatively positive or negative reactions on the part of patient and physician.

For instance, in the case of chronic and terminal illness, there is need of patient counselling and consequently the patient should be informed of the major risks, limitations and uncertainties of medical intervention, etc. so that he or she can cope with the outcome of the treatment. There are also issues which may be based upon personal values and which are of great significance to the patient and the same should be known so that patient can decide the course of action he/she feels is the best.

The benefits of informed consent can be expressed in terms of criteria laid down for informed consent. If the informed consent is legitimate and creates no tension between patient and physician, it does not create undue anxiety and fear in the patient, it does not interfere in proper care of the patient by the physician,

then the same is to be regarded as a legitimate informed consent. Proponents claim that in spite of all the problems discussed above, informed consent helps to bring about a relationship going beyond being 'moral strangers' and the same will be useful for future occasions if not the present one. Again, in informed consent situation, the patient may be able to understand better the course of disease, the treatment and the potential risks involved. Consequently, the patient will cope with the results better when they are below one's expectation. There are situations in which the patient when presented with a course of treatment and alternative to it as no intervention, will be able to understand and appreciate the consequences of treatment versus non-treatment. This understanding even if not useful for the present illness, it will serve the purpose in the future. The interaction prior to informed consent, will help the physician to have an insight into the patient's personal problems, value system, misconceptions, fears and hopes and assist the patient to be more responsive and forthcoming with information useful for treatment.

Informed consent, as we have seen earlier, for Stephen Wear, is a minimalist notion in law, understood in context of tort law on malpractice rather than a positive contribution to enhance patient autonomy. Wear argues that informed consent has not developed from the principle of 'self-determination' but from an extension to the 'clinic of legal protections'. He argued that if it was self-determination that was the foundation of informed consent, then the legal system would have been more specific on disclosure requirements, etc. It is therefore clear that although there are ethical claims in the informed consent, it is based on *minimalist* notion in the law.

In short, Stephen Wear's Medical Managenent Model (MMM) takes a realistic position regarding paternalist and autonomist approaches wherein in spite of deficiencies in the actual practice of patient autonomy, he emphasises the need for effective autonomy by demanding that physicians must in ultimate analysis take into account the values and decisions of patients. This is particularly important in view of "assmbly-line" features of modern medicine that make almost impossible informed consent.

NOTES

1 Quoted in Jay Katz, "Informed Consent in Therapeutic Relationship: Law and Ethics" in *Encyclopedia of Bioethics,* Vol. 2 Ed. by, Warren T. Reich., The Free Press, New York, 1978,p. 770.

2 Stephen Wear, *Informed Consent,* Kluwer Press, Dordrecht, 1993, pp. 12-13.

3 H. T. Engelhardt, *The Foundations of Bioethics,* Oxford University Press, Oxford, 1986,p.262.

4 Cf. *Ibid.* pp. 262-263

5 Stephen Wear (1993), p.2.

6 *Ibid.* p.6.

7 Eric J. Cassell, "Informed Consent in Therapeutic Relationship : Clinical Aspect" in Encyclopedia of Bioethics, Vol. 2, p.767.

8 T.S. Kuhn while understanding science and the major revolutions in science had coined the term 'paradigm shift' to explain how and why scientists in one generation almost totally reject the 'firm' beliefs of previous generation. Within a paradigm, he had argued, 'normal science' expresses no contradicitons and progresses. Medicine, 'an art, struggling to be a science', has more of such radical shifts in interpretation than any other science. In a casuistic approach, the causes of disease identified during the previous generation make place for new causes with advancement of knowledge. Besides, medicine may be regarded as an empirical discipline, but unlike other empirical disciplines, it cannot be an experimental science as no experimentation with crucial cases is ever allowed.

9 Cf. Stephen Wear (1993), p. 33.

10 *Ibid.* p. 37.

11 Alan Meisel and Mark Kuczewski, "Legal and Ethical Myths About Informed Consent" in *Archives of Internal Medicine*, Vol. 156, No.22, 1996 (Web Site of Center for Clinical Ethics and Humanities in Health Care, U.S.A).

12 *Ibid.*

13 Cf. Stephen Wear (1993), p.44.

14 *Ibid.* p. 44.