CHAPTER III: INFORMED CONSENT AND MEDICAL PRACTICE

In the last chapter attempts have been made to lay down a general framework within which the medical ethics functions. In this context, the unique physician-patient relationship was discussed. But the most important problem in the juxtaposing of patient and physician is the issue of patient autonomy versus professional autonomy of the physician justified in the principle of paternalism. The mediating concept between the two, namely consent, and its varied types determines whether the actions of physicians are justifiable or not. In the present chapter an attempt is made to understand the crucial concept of consent and its centrality in the understanding of medical practice.

Issues in bioethics tend to be sensationalised and gain status depending upon the dilemmas associated with it. In comparison the issue of consent seems to have very little interest except with reference to other issues where the question of consent becomes pre-eminent, but even then it is discussed as a secondary topic to main issues such as euthanasia, experimentation, abortion, etc. The question of consent may occur secondary to other issues, however, it is deemed implicit to all topics of biomedicine.

There is no simple and well defined idea regarding what constitutes consent in medicine. Medicine has at one level to depend upon legal use of the term and at another level the legal doctrine is not adequate enough to account for the implicit and explicit meanings that medical practice attaches to the term. Consent in legal
terminology means "voluntary agreement compliance 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." Consent may be implied or expressed. *Implied consent* is a consent which is not written, that is, its existence is not expressly asserted but nonetheless it is legally effective. *Express consent* is a consent that is written or oral, and its existence is expressed in distinct language. The more specific concept is however *informed consent* as consent in itself has no specific implications to the bioethical problems. Informed consent has a rather complex and at times naive meaning. There are societies which do not attempt a particularly clear definition of informed consent, particularly third world countries wherein legal system is not so mature.

**Doctrine Of Informed Consent**

The doctrine of informed consent was introduced with a view to delineate 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 obtain permission of the patient to proceed with the treatment. The objective of the doctrine was to 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 patient while you are 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.” Even other codes promulgated by the association of medical practitioners have never envisaged the need for complete disclosure. In the case of research, 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 clichés 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 judges 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 attitude 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 was 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 standard (takes into account "idiosyncratic views and character of the individual patient in determining disclosure").

Engelhardt summarises the complex justification for informed consent in the following: Informed consent (1) "respects the freedom of the individual involved and provides authority for common endeavours; (2) it recognises that individual are often the best judges 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 principles of autonomy and beneficence." 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.\(^5\)

The principle of patient autonomy though envisaged as a positive contribution 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”.\(^6\) It is in this sense that there is insistence on the part of legislators and controlling authorities that consent is a prerequisite to all medical interventions, particularly when they are of serious nature.

In legal terms, informed consent involves information regarding (a) “diagnosis for which further 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 results or prognosis if no intervention is attempted” and (d) information “regarding any significant alternative modalities with their attendant risks and benefits”.\(^7\) 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 exception, the physician may not seek informed consent as he is convinced that disclosure may cause physical or psychological harm to the patient.

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." 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 be ‘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, 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 problems get 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.
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 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.

Consent In Experimentation And Research

The question of experimentation in medicine is inseparable from that of medical practice, as there can be no progress without research and experimentation in the various fields. Besides procuring consent from rational well informed adults, there are areas where the experimentation by its very nature calls for 'proxy consent' and the 'objects' to be studied or experimented with are not adults with rational capacity to consent. Research in paediatric for instance is impossible without deemed or proxy consent. Similarly there are a number of other areas such as neurosurgery, cancer, etc. that need experimental situations to progress both in terms of diagnosis and cure.
Medicine, is relatively underdeveloped science (compared to physics, chemistry or even biology) and requires constant experimental inputs to solve problems and make progress.

That paediatric medicine needs human experimental inputs is obvious from the fact that experimentation with animals and adults are not useful as metabolistically they (adults/animals and children) differ significantly. Further children are not capable of giving 'informed consent' and parents are not always accepted as legally or morally capable of giving consent on behalf of the child. The Nuremberg Code\textsuperscript{10} clearly makes it mandatory that all experimentation be conducted after informed consent is obtained, almost excluding any experimentation with children and mentally ill persons. Even the \textit{International Code of Medical Ethics} categorically excludes experimentation with children except for therapeutic purpose. As H. K. Beecher argues: "Under \textit{no circumstances} is a doctor permitted to do anything that would weaken the physical or mental resistance of a human being except from \textit{strictly} therapeutic or prophylactic indications imposed in the interest of his patient."\textsuperscript{11} If the above is taken literally, children together with mental patients are excluded from experimentation. The World Medical Association recognised the inadequacy of the codes and in its \textit{Principles for Those in Research and Experimentation} stated that in the case of experiments with patients who are not capable of understanding implications or nature of experimentation, consent may be obtained from the individual who is legally responsible for the patient. Critiques, however question whether this provision is for experimentation that goes beyond therapeutic purposes or patient's good.
The *Declaration of Helsinki* was however explicit regarding the experimentation with children when it was argued in clause 3a that clinical research on legally incompetent may be undertaken with the consent of the guardian. After this practically all the declarations and codes recognised the validity of proxy consent. Proxy consent was recognised as valid with regard to both established therapeutic procedures and as well as experimental therapeutic procedures. After the explicit reference to experimentation with children and mental patients, experimentation for the purpose of accumulation of scientific (sic. medical) knowledge became an accepted norm.

Moral theologians and those with orthodox Christian orientations argue that the law which tolerates proxy consent to any purely experimental procedure is without moral sanction as under this condition a human being is treated as a *means* only. It may be useful if we understand the logic behind consent, legitimate consent and proxy consent so that ‘dogmatic’ and intransient positions are avoided.

To begin with, parental consent is morally justifiable in the case of the child as the parents recognise what is in the best interests of the child. And since life and health are the ‘goods’ that any child (if it was capable of deciding ) would choose as goods of life and self-preservation, parents who decide the same for the child are performing a morally legitimate act. For example, parents may decide that a particular medical intervention has to take place for the survival of the child, the same is legitimate decision as it is beneficial for the child’s self-preservation.
In non-therapeutic conditions, there are two possible arguments (premises) that one may resort to. As McCormick would argue, experimentation for non-therapeutic purposes may be treated as an "affirmation of one's solidarity and Christian concern for others (through advancement of medicine)." In the case of a more secular position, experimentation for non-therapeutic purposes may be treated as a participation in common concern for growth of medical knowledge for the sake of mankind, part of which knowledge has already been used for the survival of the experimented individual. In any case, to be an experimental subject involves three different problems: some degree of risk, pain and associated inconvenience. To accept this would be an act of Christian charity or concern for future mankind. In short, proxy consent is morally justifiable provided in the case of both therapeutic and non-therapeutic experimental situations, the conditions laid down (in various declarations) for experimentation are strictly adhered to.

**Patient Autonomy And Critique Of Paternalism**

The basic concern of medical practice was to protect the patient and promote his well being regardless of all implications. Biomedical research however developed interests sometimes contrary to the medical practice and at times the interest of advancement of medical knowledge at all cost became the credo. Under these conditions physicians involved in biomedicine began to regard patients as "guinea pigs". Whether it is Nuremberg Declaration or Helsinki Declaration, the main objective of such documents was to ensure that no exploitation of patients is carried out in the name of
experimentation. And even if experimentation is deemed as necessary, then informed consent is to be procured. Legislation controlling research and experimentation and institutionalisation of controlling bodies came into existence to ensure that the fundamental objective of medical profession is upheld.

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. As pointed out in the earlier chapter, 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.  

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 patient 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 ‘treat or not to treat’ “but to appreciate and adapt to the threatened or actual changes in ... (the life) circumstances.”

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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 understand the various details about their illness. They (the patients) seem to be content with the physician’s understanding of the problem and the course of medical intervention he prescribes. 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 seem 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 and some others that we shall see in the next section, 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 physician-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 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 and 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 the 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 resultant 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".18

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 patients. 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 informed 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
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 consent and also remove the fears and anxieties the patient faces.

**Implications**

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 the balance tilt in judging the protagonists and critics of ‘informed consent’? The following statement of Stephen Wear is an eye opener for those who want to take sides in the debate.21

Begin with the uncertainties, possibilities and probabilities inherent in many clinical situations. Next, add a viable alternative treatment or two with multiple branches for the decision tree depending on further diagnostic results, complications, or the degree to which the patient does nor does not respond to initial interventions. Then, add the idiosyncrasies of the effects on and responses of individual patients to illness and treatment. Finally, place all this within a continually evolving clinical picture that might challenge the most experienced clinician. At some point we should surely wonder if talk of the “essentials” of the decision is not just a ridiculous shorthand for situations whose concurrent complexity, ambiguity and uncertainty admit of no clear, simple, or static vision. The technical language of the profession, which supposedly can have no place in informed consent, may then instead seem absolutely necessary for the project of conceptualization, not to mention evaluating and making decisions about what has thus been so precariously fashioned. But where, we must ask, does that leave the patient, assaulted by illness, a stranger in a strange land, when he finally steps up to the podium to render judgement?

In spite of the convincing point that Stephen Wear makes, is/are there any benefit/s of informed consent?
There are normal situations in medical practice that do not seem to require any intrusion 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 participate 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.

J. Katz’s after studying mental patients proposed a model of informed consent which emphasised the need of a dialogue between the patient and the physician. Katz calls it a duty or an obligation to converse, which includes self-reflection and reflection on others. To remain silent on the part of the physician is construed by Katz as abandonment of the patient and dialogue is construed as attempts on the part of the physician to enhance autonomy of the patient from various factors both conscious and unconscious. Instead of seeing informed consent as an attempt to diminish physicians’ privilege to treat the patient on the basis of what is viewed as best for the patient, the physician should see the dialogue as part of his responsibility to prepare the patient for treatment and get rid of anxiety due to the unknown consequences of suffering and
treatment. But overall Katz’s concern is with the psychodynamics between the patient and physician and not so much with the communication process itself.

Stephen Wear’s Model Of Informed Consent

For Stephen Wear informed consent is not just a doctrine, it is an intervention with an objective, namely to the course of disease. And this is achieved by giving the patient sufficient detail regarding his situation, prospects and choices so that he can ‘authorise’ the physician to take the course of action suggested. It is needless to say that the patient should be ‘competent’ to consent to treatment. Stephen Wear’s medical management model (MMM) of informed consent can be regarded as ‘tool for medical management’. The MMM is a product of three interesting theses Wear has framed: a unique account of informed consent as a central ‘doctrine’ in clinical practice; informed consent with three stages of information dissemination; and analysis of ‘competence’.

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.
Stephen Wear also evaluates *moral pluralism* that is seen as a basis of global requirement of informed consent. It is true that the pluralistic character of medicine and contemporary society where people have divergent views regarding life, health and death, people are unlikely to understand each other's moral views. In such conditions physicians often do not take into account the moral views of the patients. But Stephen Wear points out that this is not the reason why informed consent is imperative. Informed consent is a must because no one else can speak for the patient except the patient himself. Consequently, moral pluralism is an insufficient reason for the global requirement of informed consent.

Stephen Wear is aware of the complexity of decision making in medical practice and the problems that are posed by patient autonomy and the principle of beneficence. Instead of posing the various principles in contrast to each other, Wear's constructive position regarding informed consent assumes: (a) we must proceed as though all theoretical arguments for patient autonomy and freedom are insufficient; (b) informed consent is linked to the principle of beneficence in the context of physician-patient encounter; (c) 'shared decision making' does not explain the core meaning of informed consent, there are other values that influence the clinical encounters; and (d) informed consent helps to develop a relationship beyond "moral strangers", helps the patient to realistically appreciate his situation, helps the physician understand the patient and the life meanings, and finally helps the physician in understanding patient's misconceptions, fears, hopes, etc. in relation to medical intervention.23
Stephen Wear’s MMM must be understood within the general framework of informed consent. He recognizes three stages in the process of disclosing of information. In comprehensive disclosure stage, the patient is given detailed information of the risks and benefits of a particular direction of treatment, so that the patient does not have vague or ambiguous notions. Secondly, there is core disclosure stage where the patient is provided with the essential information. And the last stage consists of assessment of treatment options in the light of patient’s choice. Stephen Wear ends his analysis of informed consent as informed consent event by claiming that it is most effective, efficient and comprehensive synthesis as against the conversational or process-oriented model.

The third characteristic of Stephen Wear’s model of informed consent is competence. Competence is assumed in clinical encounter and is assessed in terms of scale of competence measured in terms of certain favourable features. The most crucial among them is the capacity to decide on the basis of risk-benefit ratio. Stephen Wear disagrees with this assessment criteria as it fails to account for patient’s own values. Wear believes that the direct correlation between the favourability of a decision and an assessment of competence goes against the legitimacy of competence. There is opportunity for the physicians to overrule the decision of the patient if the same is viewed as against the best interest of the patient, but to make the “assessment dependent on the physician’s own preferences would go against the ... pluralism of values and consequently against the basic value of being treated as competent.”

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Stephen Wear is aware of the problems in determining competence and consequently patient's autonomy. But in order to uphold patient's effective autonomy (and not merely abstract principle of autonomy), Wear puts the onus on physician that he should work with the patient and enhance patient autonomy by removing misconceptions, confusions so that patient's own values can prove decisive.

In short, Stephen Wear's 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 "assembly-line" features of modern medicine that make almost impossible informed consent.

The Language Of Informed Consent

In Chapter I, the role of language in bioethical discourse was introduced. In this chapter a more detailed study of the influence of language and linguistic structures on informed consent is undertaken. Even a cursory glance at the informed consent discourse will suffice to raise the doubts regarding the objectivity of the legal and moral claims. The language is so imprecise and emotive that specific connotations of what the terms mean is seriously questioned. Alternatively, philosophers began to look at the informed consent as part of the performative speech-act rather than a description of the processes involved in medical practice. As Jan Marta notes that informed consent is a performative speech-act which is the result of a series of
communication acts which together constitute a dialogic, polyphonic, heteroglossial
discourse.

When the patient uses the words like "I consent", "I refuse", it reduces informed
consent to a language act and a linguistic process. It may be recalled that the model of
informed consent requires that certain conditions must be fulfilled. Firstly, the patient
can give consent only if he is disclosed the information necessary to make the decision.
Secondly, the patient should be able to comprehend the information disclosed. Thirdly,
the patient should voluntarily give his consent and should not be under any compulsion
or coercion to do so. Fourthly, the patient should be competent to give the consent.
Fifthly, the patient should consent to the intervention of the physician. The physician
acts as the informer, while the patient is the one who consents or refuses.

In ideal terms, informed consent is a positive reinforcer to patient autonomy. It
however is seen as inadequate as it does not take into consideration the fact that
sometimes the patient may not comprehend or may misunderstand the information
disclosed to him. The roles could also be interchanged. Even the roles of physician and
patient may be interchanged as patient could act as informer and physician as
consenter.

Katz's conversational model of informed consent that we referred to above, is
concerned with patient physician dialogue. H. Brody who takes off from Katz's
"conversation metaphor" and introduces "transparency metaphor" regarding clinical
thinking, focuses his attention on cognition as being an important factor rather than emotion when a patient takes a decision. In this model, physician discloses the information and the patient questions the physician till such time the patient has understood the disclosed information.

A. R. Dyer attempting to take the best from Katz and Brody, proposed a psychotherapeutic model of informed consent wherein the function of the physician is to understand the patient as a person and not merely communicate with him at the cognitive level. Dyer’s objective in the model was to resolve the dichotomies between patient’s autonomy and physician’s paternalism and beneficence. R. F. Faden and T. L. Beauchamp, proposed a model of informed consent that changed from ‘disclosure’ to ‘effective communication’ in which information is disclosed to the patient step by step so that the patient comprehends and assimilates what is conveyed to him.

Almost all informed consent models focus on the cognitive aspects, namely those of disclosure and understanding. Even when the primary focus is ‘communication’, in the ultimate analysis, the content of the disclosure gains importance. The linguistic factors together with the emotive and socio-cultural factors of communication are either ignored or marginalised. Jan Marta studied theories proposed by J. L. Austin, Roman Jakobson and Mikhail Bakhtin and noted that informed consent could be viewed as a performative speech-act, an act of communication. Such an account would take into consideration the emotive, socio-cultural as well linguistic aspects of informed consent. The performative speech-act in informed consent is “I consent” where the
focus is on the "I", i.e. the person who consents. The patient is the one who is responsible for making the decision. However, in cases where the patient is incompetent to consent, some other individual acts as the patient's proxy.

Depending upon the illocutionary force, the performatives are classified into five kinds: (1) there are verdictives (giving a verdict, making a judgement, etc.), for example, "I convict"; (2) exercitives (exercising a power, right, influence, favour or not), for example, "I appoint"; (3) commissives (promising, undertaking), for example, "I promise"; (4) behavitives (performing an attitude or social behaviour), for example, "I apologize"; and (5) expositives (making clear how the utterance fits with others), for example, "I affirm". In this categorisation, the performative "I consent" fits into the class of exercitives, whereby when one says "I consent", one exercises a right or advocates what should be done and gives a decision about a certain course of action to be taken. However, though primarily an exercitive, the act "I consent" exhibits the qualities of the other four kinds of acts, that is, it is a commissive by the fact that it commits the patient to a certain course of action and the physician is committed to its execution. It is also based on a verdict pertaining to the utterance made in the 'informing part' of the informed consent. It falls in the category of expositive as it constitutes a comment on how this utterance fits into the whole conversation. By the fact that it communicates any attitude, it is a behavitive.

The act of "I inform" on the part of the physician is also a perlocutionary speech-act in so far as it produces effects on the feelings, thoughts of the patients. It is an
expositive perlocutionary speech-act, as it exposes a subject. The act is also illocutionary in so far as the “I inform” is expressed in a conventional or ritualised way. The act of informing is more than what is being legislated in the informed consent - there are both subtle and obvious elements of persuasiveness. As Marta has argued: “Despite standards and guidelines, physicians have the same capacities for speech as other human beings, and thus are somewhat loose rhetorical cannons on the informed consent deck. But then so are patients, who also provide information to physicians. This is part of what constitutes the humanness, even the humanness, of the interaction.”

The fact is that both the physician and the patient contribute to the meaningfulness of informed consent. Once the patient gives his consent for a particular action, the physician should consent and agree to implement the decision of the patient.

Roman Jakobson goes a step further while focusing on communication as an interdependent linguistic endeavour and observes informed consent as a ‘communication act’. Jakobson holds the view that in the process of informed consent, both the physician and the patient play an important role. The physician informs the patient of the possible risks and benefits depending on which the patient agrees or refuses to the treatment. Thus there is a continuous dialogue between the physician and the patient. This dialogue occurs through language which for Jakobson is “a socially constructed material of which communication is made. Language is visible but not an obstruction, present but allowing for, creating and mediating the process and act of informed consent.” However, there are certain problems which arise as far as
the communication aspect of informed consent is concerned. The problems could be either in sending the message or in receiving the message. The sender and the receiver both have cognitive, emotional, linguistic and hermeneutical abilities. Jan Marta emphasises the hermeneutical character of informed consent when she/he writes: "Consent", "refusal" seem more adversarial, a "negotiated" contract more relational, and "choice" more independent. These connotative semblances of meaning structure the interaction of sender and receiver, and the resulting informed consent message. The message which is sent should be understood by the other, the information should be free from medico-legal jargon so that it could be understood by layman. The roles of sender and receiver are exchanged between the patient and the physician.

Mikhail Bakhtin while trying to unite Jakobson’s codes and contexts and Austin’s social construction of performatives, highlights the plurality of social discourse reflected in the individual’s utterance. Bakhtin uses the concept of heteroglossia and argues that this makes the informed consent to be inclusive of the codes and contexts that make up the social discourse. Using the concept of polyphonia Bakhtin points out that multiplicity of social voices that occur in a discourse have an unique relationship of influencing and changing the meaning of each other’s (the speaker and spoken to alternating their roles) values, options in order to consent to, or refuse a medical intervention. Individual and social discourses are in a dialogical relationship with each other, and resolve their duality without one undermining or eliminating each other. This model of the individual and social discourses seem to reflect in the physician-patient relationships in informed consent. In the informed consent situation,
the physician and patient who have distinct roles, value system, attitudes, etc. maintain their distinct character even when they enter into a dialogical relationship of interdependence and share the responsibility for the health of the patient.

Jan Marta concludes the analysis by submitting that informed consent is a "performative speech act resulting from a series of communication acts, which together constitute dialogic, polyphonic, heteroglossial discourse." Further the linguistic model of informed consent is better than a simple disclosure model, as it shows equal respect for patient and physician without treating informed consent as a battleground.

The above analysis has brought out some of the special features of informed consent and their unique role in medical practice. Importantly, the question that may be uppermost in mind of the reader, is whether a legitimate informed consent is ever possible. The doubts are due to the fact that often informed consent is seen as 'educated consent' and that the burden of this education falls on the physician who ultimately decides what is best for the patient. Ignoring the 'inputs' of the patient in the process of dialogue between the physician and patient such as patient's individual priorities, needs, concerns, beliefs, fears, expectations, etc. is almost turning blind to the realities of modern medical practice that is accountable to legal and societal controls. A solely or overly legalistic interpretation of informed consent will lead to undermining of 'person' status of the patient. One need not deny the difficulties encountered in the process of informed consent to affirm the primary necessity of
informed consent for the ensuring greater respect for the patient and enhancement of good medial care. Informed consent is justifiable not only as an expression of patient autonomy, but as a mechanism to enhance the principle of beneficence.

NOTES


5 Cf. Ibid. pp. 262-263

6 Ibid. p. 2.

7 Ibid. p.6.


9 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 contradictions 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 not experimentation with crucial cases is ever allowed.

10 The *Nuremberg Code* in the first clause argues that “voluntary consent of the human subject is absolutely essential” and further explains that “human subject must have the legal capacity to give consent, able to exercise free power of choice without intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; 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.” Appendix, *EB*, Vol. 4, p. 1764.


Paul Ramsey, R. E. W. Fisher, Bernard Haring would find it unreasonable to legitimise experimentation with children when the procedure will involve harm or pain to the child without any direct or indirect benefit to the experimented child. For these moral philosophers, humans can never be treated as instrumental ends even if it is for the sake of another human being.


Ibid. p. 37.


Ibid.


Ibid. p. 44.

Ibid. p. 52.


Ibid. p. 115.


Ibid. p. 48.


Ibid. p.51.

35 *Heteroglossia* refers to the various language approaches or perspectives that pervade the society and social discourse.

36 *Polyphony* refers to the multiplicity of social voices which embody or give utterance to, the multiple languages and perspectives of *heteroglossia*.