Informed Consent

Late Lt Gen NR Krishnan (Retd)*, Brig AS Kasthuri (Retd)*

Abstract

There have been significant changes in the doctor patient relationship with the impact of technology in day-to-day practice. More and more patients are aware of their rights and are keen to make free choice and decision on their treatment. This helps them to choose the treatment of their choice from the options available and to select a physician of their choice. Doctor's decisions are being questioned regarding their correctness and there is a need to educate the patient, on what one offers by way of treatment. In some procedures and types of treatment, patient needs to be educated and informed of the merits and demerits of the treatment available. This will help the patient to make appropriate choice and also to accept some adverse outcome of treatment. Towards this end, all countries are looking afresh at the necessity of Informed Consent. Methods adopted by some countries are highlighted to help our physicians practice them in an appropriate way. A lot of remedial work needs to be done to minimize future litigation, as many doctors misunderstand their legal obligations and haven't caught up with the change in judge's thinking.

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Clinical ethics teaches physicians, a wide range of specific ethical issues e.g informed consent, truth telling, end-of-life decisions, advance directives (substitute decision making for incompetent patients) and increasing third-party constraints on the autonomy of both patients and physicians [1].

There have been many changes, between 1965 and 1970 on the subject of medical ethics and physician-patient relationship. The traditional medical ethical principle required that the physician do what he thought would benefit the patient. The principle of mutual trust protected these decisions. The medical profession even refused to recognize the wishes of the patient and felt that he knows what is best for the patient – a paternalistic attitude. The physicians failed to accept that the patient is entitled to make his own free choice and decision – the principle of autonomy [2].

Patients had earlier placed their faith in the physician's higher education and the authority of his medical role. But of late doubts have been raised about the quality of doctor's decision, as their decisions vary depending upon the facts that :

- a. He is a long trusted physician or an emergency room doctor seeing the patient for the first time,
- b. The patient is acutely ill or is suffering from a chronic illness,
- c. The procedure / treatment is a one time or it involves

prolonged or repeated treatment,

- d. There are multiple / alternative choices or only one choice,
- e. Patient's economic and social status, source of fund for treatment, and
- f. Doctor-patient relationship [3].

The rights (autonomy) of the patient have deeply eroded the old model of doctor-patient relationship. The emerging model prefers to treat a doctor as a service provider (medical) for hire, governed by negotiation and a commercial relationship. The consumer ethics has displaced the physician from their previous prominent status and allow patients to say, "Doctors are not Gods". The patient has now the ability to select and dismiss their doctors. They have the resources and can express their preferences about making decisions on general or even specific treatments. They can ask questions, reject proposals, and often find allies in dealing not only with doctors but also hospitals from legal literature, support group, counsellors, and social workers [3].

The clinical-ethical process of shared decision-making is mirrored by the legal doctrine of Informed Consent (IC). Informed consent is defined as voluntary acceptance by a competent patient of a plan for medical care after physician adequately discloses the proposed plan, its risks and benefits, and alternative approaches. This requires a process of effective communication and

*Formerly Dean and Director, GK Naidu Memorial Hospital, Coimbatore, Tamil Nadu. *Professor and Head, Department of Medicine, Vydehi Institute of Medical Sciences and Research Centre, 82 EPIP Area, Whitefield, Bangalore 560066.

education between the physician and patient [1]. Informed consent is a process with the elements of autonomous authorization, free from coercion or manipulation, decision-making capacity, disclosures to the patients, and comprehension [4].

In academic medicine, as teaching of medical ethics became formalized in the 1970s, moral principles of respect for autonomy, non-maleficence (the obligation to avoid causing harm), beneficence (obligation to provide benefits and to balance benefits against risks), and justice, assumed a central role. Thirty years later, IC is still written with the intent to protect the medical profession from lawsuits. Indeed, court views of IC also include a therapeutic privilege for physicians not to inform a patient who may be harmed by the disclosed information [5].

Over the past two decades a considerable volume of litigation in many countries have focused on the consent issue and the doctrine of informed consent has assumed a significant role in the medical negligence debate.

Types of Consent :

- a. Implied consent is commonest which is presumed to be given when the patient enters the consultation room, or calls the doctor to his / her house or holds his / her arm for an injection. Such consent by the patient implies his / her willingness to undergo treatment.
- b. Expressed consent can be oral or written. For majority of minor examinations / procedures, oral consent is enough but should be witnessed by third party. For all major diagnostic procedure, and surgery a written and witnessed consent is necessary.

The concept of written, witnessed or expressed consent in hospitals [6], has assumed great importance because it is not possible to cover by implied consent the vastly increased number of diagnostic and therapeutic procedures, being regularly carried out and the consent is valid only for a specific procedure. The usual blanket consent form used by medical institutions in which the patient consents and authorizes the doctor to do whatever he thinks best for the patient under the circumstances may turn out to be of no value in court.

For the consent to be valued legally the following aspects should be taken into consideration. For any simple medical examination the minimum age of consent is 12 years. For consenting to have any major diagnostic or therapeutic procedure or surgery the age is above 18 years (I.P.C. Sections 87-93). The patient should be mentally sound and he/she should not be under any fear or threat or any false conception. Incomplete information

about the patient's diagnosis, therapeutic plan etc. is a misconception of omission. The patient should not be intoxicated or sedated.

Before asking for consent the doctor should explain to the patient about the diagnosis, tests to be carried out, therapeutic plan, whether any alternatives are available, risks involved in carrying out the plan, prognosis and the immediate and future cost [7]. The exceptions to the above are:

- a. Doctrine of Therapeutic Procedure: Certain procedural details (especially invasive tests or complicated surgery) may be difficult to explain to the patient. Often patients themselves do not want to know about it. It is better to explain to the family members.
- b. Doctrine of Emergency: Under section 92 of Indian Penal Code (IPC) treating without consent of patient is permissible if patient is unconscious, mentally ill or gravely sick. It is implied that the procedure / surgery is done to save the life or limb of the patient. If possible, surrogate/proxy consent should be taken.
- c. Doctrine of Loco Parents: In children in an emergency, when parents / guardians are not available, consent can be obtained from the person bringing the child (school teacher, warden).

The High Court of Australia has said that the following factors are important in deciding whether a risk from the procedure is material and must be mentioned to the patient [8]:

- a. More likely and more serious harmful results must be disclosed.
- b. Complex interventions require more information, especially when being carried out in an apparently healthy person.
- c. When patient desires for more information.
- d. When the risk involved is more important to the patient because of the medical condition or occupation.

For the competence of a patient to give consent the factors to be kept in mind are: age, soundness of mind, ability to understand and remember the information, ability to deliberate the treatment choices, and believes that the information applies to the said patient [9].

Decision making for Incompetent Patient

Traditionally next of kin are the surrogate or proxy decision makers when the patient is not competent to give the consent. Many states in United States have enacted legislations that give authority to family members to make the decision and rank them in priority- spouse, parents, children and so forth. Ethically identifying the

primary decision maker is given in Table 1 [10].

The difficulties in getting informed consent include:

- Competence and mental capacity of the patient, determining mental capacity, waxing and waning mental capacity, and unusual (socio, religious) beliefs of patient.
- Truthful disclosure, will it really benefit patient?
- Completeness of disclosure.
- Advance directives by terminally ill patients or those who anticipate grave illness.
- Durable power of attorney for health care. The holder gives the consent and decisions [8].

When somebody else other than the “patient” wants him to be medically examined and a medical certificate to be issued (employers, police etc), consent of the concerned person must be obtained otherwise the doctor runs the risk of liability to pay damages.

- Issuing certificate involving complicated process of examination or infertility in women.
- When the process is likely to affect the physical or mental well being of the patient e.g financial loss, damage to reputation, social (STD, HIV etc.).
- Medico legal cases.

Table 1

Ethically identifying primary decision maker* (* Modified)

Consent is not required in medical examination and issue of certificate for insurance policies or cases where it is issued in the interest of the community [11]. To avoid insufficient legal interpretations, IC should be understood in terms of autonomy and beneficence. A continuous interaction between the patient and the given physician is considered as an essential prerequisite for the realisation of the standards of IC [12].

The clinical-ethical process of shared decision-making is mirrored by the legal doctrine of informed consent, which applies to every clinical decision. The legal and ethical standards of informed consent are not satisfied merely by obtaining the patients signature on a routine consent form but requires a process of effective communication and education between the physician and the patient. When telling patient the truth about diagnosis, the common medical standard in United States, is to be truthful with patients and not to conceal bad news.

Conflicts of Interest

None identified

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