Review Article

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Informed Consent in Medical Practice & Research

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Abstract

Consent is an essential requirement for surgery, intervention, treatment, for participation in medical research. Same is true for research involving students and residents for research involving educational research. Informed consent is a process where a patient makes an informed and voluntary decision about medical care. One of the major element of consent is information received, its comprehension and decision making of the participants. It not only protects the rights of the patient but is also an important piece of evidence for the doctor if any medico-legal problems occur. In this paper intricacies involved in consent and limits are addressed.

Keywords: Consent; Informed Consent; Decision Making for Treatment.

The "informed consent" contains two major elements: understanding or comprehension and free consent or approval. These two elements together form an important part of a patient's "self-decision". It indicates taking hold of ones action and hold the possibility of determining what is good or right for him/her . This two elements together assumes that patient's capability to understand what has been told or informed to him/her and consent. It is a pre-supposition and will be discussed later also.

1. Comprehension or understanding: It includes understanding the condition and possibilities. Informed means patient has been given adequate knowledge about his/her condition, alternative form of treatments and prognosis. It is to be given in her own language or a language she understands. Understanding is the necessity for giving and informed consent. It also gives a freedom to choose with the available knowledge about the condition.
2. *Consent*: It should be free and voluntary. It is and act which authorises a medical professional for intervention or surgery or treatment as well as participation in research or educational intervention. Ability to choose the best option for him/her self. It also makes patient responsible for their action chosen.

Treating physicians need to be aware about own beliefs and values, and need to be aware that how their opinion may affect the information passed to the patient and their decision making in accepting or declining a therapy. How much should a physician share his/her view with the patient? Many times patient-physician interaction is influenced greatly by the professional values, clinical experience of the physician and the information is presented to the patient [1]. A consent which is obtained by coercing or pressurisng is criticised and has no value in court of law; in-fact it may be taken against the treating physician sometimes. Care needs to be taken that the physician's perspectives do not unduly influence a patient's voluntary decision

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making. Free consent is not always verifiable in concrete instances.

Many philosophical arguments have occurred about what constitutes a free and informed consent as well as rights of patients and human freedom. These differences in underlying philosophical perspectives do not, however, change the general opinion about the need for informed consent and about its basic ethical significance in medical practice and research.

It is important to know the purpose of informed consent and how it is protected.

Informed Consent- Reasons & Ethical Basis

Many people have questioned the utility of informed consent or benefit to the patient when they participate in decision making of medical care. Involving patients in such choices where their knowledge of medical care and complexities is grossly lacking, their decision may not be in their best of interest. On the other hand patient also becomes responsible if the outcome is not favourable, as it happens many times in medical care. Patient's active role in their own health may contribute positively in their well-being. It is pre-supposed that patients do know something which might be helpful in their medical care. When the patient plays the 'sick role' by being passive and submissive their well being and recovery may be effected. Patients active role as decision makers is well documented in choices of-planning to conceive, contraceptive choices, leading a responsible sexual life, treatment of alcohol abuse etc. General well being and recovery from illness is said to speeded up if the patient is actively involved in medical decision making.

The very principle of respect of individual is well reflected in informed consent. Ethics require that every individual should be treated with respect, giving them freedom to opt with requisite medical knowledge. One of these features has come to be identified as personal autonomy—a person's capacity for self-determination (for self-governance and freedom of choice). An important development in ethical theory is the widespread recognition that autonomy is the characteristic of persons and is a basis for the requirement of respect.

Humans are social beings, relating to their personalities, needs and possibilities. Human life is not adequately understood Individually in terms of human relationship and self-determination. If persons are to be respected and their well-being promoted, informed consent must be considered in the context of individuals' various relationships. Patients medical decisions are often a reflection of their relationships, personal and social, familial and institutional. They make decisions in the context of these relationships, shared or not shared. One such relationship is between patient and physician). The focus of informed consent must include many aspect of physician-patient relationship, the knowledge shared, the trust imparted and mutual benefit gained.

Constraints

Certain times many ethical question arise for the physician in implementing informed consent. How to respect autonomy of patient when serious decision must be made in challenging situations. What guidelines to follow in respecting autonomy of adolescents where the society accepts this autonomy only in limited arenas of sexuality? How much information is to be given where controversy surrounds a specific treatment? How to balance autonomy and beneficence where so many decisions are irreversible? Many more questions lurks behind when balancing ethical requirement of autonomy and key decisions.

Whenever decisions for sexuality, reproductive capacities are to be taken– patients autonomy and relationships take an upper hand. Patients perspectives and insights are both helpful as well as challenging to the clinicians

New models for the active participation of health care recipients have been created in many specialities and being developed further. Complex medical technology, gender relations historically, intersection of gender bias with race, class, attitudes and actions in individual have further complicated the issue of informed consent. Proponents argue that none of these problems makes the achievement of informed consent impossible. There is need to identify the conditions and limits, as well as the central requirements, of the ethical application of this doctrine.

Ethical Applications of Informed Consent

Informed consent includes freedom from external coercion, manipulation, or infringement of bodily integrity. This freedom is not incompatible with physician giving reasons that favour one option over the other. Medical recommendations when they are not deceptive or coercive do not violate the principle of ethical and rightful

informed consent eg convincing a patient to take a medicine to improve her health is not taking away her freedom to choose, provided that it is essential for her health.

Informed require freedom from compulsion as well as freedom from ignorance; hence to be true it requires that patients must be well informed so as to help them in correct decision making. Information must be shared in a neutral way, a way of truth telling. Adequacy of information must include the common practice for that condition, reasonable needs and expectations of a common individual and unique needs of individual patient.

Communication is central to informed consent, communication between physician and patient, family members and among other medical professionals. Documentation of informed consent is necessary in many situation specially where intervention/ surgical procedures are being carried out. Written consent can never be replaced by communication [2,3].

Many practical difficulties arise while ensuring communication necessary for informed consent-time limitation, language barriers, illiteracy, lack of decision making capability by the person, etc. Technical jargon used to communicate information may further confuse the person; hence an informed decision making at times be difficult. Costituing a policy and structure may be helpful to overcome this barrier, also use of local understandable language, avoiding too much of technical jargon also helps in better understanding and hence a better decision choices.

The Limits of Informed Consent

Fallible knowledge or imperfect communication limits the informed consent. Limitations in patients comprehension and hence in choices. Assessment of patient capacity is itself a complex matter, subject to mistakes and to bias.

Too much of knowledge sometimes incapacitates for informed consent, at these times principles of respect for persons and beneficence require that the patient be protected. In these situations, someone else must make decisions on behalf of the patient ' a surrogate decision maker ', in the best interest of patient.

Rarely, informed consent is impossible in some circumstances, indicates a kind of limit

Impossibility in achievement of informed consent suspends or limits the ethical obligation. This can be seen in emergency situations in which consent is unattainable and in other situations when a patient is not at all competent or capable of giving consent and an appropriate surrogate decision maker is not available.

Informed consent may be suspended or limited by being overridden by another obligation eg information for notifiable communicable diseases as imposed by state laws, scarcity of equipment, personnel, medical procedures, therapeutic privilege can override an obligation to disclose information and hence to obtain informed consent (where there is reasonable belief that information may harm the patient) [4].

Sometimes if patient refuses information necessary for an informed decision, or simply refusing altogether to make any decision. A waiver in such instances seems to be itself an exercise of choice, and its acceptance can be part of respect for the patient's autonomy.

Sometimes a physician may refuse a treatment which it seems potentially harmful to the patient even if it is the chosen treatment by the patient. Even in the context of justified conscientious refusal, physicians must provide the patient with accurate and unbiased information about medical options and make appropriate referrals.

In the Physician-patient relationship, each must be respected as a person, and autonomous decision to be supported as long as the decisions are overridden by other ethical obligation.

Though there are limits to ethical requirement of informed consent, but still needs to be followed wherever feasible. Committee on human rights reaffirms the following statements [e]:

1. Informed consent must be obtained for medical treatment, for participation in medical research, and for participation in teaching exercises involving students and residents
2. Seeking informed consent expresses respect for the patient as a person, bodily integrity, self-determination regarding sexuality and reproductive capacities.
3. Informed consent not only ensures the protection of the patient against unwanted medical treatment, but it also makes possible the patient's active involvement in her medical planning and care.
4. Communication is necessary if informed consent is to be realized, and physicians must facilitate communication.

5. Informed consent should be looked on as a process rather than a signature on a form. It includes a mutual sharing of information to facilitate the patient's autonomy in making ongoing choices.
6. The ethical requirement to seek informed consent need not conflict with physicians' overall ethical obligation of beneficence;
7. When informed consent by the patient is impossible, a surrogate decision maker should be identified. In emergency situations, medical professionals may have to act according to their perceptions of the best interests of the patient; rarely, they may have to forgo obtaining consent because of some other overriding ethical obligation, eg protecting the public health.
8. Because ethical and legal requirements cannot be equated, physicians also should acquaint themselves with National and state legal requirements for informed consent.

These principles of Informed consent must be followed as far as possible. Informed consent being a legal document must be complied at fullest to ensure patients autonomy, and shared decision making for the wellbeing of patients.

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