Informed Consent and Medical Ethics

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Medical ethics has a very long history and it investigates ethical issues arising in medicine and health care provision by applying the principles of moral philosophy. The ancient ethical codes were often expressed in the form of oaths. The best known medical oath in the western tradition is the Oath of Hippocrates and often regarded as the very foundation of Western medical ethics. The Hippocratic School produced a large body of writings on medicine, science and ethics. In the ensuing centuries the principles of Christian humanism dominated the practice of medicine. Towards the end of 18th century the role of physicians in dealing with disease in individuals as well as population groups led to the drafting codes of professional conduct. Changing attitudes of society and the major advances in medical science at the beginning of the 20th centuries led to recognition of the need for modification of the Hippocratic Oath. This need was met by the Declaration of Geneva, formulated by the World Medical Association in 1947, supplemented by Declaration on particular aspects of medical ethics. Now, the advanced medical technologies or revolutionary developments in the biomedical sciences as well as in clinical medicine and its communication to the public has led to a growing need for the medical professional to be fully aware of society's views on various developments. This, no doubt, enables ethical guidelines to reflect and safeguard the interests and wellbeing of patients.

Informed consent is one of the most important principles of medical ethics. The requirement of informed consent for medical treatment is now widely recognized both in law and in medical ethics. It is a process of communication and clarification. Informed consent is the also most fundamental requirements in research with human subjects. Obtaining this consent is part of a responsibility of nonmaleficence. Informed consent is a formalized procedure in which patients or their families consent in writing to medical procedures involving some degree of risks to their health or lives[1].

The underlying ethical value is protection of people from injury by others. A physical or psychological harm does not constitute a wrongful injury if a person freely and knowingly participates in an activity with a risk of harm. The physician's obligation to obtain the patient's consent to treatment is grounded in the ethical principles of patient autonomy and respect for persons. Autonomy refers to the patient's right to make free decisions about his health or health care. Respect for persons require that health care professionals refrain from carrying out unwanted interventions. So, informed consent also involves making decisions.

The elaboration of informed consent may be traced to the Nuremberg Code of 1946. The Nuremberg Code was formulated by a panel of three United States Judges in the trial of 23 German physicians charged after World War with "War Crimes and Crimes against Humanity" for their experiments with prisoners of war and civilians. It was adopted by the General Assembly of the United Nations on December 11, 1946.

According to the Nuremberg Code:

"The voluntary consent of the human subjects is absolutely essential. This means that the person involved should have legal capacity to give consent should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching 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"[2].

The concept of informed consent is also strongly accepted by the principles of the Declaration of Helsinki, Finland (1964) and revised by the 29 World Medical Assembly, Tokyo, Japan 1975. According to this Declaration:

"In any research on human beings each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she should be informed that he or she is at liberty to obtain form participation in the study and that he or she is free to withdraw his or her consent to participation in any time. The doctor should then obtain the subject's freely given informed consent, preferably in writing"[3].

The major justification of informed consent insist that it behaves physicians in the medicine to be open and honest. Alexander Capron has helpfully identified several important functions of informed consent;

i) *The promotion of individual autonomy.*
ii) *The protection of patients and subjects.*
iii) *The avoidance of fraud and duress.*
iv) *The encouragement of self security by medical professionals.*
v) *The promotion of rational decisions.*
vi) *The involvement of the public (in promoting autonomy as a general social value and in controlling biomedical research)*[4].

Anyhow, in keeping with the ethical principles of patient autonomy and respect for persons informed consent promotes patients reflective participation in health care decisions.

Elements of informed consent:

There are four elements of informed consents:

i) **Competence or capacity**
ii) **Disclosure**
iii) **Comprehension of information**
iv) **Voluntariness**

Patients are entitled to make decisions about their medical care and have the right to be given all available information relevant to such decisions. The term consent implies acceptance of treatment, the concept of consent implies equally to refusal of treatment. "Capacity or decision making capacity" means that the patient has the ability to make rational decisions or patient's ability to understand relevant information.

There are further three elements of competence:

i) Ability to understand the options.
ii) Ability to understand the relevant consequences of acting on the various options.
iii) Ability to evaluate the costs and benefits of these consequences by relating them to a set of personal values and priorities.

Capacity is an essential component of valid consent and obtaining valid consent is a policy of the Canadian Medical Association, CMA, and other professional bodies. The informed consent of the patient is a general, moral and legal requirement for the performance of medical procedures. But, in some areas, this consent is not possible e.g., in emergency medical situation, the patient may be unable to legally give consent because of the acute medical conditions. Minors are also legally incapable of giving consent. A minor is described a person who has not reached the age of 18 years. Parents or guardian usually give consent for the treatment. This type of consent is known as proxy consent.

Benjamen Freedman writes in: "A Moral Theory of Consent",

"Proxy consent is consent given on behalf of an individual who is himself incapable of granting consent. The major category of those who require proxy consent are minors but proxy consent may need to be obtained for the insane or the unconscious as well"[5].

Freedman further writes:

"In minors, proxy consent is ordinarily granted by the child's parent or guardian; exceptionally it may be given by another close relative or by an individual appointed by the court for the specific purpose of granting consent to some procedure"[6].

The other element for valid consent is disclosure i.e., the provision of relevant information by the physician. In general the physician is only required to disclose that information which a reasonable person would want to take into account in making the decision. The information must include the benefits and risks of procedures, the risk of forgoing treatment and alternate procedures that are available. One major argument in favour of the disclosure is that it is the patients' bodies and lives that are involved, not those of the physicians. Some physicians are generally opposed to disclosure of truth to the patients because such physicians feel that patients don't need to be fully informed because doctors know what they are doing and explantations of complicated medical procedure will only confuse patients. Therapeutic privilege according to this idea, a health care practitioner may withhold information which would otherwise have to be disclosed if it is judged that it would be likely to lead to harm to the patient's were that done. There is a risk that where a practitioner thinks a patients refusal of treatment is likely to prove harmful that therapeutic privilege may be invoked[7]. Effective communication is critical to the disclosure process. If the physician fosters good communication, the patient will be encouraged to provide personal information and express his values, goals and fears. Disclosure should also take account of the patient's cultural and religious beliefs. It is quite important that throughout each disclosure session the physicians should invite questions.

Comprehension of information means that physicians must give patients information in a clear way and check to see that they understand it. The physician's duty is to do his best to see that the relevant information is disclosed in a way that is understandable to the patient.

Voluntariness is an ethical requirement of valid consent. The goal of the consent process is to maximize the opportunity for decisions to be reached autonomously. The primary meaning of "voluntariness" is exercising choice free of coercion or other forms of controlling influence by other persons. Voluntariness thus refers to the ability to choose one's goals and to be able to choose among several goals if a wide choice is offered, without controlling constraints presented by other persons or institutions[8].

In short, the doctrine of informed consent is founded on two principles i.e., the principle of patient autonomy and the second principle involves the notion of a fiduciary relationship. The concept of autonomy plays a significant role in ethics and laws of biomedical practice while influential ethical theorists have based the moral right of self-determination on their conception of the persons as an autonomous. The autonomous person determines his course of action in accordance with a plan chosen by himself. Prominent figures in philosophy ranging from Immanuel Kant (1724-1804), German philosopher, J.S. Mill (1806-73) English empiricist philosopher and social reformer, Nietzsche (1844-1900) German philosopher and Sartre (1905-8), French philosopher and novelist have held that morality requires autonomous persons. J.S. Mill writes:

"The object of this Essay is to assert one very simple principle. The principle is, that the sole end for which mankind are warranted, individually or collectively, in interfering with the liberty of action of any of their number is self-protection. That the only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others. His own good, either physical or moral, is not a sufficient warrant. He cannot rightfully be compelled to do or forbear because it will be better for him to do so, because it will make him happier, because in the opinion of others, to do so would be wise, or even right. These are good reasons for remonstrating with him or reasoning with him or persuading him or entreating him, but no for compelling him, or visiting him with any evil in he do otherwise. To justify that, the conduct from which it is desired to deter him must be calculated to produce evil to someone else. The only part of the conduct of anyone, for which he amenable to society, is that which concerns others. In the part, which merely concerns himself, his independence is of right, absolute"[9].

Mill undoubtedly wanted people to exercise the greatest possible degree of control over their own destinies. So, Ultilitarianism recognizes the informed consent. Utilitarians are of the view that physicians must provide enough relevant information to allow competent people to make a meaningful decision about what is likely to serve their own interests the most. Where as Kant's view of people as autonomous rational beings require that informed consent be obtained for medical treatment. So far as the second principle is concerned it involves the notion of fiduciary relationship, that is, a bond of trust or confidence in which a person is required to act in good faith for the benefit of a dependent party.

Obtaining the patient's consent to medical treatment is a legal requirement. Failure to obtain proper consent is treated as a "battery" action. Closely related to the principle of respect for persons and self-determination, the law of "battery" makes it wrong a priori to touch or treat without the person's consent[10].

The requirement to obtain consent is affirmed by professional organizations such as the Royal college of Physicians and Surgeons of Canada, The Canadian Council on Hospital Accreditation and the CMA. Informed consent basically, promotes the physician patient relationship. Its significance cannot be ignored.

References:

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