INFORMED CONSENT IN CLINICAL PRACTICE AND BIOMEDICAL RESEARCH

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Summary

One of the most important developments in the field of bioethics during the last three or four decades has been the recognition of the patients' moral right to self-determination and to participate in making medical decisions about what will be done to them. The physician is required to provide enough truthful information about the nature of the illness (or other problem) about the proposed intervention and alternatives to it, as well as its benefits and risks to enable a mentally competent patient to participate, without coercion, in deciding what will be done to his body. This has been termed "informed consent". Sometimes additional epithets like "free" or "full" are added to this term.

For human subjects of biomedical research "informed consent" is a similar but more rigid requirement.

1. History

Historically, informed consent is a very recent concept because for millennia the physicians alone have determined what intervention is good for the patient and what information should be divulged or withheld from him. Ancient Greek and Chinese writings on medical ethics underline the respect for the patient but say nothing about securing his consent to treat. Some of these and subsequent texts, however, advise the physician to give the patient some information about the treatment in order to gain better compliance.

Informed consent is not only a moral and ethical concept, it has been incorporated in health legislation especially in industrialized countries but also in some developing countries. It has also found strong support in international and regional conventions, guidelines and other directives. Notable among these are the Declarations of the World Medical Association, Guidelines issued by the Council for International Organizations of Medical Sciences (CIOMS), Convention of Human Rights and Biomedicine of the Council of Europe, and a covenant adopted in 1966 by the General Assembly of the United Nations. (viz. p. 7 below)

Since the beginning of the 20th century, attempts have been made by the medical profession in different countries to regulate research on human subjects mainly in response to public accusations of unethical conduct. In Germany, the government (Minister of Interior) issued a circular in February 1931 prescribing "Guidelines for Innovative Therapy and Scientific Experiment on Man". These guidelines did not have legal force but in their content they come close to present-day requirements, especially in their emphasis on informed consent of subjects and independent ethical review. In spite of these guidelines, some German physicians led by a false political ideology, carried out during the second world war brutal experiments on camp inmates and prisoners of war, which resulted in serious injuries, disabilities and death in many cases. These experiments were carried out without seeking any consent whatsoever from the persons subjected to atrocious experiments. After the end of the war, these physicians were tried for their unethical and criminal behavior and a code for regulation of medical experimentation on research involving human subjects was issued. This document generally known as the "Nuremberg Code" made the voluntary consent of human subjects an absolutely essential prerequisite of research and served as a strong stimulus for enacting legislation governing these activities in many countries around the globe. The international and regional guidelines, etc. mentioned above have been elaborated taking the Nuremberg Code as a starting point.

In spite of its wide acceptance and influence in regulation of research, the code has not completely stopped unethical practices including neglect of informed consent all over the world. A few instances of research involving human subjects without the latter's full consent have been documented but these should be regarded as exceptions to the otherwise universally accepted rule of (valid) informed consent. How much influence this acceptance of consent with regard to research has had on informed consent in

clinical practice is difficult to assess.

2. Essential Information for Patients and Research Subjects

In a clinical encounter the physician should provide the patient the following information in order to get valid informed consent:

- the health problem (diagnosis) for which intervention or further investigation is proposed,
- the recommended therapy on intervention and the expected benefits and risks connected with it,
- possible result if the condition is left untreated,
- any alternative interventions with their risks and benefits, and
- any other information that may be relevant to the patient's decision to undergo treatment.

The purpose of the foregoing information is to enable the patient to make a rational decision after considering the risks, benefits and alternatives in the light of his socio-cultural values and other interests. This is possible only if he is mentally competent to do so and understands the information provided (in comprehensible language). For patients who are incompetent because of age (children, senile individuals) or disease (severe mental handicap) the consent is given by an authorized guardian or parent (surrogate consent). The criteria and modalities of patient competence will be discussed further.

2.1. Extent of Disclosure

The foregoing process of informing the patient may appear to be fairly straightforward, but in practice it presents difficulties. For example, it is not clear how much information on various aspects should be provided to the patient. By recounting all possible side effects of a drug the physician may make any drug look like ill-advised if not risky. For example, the possible side effects of the penicillin group of antibiotics include severe allergy, haemolytic anemia, leukopenia and neuropathy. Unless these risks are revealed in terms of likelihood as against the likelihood of benefits, the patient may refuse a life-saving therapy. On the other hand, if the physician omits to mention a side effect which appears later, this may invalidate the consent and he may be accused of malpractice or negligence.

The law is also unclear on this (and some other) aspects of the procedure for informed consent. However, a few standards have been developed and used over the years in different countries:

The professional standard stipulates the disclosure of information usually provided by physicians in their community under the same or similar circumstances. This standard has been justified on the grounds that the determination of the extent requires expert medical knowledge and only the physician can determine what disclosure will not have adverse reaction on the part of the patient and what information is relevant to his choice. This standard is determined entirely by the health profession and fears have been

expressed that it may erode patient autonomy and self-determination. Some courts of law have considered this standard to be inadequate and preferred the objective standard.

The objective standard has also been called the reasonable-person standard. It is based on the disclosure of all material risks or dangers inherent in or resulting from the proposed therapy, which a reasonable and prudent person needs to make in intelligent and informed choice about acceptance or refusal of the treatment. Whether a risk is material is determined by the likelihood of its occurrence and the severity of the injury it threatens to cause. But the physician may have difficulty in determining what a "reasonable person" may consider significant in arriving at a decision. In case of doubt the physician may over-inform the patient "just to be on the safe side", thus causing confusion.

The subjective standard of disclosure is adapted to the needs and views of the individual patient. These may include fears of becoming paralyzed or developing cancer or other concerns connected with the socio-cultural background of the patient. This standard remains a moral ideal, as it is difficult and time-consuming for a physician to ascertain all the concerns of individual patients of various grades of intelligence in a pluralistic society to provide information relevant to all concerns and fears. The subjective standard has to take cognizance of certain patients' wish not to receive any information about their medical problems and to avoid participation in making decisions about how to deal with them. Patient autonomy has to be respected in these cases also.

2.2. Beneficient Deception

Whatever standard of revelation is adopted the information has to be conveyed in a language understood by the patient and suited to his level of education and comprehension. Indeed some physicians test the comprehension of the patient by asking questions after the explanation has been given.

The information provided to the patient should be strictly free from fraud, coercion and biased presentation deliberately intended to get him to decide according to the wishes of the physician. This would be a denial of patient autonomy and would invalidate consent. There are, however, situations in which manipulation, modification and even withholding of information is justifiable. For example, a blunt (but true) declaration of a harsh reality like the diagnosis of an incurable metastatized cancer may cause serious emotional and mental reaction in a patient who is already suffering from a severe physical disease. This would further aggravate his distress and make him incapable of participating in medical decision-making. In such cases, modification on withholding of essential information has been considered an ethical imperative and called the therapeutic privilege.

Some patients are so sensitized mentally that revelation of possible side effects of drugs administered to them will provoke even the effects which are otherwise rare. Information to such patients whose nervous sensitivity is often known to the physician could be modified to avoid this placebo-like adverse effect.

Placebos are often used for treating certain diseases and symptoms. For example, pain

relief has been affected by a perfusion of glucose-salt solution when analgesics were not available. In these cases the patient is told that he is receiving a pain killer and begins to feel relief. In such cases it would be absurd to explain the placebo phenomenon to the patient and ask for consent to use it on him. Placebos have a wide range of therapeutic applications.

The traditional role of the physician is to console and assure the patient and not necessarily remind him always of harsh realities. It is not considered unethical for a plastic surgeon to stress the positive aspects of his work in correcting or removing blemishes which are worrying the patient whose consent is being sought.
There are many other examples of "beneficient" deceptions in medical practice but it should be pointed out that the distinction between the beneficient and true deception is not always clear and has to be judged in its context and objectives. In any case, the physician should not hesitate to tell the pure truth if he believes it is in the interest of the patient and the latter is able and willing to receive it. Also, if the patients ask direct questions they have to be answered truthfully.

Some ethicists believe that there is no difference between lying and deceiving whatever the motive and objective of the latter. They object also to the use of placebos in clinical practice and research. They may be correct philosophically, but in practice the physician has the primary duty to help the patient in any way he can. Of course, deception, however benevolent, should end as soon as the circumstances change and the patient is able to receive the true information. Similarly, the placebo should not be given (or replaced) when an effective specific treatment is (or becomes) available.

3. Exceptions to Consent

There are certain situations in which the physician can proceed with treatment or other medical intervention without asking for patient consent from mentally competent persons. In some cases; it may be possible to solicit the proxy consent of a guardian or close relative or of the patient himself later when the conditions change. Following exceptions to informed consent are well known in law and in clinical practice:

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Bibliography

Council for International Organization of Medical Sciences (CIOMS):

The following publications of the Council have articles on informed consent and related subjects by experts from different parts of the world as well as the guidelines issued by the Council and the World Medical Association:

– *Ethics and Research on Human Subjects: International Guidelines*. Proceedings of the XXVI

CIOMS Conference, Geneva, Switzerland, 5-7 February 1992, eds. Z. Bankowski and R.J. Levine, pp. 291, CIOMS Geneva, 1993

– *Ethics and Epidemiology: International Guidelines*. Proceedings of the XXV CIOMS Conference, Geneva, Switzerland, 7-9 November 1990, eds. Z. Bankowski, J.H. Bryant and J.M. Last, pp. 163, CIOM Geneva, 1991

Engelhardt Jr., H. Tristram (1996). *The Foundations of Bioethics*, Second edition. Oxford University Press, New York. [Well thought out and informative section on informed consent, especially in the clinical setting]

Faden, R. and Beauchamp, T. (1986). *A History and Theory of Informed Consent*. Oxford University Press, New York. [A good account of the history and development of informed consent with special reference to the United States.]

Fluss, S.S. (1999). *Informal Listing of Selected International Codes, Declarations, Guidelines, etc. on Medical Ethics*, pp. 27, Geneva. [A very useful and comprehensive list available from the author: Mr. S.S. Fluss, CIOMS, c/o The World Health Organization, 1211 Geneva 27, Switzerland.]

Miller, L.J. (1980). *Informed Consent: I-IV. Journal of the American Medical Association*, Vol. 244, November 7 (pp. 2100-2103), November 21 (pp.2347-2350), December 5 (pp.2556-2558) and December 12 (pp.2661-2662). [A thorough discussion of the legal aspects with examples of court cases cited from the United States where the law on patient consent is well developed.]

Wear, S. (1993). *Informed Consent: Patient Autonomy and Physician Beneficience within Clinical Medicine*, pp. 167, Kluvier Academic Publishers, Dordrecht. [A useful book for clinicians and bioethicists which discusses not only the origins, development and legal aspects, but proposes a practical model which would be helpful to the clinician in dealing with the varying situations to get patient consent.]

Biographical Sketch

M. Abdussalam - Born in Kasur, Pakistan (1913) and received early and professional education in Panjab University. Postgraduate research training in India and in the University of Cambridge in England, obtaining a Doctorate from the latter University. Post-doctoral work in the United States.

Worked as Professor and Research Officer in Pakistan. Later held leading professional positions in the World Health Organization and in the Federal German Health Office.

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