INFORMED CONSENT AND MEDICAL NEGLIGENCE

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1. INTRODUCTION

Medical ethics internationally is governed by the principle of autonomy, which recognizes the rights of individuals to self-determination. Autonomy is rooted in society's respect for individuals' ability to make informed decisions about personal matters. It is an important social value which has shifted to define medical quality in terms of outcomes that are important to the patient rather than medical professionals. The respect for autonomy is the basis for informed consent and advance directives. The Patients are capable of electing to make their own medical decisions, or can delegate decision-making authority to another party. Only if the patient is incapacitated, laws around the world designate different processes for obtaining informed consent, typically by having a person appointed by the patient or their next of kin make decisions for them. Thus the value of informed consent is closely related to the values of autonomy and truth telling. Failure to take informed consent amounts to medical negligence and the concerned doctor is held liable for damages.

2. KINDS OF CONSENT

There are various types of consent like Implied, Informed, Explicit, Active, Passive, Written and Oral. For our relevance, we have studied Implied and Informed Consent.

a. Implied consent

Consent in the context of a doctor-patient relationship, means the grant of permission by the patient for an act to be carried out by the doctor, such as a diagnostic, surgical or therapeutic procedure. Consent can be implied in some circumstances from the Action of the patient. For example, when a patient enters a Dentist's clinic and sits in the Dental chair, his consent is implied for examination, diagnosis and consultation. Except where consent can be clearly and obviously implied, there should be express consent. There is, however, a significant difference in the nature of express consent of the patient, known as 'real consent' in UK and as 'informed consent' in America. In UK, the elements of consent are defined with reference to the patient and a consent is considered to be valid and 'real' when (i) the patient gives it voluntarily without any coercion; (ii) the patient has the capacity and competence to give consent; and (iii) the patient has the minimum of adequate level of information about the nature of the procedure to which he is consenting to. On the other hand, the concept of 'informed consent' developed by American courts, while retaining the basic requirements consent, shifts the emphasis to the doctor's duty to disclose the necessary information to the patient to secure his consent.

b. Informed Consent

'Informed consent' is defined in Taber's Cyclopedia Medical Dictionary as: "Consent that is given by a person after receipt of the following information: the nature and purpose of the proposed procedure or treatment; the expected outcome and the likelihood of success; the risks; the alternatives to the procedure and supporting information regarding those alternatives; and the effect of no treatment or procedure, including the effect on the..."
prognosis and the material risks associated with no treatment. Also included are instructions concerning what should be done if the procedure turns out to be harmful or unsuccessful."

If a patient is to undergo a surgical procedure, it is necessary for the patient to receive information from the medical team about the benefits and the risks of the procedure prior to the procedure being carried out. After having heard the possible risks and benefits, if the patient deems that they wish to go ahead with the surgical procedure, they must sign a consent form signifying that they have understood and accept the potential risks. This is what is known as informed consent.

As part of the informed consent process, the medical professional/s must clearly explain the possible risks or side effects that could be caused by the medical procedure. This should include associated problems that can sometimes occur as well as less common risks that can potentially have serious effects. By giving your informed consent prior to the surgery, you are effectively acknowledging that some ill effects can occur even if the surgical procedure has been conducted in a textbook fashion. However, even though your informed consent dictates that you are aware that certain complications can occur, it does not mean that this covers negligent technique or mistakes during the surgery. Furthermore, if you have not been fully briefed about the possible ill effects of going ahead with the procedure prior to the surgery and therefore have not been able to give your fully informed consent, there could be a case for a medical negligence claim.

3. INTERNATIONAL PERSPECTIVE ON INFORMED CONSENT

- The shocking details of the post Second World War (1939-45) trial of German medical practitioners accused of conducting experiments on human participants without their consent and exposing them to grave risk of death or permanent impairment of their faculties raised grave concern about subjecting human subjects to medical research. Thus, the first International Statement on the ethics of medical research using human subjects namely, the Nuremberg Code was formulated in 1947. Although informed consent for participation in research was recorded in 1900, the Nuremberg Code highlighted the essentiality of voluntariness of this consent.
- In 1948, Universal Declaration of Human Rights (adopted by the General Assembly of the United Nations) expressed concern about rights of human beings being subjected to involuntary maltreatment.
- In 1966, the International Covenant on Civil and Political Rights specifically stated, ‘No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his consent to medical or scientific treatment.’
- Based on the preliminary efforts of the Council for International Organisations of Medical Sciences (CIOMS) in 1964 at Helsinki, the World Medical Association formulated general principles and specific guidelines on use of human subjects in medical research, known as the Helsinki Declaration, which was revised from time to time.
- In February 1980, the Indian Council of Medical Research released a „Policy Statement on Ethical Considerations involved in Research on Human Subjects” for the benefit of all those involved in clinical research in India.
- In 1982, the World Health Organisation (WHO) and the CIOMS issued the „Proposed International Guidelines for Biomedical Research involving Human Subjects.”
- Subsequently the CIOMS brought out the „International Guidelines for Ethical Review in Epidemiological studies” in 1991 and „International Ethical Guidelines for Biomedical Research involving Human Subjects” in 1993.
• Over the years, various bioethics advisory bodies in national jurisdictions like Nuffield Council of Bioethics and European Commission on Ethics have also laid down general and specific principles in specific areas of scientific research involving human beings as subjects in medical research. These ‘national’ Codes drawn from the international codes and the universal principles therein provide the ‘guidelines’ that should be followed in their respective jurisdictions.
• Meanwhile the international studies conducted in developing countries sponsored or funded by developed countries highlighted the global health divide and the ethical issues related to the 10/90 gap. National Bioethics Advisory Bodies and Funding organizations of developed nations took note of this and to rectify the situation revised guidelines which had relevance to developing countries as evident from Report of National Bioethics Advisory Committee, USA, by 2000 and Guidelines by Nuffield Council of Bioethics, UK and CIOMS, Geneva by 2002. The Helsinki Declaration underwent changes five times, the last one being in 2004.
• Still the controversy about use of placebo and post-trial access as described in it is being debated. The most recent documents on ethics are those of UNESCO’s “The Universal Declaration on Human Genome and Human Rights” (1997), “The International Declaration on Human Gene Data” (2003) and “Universal Declaration on Bioethics and Human Rights” (2005).
• Nuremberg Code: The Nuremberg Code (‘the Code’) was developed by the American judges who adjudicated the Nuremberg Trial. It involved the convergence of Hippocratic ethics and the protection of human rights into a single code. The ten principles articulated were constructed with the research subject's welfare as the focal point. This implied a change in perception with regard to the status of the research subject. While the Hippocratic ethics viewed the subject as "passive and dutiful" and assumed that the physician knows best, they nevertheless imposed ethical obligations on the physician to prioritize the welfare of the subject. The Code recognized the autonomy of an individual, at the core of which is the codification of consent. In according positive rights to the subjects, it destabilized the notion of passivity. In the Code, the principle reflecting the recognition of individual autonomy is that of voluntary consent. In order to effectuate individual autonomy, Principle 1 of the Code provides that consent is a non-negotiable precedent to an individual's participation in a clinical trial. The implications of the same are threefold. Firstly, a participant should have the legal capacity to give consent. Secondly, such consent should be voluntary and free, and not a by-product of force, coercion, fraud, deceit, duress, etc. Thirdly, such consent should be an exercise of informed choice, involving "sufficient knowledge and comprehension about the subject-matter". The individual conducting the experiment ought to discern the quality of the consent. The remainder of the provisions deal with facets of clinical trial, the design of the experiment, expected outcomes and risk mitigation, prohibiting an experiment wherever a strong likelihood of disability or death exists, adequacy of preparation, facilities, the quality of risk control equipment and the obligation of the researcher to terminate the experiment if required. The Code has not acquired the status of binding international law but it has nevertheless been instrumental in shaping medical ethics and serves as a model law.

4. LEGAL PROVISIONS IN RESPECT TO INFORMED CONSENT

a. Treatment- Code of ethics 2002: Chapter 7 - Misconduct: The following acts of commission or omission on the part of a physician shall constitute professional misconduct rendering him/her liable for disciplinary action:
7.16: Before performing an operation the physician should obtain in writing the consent from the husband or wife, parent or guardian in the case of minor, or the patient himself as the case may be. In an operation which may result in sterility the consent of both husband and wife is needed.

7.17: A registered medical practitioner shall not publish photographs or case reports of his / her patients without their permission, in any medical or other journal in a manner by which their identity could be made out. If the identity is not to be disclosed, the consent is not needed.

7.21: No act of invitro fertilization or artificial insemination shall be undertaken without the informed consent of the female patient and her spouse as well as the donor. Such consent shall be obtained in writing only after the patient is provided, at her own level of comprehension, with sufficient information about the purpose, methods, risks, inconveniences, disappointments of the procedure and possible risks and hazards.

b. The code of medical ethics laid down by the Medical Council of India (approved by the Central Government u/s. 33 of Indian Medical Council Act, 1956) contains a chapter relating to disciplinary action which enumerates a list of responsibilities, violation of which will be professional misconduct. Cl. 13 of the said chapter places the following responsibility on a doctor:

"13. Before performing an operation the physician should obtain in writing the consent from the husband or wife, parent or guardian in the case of a minor, or the patient himself as the case may be. In an operation which may result in sterility the consent of both husband and wife is needed."

c. Guidelines to doctors, issued by the General Medical Council of U.K. in seeking consent of the patient for investigation and treatment:

"Patients have a right to information about their condition and the treatment options available to them. The amount of information you give each patient will vary, according to factors such as the nature of the condition, the complexity of the treatment, the risks associated with the treatment or procedure, and the patient's own wishes. For example, patients may need more information to make an informed decision about the procedure which carries a high risk of failure or adverse side effects; or about an investigation for a condition which, if present, could have serious implications for the patient's employment, social or personal life.

You should raise with patients the possibility of additional problems coming to light during a procedure when the patient is unconscious or otherwise unable to make a decision. You should seek consent to treat any problems which you think may arise and ascertain whether there are any procedures to which the patient would object, or prefer to give further thought before you proceed."

5. JUDICIAL TRENDS - IF INFORMED CONSENT NOT TAKEN


"It is well established that the physician must seek and secure his patient's consent before commencing an operation or other course of treatment. It is also clear that the consent, to be efficacious, must be free from imposition upon the patient. It is the settled rule that therapy not authorized by the patient may amount to a tort - a common law battery - by the physician. And it is evident that it is normally impossible to obtain a consent worthy of the name unless the physician first elucidates the options and the perils for the patient's
edification. Thus the physician has long borne a duty, on pain of liability for unauthorized treatment, to make adequate disclosure to the patient."

b. The basic principle in regard to patient's consent may be traced to the following classic statement by Justice Cardozo in *Schoendorff vs. Society of New York Hospital* - (1914) 211 NY 125

"Every human being of adult years and sound mind has a right to determine what should be done with his body; and a surgeon who performs the operation without his patient's consent, commits an assault for which he is liable in damages."

c. This principle has been accepted by English court also. in Re : F. 1989(2) All ER 545 : [1990] 2 A.C. 1 : [1989] 2 W.L.R. 1025, the House of Lords while dealing with a case of sterilization of a mental patient reiterated the fundamental principle that every person's body is inviolate and performance of a medical operation on a person without his or her consent is unlawful. The English law on this aspect is summarised thus in Principles of Medical Law:

"Any intentional touching of a person is unlawful and amounts to the tort of battery unless it is justified by consent or other lawful authority. In medical law, this means that a doctor may only carry out a medical treatment or procedure which involves contact with a patient if there exists a valid consent by the patient (or another person authorized by law to consent on his behalf) or if the touching is permitted notwithstanding the absence of consent."

d. Whether in an action for negligence/battery for performance of an unauthorized surgical procedure, the Doctor can put forth as defense the consent given for a particular operative procedure, as consent for any additional or further operative procedures performed in the interests of the patient. In *Murray vs. McMurchy* - 1949 (2) DLR 442, the Supreme Court of BC, Canada, was considering a claim for battery by a patient who underwent a caesarian section. During the course of caesarian section, the doctor found fibroid tumors in the patient's uterus. Being of the view that such tumors would be a danger in case of future pregnancy, he performed a sterilization operation. The court upheld the claim for damages for battery. It held that sterilization could not be justified under the principle of necessity, as there was no immediate threat or danger to the patient's health or life and it would not have been unreasonable to postpone the operation to secure the patient's consent. The fact that the doctor found it convenient to perform the sterilization operation without consent as the patient was already under general anaesthetic, was held to be not a valid defense.

e. A somewhat similar view was expressed by Courts of Appeal in England in Re: F. (supra). It was held that the additional or further treatment which can be given (outside the consented procedure) should be confined to only such treatment as is necessary to meet the emergency, and as such needs to be carried out at once and before the patient is likely to be in a position to make a decision for himself. Lord Goff observed:

"Where, for example, a surgeon performs an operation without his consent on a patient temporarily rendered unconscious in an accident, he should do no more than is reasonably required, in the best interests of the patient, before he recovers consciousness. I can see no practical difficulty arising from this requirement, which derives from the fact that the patient is expected before long to regain consciousness and can then be consulted about longer term measures."

f. The decision in *Marshell vs. Curry* - 1933 (3) DLR 260 decided by the Supreme Court of NS, Canada, illustrates the exception to the rule, that an unauthorized procedure may be justified if the patient's medical condition brooks no delay and warrants immediate action without waiting for the patient to regain consciousness and take a decision for himself. In that case the doctor discovered a grossly diseased testicle while performing a hernia operation. As the doctor considered it to be gangrenous, posing a threat to patient's life and
health, the doctor removed it without consent, as a part of the hernia operation. An action for battery was brought on the ground that the consent was for a hernia operation and removal of testicle was not consent. The claim was dismissed.

The court was of the view that the doctor can act without the consent of the patient where it is necessary to save the life or preserve the health of the patient. Thus, the principle of necessity by which the doctor is permitted to perform further or additional procedure (unauthorized) is restricted to cases where the patient is temporarily incompetent (being unconscious), to permit the procedure delaying of which would be unreasonable because of the imminent danger to the life or health of the patient.

6. CONCLUSION

Most physicians feel they are safe if they ultimately practice good medicine. Performing procedures correctly and prescribing the correct medicine, however, are not a defense in an informed consent malpractice claim. For this reason, informed consent should be taken seriously and viewed as a process that covers disclosure of all relevant surgical risks, as well as the physician’s financial interests, research risks, and potential collaborators. Preferably, informed consent should be obtained some time prior to the procedure, so that the patient does not feel rushed or pressured to sign. In the end, respecting a patient’s autonomy is the best defense against potential informed consent, remembering that part of good medicine is good communication.