

INFORMED CONSENT: PROTECTING PATIENTS OR SALVAGING PHYSICIANS

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Abstract: History of tradition of following ethical code in medical practice is very ancient and it could be traced as back as 3500 year old document of Ebers Papyrus (Berdon 2000). Later Greek and Egyptian teachings also emphasized upon ethical practices in medicine. But the concept of formally taking *consent* (and *informed consent*) with emphasis on patients' rights and his/her autonomy emerged in early 20th century when some law suits were filed in courts, particularly in USA. Later the well known infamous atrocities carried out by Nazi doctors on prisoners during Second World War and consequent verdict by Nuremberg tribunal and milestone declaration of Nuremberg made a land mark in the history of medical ethics and provided a ground on which the doctrine of '*Informed Consent*' is built.

This paper discusses and analyzes various ethical issues related to informed consent. How the obligation of taking informed consent was established in the clinical practice and biomedical research. Discusses whether informed consent is a moral obligation or legal necessity with reference to various historical cases and presentation of views by some authors. This paper also analyzes famous legal litigations that helped to provide foundations for the patients' rights and autonomy in clinical, such as cases of Shoendorff v. New York Hospital of 1914; Prince v. Massachusetts litigation of 1944; Canterbury v. Spence lawsuit of 1972; Large v. Superior court of Arizona legal case of 1986 and Younts v. Francis Hospital suit of 1986. A discussion is also made regarding five universally accepted components of informed concept (disclosure to the patient/research subject, comprehension by the patient, his/her competency, voluntariness and willingness), which are variously and sometimes conflictingly interpreted in different contexts and situations. Situations are highlighted where these problems create ethical dilemmas and legal conflicts in clinical and research environment and a reference is made to ongoing discussion whether informed consent has been primarily devised for protection of the patients or it is a tool to rescue physicians when they are brought to courts to face law suits.

Keywords: Informed consent, Autonomy, Ethical principles

Introduction: This article highlights and analyzes various ethical issues relating to one of the fundamental element of contemporary bioethics i.e. principle of *informed consent*. Beginning with the historical background of this principle, a discussion will be made about reasons that prompted the practice of obtaining informed consent; arguments will be analyzed if informed consent is a moral obligation or legal necessity. And a discussion about various issues related to descriptive ambiguity of five universally accepted components of informed consent will be made which are differently interpreted in changing contexts and situations.

History: Concept of bioethics can be traced as back as 4000 BC but the oldest documentary evidence of code of medical ethics is found in 3500 years old Ebers papyrus (Berdon 2000). Earliest code of medical ethics that was enunciated during the period of Hammurabi (Encyclopedia medicine, history), Oath of Hippocrates and all other ancient as well as modern teachings stress upon the end of human sufferings in a disinterested manner, irrespective of remuneration, status and personal reputation. These early teachings reflect the honesty of physicians and advocate the paternalistic attitude of physicians in a *noblesse oblige* manner. But in the ancient code of medical practice no mention of consent (or informed consent) was made including that of Greek period and the Egyptian civilization (Kour and Rauff 1992), strongly leading to the presumption that patients were submissive to physicians' authority. A little more than two centuries ago with US revolution (US declaration of Independence) there was emphasis on Human rights (and consequently those of patients'). Later, the concept of informed consent emerged during post-Second World War era when the war tribunals discovered indiscriminate use of human subjects in brutal experimentation and stressed upon rights of human subjects in biomedical research.

The idea of written *consent* (not the *informed consent*) roots in the famous case of Schoendorff v. Society of New York hospital, 211 N.Y 215, 105 N.E. 92, 1914 (Murray, 1999 and Lombardo 2005), which made the basis of necessity of consent in clinical practice, wherein Justice Benjamin Cordozo, stressed heavily on the participation of patient in the decision making process and made the verdict: "*every human being of adult years in sound mind has the right to determine what shall be done with his own body; and the surgeon who performs operation without his patients' consent commits a battery for which he is liable in damages*"

The imbalance of power between physician and patient in clinical situations or between researcher and research participant is multiplied by circumstances when patient or research subject belong more vulnerable group of population who are deprived of basic rights (Zion, Gillam & Loff 2000). This happened in World War II when

extreme cruelties were made on the prisoners of war in the name of medical research. This made the beginning of the end of long-practiced trust of patients in the physicians and weakened the till-respected principle of paternalism. Nuremberg tribunal not only convicted the Nazi physicians but to avoid such brutalities in future set a code of ethics for medical research in the form of Nuremberg Code. Similar type of codes and declarations (Helsinki declarations, Belmont Report) stressed upon the need of voluntary participation of human subjects in experiments besides setting other codes of conduct. These steps provided basis for necessity of informed consent in biomedical research and formed fundamental milestones for this moral necessity.

With this, the notion of *consent* was changed to doctrine of *informed consent* promoting the need to fully inform the patient about the treatment procedure (such as surgery), explain available treatment alternatives and probable risks and benefits without implicit or explicit coercion. In contrast to *informed consent*, some of the authors mention *Valid consent* (Singh 2008), wherein the burden of explaining the details of procedure does not lie on the physician. But most of the literature uses the term *informed consent* wherein by letter and spirit physician carries the onus of explanations to the patient.

Informed consent, moral or legal requirement: Though the roots of informed consent are based in legal happenings such as Nuremberg code but still there is debate whether it is *legal* necessity to be fulfilled by the physicians or of *moral* obligation to be discharge by health care professionals. Most of authors are in favor of its moral side but recent publications of Indian journals heavily support the idea that it is primarily a legal document (Singh 2008 and Bastia 2008). Besides this difference of opinion, both of these authors argue that the informed consent is a document and a tool to rescue physicians in situations where they are entangled in court litigations. Their position is strongly contended by Farhat Moazam (2008), arguing that neither it is one-step and get-signed document nor it solely carries the legal importance. But it is an on-going process between patient and physician and has more moral value than the legal importance.

There is almost universal consensus to ensure the fulfillment of five elements of informed consent (disclosure, competency, comprehension, voluntariness and decision-making) amongst the medical and legal fraternity. Here is analysis of few issues that would help us to dis-entangle the dilemma arising from practical application of informed consent and its ramifications in various contexts (geographic locations, cultures and religions).

Extent of disclosure: Not infrequently it remains unclear how much information is to be disclosed to the patients by a physician to comply with requirements of *moral* informed consent. Frequently it is considered unnecessary by the physician to disclose remote possibilities and least probabilities to the patient and these are usually preferred to be ignored. Reference to an important case (Canterbury v. Spence case 1972) is worth mentioning here as this indicates how much burden lies on the physician with regard to disclosure of information. Canterbury a minor child suffered from backache that was diagnosed by Dr Spencer (the neurosurgeon) as having ruptured disc of vertebral column and recommended surgery (laminectomy). He gave brief description of the surgical procedure to child's mother but did not mention that paralysis was known complication of this type of surgery (whose probability was 1% as testified by Dr Spencer later during proceedings). Though the surgery was uneventful but sometime after operation, the patient fell, lost bowel functions and developed paraplegia. In this case, court held Dr Spencer guilty of not obtaining complete informed consent. According to the court: "*1% chance of such a grave consequences as paralysis was reasonable to disclose, and a hypothetical reasonable patient would likely consider that information as significant while making his decision of whether or not to consent to the operation*".

This is the case of a time (year 1972) when bioethics and tradition of taking informed consent was in early years of its practice. Today when medical science and biomedical technology has shown tremendous development, the complications of treatment and resultant responsibilities of taking full informed consent pose great responsibility on the shoulders of physician. According to this case there are two exceptions to full disclosure of information by the physician. One, when the patient is unconscious and potential harm resulting from failure of the treatment is more than potential harm from initiating the treatment. Secondly, when the patient is so emotionally unstable that full disclosure would prevent the patient from making a rational decision as to his/her treatment (Canterbury v. Spence case, High Court Summaries).

Patient's competency in clinical settings and other legal environments: Standards of giving legal consent differ from that of discharging informed consent for medical purposes. In this regard a case is mentioned here i.e. Large v. Superior Court of Arizona, 714 P.2d 399, 1986 (Murray 1990). A woman with Organic brain syndrome with resultant poor brain function was admitted to a hospital with hip fracture. The attending physician before undertaking surgery obtained informed consent after explaining expected outcome of the surgical procedures and probable risks. Simultaneously she also executed will in the presence of a lawyer about her properties. After the surgery the patient died and the court reviewed her consent for surgical procedure and the executed will. The court found that her will was invalid due to the reason that she lacked testamentary

competence, while surgical consent was considered valid because the patient was able to understand the surgical procedure and the associated risks and benefits.

Evaluation of comprehension: To assess whether the patient is able to understand the details explained to him/her for the intended medical procedure as part of informed consent, besides sound mental health the age is one of the important factor. A mature minor (say about 15 years age), though younger than the legal adult age (say 18 years, though varies in different countries) creates legal complexity regarding his/her capacity to give informed consent and this becomes more problematic when the parents or guardians are not available. I would like to present here a case in this regard. A 17 year old girl was visiting hospital to see her unconscious mother who had undergone major surgery. During her visit the girl got her finger injured in the hinge while closing the door of her car. The injured girl was taken to the emergency room and operated upon after obtaining her consent (Hartman 1999). Though the procedure was successful but later her mother objected upon the surgery and brought suit in the court on the grounds that the obtained consent was not valid as the girl had not attended the legal age. She further contented that had she been consulted for the consent she would not have given the same, instead she would have sought the opinion of family physician. The court remarked that as the patient was 17 years old (the legal adult age being 18 years) and had apparent ability to understand the complexities of the situation, the patient was reasonably able to comprehend the nature and consequences of procedure and was mature enough to “knowingly consent to the beneficial surgical procedure made necessary for accident”. Here is an important point to be noted, i.e. court remarked that the situation was not life-threatening emergency but the consent was valid under *mature minor* exception.

Voluntariness: As is apparent, any consent given under force or coercion is not valid. But not infrequently the compelling force is not apparently visible. In Washington DC a lady patient was advised that if she did not undergo procedure of tubal ligation (sterilization) she would suffer her welfare benefits. The District Court of Washington considered it as duress and deemed any consent given under these circumstances for tubal ligation as invalid and not a voluntary one (Murray 1990).

Authority of decision making: Supreme authority and importance of autonomy of patient regarding his/her own body is exemplified by judgment of Natanson v. Kline case (Murray PM, 1990), where the judge declared: “A man is master of his own body and he may expressly prohibit the performance life-saving surgery or other treatment”. This is a situation when patient’s decision is against one of the basic principle of bioethics i.e. non-maleficence. Physicians find themselves in real ethical dilemma in situations like this. In fact the principle that patients has authority on his own body is based on the doctrine that a person has right to choose about his person or body, whether he has chosen correctly or incorrectly (Englehardt 1986) i.e. his decision might be incorrect in physician’s view.

Informed consent in special situations: Proxy consent given on behalf of children has some limitations. This particularly applies on parental authority to refuse to consent in clinical settings where because of certain beliefs the parents refuse to certain treatments and thus their children are put into danger. Examples are refusal of Jehovah’s Witness refusing blood transfusion and Fundamentalist Christians in southern West Virginia requiring children to handle snakes during worship services and refusing them medical attention when bitten. In this regard a judgment was declared by Supreme Court of USA in 1944 in case Prince vs. Massachusetts, 321 US 158, 1944 (Prince vs. Massachusetts case, 1944) and said: “Parents may be free to become martyrs themselves, but it does not follow that they are free, in identical circumstances, to make martyrs of their children before they have reached the age of full and legal discretion when they can make that choice for themselves”

Conclusion:

It should be appreciated that the principle of informed consent has legal foundations but it is the reflections of both the moral obligation and legal necessity. Informed consent obtained in clinical practice has more legal worth as has been discussed above in various court suits. While the consent in perspective of biomedical research has roots in moral and ethical codes (Carmen & Joffe 2005). Through the informed consent, both in clinical and research environment patients’ autonomy is respected and he/she is given full right and provided options to proceed with, but it has some inherent limitations i.e. available choices in particular situation may not be the all possible choices offered in other contexts. Also socio-cultural differences may not allow any patient to exercise his/her autonomy particularly in Asian and African countries where extended families give this right to the family head or women may not be fully empowered to deliver their consent without spouse’s will. Lastly by virtue of the codes and oaths of the medical practice physicians are the trustees of the patients’ *possessions* including the informed consent, therefore it should not be devised or constructed with an intention to rescue physicians when they are brought to court litigations. Rather its primary spirit of practice is to respect patients’ autonomy thus it is the instrument to protect their rights.

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