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A relook at the Informed Consent

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Informed Consent is the corner stone of patient Autonomy. It is a vital part of contemporary medical practice. The purpose of IC is primarily to protect the rights of patients and a guide to ethical practice in medicine. It is a document of mutual agreement or contract with ethical and legal binding. In the Indian context, physicians have had a paternalistic attitude towards their patients. Thus IC was practically nonexistent till the Consumer Protection Act was made applicable to the medical profession. With the increasing awareness among patients, it's imperative that the physicians need to be well informed about the current guidelines.

History of Informed Consent: It was in the nineteenth century that the physicians began testing new treatments and technologies, which gave rise to new challenges to ethical medical practice. Thus medical ethics in its modern form as we know today started taking shape in the aftermath of reports of medical and experimental atrocities committed by the German Nazi regime during World War II. In this background the Nuremberg Code was adopted in 1947, following the Nuremberg trial [1]. *The code made it mandatory to obtain voluntary and informed consent of human subjects* [2].

The Nuremberg Code, however, had no binding or legal authority. Thus the practice and implementation of the Code was variable among physicians in different parts of the world. A typical case in point is the "Tuskegee Study of Untreated Syphilis in the Negro Male" initiated by the Public Health Service, USA in 1932. By 1947 the Nuremberg Code was adapted, but the shadowy study continued for forty long years, until 1972, when there was a public outcry and the study was abandoned and repatriation began [3].

In the ensuing years several loopholes, which jeopardized the safety of the patients were noted. Thus the Declaration of Helsinki was adopted by the 18th World Medical Association in 1964. The Declaration of Helsinki included guidelines pertaining to Clinical and Non-Clinical Research. It emphasized the importance of obtaining *"freely given (voluntarily) informed consent after giving full explanation"*. The concept of legal guardian when the patient is incapable of giving consent also found mention [4-5].

Since 1964, the declaration of Helsinki has undergone eight revisions, which widened the ambit of Informed consent from being a mere formality to being the essential, undisputed legal and ethical prerequisite for the most minimal to major diagnostic and therapeutic decision making. It made the physicians responsible under the ethical, civil and criminal laws of their own countries [6]. The Indian medical professional is bound by the guidelines laid down by The Medical Council of India (Professional conduct, Etiquette and Ethics) Regulations, 2002 [7]. But the Indian medical professional like all the fellow countrymen is also bound by all the civil and criminal laws of the land. The Indian contract Act 1872 and The Consumer Protection Act 1986 are notable among them.

Essential elements of Informed Consent [8-11]:

A mere signature of the patient to a standardized consent form does not make it a valid Informed consent. The IC is said to be valid by the law only if it incorporates all the essential elements.

1. IC should be taken for a *specific course of action* like particular diagnostic or therapeutic procedure/ treatment protocol/ surgery/ anesthesia/ blood transfusion or admission to ICU and so on. *Blanket consent is invalid.*
2. For complex surgeries consents for the surgery, risk of anesthesia, blood transfusion and any prosthetics to be used must be taken separately or care should be taken to incorporate them explicitly in a common consent form.
3. IC should always be sought and taken from the patient himself, when the patient is an adult aged above 18yrs, of sound mind, is capable and competent to understand the nuances of the procedure and not barred by the law.
4. The IC is to be signed by both the parties the patient and the attending physician/ surgeon/ anesthetist. A witness signature will further strengthen the legal validity of the IC. It would be a good practice to make the spouse/ parent as witness to IC.
5. The basic concept of consent is based on sharing adequate information by the doctor and optimum understanding by the patient. The unbiased information should help them take a balanced decision. The physician or his team should disclose information regarding patient condition, prognosis, treatment benefits, adverse effects, available alternatives, in simple language without medical jargon and in the language that patient understands. Questions and queries from patients must be encouraged and responded adequately.
6. In sterilization procedures and conditions where the therapy/ surgery may affect the reproductive capacity of the patient, the consent of both husband and wife is essential.
7. The consent of a minor is called Assent and should be taken if child is above 10yrs along with parental consent.
8. The IC should be of free will and voluntary.
9. IC for unethical/ illegal therapy or surgery is null and void and does not give any protection to the physician.
10. IC should be taken before the said procedure and consent taken during the procedure is invalid unless the procedure is done to overcome life threatening complications.
11. The IC must be documented in writing. If additional documentation is done by audio or video, the patient should be informed about it. Video documentation is very helpful in cases of sharing of information and counseling related to patients in NICU, ICU, etc and when patient is incompetent to give consent, and consent is sought from parent or guardian.
12. In life threatening situations, non availability of consent is not a valid reason to withheld emergency care. Failure to do so maybe alleged to amount to negligence.

Over the past seven decades, the process of informed consent has become increasingly regulated and standardized, while the challenges are increasing and hard to overcome. Consent forms are increasingly long and complicated, obscuring important details. Data shows that participants often have a limited understanding of study information even when they have signed a consent form [12]. Several complaints of alleged malpractice, negligence, battery or assault are actually cases of invalid or incomplete consent.

Methods for improvement in obtaining Informed Consent [13-14]:

1. Acceptance of the fact that "One form fits all" does not work for Informed consent. IC has to be tailored to meet the particular medical condition, appropriate to the medical setting (primary, secondary or tertiary level), and suitably adjusted to the level of patient understanding.
2. Paternalistic attitude of doctors is particularly prevalent in India and more so in smaller cities catering to semiliterate populations. But with changing times, it is advisable to move towards a more patient centric, shared decision making. The patients should be involved in every aspect of diagnosis, treatment and care and not just be informed about the risks.
3. Check and strive for patient comprehension and understanding. Printed patient information material in local language and pictorial depictions

maybe provided and also attached to the consent form.

4. Educate, familiarize and retrain the personnel involved in obtaining the IC emphasizing the need to be sensitive and tolerant towards the patient while understanding the legal and ethical importance of the same.
5. Set goals of care jointly with the patients for complex conditions like management of longstanding diabetic, multiple trauma due to road traffic accidents, management of breast cancer, etc,. This will avoid any misunderstanding later about the outcome.
6. Documentation of IC may need more than one means. Documentation maybe hand written, videotaped or/and witnessed by a third person.

Conclusion: Informed Consent has evolved and refined in the past 70 years since the Nuremberg code to become an important ethical and legal document to protect the rights of the patients and guide ethical medical practice. IC is variably practiced and it is practically difficult to attain the ideal standards laid down theoretically. The process of IC is an occasion to build trust. In the current perspective IC is a continuous process of shared decision making between the physician and the patient. Adherence to all the principles of IC would be a win-win situation to both; as it reduces risk to the physician and provides patient Autonomy in the real sense. Hence constant efforts are essential to achieve the goals of Informed consent.

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