INFORMED CONSENT: LAW OR ETHICS

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Abstract:

Informed consent or the learned acquiescence is an important and underlying principle of bio-ethics. The specific character of the informed consent as it is in the present form has been due to it assuming a dominant and important character in the otherwise translational relationship between the patient and the doctor during the course of twentieth century. The earlier distinctive spirit of medicine as founded on the trust in physician's decision based upon the fact that "doctor knows best" has seen a steady decline resulting in a trust deficit and here upon, developing the doctrine of 'informed consent' wherein, the patient has been put in charge of his own care through the propagation and advancement of his own will and right to self determination as advocated in Article 21 of the Constitution. The current study is based upon critical analysis and doctrinal method.

Index Terms: **Informed consent, Doctrine, Constitution, Right.**

Introduction

Informed consent is an imperative record while playing out all careful and tasteful methodology, especially in the present day clinical practice. Legitimate documentation and advising of patients is vital in any interaction with the doctor and an educated assent obtained after dissemination of all the required essentials is the most important and vital form of a clinical practice.

The Basis of Informed Consent

Medicinal practice today isn't basic in view of different elements impinging on the specialist-patient relationship. Common trust frames the establishment for good connection amongst specialist and patient. Today, patients have a tendency to be educated thoroughly about their ailment regarding the onset, the clinical historical perspective of the pathology, the various modalities of diagnostic procedure, the therapeutics being involved and the consequent wellbeing emanating out of the said endeavour.

With the hype created in the print and visual media regarding ‘beauty’, ‘shape, size and appearance of body parts’, ‘quality and quantity of hair’, etc., patients tend to come to dermatologists with unreasonable demands and unrealistic expectations. Therefore, providing adequate information and educating the patient about realities become very important. The concept of consent arises from the ethical principle of patient autonomy and basic human rights. Patient should have all the flexibilities of various opinions offered to

him/her regarding the diagnosis and treatment of the disease for which the consultation is sought and is at a liberty to choose what ought to or what ought not to occur to his/her body and to accumulate data before experiencing a test/technique/medical procedure.

The Legal and Clinical Right of the Patient

No one else has the right to coerce the patient to act in a particular way. Even a doctor can only act as a facilitator in patient's decision making and obtaining informed consent before subjecting a patient to any test/procedure/surgery is very essential. There is also a legal angle to this concept. No one has the right to even touch, let alone treat another person. Any such performance, managed without authorization, is delegated "battery" - physical attack and is culpable under the law. Henceforth, getting assent is an unquestionable requirement for something besides a routine physical examination.

Consent Defined: From Past to Present

The very act of a patient entering a doctor's chamber and expressing his problem is taken as an implied (or implicit) consent for general physical examination and routine investigations. But, intimate examination, especially in a female, invasive tests and risky procedures require specific expressed consent. Expressed (explicit) consent can be oral or written. Informed consent in the written form are ideal in circumstances including future follow ups, intercessions in cases of high risk diseases and corrective methodology and medical procedures.

It is also needed for skin biopsy, psoralen with ultraviolet therapy, intralesional injection, immunosuppressive therapy, electrocautery etc.

Consent is necessary for photographing a patient for scientific/educational/research purpose or for follow up. Specific consent must be taken if the identity of the patient is likely to be revealed while publishing.

Consent is a must for participation in clinical trials and research projects.

Legal Basis of Informed Consent

Educated assent of the patient by exposure to adequate data regarding the disease, its progression, the treatment (required/provided) is a pre-requisite before obtaining the informed consent in the written form. Assent can be tested on the ground that satisfactory data has not been sufficiently revealed to empower the patient to take an appropriate and proficient choice. Consequently, exact, sufficient and pertinent data must be given honestly in a frame (utilizing non-logical terms) and dialect that the patient can get it. It can't be a patient's mark on a dabbed line acquired routinely by a staff part. The data disclosed ought to include:

- The condition/issue/illness that the patient is having/experiencing

- Necessity for additionally testing
- Natural course of the condition and possible complications
- Consequences of non-treatment
- Treatment options available
- Potential risks and benefits of treatment options
- Duration and approximate cost of treatment
- Expected outcome
- Follow-up required

Patient should be given opportunity to ask questions and clarify all doubts. There must not be any kind of coercion. Assent must be wilful and patient ought to have the opportunity to repudiate the assent. Assent given under duress or excessive pressure, misguided judgment or deception of certainties can be held invalid.

Patient should be competent to give consent; must be an adult and of sound mind. In case of children, consent must be obtained from a parent. In case of incapacitated persons, close family members or legal guardians can give consent. Adequate information should be provided to a prudent patient during informed consent.

Consent: Based Upon the Prudent Man Doctrine

Prudent patient means a reasonable or average patient. To decide whether adequate information has been given, courts rely on this “Prudent Patient Test”. It is not easy to answer the question, How much information is “adequate”? A netizen may expect and demand detailed information. On the other hand, an illiterate may say that “I do not understand anything, doctor, you decide what is best for me!” If a patient knowingly prefers not to get full information that attitude also needs to be respected as a part of patient's right to autonomy.

Maintaining the Individualism of the Patient

Patients' perception of risk of a medical intervention is also highly individualistic, variable and unpredictable. The information provided to a patient should include all material risks. But, the list of risks and side effects cannot be exhaustive to the level of absurdity and impracticality. For example, hardly any patient can go through the product information leaflet included in any drug pack and if somebody does, it is unlikely that the drug is consumed. So, what is expected is that the doctor should provide information that a prudent or reasonable patient would expect to make a knowledgeable decision about the course of action to be taken in the presence of alternatives.

What and What Not To Divulge

If a doctor is of the opinion that certain information can seriously harm a patient's health - physical, mental or emotional - he has the privilege to withhold such information. But, it should be shared with close relatives. This situation usually does not occur in cutaneous aesthetic surgical procedures. Use of placebos in certain self-limiting conditions or in patients with high psychological overlay or in those who insist for some form of medication is justified as there are high chances of benefit to the patient with negligible risk. Revealing the truth to the patient takes away the very purpose of administration of placebo. A comprehensive agreement to the impact "I permit [such/such a person] to complete any test/medical procedure over the period of my treatment" isn't legitimate. It ought to be particular for a specific occasion. On the off chance that, assent is taken for surgery of gall bladder stone, say, can't be legitimate for some other procedure like bladder stone.

Additional consent will have to be obtained before proceeding with the latter.

If a consent form says that patient has consented to undergo laser resurfacing by say Dr. A, the procedure cannot be done by Dr. B, even if Dr. B is Dr. A's assistant, unless it is specifically mentioned in the consent that the procedure may be carried out by Dr. A or Dr. B (or his authorized assistants).

The Procedural Aspect of Consent Taking

It is important to document the process of consent taking. It should be prepared in duplicate and a copy handed over to the patient. It should be dated and signed by the patient or guardian, the doctor and an independent witness. Assisting nurse preferably should not be a witness. Like all other medical records, it should be preserved for at least 3 years. Patient has got the right of self-determination. If, a doctor diagnoses varicella in a child, the parent may choose to avail no treatment because of religious belief. Doctor's duty is to explain the possible consequences of non-treatment and benefits of treatment and leave the decision to the parent. Such informed refusals must be documented clearly. But, a patient's freedom cannot impinge on the rights of others or cause harm to a third party or community. Therefore, the said parent's freedom of choice cannot extend to sending the child to school, as the infection can spread to other children.

Discharge against medical advice also falls into this category and needs to be properly recorded in the case sheet with signature of the patient/guardian.

In an emergency situation, for example intestinal perforation, a doctor may have to operate even in the absence of consent, to save the life of the patient. It is possible that even with such an intervention, the patient may not survive. Assuming that the doctor is competent and has exercised due care and diligence, doctor cannot be held responsible for patient's death, as he has acted in good faith and in the best interest of the patient. This protection is given under Section 88 of Indian Penal Code.

Is Consent Legal or Ethical or Both?

Obtaining consent is not only an ethical obligation, but also a legal compulsion. The level of disclosure has to be case-specific. There cannot be anything called a standard consent form. No doctor can sit in comfort with the belief that the "consent" can certainly avoid legal liability. This is highlighted by the note of The California Supreme Court:

"One cannot know with certainty whether a consent is valid until a lawsuit has been filed and resolved."

One can only take adequate precaution and act with care and diligence. Maintaining good relationship with patient often works better than the best informed consent!

Conclusion

At the turn of the 21st century new uncertainties or waverings regarding the context of the informed consent as in evolution or recuperating from the divisiveness of its fracture and co-adaptation between the legal and ethical standard of adaptation has seen many pulsating sinucisation in its rise or fall but the maintenance of the core of the doctrine fathomed in the entails of the Constitution, especially Article 21 has been preserved. Howsoever, the scholars would be at variance of their opinion regarding the methodology of the application of this doctrine, when a patient is serious, in mortal danger and the medical procedure risky, dialectic and factious and the scepticism is very high, it is the force of the resilience of requirement of preservation of the doctrine which is consolidated in the face of the constricting constrains imposed upon by the circumstance.

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