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Informed vs. Valid Consent: Legislation and Responsibilities

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The consent taking is an integral part of Medical practice. It is taught to 3rd year MBBS students as a small note during their study in forensic medicine, at a time when the students are not mature enough to understand the intricacies involved in it. There are no guidelines ever published by either Medical Council India, Indian Medical Association, or any other body involved in helm of affairs of clinical enterprises. All over India there are diversities in the way consent are taken and interpreted. There have been instances to my notice where consents have been highly inadequate to entirely missed.

What constitutes an ideal consent is still elusive, nor is it possible to frame it for all cases as a prototype template. The ambiguity in the consent document leads to variable interpretations that have resulted in damages to medical fraternity at large.

The Supreme Court of India in a recent Judgment Samira Kohli vs. Prabha Manchanda Dr. & ANR 1(2008)CPJ 56 (SC) has elaborated various aspects of consent taking. It has further laid down certain guidelines (Law!) for taking a real or valid consent. As such it is an attempt to stream line consent process in India.

The judgment was related to a Gynecological case where Hystrectomy was done as an additional procedure. While the initial consent was obtained for diagnostic laparoscopy, hysterectomy and removal of both ovaries was performed in the same sitting under general anaesthesia . The consent for hysterectomy was however obtained from the mother of the patient. The Supreme Court held the doctor liable for malpractice overruling the order passed by the National Consumer Dispute Redressal Commission. **The Supreme Court opined that additional surgery however beneficial to the patient in saving time, expenses, pain and suffering are no ground for defense. It however rendered the exception as well.**

The judgment has taken into consideration virtually all aspects of consent taking in India while giving reference to practiced in UK, Australia, Canada and USA.

Judgment has further differentiated between Informed consent and Real or Valid consent More over it has elaborated various aspects involved in the treatment including poor patient, long waiting period, lack of infrastructure and commercialization of medical practice. Honorable Supreme Court has expressed major concern over ignorance on the part of Indian patients in understanding what they would sign and has thus concluded the type of consent that shall be practiced in India.

It however poses new threats for all of us such as who should take a consent, what exactly is adequate information to the patient, what is additional procedures in surgical or neurosurgical practice and certain other issues which should be addressed by collective efforts of Neurosurgeon practicing any where in India.

Various issues that are addressed in this article related to consent taking are based upon the recent Supreme Court Judgment .It is further analyzed in term of Neurosurgical practice so that we are mentally prepared to incorporate necessary amendments in our endeavor of consent taking.

WHAT IS A CONSENT?

Consent in the context of medical profession implies to permission by the patient to perform an act on his body either for diagnosis or therapeutic procedure. It can be implied, expressed e.g. as a patient enters a clinic for his examination, sits on dental chair for the same purpose. There are several types of consent being practiced across the world. In USA the concept of

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informed consent is prevailing whereas UK it refers to real or Valid consent.

In UK the essential elements of consent which is considered as Valid or Real when

1. patient gives voluntary consent without any coercion
2. the patient has the capacity and competence to give the consent
3. Patient has minimum of adequate level of information about the nature of the procedure being performed

However in America and some other countries across the world, Informed Consent is a must before considering the patient for any procedure.

It has the basic ingredient of consent as that of real consent except it poses the onus on the doctor to furnish all details of the procedure to the patient. According to Tabers Cyclopedic Medical dictionary, it covers

1. nature and purpose of the procedure
2. Likelihood success and risks
3. alternative procedure
4. effect of no treatment
5. Instruction concerning the procedure to be adopted in case it turns out to be harmful or failure.
6. According to Canturbury v. Spence 1972 (464) Federal report 2^{d} 772 it should be free from imposition and it is a settled rule that a therapy not authorized by the patient shall amount to tort- a common law battery .Thus a physician is bound to make adequate disclosure to the patient.

IS CONSENT NEEDED?

The basic principle in regard to patient consent is traced to the statement of Justice Cardozo in Schoendorff v. Society of New York Hospital 1914 ,211 NY 125

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

It is there fore essential to take a written consent for all procedure being performed in the patient, particularly invasive in nature.

The implications are clear even. lumbar puncture, ventricular tap, invasive monitoring e.g. ICP shall have valid consent. Nerve or bone harvesting, putting any foreign body as implants, coils and devices requires clear mentioning in the consent form.

WHAT IS AN INFORMED CONSENT?

Essential ingredients of the informed and real/valid consent has been differentiated previously. Whereas valid consent presume heavily upon on the understanding of the patient as reasonably prudent patient test, informed consent on the other hand has more stringent ramifications. The patient is entirely dependent on the treating doctor to intimate almost all aspects of the treatment. From the text pertaining to consent taking as above and from experience of several litigations it is advisable to include several ingredients in real or informed or more appropriately an ideal consent for the procedure. Vide infra.

WHAT IS THE EXTENT OF DISCLOSURE REQUIRED FOR THE PATIENT?

The adequate information to be provided by the doctor should enable a patient to make a balanced judgment as to weather he should submit himself to a particular treatment or not. This means that a doctor should disclose nature and procedure of the treatment and its purpose, benefits and effects. It should also provide alternatives if available, substantial risk and adverse consequences of refusal of treatment offered. But there is no need to explain the remote or theoretical risks which may frighten the patient resulting in refusal of treatment or opting for fanciful or unnecessary options or resulting in psychological stress o the patient.

Nature of disclosure shall also depend upon physical and mental condition of the patient. Here also Supreme Court has consciously preferred the concept of real consent taking into account the ground realities of medical and health care in India.

CAN CONSENT FOR DIAGNOSIS BE EXTENDED FOR PERFORMING ADDITIONAL OR SURGICAL PROCEDURE?

As per the judgment of Supreme Court no additional procedure can be performed in violation to what had been explained to the patient. Even if the procedure is time, money and pain saving . Any additional act amounts to assault and deficiency in services. Judgment has given

exception for life threatening situation only.

For Neurosurgical practice this point has several important ramifications e.g. during craniotomy for any brain surgery performing duraplasty from facia lata or artificial dura., cranioplasty with autologous or artificial sources may be read as additional procedure. Unless the consent for second incision and harvesting facia lata may be trespassing the limits of the surgery explained even if it may be considered as a part of surgery. Similarly putting artificial dura amounts to insertion of foreign substance in the human body, hence the appropriate consent need to be modified while performing corpectomy putting iliac crest bone graft or G bone are additional steps with similar grounds. Coiling a patient for aneurysm but landing in craniotomy requires fresh consent from the patient unless life threatening where it may be obtained from the relatives. Unplanned removing part of the brain (lobectomy) during surgery would amount to additional surgery. The court allows additional surgery in life threatening situations or to preserve health of the patient, it leaves several unclear grounds for that. Hence in our routine practice we shall exercise our own wisdom in understanding legal responsibilities by over protection for the safe practice.

WHO SHOULD OBTAIN CONSENT?

The judgment has made a side reference to this aspect .While passing no guidelines on this, it has left another grey area for us. The principal behind is important. Weather an unqualified person is capable of providing all information and has the potential to make a patient understand all related aspect of surgery. A house surgeon, interns or even a postgraduate (resident) are the ones who obtain the consent. Are all these personnel qualified and experienced to explain all aspects needed in an informed / real consent?

WHO SHOULD SIGN THE CONSENT

Consent has to be signed by the patient unless minor, unconscious or insane. Even in emergency unless patient is unconscious the consent offered by the parents of major is void and amount to negligence. The judgment held doctors liable who performed Hystrectomy and bilateral salpingo ophorectomy under anesthesia after taking consent from the mother of the patient. Patient alleged that the procedure was not life saving and she had consented only for diagnostic laparoscopy. Moreover removal of uterus and ovary deprived her from chance of pregnancy. Interestingly the age of the patient was 44 years. There may be several such situations in neurosurgery as well, hence we should keep this aspect in our mind while doing our duty.

WHAT IS THE ROLE OF WITNESS?

The Supreme Court does not touch upon this aspect at all. There had been several instances that patient has alleged forgery or had claimed signing it under pressure of doctors, stress without actually understanding the document. It is advisable to have consent from at least two persons .One from the patient and other from spouse, parents or close relatives.

WHAT SHALL BE THE IDEAL (REAL OR INFORMED) COMPONENT OF CONSENT FORM

From the guidelines of this judgment and from our own experience the consent form can be modified depending upon the requirements. The ideal consent form will therefore depend upon the individual case and circumstances. Nonetheless certain essential ingredients of an Ideal consent form shall provide all possible and likely happenings in most of the cases. The following criteria shall be incorporated in each consent, preferably in all major operations.

Name of the patient with age

Name of Principle surgeon and its team

Name of anesthetist and team

Name of staff nurses

Diagnosis and nature of primary disease.

Incorporate DM, CAD, CVA, Asthama etc if so existing as risk factors.

Kind of surgery or procedure to be performed

Elective or emergency surgery

Reasons for emergency if so.

Kind of anesthesia and risks

The known and likely complications involved

Need for harvesting bone, nerve, fascia etc

Requirement of any implant or device.

Special risks in a particular patients e.g. Post op MI, DVT, Asthma, aspiration, Need for ventilator, Recurrence, hematoma etc These special risk would

vary depending upon the nature of disease and surgery.

Need for blood transfusion and consent for the same during procedure

A text covering following lines shall be useful for all kinds of procedures…….

That I/ we have been informed in details about the nature and steps involved in the surgery / procedure.

That I/ we have understood all aspect of surgery its consequences and or complications and

That there can be deviations from the normal practice depending upon the condition of the surgical field and brain and I/ We entrust the doctors to make decision on our behalf for the benefit of the patient. Please note that it shall require additional consent for additional procedure.

There is no doubt left in my/our minds requiring clarification

Hence I/ we give our voluntary consent for the surgery of our patient