**Informed Consent for Oncosurgical Procedures; what is ideal? An attempt based on review of literature, experience, legal aspects and logic.**

The need for consent for a surgical procedure was recognized by the early surgeons (1). Norfod in his 1753 article generalized that "cancer is a bad habit of the body and is the most lamentable of all other diseases. But how shocking and deplorable a state must those unhappy People be in, in former days, who were afflicted with it, and *consented* to come under the surgeon’s hands?" (2) This is probably the first reference about consent in the history of surgery.

**Consent in modern surgery**

Surgical treatment became safer with scientific advancements which provided state of the art gadgets and modern anesthesia techniques. This has reduced the morbidity and mortality associated with surgery and extensive surgeries became possible even in secondary level general hospitals. Today surgeons are the primary care providers in most solid tumors. Today's surgeons are duty bound to give quality care to all patients and ensure safety of each and every patient under their care. We are aware of most of the possible complications related to every surgery and surgeon is responsible to discuss those issues with the patient and the relatives and get formal informed consent from them before any surgical procedure is undertaken. Recent times has seen considerable increase in legal importance of informed consent which proves the participation of a well informed patient and his or her relatives in decision making.

Consent is necessary before any surgical procedure failing which the surgeon may be sued under civil or criminal law (3). However in dire emergencies where the formal informed consent is not possible when the patient is not at a position to give consent and no responsible relative is available, the surgeon is responsible to carry out appropriate procedure failing which he is liable to be charged for negligence (4).

In this era of increased patient awareness and more and more surgeons venturing into complicated surgical work, this important aspect of surgical and anesthetic practice cannot be overemphasized. The exponential growth of technology, sophistications in surgical and anesthetic practice and the media hype have increased the patient’s expectations. Sometimes this does not match with the ground realities, and leads to conflicts, litigations and not uncommonly violent responses against doctors and other health professionals. A segment of the media which spread half truths and exaggerations related to medical practice in an attempt to use sensationalism as a marketing strategy has increased the gap between the patient expectation and the reality.

Informed consent does not guarantee legal protection for the doctors and it does not ensure patient satisfaction. Nevertheless it shows that exchange of information has been followed in the process.

**Indian scenario**

Indian and British courts generally follow a doctor oriented approach to the medicolegal cases where as North American courts follow a liberal patient oriented approach (4). In India where the majority of the patients are not educated enough to understand the medical complexities and submit themselves entirely to the hands of doctors for the treatment decisions, it is natural for some medical professionals to conclude that a fully informed consent is not applicable in Indian context. In the face of inadequate treatment facilities, overcrowded hospitals, long waiting list for diagnostic and therapeutic procedures with many patients with serious ailments like cancer and cardiac illness being unable to avail treatment before disease progression or death, any treatment is a boon to majority of Indian rural population (5). However in a study reported from the All India Institute of Medical Sciences, New Delhi, majority of the urban Indian patients are able to understand the surgical procedure and its complications and want to be explained about the same more in detail (6). Doctors from a university hospital in Pakistan found in their study that there is enough room to improve the process of informed consent by educating both patients and the doctors regarding patient autonomy (7). A study published from the Christian Medical College (CMC), Vellore, India, also showed that the understanding of informed consent among the patients is inadequate. Implicit faith combined with a deep and abiding respect for doctors and the fear that asking questions to the doctor would be seen as rude behavior prevented patients from participating in decision making. These cultural influences cut across different sections of society and being educated did not imply being proactive (8).

**Essential aspects of an ideal consent**

The patient and the relatives have the right to be informed of every possible complications related to the procedure. This is a considerable challenge in the part of the clinician to formulate the perfect consent and explain it to the patient party for each case he or she operates. When surgeons care more about explaining and documenting the complications specific to a particular procedure, some aspects of the consent related to systemic complications that can arise intraoperatively or postoperatively are very commonly missed. In the modern surgical practice where we deal with an ageing population with record number of lifestyle diseases, unexpected complications sometimes arise and are many a time not anticipated. This lands the surgeon and the anesthetist in a very critical situation where they have to face the ire of the patient and his or her kith and kin that often put forward difficult questions if not the worse.

In this article I intend to discuss the essentials of the surgical consent in the modern oncological practice in an attempt to reach the most ideal and complete surgical consent applicable in surgical oncology. In general, a surgical consent should include the nature of patient's disease, the surgery planned, alternative options available, and every possible complication that are described for the procedure so far and plans to tackle them if need arise. Generally any complication which has an incidence of more than one percent should be included, but omitting any major complication well known for the procedure is not acceptable. Optimum information is to be conveyed to the patient, while too much information may confuse the patient and too little information may make consent invalid (9, 10). Some important points to be considered when obtaining an informed consent are discussed here.

**Who should sign consent?**

Consent should be signed by the patient if the he or she is an adult and a witness, preferably a close relative or a friend. The person signing the consent should have attained maturity which as per Indian law is 18 years of age (11) and should have sound mind and be capable of understanding the risks and benefit of the treatment proposed. A person with mental disorder is considered incapable of giving informed consent if the disease prevents him/her from understanding what s/he consents to, from choosing decisively, from communicating his/her consent or from accepting the need for a medical intervention (12). If the patient is minor both the parents or in their non-availability the legal guardian should provide informed consent for the procedure. The child should be explained about the procedure in an apt manner if he or she is of comprehensible age and his or her ascent needs to be obtained. The consent should be countersigned by the surgeon.

**Who should explain consent?**

The primary surgeon is the right person to explain the consent. As per UK guidelines the person explaining the consent should be personally capable of doing the procedure or should have received training in obtaining informed consent (13). This ensures that all patients’ queries are answered to satisfaction.

**When should the consent be obtained?**

Consent should be explained to the patient well in advance. More often it is a staged process. The busy outpatient department will not provide optimum air to exchange complete information. Better place would be in the wards after the patient is admitted, where the patient feels that the doctor has come down to 'their level' as reported by the participants in the study reported from CMC, Vellore (6). The consent should be obtained at least a day prior to surgery to ensure that patient gets adequate time to think over. On the day of surgery, if consent is discussed, some patients may feel under duress to proceed after all arrangements for the surgery are made (14).

**How should the consent be obtained**?

Consent should be obtained in patient’s own language. If the patient is illiterate it should be documented that it was explained to the patient in a language understood by him or her. However every attempt should be made to obtain consent from a literate relative in such cases. Consent is ideally hand written by the patient himself or herself or by a close relative in order to make sure that the patient party has gone through the entire document. This will help allay allegations that the consent was not explained and the patient or the relatives were hurried to sign the document just before the surgery. In case of a visually impaired person recorded audio consent is a valuable method of obtaining informed consent (15).

**Disease and surgery contemplated**

(a) Nature of disease should be thoroughly explained. Patient should be informed about the exact diagnosis if known, whether the disease is malignant or benign and if it is cancer whether it is confirmed pathologically or suspected clinically or radiologically. When the treatment is based on clinico-radiological diagnosis or the diagnosis of cancer is not confirmed pathologically even after multiple biopsies, but suspicion is strong, if the surgeon proceeds with curative resection at the best interest of the patient, this should be clearly informed and documented. The possibility of negative final histopathology report (HPR) should be explained and included in the informed consent.

(b) Surgery planned needs to be explained in detail including major surgical steps of resection and reconstruction. Any additional resections that may be required on table as can be anticipated from preoperative evaluation should be discussed in layman's language and included in the consent form. The surgical procedure is best explained with simple illustrations which will make it more comprehensible and the process will be more interactive. Those diagrams used for explaining consent can be attached to the patient case sheets for improved documentation. The patient and relatives should be clear about the intent of the surgical procedure, whether curative, palliative or exploratory. When technical aspects are explained, adequate information is the key, inadequate information and too much of information should be avoided. This has to be titrated for an individual patient based on patient's intellectual level and understanding.

**Need for the surgery and alternative options available**

The anticipated benefit from the surgery in terms of survival and symptomatic benefit should be explained to the patient and relatives alongside nonsurgical options available like radiotherapy and/or chemotherapy or targeted therapies with comparative merits and demerits of each treatment modality. The reason why the treating physician prefers surgery over other treatment options, if he or she does, should be clear and the patient should be an active participant in the decision making.

**Surgical complications specific to the procedure**

All major complications described for the procedure in the literature should be explained. This varies from procedure to procedure and is beyond the scope of this article. The need for prolonged stay in intensive care units and possible need for mechanical ventilation and dialysis support as applicable should be conveyed in the consent. The small chance of mortality associated with all major surgeries should be explained to all patients and documented in the consent form.

**General Complications not directly related to the procedure**

General complications that are not directly related to the procedure but the risk of which is increased in the post operative period due to increased stress response like Myocardial Infarction, Cerebro-Vascular Accidents (CVA), Deep Vein Thrombosis and Pulmonary Embolism should be explained and included in the informed consent. This is more relevant in patients who are elderly, those with diabetes, hypertension or those with a familial predisposition.

If the surgery is being carried out in a secondary level hospital where full time cardiologist, neurologist or nephrologist is not available, especially in patients with co-morbidities, the patient and relatives should be informed of this fact and alternate options like service of visiting specialist or referral to a higher center with adequate supports should be discussed.

**Need for repeat procedures**

The need for repeated procedures in some situations to rectify the morbidity following the index procedure needs to be explained. The patient should be aware of this fact and should be willing for the same. It should be clear that any such additional procedures and investigations ordered in order to manage a known complication of the index surgery are chargeable and may increase treatment cost.

**Anesthesia related complications**

Complications related to the general anesthesia and regional anesthesia should be mentioned in the consent form. The onus of explaining anesthesia related complications is on the anesthetist; however surgeon shares the responsibility as the primary care providers.

**Drug allergies and related issues-**

History of drug allergies should be obtained. The rare chance of loss of life from drug allergies in spite of all necessary precautions needs to be shared with the patient party.

**Inoperability, incomplete resection**

Patient should be aware of the possibility of inoperability and incomplete resection in spite of a localized lesion as per the preoperative scans and possible change of intent of treatment in such situations.

**Adjuvant treatment**

Need for evidence based adjuvant treatment to reduce the incidence of disease recurrence after a complete tumor resection is to be explained to the patient and relatives preoperatively and they should be prepared for that. This will avoid unpleasant situations post operatively when this is conveyed to the patient who is unaware of the need of multimodality treatment in cancer and expecting a cure with surgery alone.

**Consent for intraopeative photography or videography** for academic and teaching purposes is to be obtained from patients if this is planned (16)

**Cooperation with treatment team**

Commitment to cooperate with the doctors and other hospital staff and to follow their instructions pertaining to treatment and care is important and needs to be discussed and documented (16)

**Consent for disposal of tissues or body parts** removed during the surgical procedures need to be obtained (16). As some communities prefer to bury body parts after amputation, enquiry should be made regarding this prior to disposal in order to avoid hurting religious sentiments.

Apart from those points mentioned above, for patients getting operated in an Academic institute or a Hospital where apart from the primary surgeon, residents and other junior surgeons participate in the surgery as trainees and attend the patient in the wards, a consent to this effect should be obtained. Some leading free lancing surgeons get patient's consent for not attending personally in the post operative period. A junior colleague or a surgical team take care of the patient based on telephonic instructions from the primary surgeon in this scenarios, but ethicality of such extended consents is questionable.

Informed consent is an opportunity for the surgeon to create trust and openness with the patient party and he/she should make sure that patient expectations are realistic. In this era of rapid expansion of knowledge and rapid changes in treatment philosophy, it is important for every surgeon dealing with cancer cases to be updated in the field to ensure the right care to the right patient at the right stage of cancer and communicate with the patient and their relatives effectively to ensure their participation in all phases of decision making.

**References**

1. Onuigbo. W I B (2014) Historical Origins of Informed Consent in Cancer Surgery. J Forensic Res 5: 1000246.
2. Norford W. (1753). An essay on the general method of treating cancerous tumors 8-10, London: Noon.
3. Nandimath OV. Consent and medical treatment: The legal paradigm in India. Indian J Urol. 2009 Jul-Sep; 25(3): 343–7
4. Arun Bal. Issues in Medical Ethics. VII (2). April-June 1999
5. Karunakaran Mathiharan. law on consent and confidentiality in india: a need for clarity. Natl Med J India 2014;27:39–42
6. A K Sanwal, S Kumar, P Sahni, S Nundy. Informed consent in Indian patients, J R Soc Med 1996;89:196-8
7. Faisal Ghani Siddiqui, Jan Mohammad Shaikh, Mohammad Munir Memon. an audit of informed consent in surgical patients at a university hospital. j ayub med coll abbottabad 2010;22(1)
8. Shuba Kumar, Rani Mohanraj, Anuradha Rose, MJ Paul, George Thomas. How ‘informed’ is informed consent? Findings from a study in South India. Indian Journal of Medical Ethics, Vol IX No 3, July - September 2012.
9. Mirnezami AH. The impractical nature of informed consent. bmj.com 2002. Available at <http://bmj.com/cgi/eletters/324/7328/39>
10. Young PJ. What is reasonable informed consent? bmj.com 2002. Available at <http://bmj.com/cgi/eletters/324/7328/39>
11. Indian Penal Code, section 87
12. [C W Van Staden](http://jme.bmj.com/search?author1=C+W+Van+Staden&sortspec=date&submit=Submit), [C Krüger](http://jme.bmj.com/search?author1=C+Kr%C3%BCger&sortspec=date&submit=Submit). Incapacity to give informed consent owing to mental disorder. J Med Ethics 2003;29:41-43 doi:10.1136/jme.29.1.41
13. Department of Health (UK). Good Practice in Consent Implementation Guide: Consent to Examination or Treatment. London: Department of Health publications, 2001
14. Owen A, Anderson I, Mike J Wearne. Informed consent for elective surgery—what is best practice? J R Soc Med 2007;100:97–100
15. [G M Saleh](http://www.ncbi.nlm.nih.gov/pubmed/?term=Saleh%20GM%5Bauth%5D). Consent of the blind and visually impaired: a time to change practice. Br J Ophthalmol. 2004 Feb; 88(2): 310–11
16. General consent form for surgeries. Tata Memorial Hospital, Parel, Mumbai-400012