7 Proper Counselling and Consent of Patient for Medicolegal Aspects and Importance of Documentation

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7.1 Introduction

Earlier it was believed that revealing information to patient and giving all information regarding a fatal disease may lead to mental instability and depression. So physician used to conceal actual facts and provide minimum information about a fatal disease for better management of patient. Physician was the absolute authority to decide treatment without proper prior information to patient. In modern day practice this philosophy is no longer acceptable. Patient has all the right to know about his disease and he is the ultimate decision maker regarding his or her treatment. Concealing information may lead to court proceeding against physician. In a case in the USA a patient consented for operation in the right ear, but during surgery surgeon noticed that, the condition of left ear was much worse than right one. He operated on left ear, later the surgeon was summoned to the supreme court of Minnesota in 1905, and was found guilty [1]. In another case in 1914 a surgeon removed a malignant tumour against patient's will. The surgeon was found guilty by the court [2]. The crux of this judgement was that every human being of an adult age and sound mind has the right to decide about what should be done to his body.

In present day proper counselling of patients before any surgical intervention and taking informed written consent is utmost important for surgeon, from medicolegal point of view. Counselling is a confidential speech between patient and the doctor about the disease, possible treatment options, outcomes and complications related to the treatment that may help the patient to take proper decision along with the doctor regarding the further treatment plan. It is a continuous process starting from the establishment of diagnosis and will continue till the treatment completed.

Another aspect of modern day surgery is taking proper consent before any surgical intervention. There are many forms of consent like, implied consent, expressed consent, informed written consent. The last one is the most important for surgeon from medicolegal point of view. Another aspect I want to highlight is the record keeping. Properly conserved record not only help for patient follow-up and further treatment, research, but also help surgeon to defend himself during any court proceeding.

7.2 Counselling

Definition "Counselling is a confidential dialogue between a patient and doctor, helps patient to take proper decision regarding his or her illness". Patient should be informed about the dis-

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ease, possible treatment options, outcome of treatment, risk and benefit associated with each treatment. A doctor should reveal all treatment related facts to patient and relatives honestly. The facts should be explained in legible words and preferably in patients own language or best understandable language.

7.2.1 When to Start Counselling?

Counselling is a continuous process starts during the patient's first visit, and it will continue till the end of the treatment.

First visit: At first visit after proper history taking and complete physical examination, patient should be informed about the provisional diagnosis, possible differential diagnosis and investigation required to reach a final diagnosis.

Subsequent Visit:
After final diagnosis, following are to be explained to patient and attendant—

(a) Nature of the disease.
(b) Possible treatment option to be explained in patient's language.
(c) Outcome of treatment.
(d) Risk and benefit of each treatment option.
(e) Nature of surgery.
(f) Risk associated with surgery.
(g) Possible blood loss during surgery.
(h) Arrangement of blood product before surgery.
(i) Cost of the treatment.
(j) Waiting list of the department and delay in starting treatment.
(k) What will happen if any delay occurs in initiation of treatment.
(l) Hospital stay.
(m) Time required to return to normal lifestyle.
(n) No oral intake after surgery for how many days.
(o) Disability if any may occur after surgery.
(p) Co-morbidity and its effect on surgery.

For Cancer Patient Following Should Be Kept in Mind
(a) Risk of disease recurrence.
(b) Possibility of negative histopathology report after surgery.
(c) Chance of inoperability.
(d) Need for NG tube feeding after surgery for oral cancer patient.
(e) Fertility issue after chemotherapy and surgery like hysterectomy, oophorectomy and orchidectomy.
(f) Chance of limb salvage, and functional impairment after surgery in case of extremity sarcoma.
(g) Improving nutritional status before surgery, particularly in case of esophageal and gastric cancer.
(h) Impairment of sexual function after surgery like abdomino-perineal resection (APR), RPLND.
(i) Need for temporary and permanent stoma.
(j) Functional, sexual, social and psychological aspects of stoma.
(k) Need for long-term follow-up and importance of follow-up in picking up recurrence at earliest.

Special Situations In case of radical surgery like cytoreductive surgery and hyperthermic intraperitoneal chemotherapy (CRS + HIPEC), exenteration surgery, details of procedure, risk associated with surgery, possible benefit from surgery, functional impairment after surgery to be explained.

After Admission in Hospital for Surgery Patient and attendant should be explained in detail by the operating surgeon or operating team, about the nature of surgery, possible time required for surgery, chance of inoperability, possible blood loss, risk associated with surgery, need for blood transfusion and hazards related to transfusion, need for mechanical ventilation, ICU stay, nosocomial infection, ventilator associated pneumonia, ICU psychosis, wound complications, negative histopathology, risk of

disease recurrence, time period to be remained nil per mouth, time required to recover, possible hospital stay.

For Specific Cases

(a) Oral cancer—following to be explained—NG tube feeding, difficulty in speech, loss of mandible, need for flap, type of flap, possibility of flap necrosis, development of orocutaneous fistula, facial disfigurement after surgery, bad cosmesis.
(b) Thyroid surgery—risk of recurrent laryngeal nerve injury and voice change, risk of hypocalcaemia in post-operative period.
(c) Esophageal cancer—gastric conduit necrosis, cardiac arrhythmias, changes in feeding habit after surgery.
(d) Gastric cancer—loss of reservoir capacity of stomach and need for modification of feeding behaviour.
(e) Pancreatic cancer—pancreatic fistula formation.
(f) Colorectal cancer—change in bowel habits, sexual impairment, need for temporary and permanent stoma.
(g) Radical cystectomy—permanent urostomy.
(h) Penectomy—loss of penis, reconstruction option, impairment of sexual function.
(i) Orchidectomy—chance of being infertile.
(j) Oophorectomy—infertility.
(k) Hysterectomy—inability to conceive.

Type of anaesthesia, risk related to anaesthetic drugs, need for mechanical ventilation and complication associated with it, ICU stay and complication related to it, to be explained in details by anaesthesia team. After explaining everything to patient and attendant, surgeon should record all those things and take an informed written consent from patient and attendant. Surgeon should answer every query of patient related to surgery.

During Discharge Patient should be explained about the restriction in life style if any needed, dietary modification if needed, date, time and place of follow-up.

7.3 Consent

Starting with a story—A Perimenopausal lady medical officer by profession underwent diagnostic Laparoscopy for evaluating chronic pelvic pain. During diagnostic lap—the surgeon found that there is a chocolate cyst along with features of endometriosis. The surgeon decided to do hysterectomy to relieve her symptoms but no consent was taken before. But during the procedure, he arranged to take consent from her husband and mother for hysterectomy and surgeon did it without any malintention.

Ultimately when the medical officer came to know the fact, she filed a case that without her consent, her uterus has been removed.

Court found guilty of the surgeon and fined for his basic mistake.

So, without proper consent of the patient, surgeon should not take his own decision, even for the betterment of the patient unless it is life-threatening emergency.

Definition As per sect. 13 of "Indian Contract Act 1872"—consent is defined as—When two or more persons agree upon the same thing in the same sense they are said to consent.

Necessity of Consent Before performing any surgery or intervention surgeon should take an informed written consent from patient, husband or wife or parents in case of minor, as per Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations 2002, vide regulation No. 7.16.

Modes of Consent

1. Implied consent.
2. Expressed consent.
3. Informed consent.

1. Implied consent: It is the most common mode of consent in general and hospital practices. Most of the physician works on the basis of implied consent. It is either by words or behaviour of the patient or by circumstances under which treatment is given. When a patient comes

to a doctor for treatment, patient volunteers for history taking and physical examination without any objection. In this case the consent is implied. In such situation no separate consent is required. Physical examination is restricted to inspection, palpation, percussion, auscultation only. Procedures not more complex than giving an injection, doing an ultrasonography, implied consent is sufficient. For physical examination like per vaginal examination, per rectal examination, or drawing blood samples from patient, require expressed consent, either verbal or written.

2. Expressed consent: Anything other than implied consent is expressed consent. It can be verbal or written. Verbal consent when taken in the presence of a disinterested third party is as valid as written consent. But obtaining written consent is preferable for easy proof and reproducibility. Anything more than inspection, palpation, percussion, auscultation, like vaginal or rectal examination require expressed consent in the presence of a disinterested third party. Written consent is required in the following situations:

(a) Major diagnostic procedure.
(b) General anaesthesia.
(c) Surgical procedure.
(d) Intimate examinations.
(e) Determining age, potency, virginity.
(f) Medicolegal case.

3. Informed consent: In modern day practice it is a common scenario that a doctor is being convicted by patient, claiming that he or she was not informed about the nature of the disease, complication. It is occurred frequently when a treatment modality fails, complication arises after surgery, or disease recurs, or a patient died. So the concept of informed written consent arises. The surgeon's role is to disclose honestly all the facts related to disease and treatment. After understanding everything from doctor, the patient's role is to decide what to be or not to be done with his or her body. Informed consent is right to patient. So the patient and attendant should be explained about the following facts before proceeding for any treatment or surgery: (a) Nature of the disease. (b) Possible treatment options. (c) Risk and benefit associated with the treatment. (d) Complications related to surgery. (e) Risk of cancer recurrence. (f) Chance of inoperability. (g) Chance of success of treatment modality. (h) Prognosis and outcome of treatment.

After explaining all those facts a written consent will be obtained from the patient and the attendant. In certain circumstances disclosure of facts can be restricted to patient—

(a) If patient is wish for.
(b) May affect the psychology of the patient.
(c) When complication is trivial.

7.3.1 What Is Legally Valid Consent?

Consent is said to be valid when

(a) When given by a patient of valid age, or by parents or guardian in conscious, and stable mental condition.
(b) Informed expressed written consent.
(c) Given voluntarily.
(d) Knows all the facts related to surgery.
(e) Given before the procedure.
(f) Given without fear, fraud or force.
(g) Given in front of two witnesses.
(h) Signed by the doctor, patient, attendant/guardian, witness.
(i) Written in patients own hand writing.

7.3.2 Who Can Give Consent?

1. Any patient who is fully conscious, mentally sound above 12 years of age can give consent (Sect. 88, 90 IPC 1860).
2. As per Sect. 13 of Indian Contract Act, 1872 a person above 18 years of age can enter into a contract. As the doctor patient's relationship is a contract, 18 years of age is considered as age of giving written consent.
3. < 18 years of age—consents to be taken from parents or legal guardian.
4. For unconscious patient—consent to be taken from the parents or local guardian.

7.3.3 What Is Loco Parentis?

When a child is sick and needs emergency treatment, but parents are not available for giving consent, the person in charge of the child can give consent (like—school teacher). In contraceptive sterilization consent of both husband and wife is necessary. In case of organ donation, after death of the person, consent of spouse is necessary.

What is blanket consent? If a consent taken on a printed form, which almost mention everything about what to do on patient without mentioning specifically is called blanket consent. It is legally inadequate.

7.3.4 What Is Proxy Consent or Substitute Consent?

All the above-mentioned types of consent can take the shape of proxy consent, like parent for child, close relative for unconscious, unsound patient, and consent given by loco parentis.

7.3.5 What Is Informed Refusal?

After knowing all the facts related to treatment patient can refuse to take treatment.

7.3.6 What Is Paternalism?

Is an abuse of medical knowledge in such a way that a patient is deprived of his ability to make a rational choice. Doctor should not practice paternalism.

When consent is not valid?

When consent is not required?

7.4 Documentation

Proper documentation of medical fact is very important from treatment as well as medicolegal point of view. Documentation of patient's history, diagnosis, investigation advised, treatment proposed, date of visit, any event occurred during treatment is necessary. Proper documentation of facts will help a physician to follow-up the patient properly and review the case quickly. From medicolegal point of view it will save a physician in court case.

Main aspects of documentation:

1. Follow up of patient.
2. Research.
3. Medicolegal purpose.

Things to be noted during OPD visit: The doctor should document the following things in legible handwriting

(a) Date and time of visit.
(b) Patients' particulars.
(c) Case history.
(d) Drug allergy.
(e) Positive findings.
(f) Investigation suggested.
(g) Treatment advised.
(h) Possible drug reaction.
(i) How to take medications.
(j) Where to go in case of any emergency.

Physician should mention "*diagnosis under revision*" until a final diagnosis is reached. What other disease to be ruled out should be mentioned in patient's history sheet. In a difficult case to which specialist you are seeking referral should be mentioned. When a patient counselled about the disease and prognosis, should be documented in case sheet. When patient's condition is critical, and in case of grave prognosis, patient should be counselled, and signature of the patient in presence of a witness should be taken in the case sheet, for proof that, you have told them everything about the disease.

In case of critical case, when risk and benefit of the treatment to be weighted, after explaining the risk of treatment, and possible benefit from the treatment, signature from patient and a close relative to be taken.

After Final Diagnosis Following facts to be noted in the case sheet: (a) Diagnosis (b) Plan (c) Justification for such plan (d) Implementation of Plan.

Before Surgery Following things to be mentioned in the consent form and to be signed by the patient and attendant in presence of a witness: (a) Diagnosis (b) Surgery planned (c) Possible complications related to surgery (d) Possible risk related to anaesthetic drugs and General Anaesthesia (e) Need for ICU stay, ventilator support (f) Long-term complications (g) Risk of recurrence (h) Need for re operation (i) Need for stoma creation (j) Chance of positive margin (k) Risk related to blood transfusion.

During Hospital Stay If any event happens should be documented, like (a) drug reaction (b) blood transfusion reaction (c) morbidity during hospital stay (d) complication occurred after surgery (e) measures taken to such complication (f) positive culture report (g) wound infection (h) whether visited by consultant on not (i) discussed with consultant or not.

During Follow-Up Following to be documented (a) any recurrence (b) investigation suggested to detect recurrence (c) counselling of patient about the recurrence (d) prognosis explained or not.

If a patient provides an unreliable history, refused for physical examination, refused to take treatment, ignore the advice given by doctor, not taking medicines prescribed by doctor, taking medicines irregularly, leave against medical advice, lost to follow-up, refusing admission should be recorded in case sheet.

Preservation of Records Every doctor should preserve the records of each and every patient for a period of 3 years from the date of commencement of treatment, in a standard proforma. Hospital and nursing home should maintain the record for a minimum of 3 years. This is necessary, because if any case lodged against a doctor or an institution these documents can be produced to competent authority. In case of minor and new born record should be preserved for 3 years after attaining 18 years of age. If any patient, authorized attendant or legal authorities request for treatment related documents, the same should be provided within 72 hours.

Few Examples of Negligence in Surgery

1. Performing surgery when contraindicated.
2. Performing surgery—when lack of reasonable skill—performing cytoreductive surgery and HIPEC without prior training.
3. Delay in surgery—delaying surgery in case of bowel perforation, abscess, appendicitis.
4. Performing surgery without proper infrastructure: performing esophagectomy or commando surgery without proper ICU facility.
5. Leaving swab, instrument inside the abdomen, or wound.
6. Going beyond the area of consent: Surgeon performed cholecystectomy during appendectomy without prior consent.
7. Inadvertent burn: cautery burn during surgery, burn occurred by hot saline.
8. Performing surgery in wrong limb.

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