How informed should be informed consent?

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Informed consent is an important part of not only surgical procedure, but also any physical examination. Health care workers are expected to observe the boundaries set by the different medical and ethical bodies in their respective fields. The Good Clinical practice is that the Surgeon knows the procedure thoroughly, is able to give complete information about it, is able to reach a mutual decision about the treatment and respect the decision and trust of the patient. Here we describe a case, where breach in observing these practice guidelines resulted in activation of the legal framework with serious consequences for the health care professional.

Dr Z had known her consultant Dr FR for more than 5 years. A mother of 2 children, all born by Caesarean section was employed as government servant. She used to consult FR for her gynaecological complaints and was satisfied with her. So when she started having heavy monthly bleeding she consulted FR. After multiple tests, and Ultrasound showing a large fibroid, FR advised for removal of uterus and appendages. In the out-patient consults, FR gave options for laparoscopic removal as well as open surgery. Dr Z, had herself worked as a medical officer in the gynaecology department, and anticipated adhesions, and other complications, hence opted for open procedure. The consultant agreed, but at the same time also discussed options, advantages of minimally invasive surgery. She was advised admission on the day of surgery with all investigations and pre- operative requirements. In the Pre operative room of the theatre, FR approached Dr Z again, and informed her that she will be proceeding with minimal invasive method, as she will be more comfortable with it. In the consent form, the junior doctors in the ward had taken consent for open procedure, to which FR added laparoscopy and got it signed from the husband. Dr Z found herself in a vulnerable position, and could not resist the decision, and agreed half-heartedly. The procedure lasted for more than 6 hours, and the patient was shifted back to recovery. She was discharged in 48 hours, with operative notes of difficult surgery. The patient complained of abdominal pain a week after surgery, for which she was advised routine pain killer, and was asked to report back after 8 weeks with histopathology report. In the mean time, Dr Z got few blood tests done, as her pain and fever were not subsiding and she was quite concerned. An ultrasound report showed ureteric injury, and she underwent emergency operation of nephrostomy and ureteric reimplantation at another hospital. This was then followed by a prolonged recovery period, resulting in absence from her official job.

The couple contested that since the procedure was done against their will, FR should be penalized by the court and not by the governing body for health care professionals, resulting in the filing of a medicolegal case against the surgeon. An expert panel was constituted by the Court to identify the veracity of claims by the applicant. The experts deliberated that Dr Z was not a suitable candidate for minimally invasive surgery and indeed the surgery was done against the will of the patient. Hence the medicolegal case has been correctly registered.

This case highlights the importance of a proper informed consent. The concept of informed consent for surgical procedures embodies the two components of information and consent processes. The information part includes disclosure by the professional and its understanding. Whereas, the consent part involves understanding, voluntariness and authorization. Hence together following components make following backbone of an informed consent.

1. Disclosure
2. Comprehension
3. Voluntariness
4. Decision or plan
5. Authorization

In the above example cited, the decision between professional and patient had been decided for an open surgery. The change in the decision came at a time, when patient was in the preoperative room, separated from the family, and quite vulnerable at the same time, resulting in a medicolegal case. The failure to adhere to the basic principles of informed consent results in above situations on global scale as well. A Canadian survey identified that 65% of medicolegal cases resulted from inadequate informed consent for the procedure.[1]

It is important for the surgeons to disclose both general and specific risks and benefits of the surgical procedure to the patient, and after thorough discussion reach a management plan. All of this should be either

documented or recorded for future use. Any change in the management plan specially just before the surgery not only breaches the trust on physician but creates a situation as in the above case. The management plan mutually agreed upon by the Surgeon and the patient, should be respected by both parties. It is generally known that Surgeons do state some complications of the surgery, but fail to mention the other downsides of the surgery. As in the above case, Minimal Invasive Surgery was explained, with out its complications. Moreover, the patient being a doctor in the same field, understood all the complications of the procedure, without the Surgeon's explanation and had disagreed with the offered mode of surgery.

Surgeon's should be careful, not only for documentation and explanation of the procedure, but they should also understand that today's patient is technologically far advanced and updated, and often comes prepared with multiple questions. The International Federation of Gynaecologists & Obstetricians (FIGO) states that Informed Consent should not be a one time event, should not be done immediately before the procedure and sufficient time should be given to the patient to deliberate upon it.[2] Also the consent form should be simple, in easy to understand language, specific for the procedure. The FIGO has designed forms, specific for gynaecological procedures, which can be easily adapted in the local dialect.[2]

References

1. Hanson M, Pitt D. Informed consent for surgery: risk discussion and documentation. Can J Surg. 2017;60:69-70.
2. Topcu EG, McClenahan P, Pule K, Khattak H, Karsli SE, Cukelj M, et al. FIGO best practice guidance in surgical consent. Int J Gynecol Obstet. 2023;163:795-812.