

ETHICS FOR SURGEONS: THE ROLE OF TRAINEES, SURGICAL INNOVATIONS AND THE INFORMED CONSENT

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Abstract: Nobility of medical profession is inherently linked to ethics in their absolute dimensions. Despite the tacit understanding, our profession has time and again been subjected to questioning by the society on account of our ethical standards. Surgical disciplines, a blend of science and human skills have been specially under scrutiny. You cannot learn to play piano by going to concerts. Society expects perfection. Perfection can only come from practice. Practice is linked to training and training involves acceptance of the possibility of an error. Magnitude of the error left aside, even its potentiality is unacceptable to any patient. Surgical disciplines have evolved in experiential manner. The circle of training, practice, perfection and innovation is mired in whirlpool of ethical dilemmas. Consensus continues to elude us. We examine some of these issues in brief with an insight from the literature.

INTRODUCTION

Training in our medical programs both at the medical school and higher levels lacks in appreciation for medical ethics. As a result most doctors in the country are ill-informed and only acquire information on a need-to-know basis. This article aims to address the issues regarding medical ethics in general and for surgeons in particular. Furthermore, it focuses on the process of a valid informed consent and its importance both ethically and medico-legally.

ETHICS IN GENERAL

Ethics codes date back to the origins of medicine in virtually all civilizations. Ethical codes bound new physicians to the profession through agreement with the principles of conduct toward patients, colleagues, and society. Although less famous than the Hippocratic oath, the medical fraternities of ancient India, seventh-century China, and early Hebrew society each had medical oaths or codes that physicians swore to. The ethical backbone from the Hippocratic oath—beneficence, nonmaleficence, confidentiality, and prohibition of abortion, euthanasia, and sexual relations with patients—remained essentially unchanged for Western medicine until the mid 20th century. The World Medical Association (WMA) has made an attempt since World War II to be a general regulatory body for physicians. However, lot countries do not accept the sanctity of this body and follow their own ethical codes. This makes a lot of sense as there are significant cultural, educational and economic differences between different countries. It is imperative for all countries, including India to lay down ethical norms in general than conform to current medical practice and are not carry-over from a defunct generation of medicine. The general guidelines laid down by the WMA are listed below (Table 1).

Ethics in medicine deal with wide ranging topics such as patient-doctor trust, patient confidentiality, role of informed consent, status of minors, reporting of patient abuse, reporting of misdemeanor by colleagues etc. Discussion of all these conditions is beyond the scope of one article. We will take a look at ethics as applicable to surgeons and the role of informed consent in today's world of

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medicine.

ETHICS FOR SURGEONS

The major ethical guidelines regarding medical ethics have not come from surgical organizations. The Hippocratic Oath apparently prohibited surgery. Whether this prohibition actually outlawed surgery or simply relegated the discipline to specialists is not clear. Surgeons were once again excluded from bodies such as the American Medical association (AMA) in 1847, which have shaped the formation of ethical codes in modern day medicine. The AMA Code of Medical Ethics criticized all physicians claiming special abilities (? Surgeons) and labeled them as quacks. The American College of Surgeons (ACS), Chicago, Ill, was formed in 1913, and the Fellowship Pledge of the ACS is one of the earliest surgical ethics guidelines¹.

Surgical organizations and surgeons have traditionally had less interest in ethics discussion than their medical colleagues. Most surgeons are viewed by colleagues and society as cavalier and “cowboy” like in attitude. A daring surgeon is rated better than one who shows ethical concerns about the treatment he is about to deliver. However, given a choice most patients would like to place themselves in the hands of the latter. Surgeons are increasingly encountering bioethical issues brought about by the changing landscape of surgical intervention and the development of newer and alternative forms of treatment.

Surgeons also share a unique relationship with their patient. The invasive and potentially life-threatening nature of surgically therapy demands a high level of faith from the patient. As compared to a medical patient who to some degree always has control over his treatment, a surgical patient places his life entirely in the hands of his surgeon.

Therefore, there exists an increased need to know more about ethics pertaining to surgeons in particular and this has led to renewed interest by them in the discussion of bioethics issues. In this article we will take a look at some of the issues that surgeons encounter in their day to day practice.

ROLE OF FIRST TIMERS AND TRAINEES

Surgical residents acquire the necessary skills needed for patient care by observing and subsequently performing operations

that are the mark of the expert. Only then can they progress to being independent care givers. There always must be a "first time". However, this can be made safe and without jeopardy to the patient if the supervising surgeon is present and available if needed.

What should the surgeon and the teacher say to the patient? What is the moral position of the primary surgeon?

Both surgeon and trainee should tell the patient that the operation is being done by them as a team. However, the primary surgeon in whose hands the patient has placed his care remains legally and ethically responsible for the patient's outcome. It is neither unethical nor illegal for a trainee to be performing a procedure under the close supervision and assistance of the expert. It is the responsibility of the senior to ensure that the quality of care delivered and procedure done is of a high standard.

An operation is an exercise in trust. The surgeon must assure himself that all members of the team are up to the demanding performance expected of them at that specific time and under those specific circumstances. This means that he is putting his trust in the hospital where he works and all the people bearing even peripheral responsibility for the success of the undertaking, whether or not they work under his direct supervision. These people include those who are not actually on the team, whose duties are performed far away from the operating room. Some of them he rarely or never meets — such as those who sterilize or maintain the equipment, prepare the instruments, or hire or assign some of his assistants. When patients put their trust into a surgeon, they are entrusting their health to a whole array of systems. Because of this complex nature of the relationship of a patient with his surgeon it is unlikely that concrete laws relating to the role of trainees will appear. However, if they do, then likely they will permit trainees to perform the surgery under the presence of the primary surgeon.

NEWER SURGICAL TECHNIQUES

The development of newer surgical techniques has traditionally not conformed to the rigid standards of other medical innovations. The distinction between clinical practice and surgical research may seem trivial, but this distinction can become a complex issue when innovative surgeries are substituted for standard care without patient knowledge. At present only 7% of surgical investigators use a randomized-study design of any type, according to a report in *The Lancet* (1999). Another study found that, during the previous four decades, only 10 to 20% of surgical techniques have undergone any clinical trials. Instead, surgeons prefer to rely on case series, a type of study that tracks individual patients and records their outcomes, but does not compare the procedure with an alternative. Since most case series tend to favor any given intervention, multiple similar reports reinforce a possibly mistaken view that the surgery provides benefits. Once such a view is established, conducting definitive trials becomes increasingly difficult. Pressure to use the new technique builds, as does the impression that withholding the surgery now amounts to 'unethical' treatment, despite the lack of clear evidence of a procedures benefit. A similar event occurred during the popularity of development of surgery for cystic fibrosis. Only after many years it was found that medicines offer a better outcome. It is probably true that most proposed surgical innovations would not pass the IRB (internal review board) of the

hospital and would be dropped at the drawing board stage. Currently, it seems, there is greater oversight protection in place for laboratory animals than there is for testing innovative surgeries in humans.

On the other hand, some great surgical procedures have evolved out of a similar exploratory mode. The development of Coronary Artery Bypass Graft (CABG) was problem driven, rather than developed from a rigid protocol. It developed from an understanding of the disease process and its mechanisms. Improvement came simultaneously from many areas, including anesthesia, heart-lung bypass machines and surgical techniques. It was developed in response to patients' needs and new surgical opportunities, which depended on a high level of skill and quality of judgment on the part of the whole medical team.

It is unlikely and probably unreasonable that surgery shall ever fit the traditional "regulatory ethics paradigm". Surgical innovation is acceptable because it focuses on patients and is clinically driven. For quality control and legal standing it is imperative that all surgeons appreciate the innovativeness and experimental nature of their procedure and apply regulatory mechanisms such as retrospective reviews to ensure their safety and efficacy. To continue to perform procedures different from the acceptable standard of care without such regulation is unacceptable in today's world — ethically and legally.

THE INFORMED CONSENT

Informed consent is more than a legal requirement. It is a standard of ethical surgical practice that enhances the surgeon/patient relationship and that may improve the patient's care and the treatment outcome. True surgical informed consent has the following components :

- (1.) The name of the procedure
- (2.) The explanation of the procedure in laymans terms and in a language that is easily understood by the patient. An informed consent in English for someone who understands only Hindi has no standing. It may be written in English but should be translated into Hindi. The name of the translator should be noted (it is permissible for the surgeon to do it himself/herself). The translation should be verified by the sign of a witness who will testify to its accuracy. This can be a patients relative or a nurse in the preoperative room.
- (3.) The risks of the procedure and their effects on lifestyle. It is not adequate to consent for "Cranial Nerve VII injury OR facial nerve injury" for a parotidectomy. The resultant "asymmetry and weakness of the face" should be the correct wording on the consent form.
- (4.) The reasonable alternatives available should have been discussed and documented.
- (5.) The patient should be "competent" at the time of signing the consent

We will now take a look at some of these aspects in more detail.

How much information to patient

How do you know when you have said enough about a certain decision? Most of the literature and law in this area suggest one of three approaches:

- **Reasonable physician standard: what would a typical physician say about this intervention?** This standard allows the physician to determine what information is appropriate to disclose. However, it is probably not enough, since most research in this area shows that the typical physician tells the patient very little. This standard is also generally considered inconsistent with the goals of informed consent as the focus is on the physician rather than on what the patient needs to know.
- **Reasonable patient standard: what would the average patient need to know in order to be an informed participant in the decision?** This standard focuses on considering what a patient would need to know in order to understand the decision at hand.
- **Subjective standard: what would this patient need to know and understand in order to make an informed decision?** This standard is the most challenging to incorporate into practice, since it requires tailoring information to each patient. It also expects the patient to have great powers of understanding and an excellent state of mind to decide correctly for himself. Research suggests that patient who is sick sometimes may not judge things accurately.

In India it would seem that most often the “reasonable physician standard” is applied. However, the “reasonable patient standard” should be the required standard. Given the educational level of most of our patients, their general lack of medical awareness and their faith in their physician it is probably unreasonable to apply the “subjective standard”. If a patient desires more information, then it should be provided. In the United States different states have their own legislation which demands which standard to apply. It is generally either the “reasonable patient standard” or the “subjective standard”.

Should the consent be written?

No. It is not necessary for the consent to be written. In a life threatening situation or a situation where written consent cannot be obtained a verbal consent is adequate. In the interests of the physician a written consent is preferable. Likewise, consent can be retracted verbally by the patient (for example, a change of mind while being wheeled into the operating room should be treated as a retraction and the procedure abandoned).

Which procedures require consent?

All invasive procedures and sometimes non-invasive procedures (like HIV testing) require consent. Blood sampling and Xrays etc are normally exempt and a presumed to have been consented for by all patients.

Who is a competent patient?

Competence of a patient is sometimes a critical factor in deciding their ability to make a decision. Minors by definition are incompetent and must be decided for by the parents / caregivers. A competent patient is one who (a) understands his or her situation; (b) understand the risks associated with the decision at hand; and (c) can communicate a decision based on that understanding.

To illustrate this better lets take the example of a mentally challenged patient. Simply being “mentally challenged” does not make the patient incompetent. If he or she is able to demonstrate enough understanding of the issue being discussed then he or she is deemed competent. Likewise, he or she may be considered competent for deciding one aspect of his/her care but not for

another.

Likewise a competent patient may become temporarily incompetent once premedicated preoperatively. Therefore, it is imperative that all strong premedication be withheld till the consent process is completed. It is not justifiable though to withhold pain relievers from a suffering patient under the pretext of obtaining consent, for that might amount to some form of coercion.

Another question is whether the preoperative room is the best place for consent taking. The argument against it being the patient there is under considerable stress and therefore not competent. However, numerous studies on this issue have demonstrated that these patients take the same decision in the preoperative room as otherwise. It therefore seems justified to continue taking consents in the preoperative room.

Can patients be influenced by the consent process?

Influence can be applied to the information given to patients, and generally falls into three categories: (a) coercion, (b) manipulation, (c) persuasion

Coercion is the application of a credible threat to the patient, and is always unethical. *Manipulation* involves incomplete or nontruthful presentation of information, such as lying, omitting vital information, or deliberately deceiving. Manipulation is always ethically suspect. *Persuasion* involves the presentation of a rational argument for a choice, and is permissible, even desirable at times during the consent process. Patients recognize that physicians have expertise and advice to offer about their care, and expect physicians to be forthright with recommendations. Once again, it seems in the Indian scenario that persuasion may be the best policy. Most of our patients as mentioned earlier lack the in depth understanding wherein they can be presented all the data and statistics and ask to make up their mind themselves as to how they wish to be treated.

What risks need to be explained?

General rules to follow in consent for surgery and anesthesia are to inform the patient of common risks even if they are not serious and very serious risks, such as death, even if they are not common. It is unreasonable to expect that a doctor would explain all the risks associated with a procedure, including anecdotal ones as the list may run into several pages.

Is anesthesia covered?

While the surgical consent form does contain a phrase regarding consent for anesthesia care, the informed consent process requires that a separate discussion of anesthesia risks be carried out by the anesthesia provider.

What to do for an incompetent patient?

If the patient is determined to be incapacitated / incompetent to make health care decisions, a “surrogate decision maker” must speak for him/her. If such a person is not available then the “best interest policy” should be adopted. Herein, the physician takes a decision that he/she believes an “average patient would have taken given all the available information”. Distinction has to be made between what the physician thinks is reasonable versus what the physician thinks an average patient would consider reasonable.

Is a properly taken informed consent a fool-proof guarantee against medico-legal liability?

No. There is no ‘legally foolproof’ consent form. A signed consent form of any nature neither guarantees a doctor protection against legal action nor ensures patient satisfaction. It merely demonstrates

that some process to exchange information was followed.

WORLD MEDICAL ASSOCIATION INTERNATIONAL CODE OF MEDICAL ETHICS

DUTIES OF PHYSICIANS IN GENERAL

A PHYSICIAN SHALL always exercise his/her independent professional judgment and maintain the highest standards of professional conduct.

A PHYSICIAN SHALL respect a competent patient's right to accept or refuse treatment.

A PHYSICIAN SHALL not allow his/her judgment to be influenced by personal profit or unfair discrimination.

A PHYSICIAN SHALL be dedicated to providing competent medical service in full professional and moral independence, with compassion and respect for human dignity.

A PHYSICIAN SHALL deal honestly with patients and colleagues, and report to the appropriate authorities those physicians who practice unethically or incompetently or who engage in fraud or deception.

A PHYSICIAN SHALL not receive any financial benefits or other incentives solely for referring patients or prescribing specific products.

A PHYSICIAN SHALL respect the rights and preferences of patients, colleagues, and other health professionals.

A PHYSICIAN SHALL recognize his/her important role in educating the public but should use due caution in divulging discoveries or new techniques or treatment through non-professional channels.

A PHYSICIAN SHALL certify only that which he/she has personally verified.

A PHYSICIAN SHALL strive to use health care resources in the best way to benefit patients and their community.

A PHYSICIAN SHALL seek appropriate care and attention if he/she suffers from mental or physical illness.

A PHYSICIAN SHALL respect the local and national codes of ethics.

DUTIES OF PHYSICIANS TO PATIENTS

A PHYSICIAN SHALL always bear in mind the obligation to respect human life.

A PHYSICIAN SHALL act in the patient's best interest when providing medical care.

A PHYSICIAN SHALL owe his/her patients complete

loyalty and all the scientific resources available to him/her. Whenever an examination or treatment is beyond the physician's capacity, he/she should consult with or refer to another physician who has the necessary ability.

A PHYSICIAN SHALL respect a patient's right to confidentiality. It is ethical to disclose confidential information when the patient consents to it or when there is a real and imminent threat of harm to the patient or to others and this threat can be only removed by a breach of confidentiality.

A PHYSICIAN SHALL give emergency care as a humanitarian duty unless he/she is assured that others are willing and able to give such care.

A PHYSICIAN SHALL in situations when he/she is acting for a third party, ensure that the patient has full knowledge of that situation.

A PHYSICIAN SHALL not enter into a sexual relationship with his/her current patient or into any other abusive or exploitative relationship.

DUTIES OF PHYSICIANS TO COLLEAGUES

A PHYSICIAN SHALL behave towards colleagues as he/she would have them behave towards him/her.

A PHYSICIAN SHALL NOT undermine the patient-physician relationship of colleagues in order to attract patients.

A PHYSICIAN SHALL When medically necessary, communicate with colleagues who are involved in the care of the same patient. This communication should respect patient confidentiality and be confined to necessary information.

Adopted by the 3rd General Assembly of the World Medical Association, London, England, October 1949 and amended by the 22nd World Medical Assembly Sydney, Australia, August 1968 and the 35th World Medical Assembly Venice, Italy, October 1983 and the WMA General Assembly, Pilanesberg, South Africa, October 2006

EXCERPTS TAKEN FROM AND SUGGESTED READING

1. Thomas T, Claude HO Jr. *Ethics in Surgery Historical Perspective*. Arch Surg. 2000; 135:10-13.
2. Bal A. *Informed consent – legal and ethical aspects. A review of the case law*. Indian Journal of Medical Ethics. Apr-Jun 1999; 7(2)
3. Dangayach N, Joshi N. *Informed consent: consent with a view*. Indian Journal of Medical Ethics. Jul-Sep 2003; 11(3)
4. Moore FD. *Ethical problems special to surgery. Surgical teaching, surgical innovation, and the surgeon in managed care*. Arch Surg. 2000; 135: 14-15

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