

Legal and Ethical Aspect of Surgical Practice: In Particular Reference to Indian Scenario

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ABSTRACT

Legal and ethical issues in the field of medical practice have rapidly increased over last quarter of century. It has number of reasons which includes complicated partnership of health care providers, variable cultures of patients, wide scope of available alternatives and new advancements in surgical procedures.

Surgeons due to its nature of work are more exposed to medico-legal and ethical issues. Advancements of modern technologies in medical practice and increase in scope of human organ transplantation warranted the discussion of legal and ethical issues more extensively and delicately. Besides these, there is need to develop a minimum standard operating procedure (MSOP) including all facet i.e. from taking informed consent to different stages of managements, by the national and international associations of respective discipline.

American philosophers Tom Beauchamp and James Childress introduced the highly influential "Four Principles" approach to medical ethics. These four basic principles are Respect for autonomy, Beneficence, Nonmaleficence and

Justice. Applications of these four basic principles, alone or in combination, help to identify and resolve ethical issues in medicine. The doctor must balance the competing moral obligations against each other and, through sound judgment, determine which is most morally compelling.

Keywords: Legal and Ethical Aspect, Surgical Practice.

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INTRODUCTION

Legal and ethical issues in the field of medical practice have rapidly increased over last quarter of century. It has number of reasons. Firstly the numbers of partners are involved in providing healthcare, like health care providers, administrators, and funding agencies complicated with highly legally aware patients, resulting in clashes of views, opinions and priorities, which have major ethical and legal dimensions.

Secondly development of multicultural societies; thus healthcare-related decisions thus have to be made on the background of so many different ethnicities, religions, cultures and languages, resulting in varied spectrum of ethical and legal implications. Thirdly peoples of modern world have more opportunity to move from one country to other to seek cost effective treatments, leading to various ethical and legal issues. Fourthly development of new medical specialties and introduction of newer techniques in

medical practice have broadened the spectrum of ethical and legal issues.

As because all these aforementioned factors are involved more in surgical practice in comparison to medical practice, therefore surgeons are more exposed to medico-legal and ethical issues.

With advancement of modern technologies in surgery and increase in scope of human organ transplantation, warranted the discussion of legal and ethical issues more extensively and delicately. Besides these as because there is wide spectrum of prevalent standard method of different surgical procedures which varies place to place within and outside the national boundaries and even person to person, there is need to develop a minimum standard operating procedure (MSOP) including all facet ie from taking informed consent to different stages of managements, by the national and international associations of respective discipline.

PRINCIPLES OF MEDICAL ETHICS

During the 1970s, the American philosophers Tom Beauchamp and James Childress introduced the highly influential “Four Principles” approach to medical ethics.¹ Application of these four basic moral principles, alone or in combination, help to identify and resolve ethical issues in medicine. The doctor must balance the competing moral obligations against each other and through sound judgment determine which is most morally compelling.

These principles are briefly described as follows: -

1. Principle of Respect for autonomy

Literal meaning of autonomy is “self rule”. Autonomy refers to make choices based on their own beliefs and values.² In respect to health care, respect of patient’s autonomy necessarily requires providing adequate information by doctor.

2. Principle of Beneficence

This refers to commitment of a doctor to benefit patients by acting in their best interest. Because the conception of benefit and harm

varies from person to person, it usually requires respecting autonomy.

3. Principle of Nonmaleficence

This refers to moral obligation not to cause harm to patient. All attempts to benefit patients, whether through words, drugs, or procedures carry risk of harm. Hence nonmaleficence is best described as the obligation to avoid causing net harm to patients and should be considered in conjunction with the principle of beneficence.

4. Principle of justice

The principle of justice primarily refers to the obligation to distribute scarce health care resources fairly. It also includes the obligation to respect people’s human rights and to respect morally acceptable laws.

These four basic broad principles generate more specific rules, which provides useful check list of basic moral considerations to examine legal and ethical issues.

Table 1: Typology of ethical issue in surgery

Sl.No.	Principle	Ethical issues in surgery
1	Respect for autonomy	<ol style="list-style-type: none"> 1. Informed consent for surgery 2. Truth telling 3. Consent for the involvement of trainees in surgical procedure 4. Confidentiality 5. Respecting patient’s request 6. Good communication skills
2	Beneficence	<ol style="list-style-type: none"> 1. Surgical competence 2. Ability to exercise sound judgment 3. Continuous professional development 4. Research and innovation in surgery 5. Responsible conduct 6. Functioning equipment and optimal operating conditions 7. Minimizing harm (including pain control) 8. Good communication skills
3	Nonmaleficence	<ol style="list-style-type: none"> 1. Surgical competence 2. Continuous professional development 3. Ability to exercise sound judgment 4. Recognizing the limit of professional competence 5. Research and auditing 6. Disclosure and discussion of surgical complications including errors 7. Good communication skills
4	Justice	<ol style="list-style-type: none"> 1. Allocation of scarce resources 2. Legal issues 3. Respecting human rights 4. Whistle blowing

APPLICATION OF FOUR PRINCIPLE APPROACH OF ETHICS IN SURGERY

Respect For Autonomy

The principle of respect for autonomy mainly involves “obtaining consent”, “respecting confidentiality”, and “avoiding deception”.

Among these most important issue in surgical practice is duty to obtain adequately informed consent. To examine operate or, treat

upon a patient without consent is assault in law, even if it is beneficial and done in good faith.³ There are cases in which surgeons have been fined, where no otherwise any negligence had been proved but only on the ground that the consent was taken from relative instead of patient. Besides these in operations

which may result in sterility the consent of both husband and wife is needed.⁴

One difficulty faced commonly in surgical practice is, how much information is adequate? It is neither desirable nor practicable to describe all possible complications to patients. Providing too much information can reduce rather than enhance a patient's autonomy by confusing the patient. Excessive information about theoretical complications may frighten the patient which may result in refusal. However, whatever the rare possibility of complication to occur, if it occurs, may land the surgeon into problem if dragged in court of law by highly legally conscious society. And further more in the countries like India, the investigations and delivery of the verdict mostly conducted by medically ill-informed personnel. Many times such verdicts are passed without adequate consultation with medical experts. More ever the circumstances under which surgeons are practicing in different part of the country is not uniform rather very wide range of variations exists. However it is not uncommon that many times surgeons fail to provide necessary information also.

To solve this problem, the national level professional associations of respective discipline in consultation with medico-legal experts, should evolve a uniform standard format/protocol for obtaining informed consent for each and every procedure that may be followed all over country. However it may not cover all cases but it can be effectively used in court of law as reference where the question of adequately informed consent is to be decided.

Three factors affects the extent of disclosure; "severity of the complication", "likely hood of complication to occur" and "patient's information preference".² For example the surgeon should think of person's professional concern while taking consent for surgery of vocal cord of a professional singer or lecturer.

Some courts in England have applied the "reasonable person standard" to determine how much information should be given.⁵ This standard requires the surgeon to provide information that a reasonable person in the patient's circumstances would want to know.² The concept of full disclosure implies that "the fact which a doctor must disclose depends on the normal practice in his community and on the circumstances of the case."³ But again explanation of these vague terminologies can only be provided by respective professional associations in consultation with medico-legal experts.

One important question arises usually in medical teaching institutions or big hospitals where more than on specialists of different level of competence works together in a unit. Patients usually demands that their operation should be performed by senior most surgeon. Whether their request should be granted on the basis of respecting autonomy and greater likelihood of benefit?

Here the principle of beneficence applies to other patient also. The experienced surgeon, by definition, a limited resource, that should be shared fairly among those in medical need.² The consultant may decide to perform complex and high risk operation and delegate simple and low risk operation to residents. The right to health care surely entitles patients to adequate health care, rather than "best care".² Moreover acceding to patient's requests for the best care would have negative consequences on the training of less experienced surgeon and their ability to reduce surgical complications. The duty of beneficence is not limited to current

patients but also extends to future patients and they too should benefit from high standard of surgery.²

Beneficence

Every effort should be made to do benefit and to reduce likelihood of surgical complications. For this surgeon should not only be knowledgeable and competent but also be able to judge limitations.

Under the principle of beneficence it is important that the surgeon should update their knowledge and skill by attending conferences, seminars, workshops and reading journals to keep himself informed on the latest developments in their field.

Regulation 1.2.3 of Indian Medical Council (Professional conduct, Etiquette and Ethics) regulations 2002, states that "A physician should participate in professional meetings as part of Continuing Medical Education programs, for at least 30 hours every five years, organized by reputed professional academic bodies or any other authorised organizations."⁴

Good surgical judgment to determine appropriateness of surgery necessitates the evaluation of risks, burdens and benefits of surgery combined with belief and values of individual patient.

Judgment of limitations is not only limited to knowledge and skill of the surgeon but also includes the limitations related to lifestyle, habits, age related changes, personal physical & mental infirmities, resources etc. The senate of surgery of Great Britain and Ireland (now called surgical forum) advises that the surgeon should "avoid lifestyles and habits giving rise to potential risk to patients."⁶

The surgeon should ensure that the team has adequate rest between shifts and follows appropriate infection control measures to reduce the incidence of iatrogenic complications.² It is duty of the surgeon to ensure that all equipment's are functioning and reliable right from simple light source to most sophisticated instruments.

The surgical profession as a whole has an obligation to improve surgical outcomes to reduce complications by conducting research and participating in systemic programs of quality improvement.

However in conducting research and in using innovative techniques statutory guidelines like ICMR guideline and declaration of Helinski should be followed in letter and spirit. The surgical Forum advises that "such innovation is acceptable to the degree that a responsible body of medical opinion would agree that it has been employed in a situation where there was no alternative."⁶

Nonmaleficence

The issues discussed under the principles of beneficence like surgical competence, ability to exercise sound judgment, continuous professional development, research and innovations, checking instruments, strict infection control measures and quality development also falls under the principle of Nonmaleficence.

Another important issue which has been captured by more than one Principle is Good communication skills. Substandard communication with unclear and insufficiently detailed instructions can lead to emotional distress in patients and reduction in efficiency among the surgical teams. Rules of informed consent

require "All disclosures must be in language, the patient can understand."³

It is the moral obligations of surgeons to minimize the recurrence of surgical complications by conducting regular morbidity and mortality meetings. Involvement of autopsy surgeons is of paramount importance in these meetings. The surgeons should also describe their surgical experiences in journal articles and conferences, so that other may also benefit from any lesson learned.

Justice

Besides the principle of distributive justice, the surgeons are also required to to recognize a problem in colleague that may put patient at undue risk, such as alcoholism, drug dependence etc. Regulation 1.7 of Indian Medical Council (Professional conduct, Etiquette and Ethics) regulations 2002 states "A physician should expose, without fear of favour, incompetent or corrupt, dishonest or unethical conduct on the part of members of medical profession."⁴

LEGAL ASPECT OF HUMAN ORGAN TRANSPLANTATION

In India human organ transplantation is governed by Human Organ transplantation Act-1994 (with latest amendment in 2011) and latest rules made there under namely Transplantation of Human Organs and Tissues Rules, 2014.

1. There are three main aspect of "The Transplantation of Human Organ Act, 1994:-
 - i. It aims at putting a stop to live unrelated transplant barring few in exceptional circumstance as prescribed.
 - ii. In the case of live related transplant, it defines that the donor and recipients are near relative, with an exception if the transplant is done with prior approval of the Authorisation Committee on an application jointly made by donor and recipient.
 - iii. It accepts the brain stem death criterion.³
2. The Transplantation Rules specifies the near relatives as Spouse, Grandmother, Grandfather, Mother, Father, Brother, Sister, Son, Daughter, Grandson and Granddaughter above the age of 18 years.⁷
3. The Act defined human organ as any part of the human body consisting of a structured arrangement of tissues, which if wholly removed cannot be replicated by the body.⁷
4. The Act imposes for compulsory registration of hospitals engaged in removal, storage or transplantation of human organ.³
5. "The technician who can enucleate cornea" means the technician with any of the following qualification and experience who can harvest corneas (enucleate eyeballs or excise corneas), namely: -
 - iv. Ophthalmologist possessing a Doctor of Medicine (M.D) or Master of Surgery (M.S) in ophthalmology or diploma in Ophthalmology (D.O); and
 - v. Registered doctors of all recognised system of medicine, Nurses, Paramedical Ophthalmic Assistant, Ophthalmic Assistant, Optometrists, Paramedical worker or Medical Technician with recognised qualification of all systems of Medicine, provided the person is duly trained to enucleate a donated cornea or eye from registered and functional eye bank or

Government medical college and, the training certificate should mention that he has acquired the required skills to independently conduct enucleation of the eye or removal of cornea from the cadaver.⁸

6. In case of other organs no such removal shall be made by any person other than the registered medical practitioner.⁷
7. Notwithstanding anything contained in the Act, the eyes or the ears may be removed at any place from the dead body of any donor, for therapeutic purposes by a registered medical practitioner.⁷

TRANSPLANTATION FROM LIVING BODY

1. No human organ removed from the body of a donor before his death shall be transplanted into a recipient unless the donor is a near relative of the recipient.⁷
2. If any donor authorizes the removal of any of his human organs before his death under subsection (1) of section 3 of the Act, for transplantation into the body of such recipient, not being a near relative, as is specified by the donor by reason of affection or attachment towards the recipient or for any other special reasons, such human organs shall not be removed and transplanted without the prior approval of the Authorisation Committee.⁷
3. Living organ/tissue donation by minors shall not be permitted except on exceptional medical grounds to be recorded in detail with full justification and with prior approval of the Appropriate Authority and the Government concern.⁸
4. The transplantation shall not be permitted if the recipient is a foreign national and donor is an Indian national unless they are near relatives.⁷
5. When the donor and/or recipient belongs to a State/Union Territory, other than the State/Union Territory where the transplantation is proposed to be undertaken, verification of residential status by Tehsildar or any other authorised officer for the purpose from the State/Union Territory of domicile of donor and/or recipient shall be required.⁸
6. When the proposed donor or recipient or both foreigners, a senior Embassy official of the country of origin has to certify the relationship between the donor and the recipient. In case a country does not have an Embassy in India, the certificate of relationship, shall be issued by the Government of that country.⁸

TRANSPLANTATION FROM DEAD BODY

1. Any person above 18 yr of age in the presence of two or more witness (at least one of whom is a near relative of such person, may authorize at any time before his death, the removal of any human organ of his body, after his death, for therapeutic purposes.⁸
2. In case where brain-stem death of any person below 18 years of age certified under Section 3(6) of The Transplantation of Human Organs Act, 1994, any of the parents of the deceased person may give authority of removal of organ.⁸
3. The organ may also be removed for therapeutic person even if no authority under Section 3(2) of the act has been given, if there is no reason to believe that the person did not want to donate his/her organ(s)/tissue(s) after his/her death, by the authorization of person having lawful possession of dead

body, unless he has reason to believe that any other relative of the deceased person has objection to any of the deceased person's human organs being used for therapeutic purpose.^{7,8}

4. Where any human organ is to be removed from the body of a deceased person in the event of brainstem death, death must be certified by the board of medical experts consisting of the following namely:
 - a. The registered medical practitioner in charge of the hospital in which brain-stem death has occurred;
 - b. An independent registered medical practitioner, being a specialist, to be nominated by the registered medical practitioner specified in clause (i), from the panel of names approved by appropriate authority.
 - c. A neurologist or a neurosurgeon to be nominated by the registered medical practitioner specified in clause (i), from the panel of names approved by the Appropriate Authority; "provided that where a neurologist or a neurosurgeon is not available, the registered medical practitioner may nominate an independent registered medical practitioner, being a surgeon or a physician and an anaesthetist or intensivists subject to the condition that they are not members of the transplantation team for concerned recipient and to such condition as may be prescribed.
 - d. The registered medical practitioner treating the person whose brain-stem death has occurred.⁷

REMOVAL OF ORGAN FROM UNCLAIMED BODY

- In case of unclaimed bodies in hospital or prison, organs can be removed after 48 hours on authorization of officer In-charge of Hospital or prison.⁷

REMOVAL OF ORGAN FROM MEDICO-LEGAL CASE

- Where the medico-legal autopsy has to be performed, the person competent under this Act to give authority for the removal of any human organ from such dead body may, if he has reason to believe that such human organ will not be required for the purpose for which such body has been sent for post-mortem examination, may authorise the removal for therapeutic purpose.⁷

EXPERTS AND THEIR QUALIFICATION

- A. Kidney transplantation
 - M.S. (Gen.) surgery or equivalent qualification with three year post MS training in a recognised transplant center in India or abroad and having attended to adequate number of renal transplantation as an active member of team.
- B. Transplantation of liver and other abdominal organs
 - M.S. (Gen.) surgery or equivalent qualification with three year post MS experience in the specialty and having one year training in the respective organ transplantation as an active member of team in an established transplant center.
- C. Cardiac, Pulmonary, Cardio-pulmonary transplantation
 - M.Ch. cardio-thoracic and vascular surgery or equivalent qualification in India or abroad with at least three years' experience as an active member of the

team performing an adequate number of open heart operations per year and well versed with coronary bypass surgery and Heart-valve surgery.

- D. Cornea transplantation
 - M.D. or M.S. or Diploma (DO) in ophthalmology or equivalent qualification with three months post M.D. or M.S. or DO training in a recognised hospital carrying out corneal transplant operations in a recognised hospital or institution.
- E. Other tissues: Heart Valves, Skin, Bones etc:
 - Post Graduate degree (MD or MS) or equivalent qualification in the respective specialty with three month post M.D. or M.S. training in a recognised hospital carrying out respective tissue transplant operations and for the heart valve transplantation, the qualification and experience of expert shall be MCh degree in Cardiothoracic and Vascular Surgery (CTVS) or equivalent qualification with three months post MCh training in a recognised hospital carrying out heart valve transplantation.⁸

PUNISHMENTS FOR CONTRAVENTION OF ACT

1. Punishment for removal of human organ without authority: Imprisonment for a term which may extend to 10 yrs and with fine which may extend to Rs 20 lakh.
2. Punishment for commercial dealing in human organ: Imprisonment for a term which shall not less than 5 yrs but which may extend to 7 yrs and shall also be liable to fine which shall not be less than Rs 20 Lakh but may extend to Rs 1 crore.
3. Illegal dealing in human tissue made punishable with imprisonment for term which shall not be less than 1 year but which may extend to 3 year and shall also be liable to fine which shall not be less than 5 lakh rupees but which may extend to 25 lakh rupees.
4. Punishment for contravention of any other provision of the Act: - imprisonment for a term which may extend to 5 yrs or with fine which may extend to Rs 20 Lakh.⁷

CONCLUSION

Surgeons are more exposed to legal and ethical environment which has become more delicate after advent of newer techniques, complex procedures and legislations complicated with highly variable culture and legally aware society. It has warranted the standardization of scientific, ethical and legal principles for surgical practice both at the level of professional associations and individual and more importantly it should be combined with moral perceptions.

REFERENCES

1. Beauchamp T, Childress J (2001) Principles of biomedical ethics, 5th ed. Oxford University Press, New York.
2. Simisade Adedeji, Daniel K Sokol, Thomas Palser, Martin Mc Kneally. Ethics of surgical complications, World J Surg, 2009; 33:213-22.
3. Reddy KSN, The essential of Forensic Medicine Toxicology. Jaypee The health Sciences Publishers New Delhi 2014 33rd ed. P 50, .651.

4. Government of India Gazette, Medical council of India PartIII, Section 4, Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002, Regulation 7.16, 1.2.3,1.7.
5. Department of Health (2001). Good practices in consent implementation guide: consent to examination and treatment, DoH Publication, London.
6. Senate of Surgery of Great Britain, Ireland (1997) Senate paper 2. The surgeons duty of care: Guidance for surgeons on ethical and legal issues. Senate of Surgeons of Great Britain & Ireland.
7. Govern of India Act, The Transplantation of Human Organ Act 1994 (No.42of 94) amended in 2011, Ministry of Law, Justice and Company affairs (Legislative department). Section 2(i) 2(h), 3 (4), 10 (2), 9 (1), 9 (3), 9 (1) (A), 2 (f), 3 (1,2), 3(7), 3 (6), 5 (1), 6(b), 18, 19, 19 A, 20.
8. Government of India Gazette. Part II section3 subsection (i) Ministry of Health & Family Welfare. Transplantation of Human Organ and Tissues Rules 2014, Rule 2(f), 5(3) (g), 14, 20, 5 (b), 26 (C).

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