INTRODUCTION

This article is intended to provide a preliminary overview over questions of medico-legal nature arising in the practice of anaesthesiology, specifically in India. It is intended to be an informative review article that will provide guidance to those new to or looking to pursue professional practice and does not aim to be a comprehensive analysis of all medico-legal questions that may arise in practice. This article serves as a recollection of best practices, legal precedent and experiences from the authors’ professional interaction with these questions as anaesthesiologists. The article is structured into four sections: guidance on ethical practices in anaesthesiology; the role of consent; the importance of maintaining records; and finally, the fourth section which includes discussion on the recently introduced Consumer Protection Act (CPA), 2019 which repealed the former Act of 1986. The following section will provide an insight into guidance on ethics and ethical practices in the practice of anaesthesia.

GUIDELINES FOR THE ETHICAL PRACTICE OF ANAESTHESIOLOGY

The Medical Council of India has published a section on Ethical Guidelines which every practising doctor in India must be familiar with. Since the establishment of anaesthesia as a branch of medicine, the rapid technological growth, improved safety profile of...
Anaesthesiologists play an important role of leadership in ethics and medicine which has been established firmly during the coronavirus disease (COVID) pandemic. Ethics is concerned with what is good for individuals and society, distinctions and definitions of what is considered right and wrong in the marketplace of ideas. It suffices to say that what is considered ethical in society is fluid, and subject to changing externalities, and is dependent heavily on immediate social, cultural and economic factors. However, the medical profession, not unlike the legal profession, remains highly regulated by ethical standards, and legal rules and regulations in order to achieve ethical practice. For example, the American Medical Association (AMA) requires its members to adhere to the AMA Principles of Medical Ethics and other specific ethical guidelines. The conduct of a registered Medical Graduate is governed by the Ethics and the regulations pronounced by Indian Medical Council Act 1956. Qualified physicians must therefore abide by regulations under Indian Medical Council act, especially Professional, Etiquette & Ethics Regulations 2002 and its subsequent amendments.[2] The American Society of Anaesthesiologists (ASA) has published a set of guidelines for the ethical practice of anaesthesiology amended in 2018.[6] The Indian Society of Anesthesiologists (ISA) has also recommended similar guidelines for ethical practice.[4] Some basic principles within medical ethics are discussed below.

A. Basic Principles of Medical Ethics[5]

- Nonmaleficence: Anaesthesiologists abide by the doctrine of ‘do no harm’ to their patients.
- Autonomy: The patient is an independent being who can make fully informed decisions regarding his/her own health care and coercion is unethical.
- Justice: Anaesthesiologists should be fair when providing their services to surgical patients.
- Beneficence: While the principle of nonmaleficence is based on ‘do no harm,’ beneficence requires physicians to ‘do good’ for the patient in every situation.

B. Common Ethical dilemmas in anaesthesia practice[6]

Anaesthesia is a unique speciality in medicine where a patient is mostly unaware of the anaesthesiologist’s presence or ‘behind the screen’ work. Anaesthesia invariably involves using machines and gadgets in patient care. These factors may potentially result in dehumanisation of patient care and result in an ethical dilemma. The literature shows that very limited work has been done to incorporate the ethical value education in teaching-learning in this speciality. Ethical issues in anaesthesiology can be categorised into preoperative, intra operative and postoperative for better clarity.

C. Preoperative issues[6]

The anaesthetist and patient are usually less familiar with each other and effective communication is necessary to establish a good rapport and comfort level. Anaesthesiologists should know exactly how much to explain to patients about the anaesthetic process in order to get an ‘Informed Consent’ from the patient. It is a common occurrence where the surgeon may not approve of the anaesthetist explaining all the risks related to anaesthesia and the surgery to the patients, in the fear that patient may cancel the procedure. In some cases, a patient maybe posted for an unindicated surgery. In both events, it is the anaesthetist’s predicament to decide whether to put forth the true opinion in the best interest of the patient or to convince himself/herself that it is not his/ her place to advise the surgeon and he/she may choose not to opine in the fear of losing the practice. Many a times ‘fitness’ for surgery is given by the general physician whose opinion may be in conflict with that of the anaesthesiologist. These ethical dilemmas can be solved by skilful interaction with patients, surgeons and other colleagues without having a direct conflict.

D. Intraoperative issues[6]

Anaesthesiologists should guard the patients’ modesty and be compassionate to their feelings when they are in the operating room. The ‘captain of the ship’ tendency of surgeons is a major concern that can create conflict. Anaesthesiologists should be very diplomatic in their approach to avoid conflicts during this period. The calm and quiet nature of
anaesthesiologists may be misinterpreted as docile, so it is essential to remain assertive and avoid domination by other professionals during patient care.

E. Postoperative period

The anaesthesiologist as a perioperative physician has greater responsibilities in the postoperative period until the patient is discharged. A busy anaesthesiologist may rely on the surgeon for postoperative pain relief which can have ethical implications as inadequate pain relief is a common shortcoming. An all-purpose pre-existing Do not resuscitate (DNR) is not necessarily applicable during an anaesthetic, as aspects of anaesthetic treatment may justify the suspension of DNR orders during surgery, but the specifics of that suspension must be individualised and discussed with patients.

F. Teaching ethics in Anaesthesia

Traditional approach of learning ethical principles is through the examples set by the senior colleagues or teachers, which may not always be feasible. Problem-based learning (PBL) is an effective tool in teaching ethical value education to students. Incorporating issues pertaining to ethics into every clinical problem is very effective in raising awareness among the students. Topics like interprofessional relationships, consent signing, informing critical conditions to relatives etc., is best taught using case scenarios and communication skill modules. These skills can be assessed during exams or in Objective Structured Clinical Examination (OSCE) stations.

THE ROLE OF CONSENT

‘Every human being of adult years and sound mind has a right to determine what shall be done with his own body and a surgeon who performs an operation without his patient’s consent commits an assault. A medical practitioner cannot examine, treat or operate upon a patient, without the patient’s consent, except by committing a trespass or assault.’  Benjamin Cardozo

Literal meaning of consent is giving permission or allowing someone to do some act. In view of CPA and as per Indian Medical Council an informed written consent is must before doing any procedure. A proper informed written consent must be obtained before performing any major diagnostic or therapeutic procedure, general anaesthesia, any surgical procedure or intimate examination. Consent must also be taken before examination for determination of age, sex, potency, virginity and medico-legal cases.

A. Informed written consent

Informed written consent is a legal term that implies an autonomous, informed authorisation by a patient to undergo a medical or surgical treatment. Informed consent includes a proper discussion between physician and a patient about all relevant aspects of a proposed treatment and its alternative procedure, if available.

Components of Informed Consent

As per Indian Penal Court there are 5 essential components of an informed consent.

1. Disclosure - Transmission of proper information that is relevant and material in decision making. The patient must be informed about the following components:
   a. nature of the disease
   b. options available for treatment and management including risks and benefits
   c. success and failure rate, after effects and prognosis of disease
   d. cost of treatment

For example, in the case of A.K. Mittal (DR) V. Raj Kumar 2009 CTj 606 (CD): 2009 (2) CPR 43: 2009 (20 CPj 160 (NCDRC), a minor patient was operated for modified radical mastoidectomy (MRM) and the consent for the same was taken from his father. However, it did not mention the name of surgery and risk of facial palsy was also not explained to patient and relatives. After the surgery, the patient suffered from facial paralysis that cannot be corrected by any means. The court found the doctor negligent for not taking proper informed consent and awarded a compensation of RS 1.5 lakh.

2. Comprehension -The informed consent must be comprehensive to the patient. It should be explained in the patient’s own language and if needed an interpreter may also be used. If the patient has any communication problem (deaf, dumb or blind) special attention must be taken to make sure that he has understood everything properly.

3. Absence of any outside control - The informed consent for treatment should be given by patient’s free will, without any undue pressure or influence from doctor, nurse or any relatives.
If a patient voluntarily asks for advice, it may be given.

4. **Competence** - Consent for purpose of clinical examination, diagnosis and treatment can be given by any person who is conscious, mentally sound and above 18 years of age. Patient should not be under influence of any drug, alcohol or anaesthesia. For general physical examination, patients above 12 years of age can give consent.

5. **Actual Consent** - To make it actual and legally acceptable consent (a) everything must be in writing (b) signature of patient must be obtained in the presence of two independent witnesses to avoid disputes over legal admissibility of consent. Patient and witness should write their names below their signatures and relationship between them should be specified. In case of illiterate patient, thumb impression can be used, and name should be mentioned below the impression. Consent should be for a specific procedure and if any other procedure is required, one should take fresh consent unless it is lifesaving.

Some examples of legal disputes over questions of consent and informed consent are given below.

i. **Arjun Bala Krishnan Iyer v. Soni Hospital and others**, AIR 2003 Madras-HC 389. In this case, the patient was operated for ovarian cyst and informed written consent was taken for the same. During surgery, due to profuse uterine bleeding, a hysterectomy was done with written consent from the patient's husband. Later on, this patient sued the doctors and hospital for some complication. The patient pleaded that the consent for hysterectomy was not taken from the patient. However, this plea was denied by the court, as the procedure was lifesaving and taking consent from the patient was not possible as she was anaesthetised.

ii. **Shailesh A. Shah (Dr.) v. Aphraim Jayanand Rathod**, first appeal no. 597/95, decided on 8/5/2003 reported in 2003 LJCP p. 384 (NCDRC). In this case, patient was operated for appendicectomy for which proper informed consent was taken from the patient and relatives. Later, the patient required re-exploration because of intra-abdominal sepsis and perforation but no separate consent was taken for second surgery. For this, the court found negligence on the part of the doctor for not taking consent and a compensation of Rs 1 lakh was awarded.

For a planned blood transfusion, an informed written consent is a must but during surgery if blood transfusion is required to save the patient's life, blood transfusion can be done without consent. A separate consent for anaesthesia must be taken (as surgical consent does not include anaesthesia) and documented explaining all the pros and cons and a choice may be given to choose between anaesthesia options. In certain conditions, it is desirable to take consent from the spouse as well, like in sterilisation procedure or when surgery may affect or limit sex function or may result in death of an unborn child.

**B. Substitute consent (Proxy consent)**

Substitute consent means when consent is taken or obtained on behalf of a patient who is not competent to give consent for medical treatment or refusal for the same. This type of consent is acceptable in the case of a minor, unconscious patient, patient under anaesthesia or sedation, mentally unsound (or intoxicated) patient or in any emergency or accidental case where near relatives are not available.

For proxy consent to be valid in law, followings requirements must be met:

1. The person herself is not in a position to give consent (minor, unconscious, insane or intoxicated)
2. Medical or surgical intervention is urgently needed to save lives.

**C. Blanket consent**

It is a common practice that at the time of admission, a patient is asked to sign a printed format in which consent is taken for any type of procedure or surgery without specifying any treatment. This type of blanket consent is legally invalid, hence should be avoided.

**D. Withdrawal of consent**

Consent is a willful act, and the patient can withdraw her consent at any time. Once a patient withdraws his/ her consent, it is unlawful to continue treatment by a medical professional. Refusal to give consent is as important as giving consent and must be recorded with date and time so that we are not held responsible for any
deterioration in the patient’s condition due to delay in treatment for want of consent. It is advisable to talk to the patient’s relations and obtain their signatures as witness. In the event something undesired happens, the patient’s relations having signed as witnesses are less likely to go to the police or court.

**IMPORTANCE OF RECORDS**

‘Verba volant, scripta manent’ (meaning, spoken words fly away, written words remain) is a quote by emperor Titus addressing the Roman senate around 80 AD. Importance of good documentation has thus been known for a long time, but its true value is often appreciated when a doctor gets tangled in a legal case. Good clinical documentation ensures proper continuity in care and enhances communication in an interdisciplinary healthcare team. Medical records are those documents that explain all details about the patient’s history, clinical findings, diagnostic test results, pre and postoperative care, patient’s progress and medication. The ISA guidelines for practising anaesthesiologists in India, provide a guide on how to maintain good anaesthesia records. The demographic details of patients with a unique hospital identification number, contact numbers for the patient, the anaesthesia checklist (marked and signed) along with the ones mentioned below are some of the important points to keep in mind

- **Anaesthesia:**
  1. Regional/Block: name of block, concentration and volume of local anaesthetic agents, with any adjuvant used.
  2. General Anaesthesia: Premedicants, induction agent, muscle relaxants: name, dose and route of all drugs at appropriate times.

- **Airway management device:** Name of device, size, and if endotracheal tube is used, oral/nasal and fixation mark to be recorded.

- **Maintenance of anaesthesia:** Names and concentration of inhalational agents.

- **Ventilation:** Mode of ventilation used, with tidal volume and respiratory rate if applicable.

- **Symbols for haemodynamic parameters** e.g., SBP, MAP and respiratory parameters (SpO2, Respiratory Rate), must be entered on a chart at appropriate places along with the timelines at regular intervals.

Intravenous fluids and drugs must also be entered with the timeline. Documentation of the postoperative condition of patients is very important. All orders should be clear, legible and self-explanatory. Routine and special monitoring requirements and area of transfer to ward/recovery room/ICU must be mentioned.

The Anaesthesiologist should ensure safe transport of patients from Operation Room to Post Anaesthesia Care Unit/ICU/Ward etc., and place a shifting note documenting the vitals and status of the patient after transport. He should communicate with patient and the relatives at the end of surgery.

The Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations outlines certain duties and responsibilities of the physicians regarding record keeping as follows:

1. Every physician or hospital should maintain the medical records pertaining to the indoor patients for a period of three years from the date of commencement of the treatment.

2. If any request is made for medical records either by the patients/authorised attendant or legal authorities involved, the same must be duly acknowledged and documents should be issued within a period of 72 hours.

3. When issuing a medical certificate, all registered medical practitioners (RMPs) must maintain a register to note details of all medical certificates issued, keeping in mind:
   i. Signature and/or thumb mark of patient along with address
   ii. At least one identification mark of the patient must be present on the certificate.
   iii. Practitioners must keep a copy of the issued certificate.

The regulation also mentions that efforts should be made to computerise medical records for quick retrieval. To encourage digitalisation, the Clinical Establishment (CE) Act and Rules (2012) mandate all clinical establishments to maintain or provide Electronic Medical Records of every patient. Furthermore, based on a recent high court ruling, every medical professional whether working individually or through nursing homes, hospitals, medical universities, is obliged to follow provisions contained in the Act and consequently, adhere to the requirements of the Electronic Health Record (EHR) Standards which have been prescribed under the CE Act.
In March 2020, the Government of India released the ‘Telemedicine Practice guidelines’ wherein it is incumbent on RMPs to maintain the following records/documents too.

1. Log or record of Telemedicine interaction (e.g., phone logs, email records, chat/text record, video interaction logs etc.)
2. Patient records, reports, documents, images, diagnostics, data, etc., (digital or non-digital) utilised in the telemedicine consultation.
3. Specifically, in case a prescription is shared with the patient, the RMP is required to maintain the prescription records as required for in-person consultations.

A judge in the court is faced with two parties to a dispute who give exactly the opposite version of the case. He has no means to know who is telling the truth and who is telling a lie. Cases can be filed in the courts up to three years after the incidence happens. Court cannot rely on the memory of the parties after the lapse of such a long time. Therefore, the courts go by the records. To be of any help in litigation, the records must be legible, accurate and real time.

**Death on the Table**
Anaesthetists are more likely to experience a patient’s death on the table as compared to surgeons, which can be very stressful. It is important to understand that if a death occurs on the table, it does not always imply rashness or negligence. The cause of death can be finalised through post mortem and histopathology investigations.

- A doctor can give the Death Certificate (DC) only if he is sure of the cause of death.
- In cases of anticipated death, it is important to keep the relatives informed.
- Complete all the relevant documentation and tally the notes among the consultants.
- Do not clean the OT; preserve all ampules used during the procedure.
- The OT setup should never be found with expired drugs.
- The death of the patient should be communicated to the relatives in a sympathetic and sensitive manner.
- Always inform the police and insist on the execution of a post-mortem.

**THE CONSUMER PROTECTION ACT**

An anaesthesiologist can be taken to court either in a criminal case or in a civil case. In criminal cases, an anaesthesiologist faces prosecution and punishment, whereas civil courts award compensation for the complainant. After the introduction of CPA, most cases of medical negligence go to consumer courts for simple procedures and speedy disposal.

Consumer has been defined in the CPA as any person who buys something or avails any service for a consideration. Healthcare is not explicitly mentioned in the list of ‘service’. Still, it is widely believed that any healthcare services that are paid for, shall be covered by the gambit of the act. Any health-related service provided by Government hospital or private hospital, where a patient has been charged a fee, full or concessional, can be challenged in consumer court.

Instead of enhancing CPA 1986 through amendments, the Government brought out an entirely new act, CPA 2019 that came into force in July 2020.

The Supreme Court has considered health care a service, under CPA 1986 in *Indian Medical Association v. V P Shantha* case in 1996. It is unclear whether the same will continue to apply after CPA 2019 has come into force and how the courts of law interpret this new act and the fate of healthcare vis-a-vis CPA, remains ambiguous as of today. The Supreme court judgment stands as it is till overruled by any other judgment of the Supreme court or by an act of parliament.

Among other situations, anaesthesiologists have been or can be dragged to the courts in following instances:

- Hypoxic brain damage leading to death during general anaesthesia.
- For missing pre-anaesthetic evaluation and ensuring availability of proper equipment.
- Neurological deficit after neuraxial or regional anaesthesia.
- Lack of disclosure of information/inadequate consent.
- Inadequate monitoring during the procedure.
- Awareness during anaesthesia.

Far higher pecuniary limits have been fixed for commissions at various levels. District Commission (as it is called in the new act, the previous act referred to it as District Forum) has been empowered to entertain consumer complaints not exceeding rupees one crore in value. This limit was Rupees 20 lakhs under CPA 1986. Similarly, state commissions can entertain complaints up to 10 crores and National commission can entertain claims above 10 crores. This
can encourage people to seek higher compensations at local level.

Complaints under CPA 2019 can be filed online and in the jurisdiction of residence or workplace of the consumer, in contrast to earlier practice of filing complaints at the place of purchase or transaction. Also, provision of hearing through videoconferencing has been introduced. This adds to the convenience of filing a complaint and also attending the case from the comfort of home or office. This can translate to an increased number of cases being filed against medical professionals.

Central Consumer Protection Authority (CCPA) has been established under the new act. This Authority has been accorded wide powers, including investigative powers and power to take suo moto action against violators, to protect the rights of the consumers. It can order reimbursement of the price of services and can cancel licenses. Its relevance to the medical profession can be multipronged.

COVID-19 pandemic has seen a sudden increase in numbers of electronic platforms where doctors can provide online consultation and can charge the patient for the same. E-commerce has been included in the new act. Any service availed through online mode and paid for, shall be covered by the act.

Concept of ‘Product Liability’ has been introduced. It also covers services in ways – service that is imperfect, inadequate and without instructions. This can be exploited to the disadvantage of medical professionals.

Alternate Dispute Resolution has been inserted wherein any possibility of settlement between both the parties can be explored through mediation cells attached to every commission at every level. This will result in quick disposal of the consumer complaints. There will be no appeal against such arbitration as this is done with the consent of both the parties.

There is a need to study the new act with a new perspective and we, as medical professionals, should be ready to face any challenge, till there is explicit clarity about the exclusion of healthcare services from the gambit of CPA.

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