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REVIEW ARTICLE

Covid-19 pandemic: Medico legal aspects in anaesthesia practice

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Abstract
Anesthesiology is a specialty that delivers prompt and positive results in patient care. It is natural for the general population to expect the highest degree of care and services from anesthetist. In the present time, patients are much more aware of their rights and medical procedure-related negligence. If any catastrophe occurs, it grabs news headlines very quickly. Laypeople suspect negligence in such cases, and these cases land up in the court of law. In the courts, decisions are left to the judiciary, which can be potentially influenced by the opinion of the general public. There has been a rising trend in medical negligence cases registered in consumer courts after the decision of the Supreme Court, that the services provided by an anesthesiologist come under the word "service" of Consumer Protection Act (1986). So the apprehension amongst the anesthesiologists regarding the legal issues is rising. And it has more value in the present COVID-19 pandemic to deal with. This article highlights the importance of maintaining the standard of care and protocols by which anesthesiologists can avoid legal consequences. Doctors should have legal awareness so that they can defend their cases in courts properly. There is a need to maintain a healthy doctor-patient relationship, good record keeping, and to provide a reasonable standard of care.

Keywords
COVID-19; Medico-legal; Anesthesia; Pandemic

Introduction

Anesthesiology is a specialty with high risk, and ordinary people are not aware of this very fact. Risk is even higher in the present COVID-19 pandemic, and the anesthesiologists are amongst the most vulnerable healthcare population. The 2019-novel Coronavirus is officially called SARS-CoV-2 and is the cause of the recent pandemic.[1] It has affected almost 205 countries till date as per the WHO datasheet.[2] With the advances in the medical field, availability of safer drugs, improved quality of instruments and higher monitoring standards has made the practice of anesthesia safe as compared to older times but "To err is only human" is a common saying since ages. So anesthesiologists are unknowingly bound to make mistakes on particular occasions and complications may ensue. At times, these mistakes may be severe enough to cause morbidity and mortality.

Nowadays, as a result of commercialization and limited interaction in medical practice, mutual trust is lacking in the doctor-patient relationship. The present pandemic has also contributed to increasing this gap between doctors and patients. Patient and their attendants suspect negligence on the part of treating physicians whenever a casualty occurs, and such cases are filed in the court of law. Allegations are coming from the patients and their relatives accusing doctors of being a source of infection to the patients. With the introduction of the Consumer Protection Act in 1986[1] and incorporation of medical professionals under it, there has been a constant rise in cases registered of medical negligence with the consumer forum.[3] This results in rising apprehension among practicing anesthesiologists. WHO has formulated standardized protocols for safely conducting surgery and anesthesia like surgical safety checklist, standard operative procedures (SOPs) for obtaining consent, anesthesia machine checklist, and so on.[4] Indian Society of Anesthesiologists (ISA) had also issued an advisory to ensure the safety of patients and anesthesiologists in the perioperative period during the present COVID-19 era. In the absence of specific treatment or vaccine for COVID-19, preventive measures like regular hand washing or using alcohol-based sanitizer, use of personal protective equipment, not touching face and maintaining social distancing are essential to reduce the spread of infection.[1]

A medico-legal awareness must be present among practicing doctors to defend any cases filed against them in court. Anesthesiologists not abiding by the standard of care protocol and exhibiting negligence are liable for issuing of malpractice suits. Important medico-legal issues related to anesthesia practice are discussed below.

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Informed consent

"Every human being of adult years and sound mind has a right to determine what shall be done with his body, and a surgeon who operates without the patient's consent commits an assault

for which he is liable to damages".[5] Informed consent is a procedure in which patient decides and gives permission for treatment and invasive/non-invasive procedures after achieving an explicit knowledge of implications and facts of undergoing actions mentioned above. It is a procedure or process and not merely a signed legal document, contrary to common belief. The responsibility of obtaining consent for method or treatment lies with the doctor performing or providing the same.[6] Indian Penal Code (IPC) also highlighted the importance of informed consent in sections 88 and 89, which protects the anesthesiologist against any mishap. Sec. 88 IPC state that *"Nothing which is not intended to cause death, is an offense by reason of any harm which it may cause, or be intended by the doer to cause, or be known by the doer to be likely to cause, to any person for whose benefit it is done in good faith, and who has given a consent, whether express or implied, to suffer that harm, or to take the risk of that harm."*[7] While sec. 89 state that *"Nothing which is done in good faith for the benefit of a person under twelve years of age, or of unsound mind, by or by consent, either express or implied, of the guardian or other person having lawful charge of that person, is an offence by reason of any harm which it may cause, or be intended by the doer to cause or be known by the doer to be likely to cause to that person."*[7]

Conditions for obtaining an informed consent are first when the patient can think and decide rationally. Secondly, he has received information regarding all relevant facts, including diagnosis, nature, and purpose of treatment modalities, potential risks, and benefits of a particular therapy and alternative options if available. Informed consent should be based on adequate information regarding the procedure, or treatment.[8] AAGBI strongly recommends that a pre-operative assessment clinic is the best place for obtaining permission.[9] The physicians should focus on facilitating open communication with patients.[10]

Key points to remember while taking informed consent can be summarized as below:

a. It should be taken when the patient is conscious and coherent and not under the influence of any drugs.
b. Consent should be taken only after explaining it in the patient's language, use an interpreter whenever required.
c. The patient should be explained about the procedure, its risks and benefits, and alternatives.
d. The patient can accept or refuse any treatment (patient autonomy principle).
e. In conditions where the patient is with altered mental status, unconscious, disabled or incompetent to provide consent, next of kin may provide consent.
f. If a person is under twelve years of age, or of unsound mind consent to be given by parents/guardians.
g. Under life-threatening emergency conditions, consent should be waived and implied; still, documentation is a must. Relatives can be informed later about the decision taken.
h. Tele-consultation guidelines have been issued in India by the Board of Governors. If consent is obtained from parents/guardians over the telephone or any other electronic media, it should be documented in the presence of two disinterested witnesses before proceedings.

Malpractice

Medical malpractice is defined as a doctor's failure to exercise the standard degree of care while managing ailments of the patients.[11] Medical malpractices legally describes a specific type of negligence in which a professional (anesthesiologist) fails in following standard care and protocol and results in causing harm to a patient. To prove medical malpractice, the following things should be established:

a. The duty owed by a physician to him
b. The physician failure in fulfilling a duty: there was a breach in the duty of care
c. Standard of care and protocols not followed
d. Breach resulting in harm to the patient, the existence of close relation between act and resultant harm.

It should be kept in mind even when anesthesiologists act appropriately, and adverse outcomes may still occur; hence it becomes essential to inform the patients about potential risks and to set appropriate expectations before initiation of procedure/treatment. Bolam's principle states that "*doctors if acted in accordance with a practice accepted as proper by a body of responsible and skilled medical opinion, will not be found negligent*."[12]

Standard of care

Standard of care is the general protocol of how an anesthesiologist must act in any particular case. These standards of care protocols came to exist firstly as a result of an increase in awareness of the general public regarding anesthesia, it's safety and potential risks and secondly increasing number of lawsuits filed against anesthesiologists with the increase in insurance premiums. These circumstances led them to develop ways to reduce anesthesia-induced morbidity and mortality. The court utilizes this protocol to determine whether the medical personnel failed to perform his responsibilities or duty.[13] The standard of care is specific and subjective for each case based on the guidelines laid down by various anesthesia societies. If any lawsuit is filed against any anesthesiologist in

the court of law, then the defendant anesthesiologist will be compared with any reasonable and advisable anesthesiologist from the country.[14]

Anesthesiologists should follow the standard of care during any and all cases:

a. Anesthesia machine and breathing circuits to be checked; and emergency resuscitation equipment and drugs to be kept ready before proceeding for any case.
b. He should be present throughout while dealing with any cases of regional and general anesthesia.
c. Continuous monitoring and evaluation of vital parameters such as ventilation, oxygenation, body temperature, and circulation have to be done.
d. In general anesthesia cases, clinical signs like chest expansion, auscultation for breath sounds, reservoir breathing bag observation should be continuously done. End-tidal carbon dioxide ($etCO_2$) monitoring is also encouraged whenever possible and available. Correct position of endotracheal tube/laryngeal mask airway(LMA) to be ensured and confirmed by capnography.[15]

Another critical issue that has a close link with the standard of care during the present COVID-19 pandemic is to acquire infections from the healthcare workers. Anesthesiologists work close to the patients, thus increasing the chances of disease spread from doctors to patients if they are infected. Recently, in State of Rajasthan (India), the possible root of transmission to the patients was believed to be the same private hospital whose coronavirus-infected doctors treated hundreds of patients before themselves testing positive.[16]

In this scenario, anesthesiologists can be charged with sec. 269 and 270 IPC.[7] Sec.269 states *"Whoever unlawfully or negligently does any act which is, and which he knows or has reason to believe to be, likely to spread the infection of any disease dangerous to life, shall be punished with imprisonment of either description for a term which may extend to six months, or with fine, or with both."* While sec 270 state *"Whoever malignantly does any act which is, and which he knows or has reason to believe to be, likely to spread the infection of any disease dangerous to life, shall be punished with imprisonment of either description for a term which may extend to two years, or with fine, or with both."* That's why it is crucial to mention the risk of infection spread from the anesthesiologist to the patient. Many a times the infected person does not show any evidence of infection, and he continues to do his routine work without knowing his infectivity. This important fact has to be highlighted to the patient while taking consent. And, obviously wilfully hiding information by healthcare professionals regarding their infectivity status amounts to crime according to the above-mentioned sections of IPC.

Privacy and confidentiality

The right to privacy has been an integral part of medical ethics. International Code of Medical Ethics mandates that the health practitioner must maintain confidentiality regarding personal information of the patient, which they encounter during the treatment. Healthcare professionals can inform their colleagues who are involved in the treatment protocol of the patient but cannot notify the third party without taking consent from the patient. But, in specific situations like the COVID-19 pandemics, where the ultimate goal is to protect the society, the information of the patients can be divulged to the Government officials.

Apart from the doctors' duty towards their patients and society, it's also a moral duty of the patient and the community to behave responsibly towards the doctors and other health care professionals. Still, recently even in this pandemic time of COVID-19, there have been numerous shameful incidents of violence against doctors while they were discharging their duties in the frontlines of India's battle against COVID-19 pandemic. So for the prevention of such heinous acts, the government of India made new amendments on 22nd April 2020 to the Epidemic Diseases Act, 1987. The latest modifications include punishment for any kind of violence against doctors/health workers in the form of imprisonment for up to 7 years. The offense has been designated as a non-bailable offense. In the case of grievous hurt to the doctors, the accused can face imprisonment from 6 months to 7 years with or without fine ranging from Rs 1 lacks to 5 lacks. The investigations for such cases have to be completed within 30 days of the incident. [17]

Advanced directives

These are specific instructions to direct providers of the patient regarding the proceedings if the patient himself can no longer make decisions due to illness. Various types of advanced directives like a living will, health care proxies are present. In a living will, there are specific instructions regarding any course of treatment; for instance, it may specify that patient does not want to receive interventions like intubation, ventilator support, or CPR. However, in health care, a power of attorney, that is, another individual is appointed to make decisions on the patient's behalf.

Do not intubate (DNI)/Do not resuscitate (DNR)

Some individuals may not opt for life-saving procedures like intubation or CPR. This decision is taken by patients with end-stage diseases or terminal illnesses. Ultimately it should be kept in mind that it is the patient's right to decide whether to resuscitate or not in case of cardiac arrest. Therefore it is

imperative to discuss specific preferences of a patient before shifting to the operation theatre as these choices cannot be placed on hold once the patient is posted for surgery. This should include a discussion regarding the procedures or therapies which are acceptable or not to the patient intraoperatively. Methods or treatment usually include intubation, CPR, use of vasopressors, defibrillators. All the information should be communicated to the whole operative team and must be documented. The anesthesiologists should be very cautious in helping patients in determining their resuscitation status in the operation theatre, as our society is heterogeneous and multicultural, and assuming that a physician and patient share the same moral values is incorrect.[18,19] The American Society of Anesthesiologists has published guidelines for anesthesia care of patients with DNR orders.[20]

a. When confronted with a surgical patient who has a DNR order, schedule a meeting before surgery to include anesthesiologist, surgeon, or physician of record. The patient or patient's surrogate to review and discuss any existing directives which limit the use of resuscitation procedures or any clarification/modification of DNR directives during the anesthesia, based on the patient's preference solely.
b. Any clarification or modification of the DNR orders, as discussed in meeting with the patient and their relatives should be appropriately documented. These discussions may lead to the following possible outcomes:
c. *Full attempt at Resuscitation*- There will be a complete suspension of DNR orders during the time the patient is under anesthesia and in the postoperative period directly following.
d. *A limited attempt at resuscitation defined concerning specific procedures*- The patient or surrogate refuses certain particular procedures associated with resuscitation, such as chest compressions or defibrillations. The anesthesiologist must explain those procedures essential to the successful outcome of the planned anesthetic (intubation) and those procedures which are not.
e. *A limited attempt at resuscitation defined concerning patient's goals and values*- The anesthesiologist and surgical team should use their clinical judgment in determining which resuscitation procedures are appropriate or not given the circumstances and based on the patient's goals and values. Will the resuscitation be quick and restore the patient, or will it be more likely than not, leave the patients with permanent impairments?
f. In case of an emergency, the patient's consent is presumed, and CPR should be administered. If there is a DNR order, proceed as if the patient desires all resuscitative measures during the perioperative period.

The Expert Witness

The medical malpractice suits cover those issues, which are sometimes beyond the comprehension of the court and jury, so it results in assigning an "expert witness" by the court for establishing whether standard of care protocols were followed or not by the defendant anesthesiologist. Medical doctors are not only expert witnesses but also at certain times ordinary witnesses. They must be acknowledged in their field of expertise and expected to help or support through their skills and experience for the explanation of events that occurred in the case.[21,22]

The following criteria should be fulfilled by an anesthesiologist to serve as an expert witness:[22]

a. He should be active and familiar with practice in clinical anesthesiology
b. He should be holding qualification certified by the board or an equivalent degree
c. He should have a currently valid and unrestricted license for medical practice

As an expert witness, following guidelines to be ensured while providing the service as one:[22]

a. He should evaluate the case while keeping in mind the accepted protocol of standard of care.
b. He must assess any substandard practice that is alleged regarding patient care.
c. He must be prepared to present his evidence for peer revision.
d. The fees collected by an expert witness should not be a result of the trial but of the time spent at work.
e. He should differentiate between unfavourable results or adverse effects/events as medical malpractice is not always linked with negligent practice.
f. The review should be complete and truthful regarding medical facts without ignorance of any crucial information in favour of either of the parties.

Conclusion

The anesthesiologist should maintain a standard of care, be competent and skilled throughout their carrier, including the present pandemic. They should keep their mental and physical health in sound condition and must not hesitate to seek expert advice from their colleagues as and when needed. Thus, in conclusion, anesthesiologists should practice ethically while following particular guidelines like good record keeping, healthy doctor-patient relationship and be up-to-date with recent advances to provide proper standards of care that will keep them safe from the false malpractice and negligence

allegations, as the general public is becoming more and more aware regarding their rights.

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References

1. Yang Y, Peng F, Wang R, Kai Guan MY, Jiang T, Xu G, Sun J, Chang C. The deadly coronaviruses: The 2003 SARS pandemic and the 2020 novel coronavirus epidemic in China. J Autoimmun. 2020:102434.
2. Coronavirus [Internet]. World Health Organization. 2020 [cited 3 April 2020]. Available from: https://www.who.int/emergencies/diseases/novel-coronavirus-2019
3. Joga Rao SV. Medical negligence liability under the consumer protection act: A review of judicial perspective. Indian J Urol. 2009; 25(3):361-71.
4. WHO | WHO surgical safety checklist and implementation manual [Internet]. Who.int. 2008 [cited 2 May 2020]. Available from: https://www.who.int/patientsafety/safesurgery/ss_checklist/en/
5. Garner BA, Black HC. Black's law dictionary. Thomson/West; 2004. 1810 p.
6. Basic right to consent to medical care - Schoendorff v. Society of New York Hosp., 105 N.E. 92, 93 (N.Y. 1914) [Internet]. Biotech.law.lsu.edu. [cited 2 May 2020]. Available from: https://biotech.law.lsu.edu/cases/consent/schoendorff.htm
7. The Indian Penal Code [Internet]. Indiacode.nic.in. 1860 [cited 2 May 2020]. Available from: https://indiacode.nic.in/bitstream/123456789/4219/1/THE-INDIAN-PENAL-CODE-1860.pdf
8. Seeking patients' consent: The ethical considerations [Internet]. Gmc-uk.org. 1998 [cited 2 May 2020]. Available from: https://www.gmc-uk.org/-/media/documents/patient-consent-1998---2008-55678021.pdf?la=en
9. Samira Kohli vs Dr. Prabha Manchanda & Anr [Internet]. Indiankanoon.org. 2008 [cited 2 May 2020]. Available from: https://indiankanoon.org/doc/438423/
10. Pre-operative assessment and patient preparation - the role of the anaesthetist [Internet]. Anaesthetists.org. 2010 [cited 2 May 2020]. Available from: https://anaesthetists.org/Home/Resources-publications/Guidelines/Pre-operative-assessment-and-patient-preparation-the-role-of-the-anaesthetist-2
11. 12 key points on consent: the law in England & Wales [Internet]. Wales.nhs.uk. 2002 [cited 2 May 2020]. Available from: http://www.wales.nhs.uk/Publications/keypoints-e.pdf
12. Bolam v Friern Hospital Management Committee [Internet]. Lawteacher.net. 2018 [cited 2 May 2020]. Available from: https://www.lawteacher.net/cases/bolam-v-friern-hospital-management.php
13. Kragie S and Mather, K: Standards of Care and Specialists, American Society of Anesthesiologists Newsletter 2002; 66:2.
14. Kroll D. Professional Liability and the Anesthesiologists. Park Ridge, IL; American Society of Anesthesiologists, 1987.
15. Standards for Basic Anesthetic Monitoring | American Society of Anesthesiologists (ASA) [Internet]. Asahq.org. 2015 [cited 2 May 2020]. Available from: https://www.asahq.org/standards-and-guidelines/standards-for-basic-anesthetic-monitoring
16. Bhilwara's Tale of Negligence: Infected Docs, Latest COVID-19 Case Hint at Possible Community Spread [Internet]. News18. 2020 [cited 1 May 2020]. Available from:https://www.news18.com/news/ india/bhilwaras-tale-of-negligence-infected-doctors-latest-covid-19-case-hint-at-possibility-of-community-spread-2552595.html
17. Promulgation of an Ordinance to amend the Epidemic Diseases Act, 1897, in the light of the pandemic situation of COVID-19.Available from https://pib.gov.in/newsite/PrintRelease.aspx?relid=202493
18. Steinbrook R, Lo B, Moulton J, Saika G, Hollander H, Volberding PA. Preferences of homosexual men with AIDS for life-sustaining treatment. N Engl J Med 1986; 314:457-60
19. Dalla-Vorgia P, Katasouyanni K, Garanis TN, Touloumi G, Drogari P, Koutselinis A: Attitudes of a Mediterranean population to the truth-telling issue. J Med Ethics 1992; 18:67-74.
20. Jericho B. Ethics Resources [Internet]. Asahq.org. 2017 [cited 2 May 2020]. Available from: http://www.asahq.org/resources/ethics-and-professionalism
21. Ferrari H. Medical Malpractice Litigation, Consultants and Expert Witnesses, American Society of Anesthesiologists Newsletter 1997; 61:6.
22. Guidelines for Expert Witness Qualifications and Testimony [Internet]. Asahq.org. 2018 [cited 2 May 2020]. Available from: https://www.asahq.org/standards-and-guidelines/guidelines-for-expert-witness-qualifications-and-testimony