INVITED ARTICLE

Medicolegal Aspects of Obstetric Critical Care

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Abstract

The critically ill obstetric patient presents unique challenges. However, the general code of conduct, legal processes, and ethical principles continue to apply. Professionals need to keep themselves informed about the requirements of provisions within the legal framework.

Keywords: Consumer protection, Ethics in medicine, Medicolegal issues, Obstetric critical care.

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The field of obstetrics is unique among all medical fields. At the outset, pregnancy is not a pathological process—it is a physiological event, which is sometimes associated with derangements needing attention. Nearly all the individuals who are attended to by an Obstetrician are young. The body adapts itself to pregnancy with changes in the physiological state of organ systems. This combination is expected to be beneficial to the outcome of mother and child in a normal course. It is felt that "a perfect baby is the expectation of all parents and a perfect outcome is the mission of Obstetrics".[1] The level of acceptance of adverse outcomes is much lesser when dealing with Obstetric patients. The close interconnection of the "maternofetal unit" and its response to therapy and interventions adds to this lower threshold. It is therefore not surprising that Obstetricians face a significant number of litigations—genuine or otherwise—in comparison to most other medical specialties. In a retrospective analysis of all judgments related to medical negligence in South India passed between 2008 and 2013, Gowda et al.[2] reported the highest litigation and negative judgment rate for complaints involving Obstetricians. Nearly a quarter of all complaints ended with negligence being proven. While tubectomy failure was the most common cause for complaints being filed, maternal deaths, issues related to medical termination of pregnancy (MTP), postpartum complications, and procedures done without valid consent were the predominant situations where adverse verdicts were passed against the medical professionals. Therefore, it is essential for all involved in the care of sick Obstetric cohorts to be informed and vary about these aspects. This review will attempt to give a bird's eye view of how medicolegal hassles can be avoided.

The scope for litigation arises under several conditions. These include wrong diagnosis, wrong decision-making, negligence, poor supervision, incomplete or improper consent, intraoperative complications, and foreign body retention after surgery. The legal system, however, views the medical profession as a "noble profession". Medical professionals are expected to exhibit a minimum standard of competence while dealing with patients. The reference for this standard of care is outlined by the code of medical ethics and other regulations related to professional conduct outlined in the Medical Council of India Act 2001 along with the Indian Medical Council Act 1956.[3] These standards have been ratified and carried forward in the National Medical Commission Act 2019.[4] Some of the regulations included are

- Code of Medical Ethics
- Duties of Physicians towards patients
- Duties of consulting physicians
- Interphysician responsibility
- Physicians responsibility towards public
- Avoiding misconduct and not indulging in unethical acts
- Proposed punitive actions and deterrents.

Awareness of these facts and their implementation is essential for practitioners of medicine. However, knowledge about the legal and ethical aspects of medicine is inadequate among doctors.[5,6] The legal system does not condone such a lack of awareness. "Ignorance of Law is no excuse for its breach" is a legal dictum. Ethical concerns and dilemmas are also widely encountered while managing a pregnant lady in the intensive care unit (ICU). Quite a few of these issues arise from the relationship between maternal and fetal units. Ethics and Law are not synonymous or equal. An act which is legally sustainable or mandated, may not be ethically correct. Vice versa is equally true. Following the Law, however, leads to ethical behavior. It is therefore imperative to understand the nuances of accepted ethical behavior before we seek to understand the legal aspects of delivering care to the pregnant individual in the ICU. Four basic principles have to be adhered to so that there is a minimum deviation from the accepted ethical conduct.[7] These include respect for autonomy, the duty of beneficence, the duty of nonmaleficence, and justice. In the ethical conflict about

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maternofetal supremacy, maternal autonomy takes precedence.[8] The autonomy of a patient is not a new concept. The Nuremberg code (1947) and the United Nations Universal Declaration of Human Rights (1948) have emphasized the sanctity and importance of autonomy of thought, will, and action. This aspect comes into question when the continuation of pregnancy becomes a focal point in the ICU. When the mother reaches a state of clinical health, where the decision to continue the pregnancy becomes the focus, the right of patient autonomy has to be weighed against the duty of beneficence.

The duty of beneficence implies carrying out an act with an intention of doing good to others. This is commonly viewed as "acting in good faith" towards the patients. This principle entails removing what is harmful and promoting what is good. As an example, initiating mechanical ventilation to improve oxygenation and ventilation in a pregnant woman is an act of beneficence. While this is being achieved, no harm should fall upon the purported beneficiary (nonmaleficence). While doing good is the primary aim of all medical professionals, this duty cannot be viewed as absolute. No medical professional is expected to deliver absolute benefit to all patients, especially to critically ill patients. The expectation of the Law, therefore, is to attempt to do good within acceptable norms, with greater emphasis on not harming (nonmaleficence). The process of being beneficent is also expected to be completed at an acceptable medical cost to the beneficiary.

The principle of not harming (nonmaleficence) is integrated into medical ethics even before Hippocratic times. This principle was first taught by Galen between 129 and 199 CE.[9] The Hippocratic oath also emphasizes abstaining from what is "deleterious and mischievous".[10] During the delivery of critical care to the pregnant lady, some degree of harm may be anticipated, in order to achieve the overall target of beneficence. Examples of this might include a hematoma at the site of venous cannulation, loss of skin integrity due to the adhesive plasters uses, etc. However, the comparative degree of "harm" vs the benefit being aimed for, decides the principle of nonmaleficence. In essence, this is the basis for the principle of "primum non nocere" which all medical professionals are taught in training and strive to implement in practice.

The Laws and Acts applicable to the practice of medicine are listed in Table 1. Certain terms need to be understood in the context of applying the various Acts and Laws laid down. The basic relationship between the "consumer" and the "service provider" is what is viewed by the legal system as the crux of issues arising in medical practice. A "consumer" means any person who hires or avails of any services for a consideration, which has been paid or promised or partly paid and partly promised, or under any such system of deferred payment, when such services are availed of with the approval of the first-mentioned person. In case of death of such a "consumer", the legal heirs (representatives) of the deceased will be considered as a consumer. The "consumer" avails of a "service" from the medical professional. All services rendered to a person at a health care facility, where even a fraction of the patients are charged a fee (even at discounted prices) would make the beneficiary a "consumer". Such a consumer is deemed to have entered into a contract with the service provider.

Table 1: Laws applicable to the medical profession

Domain	*Law*
Qualifications, practice, and conduct	The Indian Medical Council Act 1956 The Indian Medical Council (Professional conduct, etiquette and Ethics Regulations) 2002 The Indian Medical Degree Act 1916
Management of patients	The MTP act 1971 Law of Contract section 13 PNDT Act 1994 and Pre conception and Prenatal diagnostic tech (prohibition of sex selection) Rules 1996 (Amendment Act 2002) The Medical Termination of Pregnancy Rules 2003
Medicolegal aspects	Consumer Protection Act 1986 Indian Evidence Act Law of Privileged Communication Law of Torts IPC section 52 (good faith), section 80 (accident in doing lawful act), section 90 (consent under fear)

Negligence is defined as the breach of duty caused by the omission to do something, which a professional with reasonable knowledge would do. It is, therefore, the responsibility of the consumer to prove beyond doubt that the provider was "negligent". The concept of negligence was defined by the honorable Supreme Court in Kusum Sharma and others vs Batra Hospital and Research Centre and others,[11] while quoting from the Halsbury's Laws of England. This definition implies that a person who has agreed to give medical advice or treatment to a patient does so with the knowledge that he/she possesses the necessary skill and knowledge. Such a person has a duty of care in deciding and administering the relevant treatment. A breach of such duties amounts to an act of negligence. Medical negligence has three essential components.

- Existence of a legal duty
- Breach of such a duty
- Damage caused by such a breach

In obstetric practice, breach of duties during labor, childbirth, and anesthesia, due to overlooked diagnosis and unindicated surgeries are reasons for involving the term "negligence". The duties expected by Law are measured in terms of the capabilities of an ordinary professional. The highest expert skill or competence is generally not used as a benchmark. However, error of judgment by the professional is not viewed by the Law as a breach of duty. Selection of one modality of treatment over another is not viewed by Law as a breach of duty. However, if this judgment has been made by a negligent act, the professional becomes liable. For example, bleeding following a procedure done on a patient to administer and monitor therapy is accepted, provided, due attention has been paid to the coagulation status of the patient. The Hon'ble Supreme Court has observed that every medical professional must exercise a reasonable "standard of care". The burden of proof will lie on the complainant to prove an "act of negligence". Certain situations, however, do not need further proof under the doctrine of "res ipsa loquitur", where the evidence speaks for itself. Operating on the wrong site, or the wrong patient, leaving surgical instruments/material in the surgical field, administering a drug to which the patient has a proven allergy, etc. are examples of such evidence.

Patients have three avenues for recourse in the event of perceived negligence. The aggrieved party can approach the National Medical Commission, or consumer forum (Civil Liability), or the police (Criminal Liability). There has been some confusion regarding the applicability of the new Consumer Protection Act (CPA) 2019 to the medical profession. This will be discussed in subsequent sections. According to the Indian Penal Code 1860, any person who acts negligently or in a rash manner that compromises

human life or safety or results in death shall be punished by imprisonment and/or fine. Imprisonment is not a remedy possible under the CPA. Medical professionals can seek defense under sections 80 and 88 of the Indian Penal Code (IPC). Under section 80 (accident while doing a lawful act), "nothing is an offence that is done by accident or misfortune and without any criminal intention or knowledge in the doing of a lawful act in a lawful manner by lawful means with proper care and caution". According to section 88, a person cannot be accused of an offense if he/she performs an act in good faith for the benefit of another, does not intend to cause harm even if there is a risk, and the patient has explicitly or implicitly given consent. The burden of proof of negligence or carelessness rests on the complainant. The Law generally insists on a higher level of evidence than visual, to uphold an allegation of negligence against a doctor. Negligence has to be established and presumed, as highlighted in Calcutta Medical Research Institute vs Bimalesh Chatterjee[12] and Kanhaiya Kumar Singh vs Park Medicare and Research Centre.[13] The consent process, therefore, assumes high significance to establish the fact that the patient willingly has taken a risk as part of the doctor-patient relationship. This aspect will be discussed in a subsequent section. The Hon'ble Supreme Court has held on several occasions that criminal prosecution of doctors without adequate medical opinion pointing to their guilt would do a great disservice to the community.

Consumer Protection Act and the Medical Profession: The CPA 2019 was notified on July 15, 2020.[14] The original draft of the consumer protection bill passed by the Lok Sabha included health care under section 24(2). This leads to some concern and unrest amongst the medical fraternity. Subsequently, a technical amendment was introduced in parliament, which removed health care from the list of "services". However, this amendment leaves the interpretation of health care as a service open. According to this revision, "service" means service of any description, which is made available to potential users and includes but is not limited to the provision of facilities in connection with banking, financing, insurance, etc. This statement makes health care still answerable to the CPA 2019, on a case-to-case basis. The amendment in no way excludes health care comprehensively from the ambit of the CPA.

As is evident from the preceding discussion, the relationship between the doctor and the patient is essentially a contract. A key aspect of such a contract is the beneficiary consenting to be treated and monitored by the professional. Any intervention or test done without valid consent is liable to be viewed by the Law as an assault or battery under IPC 351. An "informed consent" is therefore mandatory for all activities done by medical professionals related to the care of patients. An informed consent ideally should include the following and must be explained and documented in mutually understood language.

- The diagnosis includes differential diagnosis if any
- The nature of the treatment being planned and offered
- The risks involved with the treatment being planned
- The probable success rate
- The probable outcome if the treatment being offered is not carried out and the alternatives that exist

A consent taken for a diagnostic purpose cannot be used for a therapeutic procedure. For example, consent taken for a diagnostic endoscopy or thoracentesis in a critically ill patient cannot be assumed to be consent for a therapeutic endoscopic procedure or intercostal drain insertion. Similarly, if a surgical plan has to be changed during the surgery, the new plan should be discussed with the patient or her "representatives" and every attempt should be made to seek fresh consent. Exceptions can only be made in dire emergencies to save the life of the patient. Failure to take a consent is treated as a deficiency of medical service under section 2(1) of the CPA. Consent of the spouse is preferable in situations warranting a termination of pregnancy, sterilization, and any procedure, treatment, or intervention that hampers the sexual rights of the spouse. However, consent is not mandatory in emergencies, for notifying diseases in the interest of public health, and for prisoners. Consent is also not necessary if a test or intervention is being done to honor an order from the court. Examination of a pregnant individual should not be done without consent. Such examination of a female patient shall be made only by, or under the supervision of a female registered medical practitioner,[15] under section 53(2). Certain basic precautions could help the professional in avoiding the allegation of "negligence". The first step in avoiding litigation is to build a rapport with the patient and her family through good verbal communication. Second, the professional should use all reliable and relevant information to make a reasonable diagnosis and formulate a treatment plan. The third step in avoiding litigation is immaculate record keeping. All records should be complete, accurate, relevant, informative, time-stamped, and signed by the professional. This record will be the single most important evidence that will be perused by Law in the event of litigation. The next safeguard to avoid litigation is to avoid making remarks about colleagues within and outside the place of work. Similarly, all medicines being prescribed should have appropriate indications.

Another important aspect that frequently crops up while caring for a critically ill pregnant lady, is the conflict between fetal and maternal well-being. This has to be understood in tandem with the rights of the fetus as well as the autonomy of the mother. It is well accepted that a "living entity that comes into being as the result of the fertilization of a human egg by a sperm and that develops in the uterus of a woman, or that is physically separated from a woman's body, but is capable of surviving outside the uterus to some extent" defines a fetus. Such a fetus has civil and legal rights. Under the Indian legal system, the woman has a constitutionally unqualified right to abortion in the first trimester of her pregnancy. In the second trimester, this right may be limited by the health risk to the mother. This view of maternofetal welfare may appear divergent, but the overall goal is a convergence of interests.[16]

The last issue where ethical and consequently legal issues might emerge is in the context of withdrawal of care in brain dead pregnant lady. Such situations arise in the context of trauma or intracranial events, leading to maternal brain death. Continuation of somatic support to a pregnant lady, who is certified as brain dead, essentially is to tailor strategies for the fetus. While there is no definite pathway for this situation, the recently expressed wishes of the patient, viability and health status of the fetus, and the opinion of her "representatives" should be taken into account to facilitate informed decision-making.

In summary, the critically ill obstetric patient presents unique challenges. However, the general code of conduct, legal processes, and ethical principles continue to apply. Professionals need to keep themselves informed about the requirements of provisions within the legal framework.

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