

Medical Negligence and Its Legal Implications

L.Sreeja¹, R.Santhoshini²

^{1,2}3rd Yr B.Com., LLB(hons)- SASTRA UNIVERSITY

Abstract

Medical negligence is a major issue in healthcare of India and it affects the patient safety, as well as legal aspects. This paper provides a detailed examination, and determining its meaning in ascertaining the intended approach regarding medical negligence; it also focuses on specific legal methods employed by various courts of law within India. This paper delves deeply into the rudiments of medico-legal negligence — duty of care, breach of duty, causation and damage; it then elaborates upon certain statutes like The Consumer Protection Act 1986 & Section 304A Indian Penal Code 1860, The Clinical Establishments (Registration and Regulation) Act, of.

The article then examines significant judicial precedents and finally the article explores evolving jurisprudence and future directions, emphasizing the need for increased awareness, legal reforms, and updates to the legal framework to effectively address medical negligence and ensure justice for patients.

Keywords: - Medical Negligence- Legal Framework- Consumer Protection Act- Indian Penal Code - Duty of Care – Judicial Interpretations- Healthcare Standards- Medical Liability - Burden of Proof- Legal Reforms- Professional Conduct

Introduction:

Within the Indian healthcare system, medical negligence is a serious problem that affects both the legal obligations of healthcare providers and the standard of patient care. The complexity and evolution of healthcare services increase the possibility of mistakes and poor performance, which increases the public's awareness of medical negligence and its associated legal consequences. Recognizing and resolving medical negligence is important for safeguarding patient safety and maintaining the integrity of medical practice in a nation where access to healthcare is uneven and frequently restricted.

Medical negligence occurs when a healthcare provider fails to meet the established standard of care, resulting in harm or injury to a patient. This concept includes several key elements: duty of care, breach of duty, causation, and damage. Duty of care refers to the obligation of healthcare providers to deliver care that adheres to accepted medical standards. A breach occurs when there is a deviation from this standard, and causation establishes the direct link between the breach and the patient's injury. Damage represents the actual harm suffered as a result of the negligence.

The legal regime on medical negligence in India consists of numerous statutes and guidelines, which have ensured that patient rights are protected and medical practice is regulated. The Consumer Protection Act, 1986, provided for redressal machinery on the ground of complaints pertaining to deficiency in services, thereby bringing medical services within its ambit. Section 304A of the Indian

¹ Name of the 1st Author, branch and name of the university

² Name of the 2nd Author, branch and name of the university

Penal Code, 1860, [current BNS section 106(1)] also deals with criminal negligence and thus provides the legal matrix for launching prosecution in cases where death or grievous hurt is caused by negligence. The guidelines issued by the Medical Council of India (MCI), now succeeded by the National Medical Commission (NMC), further enunciate the ethical and professional standards from healthcare providers.³ This article will attempt to delve into an in-depth analysis of medical negligence and its legal implications in India. It touches on some of the basic elements of negligence, the statute and case laws relating to the subject area in question, and the practical problems that exist for patients and health professionals. Through an analysis of landmark judicial verdicts and currently relevant issues, the paper attempts to add to a greater understanding of how medical negligence is treated under Indian law and how further reform and improvement can be made in the future. This paper tries to contribute to a more informed and fair approach toward medical negligence and patient care in India.

Origin and evolution:

Medical negligence has a long history, with some of the earliest recorded cases dating back to ancient civilizations. Historical records show that even in ancient Egypt, Greece, and Rome, there were expectations for medical practitioners to adhere to certain standards of care. The famous Hippocratic Oath, originating in ancient Greece, emphasized the ethical responsibilities of physicians, laying the groundwork for modern medical ethics and the concept of "do no harm."

Definition of Medical Negligence:

In most personal injury claims, negligence is defined as a failure to behave with the same level of caution a reasonably prudent person would have exhibited. But, a different standard of care applies to certain professionals, including healthcare workers.

Medical care providers are expected to provide care that is on par with what a similarly trained professional would have offered under the same circumstances. If a caregiver's actions deviate from the accepted medical standard, this is considered medical negligence.

Omissions can also be considered medical negligence as well. If a similarly trained physician would have acted under the circumstances and the provider in question failed to act, that could constitute medical negligence.⁴

Types and examples of medical negligence:

- **Wrong diagnosis:** Upon admission to a hospital, clinic, emergency room, etc., the diagnosis is the first thing that happens. Accurately diagnosing symptoms is essential to providing any patient with medical care. However, if a diagnosis error results in the patient not receiving the appropriate care, the physician may be held accountable for any future injury or losses caused as a result of the wrong diagnosis.
Example: Cancer is one of the most commonly misdiagnosed conditions because it shares symptoms with many other diseases. For example, breast, cervical, prostate, and colon cancer are often misdiagnosed. If cancer isn't diagnosed early, it can become more difficult to treat.
- **Delay in diagnosis:** A delayed diagnosis is treated as medical negligence if another doctor would have reasonably diagnosed the same condition in a timely fashion. If a patient's sickness or injury is

³ <https://blog.ipleaders.in/medical-negligence-2/>

⁴ <https://www.forbes.com/advisor/legal/medical-malpractice/medical-negligence/>

not addressed and is allowed to deteriorate over time, a delay in diagnosis may result in unnecessary harm. Obviously, any delay in the identification and treatment of an injury can reduce the chance of recovery for the patient.

- **Error in surgery:** Even the smallest mistakes can have a significant impact on the patient, thus surgical procedures need a high degree of ability and should be performed with extreme care and caution. Surgical errors include surgery performed on the incorrect area, internal organ wounds, significant blood loss, and leaving a foreign object within a patient.
Example: Mistakes made during surgery, such as operating on the wrong body part or leaving surgical instruments inside the patient.
- **Unnecessary surgery:** Unnecessary surgery is typically linked to a patient's symptoms being misdiagnosed or to a medical decision being made without carefully considering the risks or other possibilities.
- **C-Section:** Spinal fusion surgery permanently connects two or more vertebrae in the spine, leaving decreased motion and mobility in the patient. The New York Times referred to spinal fusion as “useless” surgery.⁵
- **Errors in the administration of anesthesia:** Any significant medical procedure involving anesthesia carries a high risk, and its administration and monitoring by an expert (anesthesiologist) is necessary. The most appropriate medication to utilize for a patient's health, history, medications, etc., is determined by the anesthesiologist prior to any medical operation needing anesthesia. Malpractice related to anesthesia might occur even in the pre-operative medical examination or during the treatment.⁶
Example: Mistakes pertaining to anesthesia that may cause serious consequences or even death.
- **Childbirth and labor malpractice** - Giving birth is a challenging experience for a woman, and it can worsen if medical professionals and nurses do not treat it appropriately.
There are numerous examples of medical malpractice that occur during childbirth, such as mismanaging a challenging birth, issues with induced labor, incorrectly diagnosing a newborn's ailment, etc.
- **Long-Term negligent treatment** – Medical negligence can also occur in subtle ways over the course of a long treatment period. Usually, the negligence can take the shape of a failure to follow up with treatment, or a doctor's failure to monitor the effects of the treatment properly.⁷

Concepts relating to Medical Negligence

Laws and Regulations

Medical negligence is governed by a complex web of laws and regulations that vary by jurisdiction. These laws define the standards of care, the duties of healthcare providers, and the legal processes for pursuing negligence claims. In many countries, medical negligence laws are part of broader tort law frameworks that address civil wrongs and compensation for harm.

Standards of Care

The standard of care is a critical concept in medical negligence cases. It refers to the level and type of care that a reasonably competent healthcare professional, with similar training and experience, would

⁵ <https://groverlewisjohnson.com/unnecessary-surgeries/>

⁶ <https://nayyarssolicitors.co.uk/types-of-medical-negligence/>

⁷ https://blog.ipleaders.in/medical-negligence-india/#Types_of_medical_negligence

provide under similar circumstances. Determining whether the standard of care was met is often central to proving negligence.

Informed Consent

Informed consent is a legal and ethical requirement in medical practice. It involves providing patients with sufficient information about their diagnosis, treatment options, risks, and benefits to make informed decisions about their care. Failure to obtain informed consent can be grounds for a negligence claim, even if the treatment itself was appropriate.

Documentation and Medical Records

Accurate and thorough documentation is essential in medical practice and plays a significant role in negligence cases. Medical records provide a detailed account of the patient's history, diagnosis, treatment, and outcomes. They are crucial evidence in proving whether the standard of care was met and whether informed consent was obtained. To establish a claim of medical negligence, the plaintiff must prove four key elements:

1. Duty: The healthcare provider owed a duty of care to the patient.
2. Breach: The provider breached that duty by failing to meet the standard of care.
3. Causation: The breach of duty directly caused harm to the patient.
4. Damages: The patient suffered actual harm or injury as a result.⁸

Negligence per se: While deliberating on the absence of basic qualifications of a homeopathic doctor to practice allopathy in *Poonam Verma vs. Ashwin Patel and Ors.* (1996) 4 SCC 322, the Supreme Court held that a person who does not have knowledge of a particular system of medicine but practices in that system is a quack. Where a person is guilty of negligence per se, no further proof is needed.⁸

Res Ipsa: This Latin expression implies that the things speak for themselves. In personal injury law, it serves as an evidentiary rule. Under the Res Ipsa Loquitur concept, the plaintiff need simply provide specific facts or circumstantial evidence to transfer the burden of proof to the defendant, who has to prove that their actions were not negligent. It is not necessary for circumstantial evidence to be presented or proven in court; rather, it consists of specific facts that logically indicate the defendant's negligence. In Halsbury's Laws of England, this idea is explained.⁹

Elements Of Res Ipsa Loquitur

The doctrine of Res Ipsa Loquitur has three elements:

1. The injury that had occurred under the circumstances must be explicit and can only occur due to someone's negligence and it cannot occur in the ordinary situations
2. The injury caused by the defendant to the plaintiff must have been done with the use of some instrument which was exclusively under the control of the defendant
3. The injury caused to the plaintiff must be under the scope of the defendant's duty and it must not be due to the voluntary act or the contribution from the plaintiff's side.⁹

Provisions relating to medical negligence

- section 106(1) of the Bharatiya Nyaya Sanhita (BNS), 2023, states that a registered medical practitioner who causes death by negligence while performing a medical procedure can be punished with a fine and up to two years in prison. This section replaces Section 304 A of the Indian Penal Code (IPC), which had similar penalties.

⁸ <https://www.rafilawfirm.com/atlanta/wrongful-death-lawyer/understanding-negligence/>

⁹ legalserviceindia.com/legal/article-1956-res-ipsa-loquitur-and-its-application-in-medical-negligence.html

- Section 337 of the Indian Penal Code: This section deals with causing hurt by an act endangering life or personal safety. If a medical professional endangers the life or safety of a patient due to negligence, they can be punished with imprisonment for up to six months or a fine, or both.¹⁰
- Section 338 of the Indian Penal Code: This section deals with causing grievous hurt by an act endangering life or personal safety. If a medical professional causes grievous hurt to a patient due to negligence, they can be punished with imprisonment for up to two years or a fine, or both.
- The Consumer Protection Act, 1986: Under this act, patients have the right to file complaints against medical professionals and seek compensation for medical negligence.¹¹

The Clinical Establishments (Registration and Regulation) Act, 2010

The Clinical Establishments (Registration and Regulation) Act, of 2010 is one of the most important Acts in India for the regulation of the establishment and operation of the clinical establishment, including hospitals, clinics, and diagnostic centres.¹² The key points and objectives of the Act are as follows:

- **Purpose:** The Act relates to ensuring minimum standards of facilities and services provided by any clinical establishment to patients.
- **Applicability:** It applies to all clinical establishments in India, both in the public and private sectors, excluding those run by the armed forces.
- **Registration:** Clinical establishments need to be registered with the appropriate authority as specified by the state governments.
- **Minimum Standards:** It provides for the establishment of minimum standards of facilities and services, including personnel, equipment, infrastructure, and clinical practices.
- **Clinical Establishments Council:** The Act provides for the constitution of a Central Council and the formation of State Councils to monitor the implementation and enforcement of the Act in the country.
- **Compliance and Inspection:** Compliance by clinical establishments with the prescribed standards under the said Act, as well as regular inspection and assessment, are some of the important tasks and steps taken to ensure compliance.
- **Penalties:** Based on non-compliance, there are provisions enunciating penalties in the form of fines, suspension, or withdrawal of registration.
- **Patient Rights:** It emphasises the rights of the patients about information, informed consent, and redressal mechanisms with regard to grievances.
- **Transparent Pricing:** Clinical establishments are required to have transparency in pricing for services offered from time to time.
- **Medical Ethics:** It promotes adherence to standards of professional conduct and medical ethics on the part of healthcare providers.¹³

¹⁰ <https://www.indiacode.nic.in/bitstream/123456789/4219/1/THE-INDIAN-PENAL-CODE-1860.pdf>

¹¹ https://www.indiacode.nic.in/bitstream/123456789/6922/1/consumer_protection_act_1986.pdf

¹² https://www.indiacode.nic.in/bitstream/123456789/7798/1/201023_clinical_establishments_%28registration_and_regulation%29_act%2C_2010.pdf

¹³ <https://www.coveryou.in/blog/laws-articles-related-to-medical-negligence-in-india/#:~:text=Current%20Legal%20Framework%3A,negligent%20acts%20leading%20to%20death.>

The new Bharatiya Nyaya Sanhita (BNS), passed in December 2023 provides some relief for doctors from criminal liability for medical negligence. This amendment is intended to relieve medical professionals from the fear of criminal prosecution and allow them to perform their duties without the pressure of potential legal repercussions.¹³

Proving medical negligence can be challenging for several reasons. These challenges include:

- **Complexity of Medical Issues:** Understanding and explaining complex medical procedures and outcomes can be difficult for non-medical jurors.
- **Availability of Evidence:** Obtaining complete and accurate medical records and other evidence can be challenging.
- **Defensive Medicine:** Healthcare providers may practice defensive medicine, ordering unnecessary tests or treatments to avoid liability, complicating the assessment of standard care.¹⁴

Case laws:

1. In the case of the Indian Medical Association vs. V.P. Shanta and Ors.,

III (1995) CPJ 1 (SC), the Supreme Court finally decided on the issue of coverage of medical profession within the ambit of the Consumer Protection Act, 1986 so that all ambiguity on the subject was cleared.¹⁵

2. Kunal Saha Vs. AMRI (Advanced Medical Research Institute)

This case is considered one of the most well-known medical negligence cases in India. Saha began his fight for justice in 1999, and after losing at the Calcutta High Court and West Bengal Medical Council, he took his case to the Supreme Court. In 2013, the Saha family received a landmark compensation of 11 crore, which was a significant amount at the time.¹⁶

3. Jacob Mathew v. State of Punjab and Others

In this case, the Supreme Court established standards for governing medical negligence. The court emphasized the need to provide specific evidence to hold medical practitioners liable, and stated that a doctor may choose a procedure with a higher risk element if they have considered and deliberated on it. The court also said that a line of treatment should not be obsolete or discarded under any circumstances.

Suggestions:

- It is suggested to Implement stricter regulations and oversight to ensure compliance with medical standards and patient safety protocols.
- Clear Guidelines: Develop clear guidelines and protocols for informed consent, documentation, and standard of care to minimize ambiguity.
- Training and Education: Enhance training and continuing education for healthcare professionals to keep them updated on best practices and emerging.
- Risk Management Programs: Implement robust risk management programs to identify and mitigate potential sources of medical errors.

¹⁴ <https://blog.ipleaders.in/challenges-proving-medical-negligence-consumer-protection-act/>

¹⁵

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2779963/#:~:text=In%20the%20case%20of%20the,on%20the%20subject%20was%20cleared.>

¹⁶ <https://legaldesire.com/top-5-landmark-judgment-on-medical-negligence/>

- Foster a culture of safety within healthcare institutions where staff feel empowered to report errors and near misses without fear of retribution.
- Implement anonymous error reporting systems to identify trends and areas for improvement.
- Utilize EHRs (Electronic Health Records) to improve accuracy, accessibility, and coordination of patient care.
- Promote the use of ADR (Alternative Dispute Resolution) methods, such as mediation and arbitration, to resolve medical negligence claims more efficiently and amicably.

Conclusion:

Medical negligence is a multifaceted issue that carries profound legal, ethical, and emotional consequences for healthcare providers and patients alike. As healthcare systems evolve, the need for a robust legal framework to address and mitigate instances of negligence becomes increasingly critical. This article has explored the foundational concepts of medical negligence, examined relevant laws and judicial precedents, and highlighted the ongoing challenges in enforcing accountability within the Indian healthcare system.

To ensure patient safety and maintain trust in healthcare services, it is imperative to strengthen existing regulations, enforce compliance with medical standards, and promote a culture of transparency and continuous improvement. Legal reforms, such as the recent updates to the Bharatiya Nyaya Sanhita (BNS), provide a step forward in balancing the rights of patients with the need to protect medical professionals from undue criminal liability. However, there is still much work to be done in educating healthcare providers, improving documentation practices, and fostering better communication between patients and medical practitioners.

By implementing the suggested measures—ranging from clearer guidelines to advanced technology integration—the healthcare system can significantly reduce the incidence of medical negligence. Ultimately, these efforts will contribute to a safer, more accountable healthcare environment that prioritizes the well-being and rights of patients while allowing medical professionals to perform their duties with confidence and integrity.