MEDICAL NEGLIGENCE IN THE ERA OF ARTIFICIAL INTELLIGENCE: REDEFINING ACCOUNTABILITY AND RESPONSIBILITY IN INDIA'S HEALTHCARE FRAMEWORK

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ABSTRACT

The incorporation of artificial intelligence (AI) technology and robotics in medicine reveals inherent flaws in India's legal regime on medical malpractice. This article seeks to examine the persisting application of existing principles, specifically the Bolam test established in Jacob Mathew v. State of Punjab[1] , amidst the increasing role of algorithmic processes. Although the Consumer Protection Act, 2019[2] designates patients as consumers eligible for compensation due to poor medical care, it fails to cover damages inflicted through AI-augmented healthcare interventions.

The paper contends that the diffusion of liability under AI-powered health care makes it difficult to adhere to the conventional doctrine of duty, breach, and causation. The trend is further compounded by the emergence of patient autonomy as evident from the Montgomery v. Lanarkshire Health Board[3]. In spite of the acknowledgment of the rights of the patients as consumers in the landmark Indian Medical Association v. V.P. Shantha[4] case, the current laws have not provided clarity about the accountability of AI in the context of clinical judgment.

In order to address the legal lacuna, the paper proposes a novel liability regime based on statutory provisions and legal precedents, such as the Bharatiya Nyaya Sanhita, 2023[5] and EU's proposed Artificial Intelligence Act[6]. The suggested framework combines the concepts of medical negligence and product liability and emphasizes the need for standard-of-care guidelines for AI systems. Without such legislation, the increasing adoption of AI in the realm of health care would prove to be detrimental for the patients.

[1] *Jacob Mathew v. State of Punjab,* (2005) 6 S.C.C. 1 (India)
[2] The Consumer Protection Act, 2019, No. 35 of 2019 (India)
[3] *Montgomery v. Lanarkshire Health Bd.*, [2015] UKSC 11, [2015] A.C. 1430 (U.K.).
[4] *Indian Med. Ass'n v. V.P. Shantha*, A.I.R. 1996 S.C. 550 (India)
[5] Bharatiya Nyaya Sanhita, 2023, No. 45 of 2023 (India).
[6] Proposal for a Regulation of the European Parliament and of the Council Laying Down Harmonised Rules on Artificial Intelligence (Artificial Intelligence Act), COM (2021) 206 final (Apr. 21, 2021).

I. Introduction

The growing prevalence of AI in the healthcare industry is fundamentally changing the dynamics of medical decision-making processes, especially in the realms of diagnostic tools and robot-assisted surgeries. Although these technological innovations provide significant improvements in terms of accuracy and efficiency, they undermine the foundations of negligence law, which relies heavily on human error and accountability.

Under medical negligence law, there must exist a direct doctor-patient relationship in order for the physician's liability to be established. In India, such liabilities have been determined based on standards of reasonable care, as outlined in the case of Dr. *Laxman Balkrishna Joshi v. Trimbak Bapu Godbole*[7]. According to this ruling, the standard of medical practice requires that doctors maintain a high degree of skill and care within their professional duties. Nevertheless, in cases involving AI in the medical field, fault and causation cannot easily be established, since the process of decision-making becomes more distributed.

The problem of diffusion of responsibility leads to some critical issues of a legal nature, especially when it comes to issues related to the autonomy of patients. Informed consent is an important requirement, but the application of this concept in cases involving decision-making based on algorithmic models poses some challenges, as explained through comparative jurisprudence like *Montgomery v. Lanarkshire Health Board*[8]. However, while there have been advancements in the field, the current Indian legal system still remains centered around the human aspect and provides no guidance concerning liability in the age of technology.

This paper will investigate the problem of medical negligence in the context of AI applications and discuss why a traditional approach cannot be effective.

II. Conceptual Framework: Artificial Intelligence and Robotics in Healthcare

A. Conceptual Understanding

Artificial intelligence (AI) in healthcare can be defined as any computer technology that is designed for carrying out cognitive tasks usually done by humans, such as diagnostics,

[7] *Dr. Laxman Balkrishna Joshi v. Trimbak Bapu Godbole*, (1969) 1 S.C.R. 206 (India)
[8] *Montgomery v. Lanarkshire Health Bd.,* [2015] UKSC 11, [2015] A.C. 1430 (U.K.)

treatment, prediction and decision-making through machine learning, robots, and algorithms.[9] This definition encompasses preventive care, diagnostics, surgeries, and administration in hospitals among other areas of health care practice.

1. Diagnostic AI

Diagnosis using artificial intelligence is becoming common practice within the realms of radiology, pathology, ophthalmology, and oncology. They use machine learning to diagnose diseases through image recognition and patient information.[10] This increases efficiency within diagnosis and may even improve disease detection.

2. Predictive Analytics

Predictive analytics uses machine learning algorithms to predict outcomes such as disease progression, patient worsening, treatment success, and public health trends. The downside to these algorithms is that they can have a tendency to embed algorithmic bias into their processes from bad data input.[11]

3. Robotic Surgery

Robotic surgery helps minimize surgeries by allowing for less invasive surgeries to be done with increased accuracy, dexterity, and better recovery outcomes. However, technological malfunctions or errors may raise the complexity of any negligence lawsuit involving the robotic device.[12]

4. Clinical Decision-Support Systems (CDSS)

CDSS helps guide physicians through treatment decisions with advice and medication alerts. This may become problematic when physicians rely heavily on these systems due to their

[9] World Health Organization, *Ethics and Governance of Artificial Intelligence for Health* 15-18 (2021).
[10] Hisham Jadallah Mansour Shakhatreh & Farouq Ahmad Faleh Alazzam, *Legal Frameworks for AI-Driven Diagnostics and Robotic Surgery: Addressing Medical Malpractice and Accountability,* 33 Acta Informatica Medica 248, 249-50 (2025)
[11] World Health Organization, *Ethics and Governance of Artificial Intelligence for Health* 34-39 (2021).
[12] Francesco De Micco et al., *Robotics and AI into Healthcare from the Perspective of the European Union Regulatory Framework: How to Fill the Gap Between Technology and Existing Liability Systems?,* 11 Frontiers Med. 1428504, 5-6 (2024).

nature of increasing physician liability.[13]

B. Benefits and Drawbacks

The implementation of artificial intelligence and robotics in healthcare presents various benefits such as improved diagnostic capabilities, increased efficiency, personalized treatment, minimization of mistakes, and improved access to healthcare. Such technological innovations may be especially advantageous for resource-limited healthcare settings due to their fast and consistent performance.

However, the deployment of AI is associated with significant legal and ethical problems, such as algorithmic bias, invasion of privacy, cyber security issues, software malfunctions, and difficulty in identifying the responsible party when something goes wrong. Responsibility distribution among several parties weakens negligence theory principles of human culpability.[14]

C. Black-Box Algorithms and Lack of Explainability

One of the major issues in AI healthcare revolves around the "black-box" nature of the technology wherein no clear explanation accompanies the results.[15] This lack of explainability prevents patients from giving valid consent, deprives patients of autonomy and the right to know about the recommendations, and reduces physicians' liability for any AI recommendation or risk involved.

For liability purposes, explainability is an important element in assessing whether there is breach of duty, whether the breach is foreseeable and what the cause of the injury is under negligence law. In other words, the absence of explainable AI means that current medico-legal frameworks are insufficient to govern AI liability.[16]

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[13] Aniek F. Markus et al., *The Role of Explainability in Creating Trustworthy Artificial Intelligence for Health Care: A Comprehensive Survey of the Terminology, Design Choices, and Evaluation Strategies,* 3 NPJ Digit. Med. 161, 3-4 (2021)

[14] Francesco De Micco et al., *Robotics and AI into Healthcare from the Perspective of the European Union Regulatory Framework: How to Fill the Gap Between Technology and Existing Liability Systems?*, 11 Frontiers Med. 1428504, 7–9 (2024).

[15] Aniek F. Markus et al., *The Role of Explainability in Creating Trustworthy Artificial Intelligence for Health Care: A Comprehensive Survey of the Terminology, Design Choices, and Evaluation Strategies*, 3 NPJ Digit. Med. 161, 5-7 (2021).

[16] Proposal for a Regulation of the European Parliament and of the Council Laying Down Harmonised Rules on Artificial Intelligence (Artificial Intelligence Act), COM (2021) 206 final, arts. 13-15.

D. Increasing Legal Importance

The use of AI technology in healthcare makes it necessary to move away from traditional negligence rules applicable solely on physicians towards more complex liability theories combining elements of medical negligence and product liability along with institutional and regulatory accountability.

III. Traditional Medical Negligence Framework in India

In India, medical negligence is defined and enforced based on the concepts of tort law, consumer protection law, and criminal negligence, necessitating the identification of four critical aspects that include duty of care, breach of duty, causation, and damages.[17] The presence of these elements makes it possible for any health practitioner to be held liable for injuries or harm suffered by the patient.

1. Duty of Care

Duty of care exists when there exists a doctor-patient relationship whereby it is incumbent upon any medical practitioner to act reasonably and with skill and diligence. Under Indian medical jurisprudence, it can be argued that medical professionals owe a duty of care in their decision to accept a particular case for practice, determine treatment, and administer the treatment with caution.[18]

The Supreme Court ruling in *Dr. Laxman Balkrishna Joshi vs. Trimbak Bapu Godbole*[19] stated that for a medical practitioner to be regarded as competent, he must have a sufficient degree of skill and knowledge compared to others in the profession. However, this should not be taken as having the greatest skill or knowledge level.

2. Breach of Duty

Breach is established where the defendant fails to adhere to the medical standard of care of an ordinarily skilled healthcare practitioner in similar circumstances. The Indian legal system employs the Bolam principle to assess breaches, analyzing whether the defendant's actions

[17] *Jacob Mathew v. State of Punjab*, (2005) 6 S.C.C. 1 (India
[18] *Dr. Laxman Balkrishna Joshi v. Trimbak Bapu Godbole*, (1969) 1 S.C.R. 206 (India)
[19] *Dr. Laxman Balkrishna Joshi v. Trimbak Bapu Godbole*, (1969) 1 S.C.R. 206 (India).

conform to accepted practice among a responsible body of medical experts.[20]

This approach values the medical consensus more than the patient-oriented perspective, usually providing immunity to practitioners whose actions are supported by recognized medical opinions.

3. Causation

Causation mandates that the breach be directly responsible for any injury sustained by the plaintiff. Generally, the "but for" rule is employed to prove whether any damage would have occurred had there been no negligence. Proving causation may be challenging within Indian medical malpractice laws owing to several contributing elements, prior illnesses, or ambiguous treatment procedures.[21]

The medical negligence laws in India are typically reliant on the conduct of physicians to establish causality.

4. Damages

Damages can range from payment for physical harm, mental anguish, loss of earnings, costs of treatment in the future, and even death.[22] Legal options are open based on tort laws, consumer tribunals, and criminal laws if gross negligence is involved. The doctrine of compensation was greatly enhanced through consumer law.

IV. Prominent Judicial Rulings

1. *Dr. Laxman Balkrishna Joshi v. Trimbak Bapu Godbole*

The significant ruling laid down the principles of doctrine in relation to the duty owed by the doctors to their patients in India, stating that there is an obligation to exercise a reasonable degree of professional care in rendering treatment to their patients. Negligence cannot be established if it is due to error of judgment; it is only when the medical personnel fail to reach the standard set by other competent persons that the said act becomes negligence.[23] This

[20] *Jacob Mathew v. State of Punjab*, (2005) 6 S.C.C. 1 (India).
[21] Ratanlal & Dhirajlal, *The Law of Torts* 441-45 (28th ed. 2016).
[22] *Spring Meadows Hosp. v. Harjol Ahluwalia*, (1998) 4 S.C.C. 39 (India).
[23] *Dr. Laxman Balkrishna Joshi*, (1969) 1 S.C.R. 206

decision made it clear that the duty owed is centered on the physicians alone.

2. *Jacob Mathew v. State of Punjab*

In this case, the Supreme Court reiterated the Bolam rule and explained the distinction between civil negligence and criminal negligence by setting a higher standard of criminal negligence, which requires reckless misconduct on the part of the medical practitioners.[24] This important decision has been widely cited, although criticisms have also been raised against it.

The Bolam Test

The Bolam test stems from the case of *Bolam v. Friern Hospital Management Committee,*[25] which evaluates medical malpractice depending upon whether the medical practitioner performed the act in compliance with any practice which can be considered as an accepted standard of care by a group of professionals in that particular medical specialty.

The courts in India have relied heavily on this principle, especially since Jacob Mathew, emphasizing the importance of considering what medical practitioners think rather than what patients feel.

Restrictions

i. Excessive reliance on medical expert views

ii. Neglect of patient autonomy

iii. Weak supervision of outdated practices

iv. Failure to adapt in healthcare technology environment

Bolitho Test Modification

The Bolitho modification, established in the case of *Bolitho v. City and Hackney Health Authority*,[26] involved applying judicial review to medical professionals' practice by requiring logical validity of any accepted medical practice.[10] Thus, courts need not adhere to the expert

[24] *Jacob Mathew v. State of Punjab*, (2005) 6 S.C.C. 1 (India).
[25] *Bolam v. Friern Hosp. Mgmt. Comm.*, [1957] 1 W.L.R. 582 (Q.B.).
[26] *Bolitho v. City & Hackney Health Auth.*, [1998] A.C. 232 (H.L.) (U.K.).

view if it fails to meet this criterion.

However, the courts in India have not integrated the Bolitho rule into their principles consistently.

Consumer Protection Act, 2019

The Consumer Protection Act, 2019[27] provides remedy to patients by identifying the provision of medical care as consumer goods wherein failure in care can provide grounds for compensation. In light of the case of *Indian Medical Association v. V.P. Shantha*[28], patients can file complaints against their negligent caregivers to consumer tribunals.

It has product Liability provisions, availability of remedy for deficiencies in medical services, allowing access to the dispute resolution and greater access for consumers

But this legislation focuses mainly on conventional medicine and does not cater to injuries inflicted through AI-assisted medical procedures.

Limitations of Traditional Doctrine

Though the medical negligence doctrine is strong in theory within conventional settings, there are numerous shortcomings in India's traditional medical negligence framework:

1. Focus on Human Agency - Traditional frameworks presume direct involvement of the physician in decision-making processes, hence rendering them unsuitable for application in AI technology-assisted healthcare.

2. Insufficient Incorporation of Product Liability - Defective algorithms, faulty robots, and software issues associated with medical treatment are not sufficiently covered by the current laws.

3. Insufficient Attention to Patients' Right to Self-Determination - The Bolam test may undermine patients' autonomy due to professional consensus-based approach.

4. Challenges of Proving Causation - Establishing the link between medical decisions and

[27] The Consumer Protection Act, 2019, No. 35, Acts of Parliament, 2019 (India).
[28] *Indian Med. Ass'n v. V.P. Shantha*, A.I.R. 1996 S.C. 550 (India)

patient outcomes becomes more complicated with increasingly complex technological infrastructure.

5. No Specific Regulation - There is no comprehensive legislation governing AI healthcare liability within India.

Traditionally, The Indian medical negligence jurisprudence has offered physicians accountability through concepts of duty, breach, causation, and compensatory damages. The extensive reliance on physician-related standards such as Bolam test and Bolitho rule, coupled with insufficient modernization, makes the traditional legal framework obsolete in the rapidly evolving environment.

With the emergence of new healthcare technologies, it is necessary to reformulate legal doctrines in order to protect patient autonomy while maintaining accountability.

V. Legal Issues Created by Artificial Intelligence in Healthcare

The application of artificial intelligence technology disrupts the traditional framework for medical malpractice litigation. The existing system of medical negligence revolves around the concept of human decision-making and the associated elements of duty, breach, and foreseeability. Yet, the adoption of new technologies creates a situation in which decisions can be made by an artificial agent without a traceable involvement of any physician.[29]

Thus, the existing legal structure is unable to allocate blame in situations involving algorithmic errors. Consequently, there is a need to review the existing approach to determining liability.

1. Diffusion of Liability

One of the primary legal issues created by the introduction of AI into healthcare practice is its diffusive nature. In cases where patients suffer harm caused by AI-driven diagnostic tools, surgical robots, or predictive systems, liability could be allocated to physicians, hospitals, software developers, manufacturers, providers of data and Governmental agencies

In such cases, it would be difficult to determine who should be held responsible for patient

[29] Francesco De Micco et al., *Robotics and AI into Healthcare from the Perspective of the European Union Regulatory Framework: How to Fill the Gap Between Technology and Existing Liability Systems?*, 11 Frontiers Med. 1428504, 7-9 (2024).

injuries since not all actors possess control over medical outcomes.[30]

2. Independent Error and Algorithmic Decision-Making

AI technologies may create an independent error in diagnosing illness, suggesting treatment options, or performing procedures without continuous supervision from the doctor. Autonomous or semi-autonomous technology is incompatible with negligence laws since the error may arise without any negligence on the part of the human decision-maker.[31]

Illustrative Examples Include:

A. Misdiagnosis through machine learning algorithms

B. Failure of surgery due to malfunctioning robots

C. Improper prediction outcomes due to faulty algorithmic operations

Here, deciding the liable party among physicians, programmers, manufacturers, or hospitals is legally ambiguous. The existing tort regime fails to consider liability for autonomous technological errors.

3. Manufacturer Liability and Product Liability Law

As AI technologies become more advanced, medical instruments are increasingly regarded as products rather than services. In such scenarios, manufacturers will have to contend with questions about their liability for injuries caused by their products, including software and hardware defects and design flaws.[32]

The following would be the Legal Issues:

I. Whether an AI software considered a defective product?

[30] Francesco De Micco et al., *Robotics and AI into Healthcare from the Perspective of the European Union Regulatory Framework: How to Fill the Gap Between Technology and Existing Liability Systems?,* 11 Frontiers Med. 1428504, 7-9 (2024).
[31] Hisham Jadallah Mansour Shakhatreh & Farouq Ahmad Faleh Alazzam, *Legal Frameworks for AI-Driven Diagnostics and Robotic Surgery: Addressing Medical Malpractice and Accountability,* 33 Acta Informatica Medica 248, 250-52 (2025)
[32] Consumer Protection Act, No. 35 of 2019, Acts of Parliament §§ 82–87.

II. Should strict liability be applied to autonomous medical technology?

III. How do software updates impact liability?

In India, there is inadequate legal guidance within the scope of the *Consumer Protection Act, 2019* regarding product liability in AI technology.

4. Institutional Liability in Hospitals

The facilities in hospitals are an important part in introducing, monitoring, and integrating AI applications into medical practice. In this regard, hospitals can be held liable when they fail to introduce safe AI application, train properly medical personnel, maintain AI tools and their software, consider the risks associated with technology and protect patient data

The risk of hospital liabilities due to negligent use of technology and medical devices becomes ever more serious.[33]

The introduction of AI technology makes the responsibility extend from individual medical negligence to corporate liability.

5. Software Deficiencies and Technical Failures

One of the hardest aspects of liability for AI technology is that of software deficiency. It can be caused by, coding errors, algorithm mistakes, improper testing, poor system integration, training data impropriety and failure to update.

Different from medical malpractice, software deficiencies do not depend on physician conduct at all, so special considerations are needed to resolve them properly.[34]

There are no specific rules regulating AI technologies, which makes litigation even harder.

6. Data Bias and Discriminatory Outcomes of AI

The Artificial intelligence algorithms are heavily reliant upon data used during the training

[33] *Spring Meadows Hosp. v. Harjol Ahluwalia*, (1998) 4 S.C.C. 39 (India).
[34] Francesco De Micco et al., *Robotics and AI into Healthcare from the Perspective of the European Union Regulatory Framework: How to Fill the Gap Between Technology and Existing Liability Systems?*, 11 Frontiers Med. 1428504, 9-10 (2024).

process and optimization. A biased dataset might lead to discriminatory results, causing additional harm to vulnerable populations due to race, gender, economic condition, or geographical discrepancy.[35]

The following would be the Legal Issues:

I. Discriminatory diagnosis

II. Unequal distribution of treatment

III. Misrepresented minorities

IV. Structural injustice reinforcement

The data bias creates issues of constitutional, ethical, and consumer rights law, especially when applied to equality-based legislation and medical patient rights.

7. Cybersecurity Threats and Data Privacy

The Healthcare AI systems handle extremely sensitive information about the patient's health, which puts them at risk of cyber attacks, hacking, ransomware, and data corruption. Cybersecurity threats put at risk on patient privacy, accuracy of treatment, operation of the system and trust of institutions

There is potential for legal liability, if a cyber breach leaves the patient susceptible to physical, mental, and financial danger.[36] With an increasing presence of integrated healthcare systems, cybersecurity becomes the core principle of AI liability regulation.

8. Explanatory Gap, Black Boxes, and Regulatory Failures

One of the key problem in the realm of artificial intelligence in the medical field is that of black boxes, which refers to medical algorithms whose output lacks any degree of explanatory power as to the manner in which such a conclusion was arrived at.[37] As opposed to clinical diagnosis and other decision making processes carried out by doctors, there is no justification for the

[35] World Health Organization, *Ethics and Governance of Artificial Intelligence for Health* 54-61 (2021)
[36] World Health Organization, *Ethics and Governance of Artificial Intelligence for Health* 67-72 (2021)
[37] Aniek F. Markus et al., *The Role of Explainability in Creating Trustworthy Artificial Intelligence for Health Care,* 3 NPJ Digit. Med. 161, 5-8 (2021).

decisions taken through such processes.[38]

Such an explanatory gap poses substantial problems in the area of medical negligence due to the difficulty of assessing negligence, standards of care, foreseeability, and breach in light of the inability of these processes to be critically analyzed by the courts. Such opacity may also undermine the principle of informed consent whereby doctors lack any reasonable way of explaining the risks associated with their decisions made through AI technology. In India, the problem is further exacerbated by structural failures.

For example:

i. There is no special healthcare laws for AI in India

ii. The presence of insufficient modification of product liability for AI applications in medicine

iii. The continued persistence of human-centered negligence criteria

iv. An insufficient regulatory supervision

v. The nonexistence of obligatory algorithmic audit and there is no enforceable requirements for transparency

While the *Consumer Protection Act, 2019*[39] provides partial solutions, it falls short in addressing damages caused by autonomous systems, software errors, and algorithmic bias. Consequently, there is a regulatory gap that leaves patients unprotected and healthcare providers liable under unclear circumstances.

Thus, it becomes necessary to ensure explainability and regulatory reforms to create an accountable AI governance framework. India needs to adopt a hybrid regulatory model incorporating medical negligence, product liability, institutional accountability, and AI regulations.[40]

[38] Francesco De Micco et al., *Robotics and AI into Healthcare from the Perspective of the European Union Regulatory Framework,* 11 Frontiers Med. 1428504, 9-10 (2024).
[39] Consumer Protection Act, No. 35 of 2019.
[40] Matúš Mesarčík et al., *Stance on the Proposal for a Regulation Laying down Harmonised Rules on Artificial Intelligence - Artificial Intelligence Act*, (2022), https://doi.org/10.31235/osf.io/yzfg8.

VI. Comparative Jurisprudence: Global Perspectives on Liability for AI in Medicine

A. United Kingdom: Autonomy of the Patient and Transcending Professional Paternalism

In the United Kingdom, the medical jurisprudence landscape has advanced beyond physician-centered negligence principles, embracing patient autonomy more effectively. The *Montgomery v. Lanarkshire Health Board*[41] decision by the UK Supreme Court ruled against undue dependence on the classic Bolam test in cases involving information sharing and consent. The court ruled that physicians have a duty to guarantee patients are fully informed of all relevant risks and possible alternatives to their treatment.

In the same case, there was a shift in medical negligence jurisprudence toward the principle of patient autonomy. This decision is highly relevant in AI-based medicine because the black box nature of the algorithm may prevent physicians from adequately informing their patients of the associated risks and limitations. Therefore, AI-based systems may constitute a violation of the patient autonomy principle.

B. European Union: EU AI Act and Risk-Based Regulation

The European Union stands out in the governance of AI through its proposed Artificial Intelligence Act, which forms part of one of the world's first comprehensive regulatory laws on artificial intelligence.[1] Rather than relying on the traditional approach of addressing liability only once harm is done, the European Union employs a precautionary risk-based regulation that aims to regulate AI technology according to the levels of risk posed to patients' safety and health, as well as their fundamental rights.

In this regard, AI technologies can be categorized as follows:

i. Unacceptable-risk technologies - In the EU framework there is a complete ban owing to the significant risks posed

ii. High-risk technologies - There is a stringent regulations are required for the cases on high risked technological applications

[41] *Montgomery v. Lanarkshire Health Bd.*, [2015] UKSC 11, [2015] A.C. 1430 (U.K.).

iii. Limited-risk technologies - It is very important to make the limited risk technology as mainly transparent obligations apply

iv. Minimal-risk technologies - In this case, lightest regulation applies.

In the field of Medical AI, especially those employed for diagnostic purposes, robotic surgeries, treatment planning, and decision support, falls under the category of high-risk AI technologies owing to their direct impact on people's health and medical procedures.

Regulatory Requirements of High-Risk Healthcare AI Technologies bu the EU:

Some of the regulatory requirements for high-risk medical technologies, under the EU AI Act, include the following:

i. There is a requirement for conformity assessments before marketing the technology

ii. The mandatory disclosure requirements where high risk medical technology is being used.

iii. There is also a human supervision requirement to keep an eye and to maintain the accountability.

iv. There is clear algorithmic and technical documentation when AI is being used in high-risked medical procedures for the audits and records maintenance.

v. There is post-market monitoring, risk management and data governance to ensure that AI is being used with maintainability and a human supervision.

This approach not only allows for a pro-active approach that enables re-implementation monitoring of AI-based health care applications but also post-implementation monitoring of these technologies. This framework focuses on issues such as safety, liability, and accountability rather than taking a re-active approach to the issue of litigation.

How can India adopt these structures?

The frameworks set out by the UK and EU in addressing the use of artificial intelligence in medicine can offer considerable assistance to India as it begins to grapple with the challenges posed by the increasing presence of artificial intelligence in healthcare. The current medico-

legal framework in India, which is still heavily based on negligence law centered on physicians, must adapt to the novel technology-related challenges brought about by AI-based medical technologies.

a. To begin with, India needs to establish robust patient autonomy guidelines akin to those provided by the UK in Montgomery v. Lanarkshire Health Board. Here, physicians must guarantee that their patients have been fully informed not just about general medical risks, but also risks related to AI-based medical technologies. By establishing stringent informed consent rules, patients' rights in a technology-dependent healthcare environment will be preserved.

b. Secondly, India needs to establish informed consent guidelines concerning the use of artificial intelligence in medicine. Patients must be informed whether their diagnoses and treatment plans have been influenced by artificial intelligence technologies in any way.

c. Thirdly, employing a risk-based approach similar to the European Union's AI Act would permit India to categorize medical AI applications based on how much they affect patient safety. Those that fall under high risk, such as diagnostic algorithms, robots in surgery, and clinical decision support systems, should be more rigorously assessed legally compared to low-risk applications.

d. Fourthly, India should also implement mandatory pre-market approval procedures for high-risk medical AI technology to guarantee that all high-risk technologies have undergone appropriate assessment concerning safety, efficiency, and transparency prior to their deployment.

e. Fifthly, post-market supervision must also take place since AI applications can keep learning and adapting even after they have been introduced into practice. Consequently, regulatory bodies should supervise all systems' operations for any signs of malfunctions, cybersecurity threats, drift in the learning process, and newly emerged bias issues.

f. Ultimately, it is necessary to introduce mandatory provisions for transparency and explainability in healthcare AI technology in India. It should be ensured that doctors, patients, and judges have a sufficient understanding of the principles on which AI makes

medical decisions. Explainability is important not only from the perspective of ethics but also for the efficient functioning of the judicial process in negligence claims.

In light of the above comparative analysis, it becomes clear that India could shift away from the obsolete negligence model centered around doctors' responsibility and establish an up-to-date regulatory approach involving patient autonomy, prevention, technical accountability, and institutional controls.

VII. Policy recommendations

A. The Requirement for Structural Reform

The advent of artificial intelligence in the field of medicine has highlighted several inadequacies within the current medico-legal system in India. Conventional laws on medical negligence, consumer protection, and criminal culpability have an anthropocentric approach which is inadequate when dealing with damages due to autonomous devices and decisions generated by AI algorithms and other technologies. India needs to look beyond the adaptation of laws that were conceived decades ago and create a tailor-made legal regime to govern AI-powered medicine.

B. Creation of AI-Specific Legislation for Healthcare Purposes

There should be separate legislation enacted solely for the regulation of artificial intelligence in medicine in India. This law would require categorization of medical devices according to their risk profile, standards on accountability and safety, pre- and post-market regulations, and other mandatory requirements related to transparency, cybersecurity, and the reporting of any adverse events.

C. Specialized Regulatory Oversight

A specialized regulatory body needs to be created for regulating and overseeing the use and implementation of AI technologies in the medical field. The role of this regulatory body will include supervising the licensure process, safety audits, bias testing, and lifecycle evaluation of high-risk AI systems.

D. Explainability and Patient Autonomy

Transparency and explainability should be made legally binding for India in the use of high-risk medical AI systems. It is important to disclose information to patients if any AI technology affects their diagnoses and treatment plans, along with the associated risks. It is critical to protect the patient's autonomy through informed consent.

E. Liability Model

The modern tort law needs to integrate both medical malpractice concepts as well as product liability rules to account for the distributed risk factors surrounding AI systems. In cases of harm caused by technology, software, or algorithmic discrimination, liability should not just apply to doctors but also include institutions such as hospitals and organizations responsible for manufacturing and developing the technologies.

F. Ongoing Regulatory Oversight

Given the constant changes involved in the lifecycle of an AI system as a result of software modifications and adaptive capabilities, regulatory oversight cannot be limited only to the period before approval is granted.

The current legal system in India is inadequate to tackle the challenges presented by AI-enabled healthcare. To ensure patient safety and foster innovation, India needs to develop a forward-thinking medico-legal framework based on specific legislation, flexible liability, institutional accountability, and patient protection measures. These changes are necessary to build a robust healthcare system for the algorithm era.

VIII. Conclusion

The incorporation of AI and robotics within the healthcare system marks a revolutionary change in modern-day medical practices, bringing with it numerous advantages in terms of diagnostic precision, process efficiency, and treatment efficacy. Yet, on the other hand, this development poses a significant problem for the current Indian medico-legal doctrine that is still firmly built upon the premises of human intervention and medical negligence based on traditional notions of liability.

Speaking of the conventional legal doctrines such as Bolam test, the principles and established consumer law are insufficient in handling cases involving autonomous technologies, opacity

of algorithms, software malfunctions, and dispersed liability due to technology-driven processes. These factors render conventional legal principles concerning duty, breach, causation, and damage insufficient while simultaneously highlighting the lack of informed consent and explainability.

Examples of comparative legal structures, specifically patient autonomy in the UK and risk governance in the EU, show that future-oriented healthcare law must evolve beyond the limitations of negligence suits into statutory law. In addition, the doctrine of product liability provides key tools in managing any damage done through faulty AI technologies, thus underscoring the need for liability measures that are wider than physicians alone.

Therefore, the Indian legal approach towards healthcare driven by artificial intelligence needs to be a composite one that combines elements of medical negligence, product liability, criminal liability, patient autonomy, and algorithmic accountability. Legislation, regulation, explainability requirements, and flexible liability schemes are crucial steps to ensure that advancements in technology do not surpass the reach of law.

In essence, the question is not whether India ought to regulate artificial intelligence in its healthcare sector but rather how well it will succeed in doing so. Failure to effectuate radical reforms will leave the burgeoning field of AI open to legal ambiguity, thereby eroding the already vulnerable rights of patients. Alternatively, through the reconstruction of its medico-legal framework, India can craft an exemplary template for the regulation of AI in healthcare, one that harmonizes technological development and constitutional justice.

While the future of medicine might turn out to be algorithmic, the future of healthcare law has to remain accountable and humane.