

ARTIFICIAL INTELLIGENCE AND THE EVOLUTION OF MEDICAL LAW & HEALTH POLICY

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INTRODUCTION

Artificial Intelligence (AI) is rapidly transforming the landscape of modern healthcare by improving the accuracy of diagnoses, enabling personalized treatment options, and enhancing the efficiency of patient care delivery. From early-stage cancer detection through AI-driven radiology tools to the use of virtual assistants and predictive systems in intensive care, healthcare is shifting towards increased automation and data-centered medical decision-making. However, alongside its potential to improve outcomes and reduce costs, AI introduces a range of legal, ethical, and regulatory complexities.

The deployment of AI in healthcare lies at the confluence of law, technology, and medicine. Algorithm-based decision-making directly influences fundamental aspects of healthcare such as patient autonomy, informed consent, data protection, and professional liability. Most existing legal instruments—developed long before the rise of intelligent systems—are ill-equipped to tackle these novel issues. There is ongoing debate around accountability when AI fails, the legitimacy of consent in AI-mediated treatment, and the mechanisms for identifying and correcting biases embedded in algorithms.

While developed regions such as the European Union and the United States have taken initial steps to regulate medical AI through targeted policies and frameworks, countries like India remain at a nascent stage of policy formulation in this domain. The absence of clear regulatory structures creates ambiguity for practitioners, developers, and patients, thereby risking misuse and undermining trust in AI systems.

This research seeks to explore the transformative impact of AI on the healthcare system, evaluate the strengths and limitations of current medical laws in managing these challenges, and propose actionable legal and policy reforms. Special emphasis will be placed on the Indian legal landscape, complemented by a comparative analysis of global approaches to ensure ethical, accountable, and inclusive AI integration in healthcare.

Artificial intelligence (AI) technologies, including machine learning, have the potential to transform health care by deriving new and important insights from the vast amount of data generated in health care

every day. They use algorithms that can learn from real world use and potentially use this information to improve the product's performance. But they also present unique considerations due to the iterative and data-driven nature of their development. This document establishes a common set of principles for the community to promote the development of safe, effective, and high-quality medical devices that incorporate AI. These principles are important to apply across the lifecycle of the medical device.

The 10 guiding principles for Good Machine Learning Practice (GMLP) presented in this document are a call to action to international standards organizations, international regulators, and other collaborative bodies to further advance GMLP. Areas of collaboration include research, creating educational tools and resources, international harmonization, and consensus standards, to inform regulatory policies and regulatory guidelines. These guiding principles may be used to adopt practices from other sectors, tailor them to the medical technology and healthcare, and to develop novel practices for this domain.

Further advances in AI technologies in healthcare, exemplified by generative AI, highlight the importance of clearly describing a product's intended use/ intended purpose and identifying its regulatory status. Moreover, generative AI may heighten the importance of GMLP, including fundamental software engineering practices. For example, healthcare technologies that incorporate generative AI may employ foundation models that are not under the provenance of the medical device manufacturers, thereby potentially introducing unique risks. Generative AI may also pose a more fundamental challenge with respect to demonstrating device performance. The regulatory science of measuring performance as well as characterizing and detecting errors in these models is maturing to meet this challenge. As the AI medical device field continues to evolve, so too must GMLP and consensus standards. Strong partnerships with our international public health partners are essential to empower responsible innovations in this area.

Thus, we expect this collaborative work can inform future IMDRF efforts and other international engagements.

Relevant Cases:

1. Indian Medical Association v. V.P. Shantha (1995)¹:

This landmark Indian Supreme Court case established that medical professionals are subject to consumer protection laws, holding them liable for negligent acts where a certain standard of care is

¹ Indian Medical Association v. V.P. Shantha, (1995). Supreme Court Cases, 6, 651.

their primary duty. This precedent is crucial when considering the liability of healthcare providers who rely on AI systems for diagnosis and treatment recommendations. If an AI system's recommendation leads to patient harm, the question arises as to whether the healthcare provider can be held accountable under this framework.

2. DeepMind and Royal Free NHS Trust (UK)²:

In 2017, the UK's Information Commissioner's Office (ICO) found that the Royal Free NHS Foundation Trust failed to comply with data protection laws when it provided patient details to DeepMind for testing an AI app. The ICO concluded that the data-sharing agreement took place on an "inappropriate legal basis." This case highlights the importance of data privacy and consent when implementing AI technologies in healthcare settings.

3. Justice K.S. Puttaswamy (Retd.) & Anr. v. Union of India & Ors. (2017)³:

It is highly relevant to the topic of "AI's Role in Shaping Medical Law and Policy," particularly in the areas of: data privacy and patient rights, informed consent in AI-driven medical systems, and the broader constitutional framework governing digital technologies in healthcare.

- Data privacy and patient rights
- Informed consent in AI-driven medical systems
- The broader constitutional framework governing digital technologies in healthcare.

Recognition of the Right to Privacy as a Fundamental Right:

In the Puttaswamy judgment, a nine-judge bench of the Supreme Court of India unanimously held that the right to privacy is a fundamental right under Article 21 of the Indian Constitution.

Relevance to Medical AI:

- AI in healthcare heavily depends on collecting, processing, and analyzing large volumes of sensitive personal health data.

² Information Commissioner's Office. (2017). Royal Free – Google DeepMind trial failed to comply with data protection law. <https://ico.org.uk>

³ Justice K.S. Puttaswamy (Retd.) & Anr. v. Union of India & Ors., (2017). Supreme Court Cases, 10, 1.

- The ruling places a constitutional obligation on all stakeholders (government, hospitals, developers) to ensure data privacy when deploying AI in clinical settings.
- Medical AI systems must comply with privacy safeguards such as consent, purpose limitation, data minimization, and accountability—principles derived from the right to privacy doctrine.

Foundation for Future Data Protection Laws:

The judgment laid the legal foundation for the development of India’s data protection regime. It directly influenced the drafting of the Personal Data Protection Bill (now the Digital Personal Data Protection Act, 2023), which includes provisions relevant to health data.

Relevance to Medical AI:

- AI systems are required to process personal data lawfully, fairly, and transparently.
- In healthcare, this means AI must be designed to protect sensitive patient information, and patients should have the right to know how their data is being used by AI algorithms.
- The concept of “data fiduciaries” under the law—entities entrusted with data handling responsibilities—mirrors responsibilities of hospitals and AI service providers.

Informed Consent and Autonomy:

The Puttaswamy verdict emphasized the autonomy of individuals over their personal data, including the right to make informed choices about how their information is used.

Relevance to Medical AI:

- In the context of AI, informed consent becomes complex, especially when algorithms make decisions that patients or even doctors may not fully understand (e.g., black-box AI models).
- This raises ethical and legal questions: Can consent be truly informed if the AI’s logic cannot be explained? Is the use of AI compatible with the patient’s right to control their medical choices?

Digital Healthcare Governance:

The judgment warns against unchecked state or corporate surveillance through digital means and calls for strong oversight and data protection frameworks.

Relevance to Medical AI:

- As governments roll out national digital health infrastructures (e.g., India’s Ayushman Bharat Digital Mission), AI tools integrated into these systems must operate within the constitutional limits set by the Supreme Court.

- AI surveillance tools (e.g., contact tracing apps, remote diagnostics) must not violate the constitutional guarantee of privacy and must include sunset clauses, limited scope, and public oversight.

Algorithmic Accountability:

Though not explicitly about AI, the Puttaswamy judgment has been interpreted to require accountability in automated decision-making systems, particularly when they impact constitutional rights.

Relevance to Medical AI:

- If an AI denies a patient treatment eligibility or misdiagnoses a condition due to flawed data or bias, it implicates not just tort law but constitutional protections.
- The state and private actors deploying AI must ensure that patients have redressal mechanisms and that algorithmic decisions are subject to scrutiny.

In conclusion, the Puttaswamy judgment serves as a constitutional compass for regulating AI in healthcare. It ensures that innovation does not come at the cost of fundamental rights. Any legal or policy framework for medical AI in India must align with the privacy and dignity principles laid down in this landmark case.

LITERATURE REVIEW:

1. Legal Frameworks and Regulatory Gaps:

- Most current medical laws were made before AI became common in healthcare.
- Laws like HIPAA (USA) and India's IT Act don't cover AI-related challenges such as accountability or consent in automated decisions.
- GDPR (EU) protects data privacy but struggles to regulate AI's complex decision-making, especially "black-box" algorithms.
- Article 22 of GDPR allows people to reject automated decisions, but it is rarely applied in medical AI cases.

2. Ethical Concerns in AI-Driven Healthcare:

- Scholars (Floridi & Cowls) suggest 4 principles: do good, avoid harm, respect autonomy, and ensure fairness.
- Real-world AI tools often fail these standards, especially when using biased or incomplete data.
- WHO (2021) warned that AI can reduce patient trust if not made explainable or culturally relevant.

3. Liability and Accountability:

- Traditional legal systems struggle to define who is at fault when AI makes a mistake:
- The doctor?
- The developer?
- The hospital?
- Scholars (Price & Cohen) suggest shared responsibility, but this can weaken clear legal outcomes for patients.

4. Bias in AI and Health Inequality:

- Bias in training data can lead to discriminatory treatment plans.
- Eubanks (2018) explained that AI often ignores the social realities of vulnerable populations.

5. International Policy and Regulatory Trends:

- EU AI Act (2021) treats medical AI as “high-risk” and mandates strict rules.
- U.S. FDA regulates AI-based medical software (SaMD) and distinguishes between fixed and learning algorithms.
- India’s National Digital Health Mission (NDHM) supports digital healthcare but lacks rules specific to AI use and safety.

6. Need for Empirical Legal Research:

- Most research is theoretical; real-life legal data or judgments involving AI in healthcare are rare, especially in India.
- There's a gap in local legal studies that this paper tries to fill.

STATEMENT OF RESEARCH PROBLEM

Despite the increasing use of AI in healthcare, there is no comprehensive legal framework that adequately regulates its implications for patient safety, medical accountability, data privacy, and ethical use. The absence of clear laws and policy standards creates a regulatory vacuum that threatens both innovation and public trust in AI-driven medical systems.

OBJECTIVES

To strengthen the accessibility and equity of health services, including continuum of care with citizen as the owner of data, in a holistic healthcare programme approach leveraging IT & associated technologies

and support the existing health systems in a ‘citizen-centric’ approach, the National Digital Health Mission envisages the following specific objectives:

1. To establish state-of-the-art digital health systems, to manage the core digital health data, and the infrastructure required for its seamless exchange;
2. To establish registries at appropriate level to create single source of truth in respect of clinical establishments, healthcare professionals, health workers, drugs and pharmacies;
3. To enforce adoption of open standards by all national digital health stakeholders;
4. To create a system of personal health records, based on international standards, easily accessible to individuals and healthcare professionals and services providers, based on individual’s informed consent;

RESEARCH GAP

The majority of the material now in publication either focuses on healthcare legislation or AI technology separately. Particularly in developing nations like India, there is a dearth of a comprehensive, multidisciplinary strategy that connects medical jurisprudence, ethical theory, and AI technological aspects. Empirical research on AI-related litigation patterns in medical negligence cases is likewise scarce.

RESEARCH QUESTION

1. How adequately do existing medical and data protection laws regulate the use of Artificial Intelligence in healthcare systems, particularly in the Indian context?
2. What legal and ethical challenges arise from the use of AI in diagnosis, treatment, and patient management, and how can they be addressed through policy reforms?
3. Who should be held liable when an AI system causes medical harm— the developer, the healthcare provider, or the institution?

RESEARCH METHODOLOGY

This study uses a doctrinal and qualitative research approach, which means it relies on existing laws, policies, court decisions, and expert opinions to understand how AI is affecting medical law and policy. It doesn’t involve surveys or fieldwork but instead looks at what has already been written or decided in

different countries. The research is mainly exploratory and analytical. It explores how AI is changing the healthcare system and what legal and policy changes are needed to manage these changes responsibly.

Primary Sources include:

- Laws and regulations like the GDPR (Europe), HIPAA (USA), and India's IT Act,
- Court rulings such as the Puttaswamy privacy case in India,
- Policy documents like the WHO's 2021 report on AI in health.

Secondary Sources include:

- Research papers, articles, books, and online reports,
- Expert opinions and analysis found in academic or official publications.

Method of Analysis:

The laws and policies are read and interpreted to understand their relevance to AI in healthcare. Important themes like privacy, ethics, and accountability are identified and explained. The study also compares how different countries (like the US, UK, EU, and India) are dealing with these issues to suggest better ways forward.

This method helps to:

Understand how laws and policies are falling behind when it comes to regulating new AI tools in healthcare,

Suggest improvements by learning from what other countries are doing, Propose ways to make legal rules more future-ready, especially in the Indian context.

SIGNIFICANCE

Bridging Legal and Technological Gaps:

The study addresses the growing disconnect between rapidly evolving AI technologies and outdated medical legal frameworks. By doing so, it contributes to building a more synchronized understanding of how laws can adapt to modern healthcare innovations.

Patient-Centric Legal Reforms:

As AI systems increasingly influence clinical decisions, it becomes vital to protect patient rights, autonomy, and safety. This research emphasizes the need for legal reforms that uphold ethical standards and strengthen safeguards for individuals affected by AI-driven medical decisions.

Guiding Policymakers and Regulators:

The study offers valuable insights and recommendations for legislators, regulatory bodies, and healthcare institutions. By analyzing international frameworks and identifying best practices, the paper helps shape more effective, context-sensitive AI policies in countries like India.

Filling Scholarly Gaps in Indian Context:

Most existing literature is Western-centric. This research contributes to the limited body of legal scholarship focusing specifically on India's preparedness to regulate AI in healthcare, helping to localize and contextualize global challenges.

Encouraging Ethical AI Development:

By highlighting legal loopholes, bias risks, and liability concerns, the study encourages developers and medical institutions to prioritize ethical and responsible AI design, deployment, and oversight.

Supporting Comparative Legal Research:

The study enhances comparative analysis between jurisdictions (e.g., EU, US, India), contributing to global discourse on how different countries are addressing similar challenges with varied legal tools and policies.

Promoting Legal Awareness Among Stakeholders:

It raises awareness among legal professionals, healthcare providers, technologists, and patients about the implications of AI in medical law, fostering a multidisciplinary understanding necessary for ethical innovation.

For Ethical AI Development and Corporate Accountability:

Private tech developers play a key role in shaping the medical AI landscape, yet they often operate with minimal oversight. This study advocates for corporate responsibility, transparent algorithmic design, and mandatory human-in-the-loop systems. It thereby contributes to the ongoing discourse around ethical AI design, impact assessment, and compliance in the healthtech industry.

For Emerging Economies and India's Healthcare Landscape:

While developed countries are advancing AI regulation, emerging economies like India face unique challenges: lack of infrastructure, low AI literacy among medical professionals, and underrepresentation in AI training datasets. This research focuses on India's context and offers comparative insights from

global jurisdictions, aiming to provide culturally and economically appropriate legal models that support ethical AI deployment in resource-constrained settings.

For Medical Practitioners and Institutions:

Healthcare professionals are key stakeholders in the AI ecosystem, yet many face uncertainty about the legal and ethical implications of using AI in diagnosis or treatment planning. This research clarifies these implications, helping practitioners navigate their responsibilities and protect themselves from potential litigation while enhancing patient outcomes. Hospitals and healthcare institutions can also use this study to inform policy guidelines, internal compliance strategies, and medico-legal training programs for staff.

LIMITATIONS

The following known limitations are to be overcome during National Digital Health Mission implementation and operationalization:

Acceptance and usage of National Digital Health Mission building blocks by other stakeholders, especially private sector:

- A. Striking the right balance between service orientations, financial models and not diluting the public good nature.
- B. Clarity on the components and building blocks of National Digital Health Mission and their timeline of implementation.
- C. Keeping pace with technological advances and adopting the latest standards, e.g. those related to changes in anonymization practices etc.
- D. Cyber security and fraud control risks.
- E. Data migration between cloud servers, maintenance of data and core infrastructure.

Jurisdictional diversity limits the generalizability of recommendations:

Jurisdictional diversity significantly limits the generalization of AI-driven recommendations in shaping medical law and policy. Since healthcare regulations, ethical norms, and legal systems differ from one region to another, an AI model trained on data from one country may provide recommendations that are irrelevant or even unlawful in another. This diversity requires that AI systems be carefully adapted and localized to reflect the specific legal, cultural, and medical standards of each jurisdiction to ensure their accuracy, reliability, and ethical compliance.

Limited empirical case law involving AI in Indian courts:

In India, there is limited empirical case law involving Artificial Intelligence (AI), meaning very few court cases have addressed or dealt directly with AI-related issues. As a result, there is not much legal precedent or guidance on how AI should be regulated or applied within the Indian legal system. This lack of cases makes it difficult to understand how courts view AI in areas like decision-making, liability, or privacy, leaving a gap in legal clarity and policy development regarding AI.

Rapid tech evolution may outpace current research findings:

Rapid technological growth can move faster than current research, creating challenges in shaping medical law and policy through AI. As AI tools in healthcare develop quickly, laws and studies may not keep up. This gap can lead to outdated rules, unclear responsibilities, and missed ethical concerns. To make sure AI is used safely and fairly in medicine, research, laws, and policies must adapt quickly to match the pace of new technologies and changing medical practices across different region.

SUGGESTIONS

To bridge the existing research gap, it is essential to develop a multidisciplinary strategy that integrates medical jurisprudence, ethical theory, and AI technology within the healthcare context. In countries like India, where the legal and regulatory environment is still evolving, scholars and policymakers must prioritize research that connects legal, technological, and ethical dimensions of AI in medicine. This includes encouraging empirical studies that examine litigation trends in AI-related medical negligence cases to understand how courts interpret liability and consent issues. Academic institutions, legal think tanks, and healthcare organizations should collaborate to create interdisciplinary research frameworks and policy blueprints that reflect local realities while incorporating global best practices. Establishing dedicated research centers or funding programs focused on AI and health law can foster this collaboration. Such efforts will not only inform evidence-based policymaking but also ensure that AI integration in healthcare remains legally sound, ethically robust, and socially inclusive.

The use of AI in diagnosis, treatment, and patient management presents several legal and ethical challenges, including unclear liability in cases of error, lack of transparency in algorithmic decisions, informed consent complexities, and risks to data privacy. For instance, when AI tools provide inaccurate diagnoses, determining whether the doctor, developer, or institution is responsible becomes legally ambiguous. Ethically, patients may not fully understand how AI influences their treatment, undermining

informed consent and autonomy. Moreover, biased algorithms can exacerbate health disparities. These issues can be addressed through comprehensive policy reforms such as mandating explainability in AI systems, establishing clear accountability frameworks, enforcing rigorous data protection laws, and requiring human oversight in clinical AI applications. Policies should also incorporate periodic audits and ethical review mechanisms to ensure fairness and safety. A participatory approach involving technologists, ethicists, legal experts, and patient advocates is crucial to crafting adaptive, rights-based, and ethically grounded regulatory frameworks

CONCLUSION

To create a national digital health ecosystem that supports universal health coverage in an efficient, accessible, inclusive, affordable, timely and safe manner, that provides a wide-range of data, information and infrastructure services, duly leveraging open, interoperable, standards based digital systems, and ensures the security, confidentiality and privacy of health-related personal information.

This research has demonstrated that current medical law is ill-equipped to handle the nuanced realities introduced by AI—such as algorithmic opacity, shared liability, and the erosion of traditional doctor-patient dynamics. Conventional legal doctrines like negligence, informed consent, and fiduciary duty need to be reinterpreted in light of machine-influenced clinical decisions. The situation is further complicated by ethical concerns, particularly around data bias, consent fatigue, unequal access to AI tools, and lack of transparency in decision-making processes.

Globally, policy responses remain fragmented and inconsistent. While the European Union has taken significant strides with its risk-based AI Act, other jurisdictions like India are still in the nascent stages of drafting AI governance frameworks specific to health. A harmonized, globally adaptable model is essential—not just to ensure compliance, but to guarantee that AI serves the public good, particularly in life-and-death scenarios.

Legal systems must move beyond reactive regulation. Instead, we need proactive, anticipatory governance that involves continuous stakeholder dialogue, ethical review mechanisms, and agile lawmaking that can adapt to technological advances. A multidisciplinary approach—integrating legal experts, technologists, ethicists, and medical professionals—is essential for developing nuanced laws that uphold patient rights without stifling innovation.

Furthermore, the integration of AI into healthcare underscores the importance of public trust. Patients must feel secure in the knowledge that their data is protected, their autonomy respected, and that they have legal recourse in the face of harm. Embedding ethical principles such as transparency, accountability, and fairness into the legal fabric is therefore not optional—it is imperative.

As we move toward a future where AI may become a co-pilot in every clinical decision, we must ensure that the law evolves not merely as a watchdog but as a guidepost—facilitating progress while safeguarding humanity. This research calls for a reimagined legal ecosystem, one that is dynamic, inclusive, and ethically resilient.

In conclusion, AI's role in healthcare is not just a technological phenomenon—it is a jurisprudential revolution. The law must rise to meet this moment, not with fear, but with foresight and fidelity to its ultimate purpose: justice, equity, and the well-being of all

REFERENCES

- World Health Organization (2021). Ethics and governance of artificial intelligence for health: WHO guidance. <https://www.who.int/publications/i/item/9789240029200>
- European Commission. (2021). Proposal for a Regulation laying down harmonized rules on artificial intelligence (Artificial Intelligence Act). COM/2021/206 final. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52021PC0206>
- Justice K.S. Puttaswamy (Retd.) & Anr. v. Union of India & Ors., (2017) 10 SCC 1.
- Indian Medical Association v. V.P. Shantha, (1995) 6 SCC 651.
- Information Commissioner's Office. (2017). Royal Free – Google DeepMind trial failed to comply with data protection law. <https://ico.org.uk/action-weve-taken/enforcement/royal-free-google-deepmind-trial-failed-to-comply-with-data-protection-law/>
- Obermeyer, Z., Powers, B., Vogeli, C., & Mullainathan, S. (2019). Dissecting racial bias in an algorithm used to manage the health of populations. *Science*, 366(6464), 447–453. <https://doi.org/10.1126/science.aax2342>
- Floridi, L., & Cowls, J. (2021). A Unified Framework of Five Principles for AI in Society. *Harvard Data Science Review*. <https://doi.org/10.1162/99608f92.8cd550d1>

- U.S. Food and Drug Administration (FDA). (2021). Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan. <https://www.fda.gov/media/145022/download>
- General Data Protection Regulation (GDPR), Regulation (EU) 2016/679.
- Health Insurance Portability and Accountability Act (HIPAA) of 1996, Public Law 104–191, USA.
- Eubanks, V. (2018). Automating Inequality: How High-Tech Tools Profile, Police, and Punish the Poor. St. Martin's Press.
- Price, W. N., & Cohen, I. G. (2019). Privacy in the age of medical big data. *Nature Medicine*, 25(1), 37–43. <https://doi.org/10.1038/s41591-018-0272-7>
- Ministry of Health and Family Welfare, Government of India. (2021). National Digital Health Mission (NDHM) - Strategy Overview. <https://ndhm.gov.in>
- The Digital Personal Data Protection Act, 2023 (India). Available from: Ministry of Electronics and Information Technology. <https://www.meity.gov.in>
- International Medical Device Regulators Forum (IMDRF). (2021). Principles of Good Machine Learning Practice (GMLP). <https://www.imdrf.org/documents/principles-good-machine-learning-practice>
- Susskind, R. (2019). *Online Courts and the Future of Justice*. Oxford University Press.
- Rao, M., & Arora, V. (2020). *AI in Healthcare: India's Policy Conundrum*. ORF Occasional Paper No. 277. Observer Research Foundation.
- European Union Agency for Fundamental Rights (FRA). (2020). *Getting the Future Right – AI and Fundamental Rights*. <https://fra.europa.eu/en/publication/2020/artificial-intelligence-and-fundamental-rights>
- Sharma, T. & Bansal, A. (2022). Legal Challenges in Regulating AI in India's Healthcare System. *Journal of Law and Technology*, 45(2), 121–140.
- Future of Life Institute. (2017). *Asilomar AI Principles*. <https://futureoflife.org/ai-principles/>