



Regulating Artificial Intelligence in Healthcare Services in India: Legal and Policy Challenges

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Abstract

Artificial Intelligence (AI) is rapidly transforming healthcare systems worldwide, and India is no exception. From AI-powered diagnostic tools and predictive analytics to robotic surgeries and personalized medicine, AI has the potential to significantly improve healthcare delivery, accessibility, and efficiency. However, the rapid deployment of AI technologies in India's healthcare ecosystem raises complex legal, ethical, and policy challenges. Unlike jurisdictions such as the European Union, India does not yet have a comprehensive standalone legal framework specifically regulating AI. Instead, governance is fragmented across sectoral laws, ethical guidelines, and policy initiatives, leading to regulatory uncertainty and enforcement gaps.

This research article critically examines the evolving regulatory landscape governing AI in healthcare services in India. It analyses existing legal instruments such as the Information Technology Act, 2000, the Digital Personal Data Protection Act, 2023, and the Medical Devices Rules, 2017, along with policy initiatives like the National Strategy for Artificial Intelligence and ethical guidelines issued by the Indian Council of Medical Research (ICMR). The article identifies key legal and policy challenges, including data privacy concerns, lack of accountability, algorithmic bias, absence of transparency, and regulatory fragmentation. Special attention is given to privacy risks arising from the use of sensitive health data and the adequacy of India's emerging data protection regime. The study concludes that while India has adopted an innovation-friendly, "light-touch" regulatory approach, a more coherent and sector-specific legal framework is necessary to ensure safe, ethical, and equitable deployment of AI in healthcare. It recommends the development of comprehensive AI legislation, stronger institutional oversight, enhanced data protection safeguards, and a balanced approach that fosters innovation while protecting patient rights.

Keywords: Artificial Intelligence, Healthcare Regulation, India, Data Privacy, Legal Challenges

Introduction

Artificial Intelligence (AI) has emerged as one of the most transformative technologies of the 21st century, reshaping industries across the globe. In the healthcare sector, AI is revolutionizing clinical decision-making, diagnostics, drug discovery, patient monitoring, and public health management. In India, where the healthcare system faces challenges such as inadequate infrastructure, shortage of healthcare professionals, and unequal access to medical services, AI offers a promising solution to bridge systemic gaps and improve healthcare outcomes. The Indian government has actively promoted the adoption of AI in healthcare through various initiatives. Institutions such as the All

India Institute of Medical Sciences (AIIMS) and other centers of excellence have been designated to develop AI-based healthcare solutions. Additionally, collaborations with organizations like the Indian Council of Medical Research (ICMR) and private technology firms aim to harness AI for disease surveillance, diagnostics, and treatment optimization. These developments reflect India's broader vision of leveraging AI as a "force multiplier" in addressing healthcare challenges.

Despite these advancements, the integration of AI into healthcare raises significant legal and policy concerns. AI systems rely heavily on large volumes of data, including sensitive personal health information. The

collection, storage, and processing of such data create risks related to privacy breaches, misuse of information, and unauthorized access. The landmark judgment in *Justice K.S. Puttaswamy v. Union of India* recognized the right to privacy as a fundamental right, thereby placing a constitutional obligation on the state to safeguard personal data. However, the practical implementation of privacy protections in AI-driven healthcare systems remains a complex challenge. India's regulatory approach to AI is characterized by the absence of a dedicated AI law. Instead, AI governance is shaped by a combination of existing laws, guidelines, and policy frameworks. The Information Technology Act, 2000 serves as the primary legislation governing digital transactions and cybercrime, including data breaches and identity theft. The Digital Personal Data Protection Act, 2023 (DPDP Act), along with its rules notified in 2025, establishes a framework for data protection, imposing obligations on entities handling personal data and granting rights to individuals.

In the healthcare context, AI-based diagnostic tools are increasingly being classified as medical devices, thereby bringing them under the regulatory purview of the Central Drugs Standard Control Organisation (CDSCO) and the Medical Devices Rules, 2017. This development reflects an attempt to ensure safety and efficacy in AI-driven healthcare technologies. However, regulatory oversight remains fragmented, with multiple authorities overseeing different aspects of AI, including data protection, medical regulation, and digital governance.

Furthermore, the Indian Council of Medical Research has issued ethical guidelines for the application of AI in biomedical research and healthcare. These guidelines emphasize principles such as accountability, transparency, fairness, and patient safety. While these guidelines provide a valuable ethical framework, they lack enforceability, limiting their effectiveness in addressing real-world challenges. The absence of a comprehensive regulatory framework has led India to adopt a "light-touch" approach to AI governance. This approach prioritizes innovation and economic growth while relying on principles-based guidelines rather than strict regulatory controls. Although this strategy encourages technological advancement, it raises concerns about the adequacy of safeguards to protect patients and ensure ethical use of AI in healthcare.

The challenges associated with AI in healthcare are multifaceted. They include issues of data privacy, algorithmic bias, lack of transparency in decision-making, liability for errors, and ethical dilemmas related to patient consent and autonomy. For instance, AI systems trained on biased datasets may produce inaccurate or discriminatory outcomes, disproportionately affecting marginalized populations. Additionally, the "black box" nature of many AI algorithms makes it difficult to understand how

decisions are made, raising questions about accountability and trust.

Another critical issue is the lack of clear legal liability in cases where AI systems cause harm. Traditional legal frameworks are based on human accountability, making it challenging to assign responsibility for decisions made by autonomous or semi-autonomous AI systems. This gap in the legal framework creates uncertainty for healthcare providers, developers, and patients alike. Moreover, the integration of AI into healthcare requires robust data governance mechanisms. The National Health Data Management Policy aims to provide a framework for managing health data and supporting AI applications. However, the effective implementation of such policies requires coordination among various stakeholders, including government agencies, healthcare providers, technology companies, and patients.

In this context, it is essential to examine the legal and policy challenges associated with regulating AI in healthcare services in India. This research article aims to provide a comprehensive analysis of the existing regulatory framework, identify key challenges, and propose recommendations for developing a more robust and coherent governance system. By addressing these issues, India can harness the potential of AI in healthcare while ensuring the protection of patient rights and ethical standards.

2. Legal Framework Governing Artificial Intelligence in Healthcare in India

2.1 Absence of a Dedicated AI Law

India currently does not have a specific or comprehensive law that directly regulates artificial intelligence, especially in the healthcare sector. Instead, AI is governed indirectly through existing laws related to information technology, data protection, and medical regulation. This creates a fragmented legal framework where no single authority or statute addresses all aspects of AI. As a result, there is confusion about how AI systems should be regulated, particularly when they are used in sensitive areas like diagnosis, treatment, and patient care.

The absence of a dedicated AI law also means that there is no proper classification of AI systems based on risk. For example, a simple administrative AI tool and a high-risk diagnostic AI system are not treated differently under the law, even though their impact on human life varies significantly. This lack of differentiation can lead to insufficient oversight of critical AI applications. Furthermore, without a central regulatory body for AI, enforcement becomes weak and inconsistent. Different authorities regulate different aspects, which leads to overlap and gaps.

Another issue is the reliance on guidelines and policy documents instead of enforceable laws. While these

guidelines promote ethical practices, they are not legally binding, and organizations may choose not to follow them strictly. Overall, the lack of a dedicated AI law creates uncertainty, reduces accountability, and may compromise patient safety in the healthcare sector.

2.2 Information Technology Act, 2000

The Information Technology Act, 2000 is the primary law governing digital activities in India. It deals with issues such as cybercrime, electronic transactions, and data protection. Although it plays an important role in regulating the digital environment, it was enacted long before the development of artificial intelligence technologies.

Some provisions of the Act, such as those related to data breaches and unauthorized access, are relevant to AI systems. For example, companies can be held liable if they fail to protect sensitive data, including health data. However, the Act does not specifically address the functioning of AI systems, such as automated decision-making, machine learning, or algorithmic accountability.

One major limitation of the IT Act is that it focuses mainly on data protection and cyber offenses, rather than the outcomes or decisions produced by AI systems. It does not provide any guidance on who is responsible if an AI system makes an incorrect medical decision. Additionally, it lacks provisions for transparency and explainability, which are crucial for building trust in AI-based healthcare systems. Therefore, while the IT Act provides a basic legal foundation, it is not sufficient to regulate the complexities of AI in healthcare.

2.3 Digital Personal Data Protection Act, 2023

The Digital Personal Data Protection Act, 2023 is a major step forward in protecting personal data in India. It is particularly important for AI in healthcare because these systems rely heavily on large amounts of personal and sensitive data, such as medical records and health histories. The Act is based on key principles like consent, purpose limitation, data minimization, and accountability. It requires organizations to obtain consent from individuals before collecting and using their data. It also gives individuals certain rights, such as the right to access, correct, or delete their data.

However, applying these principles to AI systems presents several challenges. AI technologies often require large datasets to function effectively, which may conflict with the principle of data minimization. Similarly, obtaining meaningful consent can be difficult because AI systems are complex and not easily understood by patients. This raises questions about whether consent is truly informed.

Another challenge is that the Act does not clearly address automated decision-making. In healthcare, AI systems may make decisions that directly affect patients,

but the law does not provide clear safeguards against such automated decisions. Additionally, issues related to cross-border data transfers and data anonymization remain unclear. While the DPDP Act strengthens data protection, it still needs to evolve to address the unique challenges posed by AI in healthcare.

2.4 Medical Devices Rules, 2017 and CDSCO Oversight

In India, certain AI-based healthcare tools, especially those used for diagnosis and treatment, are classified as medical devices. These are regulated under the Medical Devices Rules, 2017 and overseen by the Central Drugs Standard Control Organisation (CDSCO). This approach ensures that AI systems meet certain safety and quality standards before they are used in clinical settings. It also aligns India with international practices, where AI-based medical tools are subject to regulatory approval.

However, this framework has limitations when applied to AI. Traditional medical devices are static, meaning their design does not change after approval. In contrast, AI systems can evolve over time through continuous learning and updates. The current regulatory system does not fully account for this dynamic nature.

There is also a lack of clarity regarding the classification of AI tools. Not all AI applications clearly fall within the definition of medical devices, which creates uncertainty for developers and regulators. Moreover, regulatory authorities may lack the technical expertise needed to evaluate complex AI systems. Thus, while the Medical Devices Rules provide some level of oversight, they are not fully equipped to handle the unique characteristics of AI technologies.

2.5 Ethical Guidelines by ICMR

The Indian Council of Medical Research (ICMR) has issued ethical guidelines for the use of AI in healthcare. These guidelines focus on principles such as transparency, accountability, fairness, patient safety, and data privacy.

These ethical principles are important because they help ensure that AI systems are used responsibly and do not harm patients. They also promote trust among healthcare providers and patients.

However, the main limitation of these guidelines is that they are not legally binding. This means that organizations are not legally required to follow them, and there are no penalties for non-compliance. Additionally, there is no formal system to monitor whether these guidelines are being implemented effectively. As a result, while the ICMR guidelines provide valuable direction, they are not sufficient on their own to regulate AI in healthcare.

3. Key Legal and Policy Challenges in Regulating AI in Healthcare

3.1 Data Privacy and Protection

Data privacy is one of the biggest challenges in AI-driven healthcare. AI systems rely on large amounts of sensitive health data, which increases the risk of data breaches and misuse. Even anonymized data can sometimes be re-identified, posing additional risks. Although the Digital Personal Data Protection Act provides a framework for protecting data, it does not fully address the specific risks associated with AI, such as predictive analytics and data profiling. Ensuring strong data protection measures is essential to maintain patient trust.

3.2 Lack of Accountability and Liability

Determining who is responsible when an AI system causes harm is a major legal challenge. In traditional healthcare, doctors and hospitals are held accountable for their actions. However, in AI-based systems, responsibility may be shared between developers, healthcare providers, and the AI system itself. This lack of clarity creates legal uncertainty and makes it difficult for patients to seek compensation. It also discourages healthcare providers from adopting AI technologies due to fear of liability.

3.3 Algorithmic Bias and Discrimination

AI systems can produce biased results if they are trained on incomplete or unrepresentative data. In a diverse country like India, this can lead to unequal treatment of different populations, particularly marginalized groups. For example, an AI system trained primarily on urban data may not perform well in rural settings. This can result in incorrect diagnoses or unequal access to healthcare services.

3.4 Transparency and Explainability

Many AI systems operate as “black boxes,” meaning their decision-making processes are not easily understood. This lack of transparency makes it difficult for doctors and patients to trust AI systems. It also raises legal concerns, as it becomes challenging to explain how a particular decision was made. This can affect accountability and the ability to challenge incorrect decisions.

3.5 Regulatory Fragmentation

The regulation of AI in healthcare is spread across multiple laws and authorities. This leads to overlapping responsibilities and lack of coordination among regulators. As a result, enforcement becomes inconsistent, and gaps in regulation remain unaddressed. A more unified regulatory framework is needed to ensure effective governance.

3.6 Ethical Concerns and Informed Consent

AI raises important ethical issues related to patient autonomy and informed consent. Patients may not fully understand how AI systems work or how their data is being used. This makes it difficult to obtain truly informed consent. There is also a risk that AI systems may make decisions without adequate human oversight, raising ethical concerns about patient care.

3.7 Cybersecurity Risks

AI systems are vulnerable to cyberattacks, which can compromise their reliability and safety. Attacks such as data manipulation or hacking can lead to incorrect medical decisions. Ensuring strong cybersecurity measures is essential to protect both data and AI systems from such threats.

3.8 Lack of Standardization and Infrastructure

The effective use of AI in healthcare requires standardized data formats, reliable infrastructure, and interoperability between systems. In India, these elements are still developing. The lack of standardization makes it difficult to integrate AI systems into existing healthcare frameworks. Additionally, limited digital infrastructure in rural areas poses a challenge for widespread adoption.

4. Conclusion

The integration of artificial intelligence into healthcare services in India presents both immense opportunities and significant challenges. While AI has the potential to revolutionize healthcare delivery, improve efficiency, and enhance patient outcomes, its deployment must be carefully regulated to address legal, ethical, and policy concerns.

India’s current regulatory framework for AI in healthcare is characterized by fragmentation and the absence of a dedicated AI law. Although existing laws such as the Information Technology Act, 2000 and the Digital Personal Data Protection Act, 2023 provide a foundation for governance, they are insufficient to address the unique challenges posed by AI technologies. Ethical guidelines and policy initiatives offer valuable direction but lack enforceability.

To ensure the responsible use of AI in healthcare, India must adopt a comprehensive and coherent regulatory framework. This should include sector-specific legislation, stronger data protection measures, clear accountability mechanisms, and robust oversight institutions. Additionally, there is a need for international collaboration, public engagement, and continuous policy adaptation to keep pace with technological advancements.

By striking a balance between innovation and regulation, India can harness the transformative potential of AI in healthcare while safeguarding patient rights and promoting ethical practices.

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