



# The Indian Journal for Research in Law and Management

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Editor-in-Chief – Dr. Muktai Deb Chavan; Publisher – Alden Vas; ISSN: 2583-9896

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## AI IN HEALTHCARE:

### LEGAL IMPLICATIONS AND ETHICAL CONCERNS

- GAUTHAMI VINOD MANKAME

The inclusion of AI in the market has ushered in a new era in the world of medicine and the healthcare sector. In India, hospitals and various other startups have adopted AI for faster diagnostics, personalized treatment planning, patient health monitoring, and efficient administrative processes. Whether it's an algorithm helping the surgeons in conducting surgery without the mark on patients' bodies, a radiologist detecting cancer at an early stage, or AI predicting the patients' readmission, the AI integration into the medical and healthcare sector has shown significant transformation in patients health scale by its integration as a tool. However, while these technologies offer various benefits and operational movements, they also raise concerns-both legal and ethical challenges. Traditional laws governing the aspects of health are not sufficient to keep pace with machine-led decision-making. As the stakes in this field are much higher, one wrong diagnosis can lead to adverse consequences, ultimately affecting the Right to Life of an individual.

This blog shall explore India's evolving stance on AI and Healthcare to address the unique legal and ethical implications.

Imagine an AI tool used in the hospital goes wrong with its analysis, the treatment is delayed, and this leads to severe harm; in such scenarios, determining liability becomes difficult. The question arose as to who should be responsible for such misdiagnosis. The Indian legal system lacks a clear answer, since AI often operates as a tool for decision support, there is no set jurisprudence on whether medical practitioners can solely rely on AI or are obligated to second-guess the outputs given by the same. While the technology is a crucial component of development but in the context of healthcare, such uncertainties are dangerous, which extends not only to legal liability but also to clinical accountability of the healthcare professionals;



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therefore, the requirement for proper regulatory reform is essential to protect the rights of both patient as well as healthcare providers.

The normal cases of medical negligence or health data breaches are governed by the Consumer Protection Act, the Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011, and the Digital Personal Data Protection Act, 2023. These regulatory frameworks are comprehensive but lack healthcare-specific rules addressing how medical data should be protected, anonymized, and stored when used for AI developments or prediction models. Moreover, many hospitals lack a robust digital infrastructure or cybersecurity protocols, increasing the risk of breaches.

There are various other regulatory blind spots when it comes to AI to be used as a tool when used for medical purposes, that mainly unlike the drugs and medical devices; AI in the Indian context is at the moment not subject to any formal approval process, also, currently there are no dedicated AI regulations or safety validation requirements from the Ministry of Health and family welfare or any other authorities in this sector. The absence of a regulatory framework causes significant risk, as the AI tools shall be deployed without being tested for accuracy on the Indian Population. For example, the AI model that is being trained with the European dataset shall not match the Indian Demographics, as the pattern of disease, medications, and behaviour may be according to the regions of the patient's belonging. Globally, the EU or the US FDA has developed a framework for approving such tools or models; these frameworks show what constitutes a high risk as well as the requirements of assessment and transparency.

Another risk associated with the use of AI in healthcare could be “biases”. The model requirement should be based on an understanding of the Indian demographics, which includes people of varied cultures. The legal framework should ensure that the AI system used in the healthcare sector is audited and brings fairness and accuracy across a diverse patient population. As every machine is made by humans and the data inputs are also human-made, hence, the bias of individual perspective shall result during the diagnosis.



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AI in healthcare is only useful in such cases wherein there is trust from the patient's side, and this should be ensured by following the constitutional rights of the individual are not infringed. But this concept often clashes with the AI tools, mostly, are black boxes, which means they give results without offering any information as to how they reached such a conclusion. In high-risk cases like surgery, oncology, etc, such opaque algorithms are a safety hazard. The primary idea is to understand to AI decisions are being influenced to make decisions.

While the startup or tech companies play a crucial role in developing such models, specifically in the healthcare sector, such models must align with the ethical principles of medical practices. The idea we rely on should be healthcare delivering patient patient-centric approach, even in the digital and technology-driven era. Various bodies, both nationally and internationally, are in the process of establishing standards to promote public health with innovation.

The innovation is boosting, which has led to outpacing the legal and ethical safeguards for providing equitable care. India must dynamically bring up the healthcare laws reflecting the scope of inclusion of AI-powered systems, setting clear rules, guidelines, as far as liability, transparency, accountability and various other reasons concerned. By embracing such a balanced position it is possible to have a AI driven healthcare system.

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