



**2025**

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**Recommended Citation**

Srinithi R, *Critical Analysis on the Legal Implications of AI in Healthcare and Its Relation to Human Rights Law*, 4 IJHRLR 164-173 (2025).  
Available at [www.humanrightlawreview.in/archives/](http://www.humanrightlawreview.in/archives/).

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# Critical Analysis on the Legal Implications of AI in Healthcare and Its Relation to Human Rights Law

**Srinithi R**

*Law Student, 3<sup>rd</sup> Year, BBA.LL.B. (Hons.),  
School of Law, CHRIST (Deemed to be University)*

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**Manuscript Received**

19 Mar. 2025

**Manuscript Accepted**

21 Mar. 2025

**Manuscript Published**

24 Mar. 2025

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## ABSTRACT

*Artificial intelligence (AI) is one of the fastest growing fields in the world and its intersection with the healthcare sector has boosted the innovation of new practices and procedures equipped by this sector. AI helps in making the job easy by equally competing with the human minds in reducing the manpower, saving the time, and also by reducing the cost and expenses incurred. The use of Artificial intelligence in the healthcare industry helps in early diagnosis of any disease such as cancer where with the help of AI, mammograms can now be reviewed and translated 30 times quicker and with 99% accuracy, which eliminates the need for pointless biopsies and the research in the medical field has seen an innovation with the involvement of AI. Investigating drugs and coming up with new ones is one of the more recent uses of AI in healthcare. There are possibilities to greatly reduce both the time and the costs incurred due to the development of new compounds as well as their re-purposing by applying the current state of the art in AI towards drug discovery processes. Likewise it also helps in maintaining the patient's life in good condition by increasing the ability of the doctors and other medical practitioners. While AI aids the modern day emerging fields, it also has its own drawbacks. This article streamlines its discussion to the regulatory framework of the intersection between AI and medicine and addresses the legal implications of issues including patient's privacy, consent, liability and data protection. The rapid advancements in artificial intelligence could create patent challenges, in particular on the algorithms and on the applications of data. The challenge of*

*enforcing patents on proprietary technologies while still ensuring that all applicable patents are respected raises legal difficulties and this article advocates for keeping the intersection between AI and medicine in check and balancing the medical ethics under the innovation of AI.*

### **KEYWORDS**

*Artificial Intelligence in Healthcare, AI-driven Diagnosis, Drug Discovery and AI, Legal and Ethical Challenges in AI, Patient Privacy and Data Protection.*

### **INTRODUCTION**

The healthcare sector is under a revolution where it is undergoing a massive transformation and the medical practitioners around the world often face difficulties in managing the existing healthcare systems. One such important incident in recent times which advocates for this issue is the COVID-19 pandemic which has posed many challenges to the world's healthcare systems, including issued hospitals, shortages of resources, and the demand for quick turnaround times on testing and diagnosis. The influx of patients and the pressure for effective control management CDI on Information technology, most especially artificial intelligence technology (AI), has been identified as the solution for such issues in the health sector. Indeed, AI was instrumental in improving the accuracy of diagnoses using images, as well as analyzing and predicting trends in patient volume, and even enabling visits through telecommunications devices. Furthermore, drug development was fast-tracked by AI, and so was improved management of the hospital, which in turn relieved some work overloads on the healthcare personnel. The pandemic revealed the need for changes in the healthcare systems which include adopting and assimilating AI systems for better preparedness in the face of health threats.

In healthcare, AI has introduced innovative treatments to patients, new diagnostic procedures, and improved efficiency; however, it also introduced a plethora of legal connotations that must be sensitively negotiated. As the entire healthcare system evolves with considerations surrounding the COVID-19 pandemic, the connections between law and technology only grow more complex. Such applications involve diagnosing algorithms and predictive analytics under the healthcare domain but at the same time raise issues on regulatory compliance, data privacy, liability, and ethical considerations. For instance, the

Health Insurance Portability and Accountability Act includes very strict patient data protection rules; yet integration of AI does not necessarily make it any easier to comply with, simply due to the different kinds of data processing involved. This also means that in the event of a wrong diagnosis or failure to treat appropriately, liability will become important if AI systems have become integral to clinical decision-making. Identifying who bears liability—the providers, the developers, or both—indicates the need to redraw the traditional lines that have been drawn about what constitutes malpractice. The use of AI in healthcare should also address issues related to bias and equity since algorithms trained on flawed data can extend and perpetuate any inequalities in care. The urgency of these challenges was compounded by a pandemic where the rate of AI adoption oftentimes outpaced the formation of regulatory frames to prioritize patient safety and ethics in practice. As such, it is quite instructive for legal scholars and practitioners to create adaptive regulatory structures that not only protect patients' rights but also promote innovation in AI technologies. Now, as long as this health landscape is unfolding, the implications of AI will mandate an ongoing discussion between legal experts, healthcare professionals, and policymakers to set clear guidelines. One would need this multifaceted discussion not only in response to the challenges at hand but for the preparedness of future health emergencies so that legal tools can be invoked properly in the right sense to conserve public health on technology front. To be brief, the legal implications of AI in healthcare are broad and plural, requiring prophylactic action to protect against risks and take full advantage of these new technologies.

## **LANDSCAPE OF AI IN HEALTHCARE**

The AI in the healthcare landscape is changing fast, with numerous applications that should contribute to better patient outcomes, increase efficiency of processes, and lower costs. Algorithms that aid in diagnosis determination, personalized medicine, robot-assisted surgery, and telehealth integration are becoming increasingly common in the delivery of clinical practice. However, while these developments offer immense potential, they raise important legal, ethical, and human rights concerns that must be addressed if these technologies are to be used responsibly.

### ***i. Compliance with regulations***

The application of AI technologies in health creates immense

legal implications related to compliance with the requirements of legislation by the laws currently in place on medical practice, patients' rights, and data protection. The aim of the enacted law is to safeguard the sensitive information of the patient and ensure the medical provider maintains standards to their highest level in the provision of care. In the United States, the cornerstone regulation in control of the privacy and security of health information is HIPAA, passed in 1996. HIPAA imposes stringent requirements on healthcare entities to ensure confidentiality, integrity, and availability of patient data. Applications involving AI processing of sensitive health information must therefore be compliant with these regulations to protect the privacy of patients as well as maintain public trust.

Access is granted to the patient's data only to authorized persons, which makes the whole thing increasingly complex when this amount of health data is put into the analysis by AI systems. It is the responsibility of the developers to implement access controls as well as encryption protocols in an effort to deny unauthorized access or cyber threats to sensitive information. Apart from that, AI systems must have to ensure that data is safe from the point of collection and processing up to its storage and sharing. This is quite vital in the medical industry, which has experienced a worrying increase in data breaches; medical information concerning the patients might be lost and lead to severe legal action.

Data integrity also is very crucial in that it ensures that the data is valid, reliable, and trustworthy. Mechanisms for validation of data integrity should also be incorporated into the system; for instance, audit trails showing other changes made to the patient's records. This is quite critical in the health sector because clinical decisions depend so much on the accuracy of the data. By processing incorrect or manipulated data, an AI system can cause a misdiagnosis, inappropriate treatment plan, and, in extreme cases, harm a patient. Thus, data integrity has to be part of a developer's compliance strategies for AI systems.

Availability is the need by authorized users to access patient data at any given time, especially when urgent. Thus, applications of AI that make decisions in real time require very robust infrastructure systems to provide access to data for the health caregiver when needed. Such may require redundancy and comprehensive backup strategies that minimize downtime, with availability of critical information being guaranteed.

While HIPAA provides a pretty good starting ground to protect the data, compliance is not, after all, only a matter of following rules - it has been always demanding continuous effort to implement appropriate data security measures, conduct regular audits, and train people on proper best practices for handling data. Such regular risk assessments can bring vulnerabilities out in AI systems and make organizations proactive in avoiding some risks that eventually may surface. Violation of HIPAA results in severe legal sanctions in the form of fines and penalties and even criminal prosecution and reputational damage and heavy erosion of patients' trust.

The regulation, like the GDPR in Europe, therefore offers a comprehensive framework that goes further into the regulatory landscape for AI in healthcare. The GDPR heavily focuses on the protection of personal data, mainly sensitive health information. Such principles would include, for instance, data minimization, where there should only be data gathering when it is needed to serve a certain purpose. For AI applications, this principle requires developers to ensure their algorithms are designed to collect and process only what data is needed for its functioning, thereby lessening the danger of privacy infringement.

The other critical tenet of GDPR is purpose limitation, which stipulates that personal data is collected for specific, legitimate purposes and not further processed in a way that is incompatible with those purposes. This principle happens to present a challenge to AI developers, who often rely on large datasets to train algorithms. They need to de-noise and delineate the purposes for which data is collected to ensure subsequent uses do not contravene GDPR stipulations. In this regard, clarity is key in terms of keeping the compliance and avoiding legal pitfalls.

Explicit consent, in this regard is one of the key doctrines under GDPR, whereby a person has to be notified that they will give an informed and affirmative consent to the processing of their data. Obtaining informed consent is a complex affair for any AI health technology. There should be transparency on why patients' data will be used; who will be given access to this kind of data and risks that may come along with an AI application. Therefore, it also demands that healthcare providers adequately communicate and are transparent with their patients such that consent is both sought and meaningful.

GDPR also gives the patient certain rights regarding his data, including the right to access his information, the right to rectify

inaccuracies, and the right to erasure, which can be called the "right to be forgotten". These rights add a further layer of complexity to the AI and healthcare providers, who must ensure that the systems they design will facilitate these rights' exercise in patient affairs. GDPR compliance demands proactive management of data through a view of patients' rights and determines processes to comply with requests regarding personal data.

The impacts of regulatory compliance extend far beyond national borders because AI advances in its role in globalization in healthcare. There will be different regulations in different jurisdictions and different chaos for the healthcare providers and the developers of AI to contend with. This underlines the need for international cooperation in data protection, where best practices and regulatory frameworks inform each other. There are challenges that relate to compliance with local laws and at the same time aspired to have high standards of data protection, with global patients increasingly expecting health care organizations to handle their data responsibly.

## ***ii. Liability Issues***

Liability becomes sharply contentious in cases of misdiagnosis or adverse patient outcome with AI integration into clinical decision-making. The traditional basis of malpractice may be insufficient to address the issues that the introduction of AI does to healthcare. As Hodge Jr. (2021) explained, "the law's unsettled landscape around AI in healthcare creates uncertainty regarding accountability when an AI system delivers an erroneous recommendation."<sup>1</sup>

Liability for AI-based health care thus needs a judicial re-evaluation of the existing legal framework. So far as whose fault it should be—the healthcare provider who used the AI technology, the developers of the AI system, or both—it would make it impossible for patients to seek redress in case they suffer injuries. There is an urgent need for bright-line rules that establish responsibility. Legal scholars would then advocate for a new set of standards which explicitly detail the specifics of applications in health care, such as informed consent and criteria for assessment of AI performance.

Another controversial concept in this regard is "autonomous

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<sup>1</sup> Samuel D. Hodge Jr., *The Medical and Legal Implications of Artificial Intelligence in Health Care—An Area of Unsettled Law*, 28 *Rich. J.L. & Tech.* 405 (2021).

systems." Even when there is no human oversight or control, issues of fault become even more complicated. The task of developing proper law-making frameworks and provisions with AI specifics to clarify accountability and provide redress mechanisms in malpractice maladies will continue.

### **iii. Informed Consent and Patient Autonomy**

Medical ethics and human rights law are the founding principle of informed consent; it gives the patient a right to be fully informed about their options for treatment and the role of AI in their treatment. Key questions with respect to transparency and adequacy of consent arise as a result of the deployment of AI technologies. Patients need to be informed how AI impacts their diagnosis and treatment as well as the risks and benefits accompanying these technologies (Schönberger, 2019)<sup>2</sup>.

This also includes explaining complex AI processes to patients in a language that they can understand and within a familiar framework. The process of any AI algorithm and its decision-making process is technical by nature, and it might be difficult for patients to realize how these technologies affect their care. Lack of proper information might undermine patient autonomy and violate the legal standards regulating informed consent.

This is a challenge for providers to develop the means of giving patients information that is simple, clear, and accessible as regards what the technologies do as well as how such AI systems work and also about which limitations and uncertainties are involved in such applications of technology. Shared decision-making refers to the support and facilitation of patients in preparing to make informed choices about their care, consistent with the human rights principles that prioritize individual autonomy and informed consent.

### **iv. Data bias and fairness**

AI systems, in most cases, rely on learned functions developed from historical data that may perpetuate ongoing biasedness and inequalities in healthcare. Algorithms are usually developed based on datasets that lack diversity or misrepresent populations being served, and such may lead to biased outcomes affecting different groups of persons disproportionately. The severity of these concerns raises ethical as well as legal issues related to human rights, particularly in

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<sup>2</sup> Daniel Schönberger, *Artificial Intelligence in Healthcare: A Critical Analysis of the Legal and Ethical Implications*, 27 *Int'l J. L. & Info. Tech.* 171 (2019).



the contexts of equality and non-discrimination (DePaul Journal of Health Care Law, 2019-2020)<sup>3</sup>.

This implies the need to ensure that all patients receive just and equal treatment. It requires legal structures that will also establish rules relating to transparency of AI algorithms, in addition to further assessments to be made on the effects it has on the patient population. Additionally, it requires guidelines to recommend the use of representative datasets, continuous monitoring of AI performance towards the ability to identify and eliminate bias effects.

Aside from this, health institutions must ensure diversity and inclusion when designing and implementing AI technologies. This results in a more balanced system and also raises trust among patients who may have been cynical about the interventions by the AI. They had instances of bad experiences in discrimination in healthcare. Lastly, legal requirements should correspond to these approaches so that the AI technologies do not empower the high disparity in healthcare.

#### ***v. Ethical Considerations and Human Rights Law***

This will also raise deep questions on the ethical dimensions of AI in healthcare and implications for human rights law. The International Human Rights Instruments make provisions for a state to ensure the right to health by guaranteeing access to satisfactory quality healthcare by every individual. With the coming of technological advancement through AI, especially in the field of health care, the reformation of the current landscape brings with it very significant implications for this fundamental right.

The focus of human rights law on principles of dignity, equality, and non-discrimination would thus call for AI use to be in conformity with such principles to ensure that the new technologies do not disproportionately worsen existing inequalities in healthcare. Legal scholars such as Schönberger (2019)<sup>4</sup> argue that human rights frameworks need to accompany the development and deployment of AI in health for such rights to be secured.

This involves a multi-stakeholder approach that would see

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<sup>3</sup> Artificial Intelligence and Technology in Health Care: Overview and Possible Legal Implications, 21 DePaul J. Health Care L. 1 (2019-2020).

<sup>4</sup> Daniel Schönberger, Artificial Intelligence in Healthcare: A Critical Analysis of the Legal and Ethical Implications, 27 Int'l J. L. & Info. Tech. 171 (2019).

collaboration between the governments, healthcare providers, AI developers, and civil society. Such cooperation may facilitate the establishment of guidelines from ethically aimed perspectives that feature the patients' rights and welfare as top priority concerns, where patients have better access to proper health care through utilization of AI technology.

### **CONCLUSION**

While the promise of transforming patient care with AI in healthcare may improve health outcomes, legal implications of the mentioned AI technologies are sizable and deserve careful consideration. Some of the areas that require consideration are regulatory compliance, issues of liability, informed consent, data bias, and ethical considerations where human rights law becomes an integral intersection.

As health care continues embracing AI solutions, now is the right time to collaborate towards developing legal frameworks that promote innovation with adequate protection for the patient rights and accountability. Overcoming these challenges will allow the healthcare sector fully to realize the potential of AI in fostering better care delivery, equity, and fundamental principles based on human rights.

Ultimately, therefore, responsible integration of AI in healthcare would have a positive impact on the quality of care by instilling confidence and trust among patients, especially since it could serve to ensure that technological developments advance human dignity and equality in health.