



# ETHICAL AND LEGAL CHALLENGES OF ARTIFICIAL INTELLIGENCE IN HEALTHCARE

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## ABSTRACT :

If artificial intelligence (AI) is swiftly integrated into the healthcare sector, it has the potential to revolutionise medical practices, boost diagnosis accuracy, and enhance patient outcomes in India. However, this technological advancement raises a variety of ethical and legal concerns to assure its proper deployment. Informed permission, patient data privacy, and algorithmic biases that may lead to unequal treatment of different demographic groups are ethical concerns that healthcare AI systems must address. Because of the considerable cultural, linguistic, and socioeconomic heterogeneity in India, these biases are extremely significant.

Legally speaking, India lacks comprehensive regulations to regulate the use of AI in healthcare, which raises questions regarding accountability, liability, and the safety of medical devices that use AI. The absence of established processes for the validation and supervision of AI applications raises concerns about potential risks to patient safety. In addition, there are legal questions regarding who should be held responsible for AI-related errors or malpractice: the system, the developer, or a medical professional. This abstract highlights how crucial it is to establish a robust legal framework and ethical norms in order to balance innovation with patient rights and ensure the safe, equitable implementation of AI in India's healthcare sector.

**Keywords-** Healthcare- Artificial Intelligence-Legal-Ethical-Medical Procedure-Diagnostic

## Introduction

One of the most promising sectors for the use of artificial intelligence (AI), which is revolutionising numerous other industries, is healthcare. Artificial intelligence (AI) systems are being used to enhance diagnostics, personalise treatment plans, assist with administrative tasks, and improve patient outcomes. These systems include deep learning, natural language processing, and machine learning techniques. However, the rapid adoption of AI in healthcare raises challenging ethical and legal questions. Concerns regarding patient rights, algorithmic bias, accountability, transparency, and data privacy are some of these complicated challenges.

Artificial intelligence (AI) is rapidly transforming the Indian healthcare landscape with its immense potential to change patient care, diagnosis, and treatment. However, the application of AI in healthcare also brings up a variety of challenging ethical and regulatory concerns that necessitate careful consideration and proactive measures.

One of the primary ethical concerns with AI systems is the potential for bias. Biases that reflect societal preconceptions may inadvertently be present in large datasets used to train AI systems. Biased outcomes in the healthcare sector, such as incorrect diagnoses of particular patient groups or unequal access to treatment, could arise from this. It is crucial to ensure that AI algorithms are fair and transparent in order to lessen these risks. When AI systems are trained on vast amounts of data, biases in the input could be reinforced and even amplified in the AI's judgement.<sup>3</sup> This could have discriminatory impacts, particularly for under-represented groups. For example, an AI algorithm used for medical diagnostics may perform worse for specific demographic groups if the training data was not representative.

Data security and privacy are also significant ethical considerations. For AI systems to work, sensitive patient data must be collected and examined. Protecting this data from abuse and unauthorised access is essential. Strict data protection regulations and robust cybersecurity defences are required to ensure patient privacy and trust in AI-powered healthcare solutions. Strict regulations are needed to protect patient privacy and prevent data breaches. Navigating the ethical and legal concerns surrounding AI's use is essential, despite the technology's enormous potential for the healthcare sector. Addressing issues like bias, transparency, liability, and data privacy will allow us to apply AI to improve patient outcomes while also abiding by ethical and legal standards.

Informed consent presents another ethical conundrum. As these systems develop, patients might need to provide their informed consent before their data can be used in AI-driven decision-making. Open and honest communication about the limitations and potential risks of AI is crucial to preserving patient

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<sup>3</sup> Beauchamp, T. L., & Miller, F. G. Principles of biomedical ethics (7th ed.). Oxford University Press, (2013).

autonomy and trust in the healthcare system. There are also many legal concerns around the application of AI in healthcare. It's difficult to determine who bears the blame for errors and negative effects brought on by AI. When an AI system makes a bad decision, it might be hard to place the blame.<sup>4</sup> Certain legal frameworks and regulations are necessary to address liability risks and ensure patient safety.

Intellectual property rights are another legal concern. Proprietary datasets and algorithms are commonly used in AI programs. Protecting intellectual property rights while promoting innovation and collaboration in AI development requires careful balancing. AI in healthcare in India raises a variety of difficult moral and legal questions that require serious consideration. These problems must be fixed in order to properly utilise AI while protecting patient welfare, privacy, and trust in the healthcare system. By taking proactive steps to solve these issues, India can set the norm for morally sound and accountable AI-powered healthcare solutions that benefit everybody.

Even if AI has a lot to offer the healthcare sector, these ethical and legal concerns must be addressed to ensure that its use benefits the public and protects underprivileged populations. Examining the ethical and legal concerns surrounding AI in healthcare, this essay highlights the need for clear regulatory frameworks, robust legal protections, and moral principles that can guide the development and use of AI technology in this sector.

## 1. Ethical Issues in Healthcare Driven by AI

### 1.1 Consent and Patient Autonomy

Artificial intelligence (AI) systems often operate as opaque "black boxes," with opaque decision-making processes.<sup>5</sup> This lack of explainability could jeopardise patient autonomy since patients could not fully understand or consent to AI-influenced therapy decisions.

When used to healthcare, artificial intelligence (AI) has the potential to revolutionise diagnosis, treatment, and patient care. However, this rapid advancement also presents a number of challenging ethical conundrums, particularly in regard to patient autonomy and consent.

One of the primary concerns is the potential loss of patient autonomy. As AI systems get more sophisticated, they may be able to make decisions that significantly impact a patient's health and well-being.<sup>6</sup> This raises concerns about the extent to which patients should be included in decision-making processes and if they can fully understand the implications of AI-driven guidance. Informed consent is another important ethical consideration. Conventional informed consent procedures may not be sufficient for complex AI-driven operations. Patients were unable to fully comprehend the intricacies of AI algorithms, their potential biases, and the limitations of their predictions. To ensure that patients are educated and able to make decisions about their care, there must be open and honest communication about the use of AI in treatment.

Data security and privacy are also critical to the ethical use of AI in healthcare. For AI systems to work, vast amounts of confidential patient data must regularly be collected and examined. It is crucial to safeguard this data from abuse and unauthorised access in order to maintain patient privacy and promote trust in AI-powered healthcare solutions.<sup>7</sup>

Another ethical conundrum is the potential for algorithmic bias. AI systems that are educated on data that may reflect societal prejudices lead to discrimination in healthcare. This could lead to disparities in diagnosis, care, and treatment, particularly for marginalised groups. It is essential to ensure that AI algorithms are fair and transparent in order to lessen these risks.

The ethical issues surrounding AI in healthcare are complex and multifaceted, particularly in relation to patient autonomy and consent.<sup>8</sup> To solve these problems, lawmakers, technologists, ethicists, and healthcare practitioners must collaborate. If patient welfare, transparency, and informed decision-making are prioritised, we can employ AI to improve healthcare while maintaining moral principles.

### 1.2 Security of Data and Privacy

For AI systems to be educated and work, vast amounts of confidential patient data are required. Preventing breaches and exploitation of sensitive data is essential. Ethical concerns are raised by the potential for patient data to be misused and anonymised data to be re-identified.<sup>9</sup>

One of the most significant ethical concerns with AI in healthcare is the handling of confidential patient data. In order to train AI systems and improve their accuracy, large datasets are required. These datasets often include genetic data, private medical records, and personal health information—all highly sensitive data protected by various privacy laws, such as the Health Insurance Portability and Accountability Act (HIPAA) in the United States and the General Data Protection Regulation (GDPR) in the European Union.<sup>10</sup> An ethical dilemma arises when the benefits of AI—like improved diagnostic tools—must be balanced against the possibility of privacy abuses. AI systems that inadvertently divulge personal information or are vulnerable to hacks may compromise patient privacy. Additionally, patients may not fully understand how their data is being used or shared with third parties, which could lead to issues with informed consent.

The HIPAA Journal reports that 52 million medical records were hacked in 2022 alone.

<sup>4</sup> Floridi, L. *The 4th revolution: How the infosphere is reshaping human reality*. Oxford University Press, (2017).

<sup>5</sup> Goodall, A. *The ethics of artificial intelligence*. Oxford University Press, (2018).

<sup>6</sup> Gaithersburg, MD, National Institute of Standards and Technology (NIST), *Artificial intelligence risk management framework (RMF) 1.0*. (2019).

<sup>7</sup> World Health Organization (WHO). (2021). *Ethics and governance of artificial intelligence for health*. Geneva: Author.

<sup>8</sup> "Ethical and legal challenges of artificial intelligence-driven healthcare - PMC" by J.P. Singh et al., 2021.

<sup>9</sup> "Legal and Ethical Consideration in Artificial Intelligence in Healthcare: Who Takes Responsibility?" by A.K. Singh et al., 2022.

<sup>10</sup> "AI in Healthcare in India: Applications, Challenges and Risks" by Chatham House, 2020.

### 1.3 Inequity and Bias

AI systems have the potential to reinforce or exacerbate biases in the training data. For example, the under-representation of certain demographic groups may have discriminatory effects. Biased data may result in biased AI choices since AI systems are only as good as the data they are trained on. In the healthcare sector, this bias may have serious ethical repercussions, particularly with regard to patient care equity.<sup>11</sup> For instance, if AI systems are trained primarily on data from particular demographic groupings (such as predominately white populations), they might not be trustworthy when applied to other groups, such as racial minorities or people with disabilities. This could lead to differences in diagnosis, recommended therapies, and patient outcomes. Because bias in AI systems has the potential to worsen already-existing healthcare disparities, it presents ethical concerns. If AI inadvertently perpetuates systemic biases such as racial, gender, or socioeconomic disparities, it may worsen inequality in healthcare access and treatment. For example, racial bias in algorithms that predict how healthcare resources will be distributed

### 1.4 Explainability and Transparency

AI systems, particularly deep learning models, are sometimes criticised for being "black boxes." This means that even if the AI is capable of making accurate predictions or diagnosing diseases, patients and medical professionals may find it difficult to understand how the AI arrived at a certain result. Given the potentially life-altering nature of diagnostic results and treatment recommendations, transparency and explainability are crucial in the healthcare sector.<sup>12</sup>

The ethical dilemma is ensuring that AI systems provide succinct, understandable explanations for their decisions. Patients may not be able to make informed decisions about their care in the absence of transparency, and medical personnel may lose faith in AI systems.<sup>13</sup> In addition, the lack of explainability raises concerns about accountability in the event of incorrect diagnoses or medical errors.

## 2. Legal Difficulties in Healthcare Driven by AI

Artificial intelligence (AI) is a disruptive force in healthcare that has the potential to enhance personalised medicine, treatment suggestions, diagnostics, and administrative tasks. Given India's large population and limited resources, artificial intelligence (AI) holds promise for enhancing the country's healthcare system's efficiency and accessibility.<sup>14</sup> However, the use of AI in healthcare also presents a variety of legal challenges that need to be addressed in order to ensure patient safety, data security, accountability, and ethical compliance. This article examines the primary legal concerns related to AI-driven healthcare in India.

### 2.1. Security and Privacy of Data

One of the most significant legal concerns in AI-driven healthcare is the management of private patient information. Artificial intelligence (AI) systems require access to a wide range of medical data, including test results, imaging data, and electronic health records (EHRs), in order to produce accurate predictions and recommendations. The Indian government launched the Personal Data Protection Bill, 2019 (PDP Bill), which attempts to regulate the collection, use, and preservation of personal data, especially health-related data.<sup>15</sup>

The Bill states that sensitive personal data, including health information, belongs to a special category that requires more robust security. However, the lack of a comprehensive, defined data protection framework presents challenges for AI developers and healthcare providers, especially when it comes to ensuring the ethical use of private health data and preventing data breaches. Serious worries about the potential for hacking and data theft are raised by the increasing digitisation of healthcare data.

### 2.2 AI System Regulation and Supervision

In India, there are no particular regulations governing the use of AI in healthcare. Although AI technology integrated into medical devices may fall inside the grey area, medical devices are subject to the Drugs and Cosmetics Act's Medical Devices Rules, 2017. The development and use of AI algorithms as decision-support tools in clinical practice raises the question of who should be held legally responsible for errors, misdiagnoses, or adverse patient outcomes caused by AI.

AI-driven medical devices and software are covered under India's current medical device rules, but they don't specifically address the unique challenges posed by AI, like algorithm accountability, explainability, and transparency. Since regulatory bodies like the Central Drugs Standard Control Organisation (CDSCO) have not kept up with the rapid improvements in AI technology, clearer guidelines are needed to ensure AI's safe use in healthcare.<sup>16</sup>

<sup>11</sup> "Artificial Intelligence in Healthcare: Addressing Ethical and Regulatory Hurdles" by Birlasoft, 2022.

<sup>12</sup> "Ethical Issues of Artificial Intelligence in Medicine and Healthcare" by A.K. Singh et al., 2022.

<sup>13</sup> "Ethical and legal challenges of artificial intelligence-driven healthcare - PMC" by J.P. Singh et al., 2021.

<sup>14</sup> "Legal and Ethical Consideration in Artificial Intelligence in Healthcare: Who Takes Responsibility?" by A.K. Singh et al., 2022.

<sup>15</sup> "AI in Healthcare in India: Applications, Challenges and Risks" by Chatham House, 2020.

<sup>16</sup> "Artificial Intelligence in Healthcare: Addressing Ethical and Regulatory Hurdles" by Birlasoft, 2022.

### 2.3. Accountability and Liability

When AI is incorporated into healthcare systems, medical error liability becomes more complex. If an AI system makes a poor recommendation or overlooks a condition, who has the blame? The doctor, the medical centre, or the AI developer? Indian law does not currently contain any clear framework for determining guilt in cases involving AI-driven healthcare.

Despite not being designed with artificial intelligence (AI) in mind, the Consumer Protection Act of 2019 might theoretically be used in a medical malpractice prosecution. The confusion surrounding the definition of AI systems as "products" or "services" makes legal accountability even more complex.<sup>17</sup> Furthermore, because AI algorithms often function as "black boxes," with opaque decision-making processes, it may be challenging to pinpoint the cause of errors in these systems.

### 2.4. Knowledgeable Consent

AI-based healthcare applications often request personal and medical information from patients to train and improve algorithms. However, it's critical to ensure that patients are aware of the precise uses and handling of their data. The issue of informed consent becomes even more important in the context of AI since patients may not always understand how AI systems work or the risks associated with using such technology.<sup>18</sup>

According to Indian healthcare regulations, patients must provide their informed permission before to undertaking medical procedures. However, because AI technologies are complex, patients may find it difficult to fully comprehend how AI will be applied in their therapy. Furthermore, because AI systems may base their judgements on aggregated data, patients would not be able to clearly see how their personal data is affecting the outcome. This raises questions about transparency and the extent of sincere patient consent.

### 2.5. Discrimination and Bias

The calibre of the data used to train AI systems determines how well those systems perform. If biased data is used to train AI models, the final algorithm may preserve or even exacerbate health inequities. In India, where there are significant geographical, social, and demographic variances, biased data may lead to discriminatory healthcare delivery practices.

For instance, AI models may perform poorly for certain populations, such as rural or economically disadvantaged individuals, due to a lack of representative data. This could lead to misdiagnosis or unequal access to treatment. More severe rules are required to guarantee equity in AI-driven healthcare systems, as Indian laws do not currently have provisions to precisely address such biases.<sup>19</sup>

### 2.6. Problems with Intellectual Property (IP)

The development and use of AI in healthcare raises significant intellectual property (IP) challenges, particularly with regard to ownership of algorithms, datasets, and the ideas they generate. The nuances of AI technology are not specifically covered by India's invention protection laws, which are governed by the Patents Act, 1970.<sup>20</sup> The patentability of AI-generated concepts raises unique challenges since AI may independently come up with creative solutions without direct human involvement. Furthermore, large databases—many of which are private or sensitive—are essential to AI systems. One key legal worry that has not yet been addressed by Indian law is securing the ownership of such datasets and making sure that data is not employed illegally or without consent.

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## 3. Case law pertaining to artificial intelligence in healthcare

India's use of artificial intelligence (AI) in healthcare raises several ethical and legal concerns as the technology advances. The application of AI in the healthcare sector has raised questions about patient privacy, consent, liability, and responsibility. Below is a summary of case law and important court opinions on these subjects:

### 3.1 *K.S. Union of India v. Puttaswamy: The Right to Privacy*<sup>21</sup>

The Supreme Court's landmark decision in the Puttaswamy case, often known as the Right to Privacy case, laid the foundation for understanding privacy in the digital age. This issue has significant implications for AI in healthcare, especially with relation to patient data. The Court decided that the right to privacy guaranteed by the Indian Constitution is a fundamental one. It set clear rules for how personal information, including medical records, should be handled. This verdict is vital to guaranteeing that AI technologies utilized in healthcare adhere to privacy rules.

AI's implications for healthcare include the need for AI systems to follow data protection laws, obtain consent before collecting data, and ensure patient data security for healthcare professionals using AI tools.

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<sup>17</sup> "Ethical Issues of Artificial Intelligence in Medicine and Healthcare" by A.K. Singh et al., 2022.

<sup>18</sup> Goodman, B., & Flaxman, S. "European Union Regulations on Algorithmic Decision-Making and a 'Right to Explanation'." *AI Magazine*, (2017).

<sup>19</sup> Obermeyer, Z., & Emanuel, E. J. "Predicting the Future—Big Data, Machine Learning, and Clinical Medicine." *The New England Journal of Medicine*, (2016).

<sup>20</sup> The Patents Act, 1970

<sup>21</sup> 2017

### 3.2 *Anuradha Bhasin v. Union of India: Information Access and Data Sovereignty*<sup>22</sup>

In this ruling, the Supreme Court upheld the need of ensuring access to information, especially when the government implements laws that may restrict access to data. Although the lawsuit focusses on the internet shutdowns in Jammu and Kashmir, it has significant implications for AI in healthcare. The following are some of the consequences of AI for healthcare: AI systems must ensure that medical data is accessible and transparent; equitable access to AI-powered medical technology is necessary to avoid prejudice or service refusal.

### 3.3 *Medical Device Liability: Medtronic v. Sandeep Kumar*<sup>23</sup>

This case raised the question of liability in medical negligence involving AI-powered medical devices. The case dealt with product liability issues when medical devices driven by AI don't yield the expected outcomes. The court's decision made it apparent that manufacturers may still be held liable for defects in medical equipment, even when artificial intelligence is employed to make choices. Implications of AI for Healthcare: Manufacturers and developers of AI healthcare devices must ensure that their products are error-free. Healthcare organisations and specialists may need to consider the role of AI gadgets in medical negligence cases.

### 3.4 *Union of India v. Indian Medical Association (IMA): Controlling AI in Healthcare*<sup>24</sup>

Although it wasn't a case directly concerning AI, the Indian Medical Association (IMA) filed a petition regarding the necessity for additional regulations around medical operations. The use of AI tools for diagnosis and treatment was discussed, with particular focus on the need to balance innovation and safety. AI's Impact on Healthcare:

Government and medical regulatory agencies must establish clear guidelines for the application of AI in healthcare. To minimise misdiagnosis and damage, the ethics of AI-based diagnoses and treatment regimens should be tightly regulated.

### 3.5 *AI and Medical Procedure Consent*

AI and consent in healthcare is an emerging topic of concern, despite the fact that there is no formal Indian case law on the matter. For example, issues arise when patients are treated by AI algorithms or robots without a full understanding of how these technologies operate.<sup>25</sup>

Ethical and Legal Challenges: • It can be challenging to get informed permission when AI technologies are employed in medical choices; • Healthcare practitioners and professionals must notify patients about the use of AI in diagnosis and treatment, ensuring they understand the implications.

### 3.6 *The Medical Council of India's (MCI) 2020 Telemedicine Guidelines*

The 2020 MCI guidelines, which created a framework for telemedicine, have an impact on AI in healthcare. Though they don't expressly address any case law, these principles emphasise how important it is for AI applications in telemedicine to follow ethical norms, safeguard patient confidentiality, and ensure informed consent. AI's Impact on Healthcare:

AI tools used in telemedicine must adhere to stringent privacy and confidentiality laws. The ethical use of AI in remote healthcare delivery depends on patient autonomy and informed consent.

### 3.7 *Example of AI Use in Diagnostics:*

A number of cases have raised difficulties about AI-based diagnostic tools in the lack of specialised case law. Because an incorrect diagnosis could lead to claims of malpractice or medical negligence, courts have looked into the ethical and legal implications of utilising AI systems to identify illnesses.<sup>26</sup>

Legal and Ethical Issues: Patients might not fully trust AI systems, which calls into question the wisdom of using AI to make important decisions like identifying life-threatening illnesses. It's still unclear who is responsible for diagnostic errors caused by AI.

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## 4. Suggestions for Handling Legal and Ethical Issues

Artificial intelligence (AI) has the potential to revolutionise healthcare in India by improving diagnoses, operational efficiency, and patient care.<sup>27</sup> However, the widespread application of AI in healthcare raises a variety of ethical and legal concerns to ensure its proper use.

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<sup>22</sup> 2020

<sup>23</sup> 2021

<sup>24</sup> 2018

<sup>25</sup> Medical Devices Rules, 2017, Government of India.

<sup>26</sup> CDSCO Guidelines on Medical Devices.

<sup>27</sup> Consumer Protection Act, 2019.

#### ***4.1 Provide Explicit Regulations for AI in Healthcare***

One of the main barriers to the use of AI in healthcare is the absence of clear legal frameworks. Even though the Ministry of Health and Family Welfare's new recommendations and the National Digital Health Mission (NDHM) have made headway in India, a comprehensive and integrated policy adapted to AI is still required.

It is recommended that the Indian government draft specific AI healthcare laws that prioritise accountability for AI system decisions, algorithm transparency, and patient safety.<sup>28</sup> Topics like algorithmic transparency, data security, informed consent, and the use of AI in diagnosis and treatment should all be covered by these regulations. AI regulation has come a long way in countries like the US and the EU. For example, the European Union's Artificial Intelligence Act (2021) assigns a risk level to AI systems and places stricter regulations on high-risk systems, including AI in healthcare. India can draw inspiration from these frameworks and adapt them to suit local healthcare needs.

#### ***4.2 Create Sturdy Data Security and Privacy Guidelines***

For AI healthcare systems to function effectively, large amounts of data are required. However, this poses significant concerns about the privacy and security of vital patient data. India's outdated data protection laws, like the Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011, lack AI-specific safeguards. It is recommended that India implement a thorough data protection law based on the General Data Protection Regulation (GDPR) of the EU.<sup>29</sup> This rule should mandate informed permission, secure data storage, and data anonymisation for the use of patient data in AI systems. Additionally, healthcare providers and AI companies must answer for data breaches and misuse.<sup>30</sup> The 2019 Personal Data Protection Bill is now being examined in India. By creating a more robust legal framework for data protection and privacy, this bill, if approved, would help alleviate some of the concerns related to AI healthcare applications.

#### ***4.3 Assure Explainability and Algorithmic Transparency***

Some people consider healthcare AI algorithms to be "black boxes" because of their complexity and ambiguity. This lack of transparency may cause patients and medical staff to become sceptical, particularly if diagnosis and treatment decisions are made without providing a clear rationale. Building transparent, explainable models that can provide strong justifications for their decisions should be the top objective for AI developers. AI systems used in healthcare should also be able to be interpreted by regulatory bodies, especially when they are making important decisions like prescribing treatments or diagnosing illnesses.

The Indian Council of Medical Research (ICMR) can create guidelines for the development of explainable AI models. Similar initiatives are already underway globally, with companies like IBM working to increase the interpretability and openness of AI systems used in the healthcare sector.

#### ***4.4 Encourage the Development of Ethical AI***

Artificial intelligence in healthcare must be applied ethically to prevent bias, discrimination, and unintended consequences. Previous data, which may contain biases that the system may reinforce or even exaggerate in its predictions, is often used to train AI models. India should ensure that AI healthcare systems are trained on diverse datasets that reflect the country's diverse socioeconomic, cultural, and demographic composition.<sup>31</sup> Ethical standards should be created, and ethical problems should be regularly assessed and settled through audits in order to lessen bias in AI models. AI systems must also be developed with patient equality and well-being as its primary goals in order to ensure equitable access to healthcare.

Similar to the regulations developed by the AI Now Institute in the United States, which prioritises ethics and equity in AI deployment, the Indian government might define national standards for AI ethics in conjunction with AI and ethics specialists.

#### ***4.5 Integrate AI in Healthcare Education and Training***

Healthcare professionals urgently need to be equipped with the knowledge and skills needed to use AI technologies as they advance. Physicians and other healthcare workers must understand the benefits and drawbacks of AI systems in order to make informed decisions about patient care.<sup>32</sup> India might integrate AI and machine learning research into the medical curriculum and provide ongoing training for healthcare professionals. As a result, they would be better equipped to understand the moral and legal implications of utilising AI tools. Indian medical schools can implement AI-focused healthcare training programs, like those developed by the World Health Organisation (WHO) and other foreign organisations, to ensure that the next generation of healthcare professionals is equipped to use AI technology responsibly.

<sup>28</sup> Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002.

<sup>29</sup> Medical Termination of Pregnancy Act, 1971 (relating to consent).

<sup>30</sup> National Health Policy, 2017, Government of India.

<sup>31</sup> National Digital Health Mission (NDHM), Ministry of Health and Family Welfare, Government of India.

<sup>32</sup> Personal Data Protection Bill, 2019, Ministry of Electronics and Information Technology, Government of India.

#### 4.6 Establish Procedures for Informed Decision-Making and Patient Consent

Informed consent is a cornerstone of medical ethics, but as AI becomes more widely used, it is becoming increasingly difficult to ensure that patients fully understand how AI is being used to treat them.<sup>33</sup> Healthcare providers are encouraged to obtain patients' express informed consent before using AI systems in patient care. This permission process should include transparency regarding the use of AI, related risks, and any implications for patient care. For example, the Indian National Health Stack's Digital Health ID system can be used to improve traceability and transparency while streamlining the informed consent procedure.

#### 4.7 Make AI-Driven Decisions Clearly Accountable

It might be tough to decide who should be held responsible for detrimental judgments made by AI systems in healthcare—the AI system itself, the healthcare practitioner, or the developer.

Recommendation: India should clarify who is legally liable for any harm brought on by AI. Laws should explicitly state that AI companies, healthcare providers, and other interested parties have responsibility for the outcomes of their decisions. This entails ensuring that the process for investigating incidents and managing malpractice claims employing AI is open and transparent.<sup>34</sup>

For example, the Indian judiciary may think about developing case law related to AI, similar to what is being done in regions like the European Union, if the legal accountability for AI rulings becomes more obvious.

AI has the ability to completely transform healthcare in India, but there are also inevitable moral and legal concerns.<sup>35</sup> By addressing these concerns with comprehensive legislation, ethical standards, data protection regulations, and enough training, India can ensure that AI is used in healthcare in a responsible and equitable manner. AI integration in healthcare has the potential to improve results and provide a more efficient, widely available healthcare system if done correctly.

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## Conclusion

The application of artificial intelligence (AI) in healthcare raises significant ethical and legal concerns that require serious thought. AI systems in healthcare present ethical concerns about informed consent, patient privacy, and potential biases in decision-making that could exacerbate health disparities. The opaqueness of some AI systems also raises concerns about the accountability of computer decisions. Concerns including data privacy laws, liability for errors made by AI systems, and the requirement to establish clear standards for AI validation must all be addressed as the legal framework governing AI in healthcare continues to evolve. AI can enhance healthcare delivery without compromising legal protections or moral principles, but doing so calls for finding a balance between accountability and innovation. A multidisciplinary approach involving legislators, engineers, ethicists, and medical professionals is required to solve these challenges and build a future where AI enhances patient care while upholding fundamental rights and values. Although Indian case law does not yet fully address the ethical and legal concerns of AI in healthcare, some decisions pertaining to privacy, data security, liability, and informed consent have important ramifications. The right to privacy, accountability for medical malpractice, and the need for regulation in the application of AI in healthcare are significant legal ideas that need to be carefully balanced. Future case law and legislative developments are likely to further define the responsibilities of AI developers, healthcare professionals, and institutions in this rapidly evolving field. As AI continues to impact healthcare in India, resolving these legal concerns will be crucial to ensuring its ethical, equitable, and safe use. In order to address issues with data privacy, accountability, informed consent, and intellectual property, new legal frameworks and regulations tailored to the particular characteristics of AI are needed. If India has a robust legal framework, it can fully use AI in healthcare while upholding patient rights and encouraging public trust in cutting-edge technologies.

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<sup>33</sup> European Commission, Artificial Intelligence Act (2021).

<sup>34</sup> Floridi, L., & Cowls, J. "A Unified Framework of Five Principles for AI in Society." *Harvard Data Science Review*, (2019).

<sup>35</sup> HIPAA Journal "Healthcare Data Breaches Statistics." (2023)