REGULATING ARTIFICIAL INTELLIGENCE IN HEALTHCARE (ACCOUNTABILITY, ETHICS AND THE INDIAN LEGAL VACUUM)

Mehek Kalra*

ABSTRACT

Artificial Intelligence (AI) has become an important part of modern healthcare, particularly in areas such as diagnosis, treatment planning, patient monitoring, and clinical decision-making. The growing use of AI-based systems has increased efficiency, reduced human error, and improved access to healthcare services. However, the increasing reliance on AI has also raised serious legal and ethical concerns. Existing legal frameworks dealing with medical negligence and product liability are largely designed around human decision-making and often fail to address the challenges posed by autonomous and learning-based AI systems. This paper examines the issues of accountability and ethics arising from the use of AI in healthcare, with a specific focus on the Indian legal system. It analyses how the absence of AI-specific regulation creates uncertainty regarding liability when AI-assisted medical decisions lead to patient harm. The study adopts a doctrinal and comparative approach, analysing legal frameworks and regulatory practices from jurisdictions such as the United States, the European Union, and the United Kingdom, along with ethical guidance issued by the World Health Organisation. The paper finds that India currently relies on general technology laws, data protection legislation, and traditional principles of medical negligence to govern AI in healthcare. These mechanisms remain insufficient to address concerns such as accountability and transparency. The paper argues that this regulatory gap poses risks to patient safety as well as legal certainty for healthcare professionals and developers. It concludes by highlighting the need for a healthcare-specific, risk-based, and human-centred regulatory framework for AI in India.

*BBA LLB (HONS.), SECOND YEAR, NMIMS KIRIT P. MEHTA SCHOOL OF LAW.

Keywords: Artificial Intelligence, Decision-Making, United States, World Health Organisation, Accountability.

INTRODUCTION

A significant part of the contemporary healthcare ecosystem is artificial intelligence (AI). AI-driven technologies are transforming the healthcare sector, from the assistant's function in duties like early disease detection and diagnostic imaging to support decision-making. Advances in AI technology offer improved access to healthcare, decreased human error, and increased efficiency. But the quick rise in use of AI-driven technologies has also raised difficult moral and legal issues.

AI systems, unlike conventional medical tools, often function autonomously and rely on large datasets and machine learning algorithms that evolve. The adaptive nature of AI poses serious challenges to traditional laws governing medical negligence, product liability, and accountability. Determining liability becomes legally ambiguous when AI contributes to a medical error or patient harm. The major question that arises while dealing with AI-driven technologies in the healthcare sector is whether the liability should rest with healthcare professionals, hospitals, developers or the regulating body, thereby exposing a critical accountability gap.

The use of AI has given rise to significant ethical considerations about bias, transparency, patient autonomy and data protection. Several AI systems function as “black boxes,” making their decision-making process complex.[1] The lack of transparency undermines the trust built by medical professionals over the period of time. Also, unrepresentative or flawed datasets may lead to algorithmic bias, which might worsen the already existing healthcare disparities. These ethical risks should be addressed at the earliest, and a regulatory approach that prioritises patient safety and human oversight without obstructing technological advancement must be introduced.

At the global level, these challenges have started to be addressed by the government through specific AI-centred regulations. The European Union has adopted a risk-based AI regulation, categorising healthcare-related AI systems as high risk and subjecting them to stricter compliance obligations.[2] In the United States of America, Oversight mechanisms have been

[1] European Parliamentary Research Service, *Artificial Intelligence in Healthcare* (European Parliament 2022)
[2] EPRS, *Artificial Intelligence in Healthcare*.

introduced for AI-based Software as a Mechanical Device, with an emphasis on safety and performance standards.[3] The World Health Organisation has also issued ethical guidelines aimed at promoting the responsible use of AI in healthcare.

In comparison to global regulations, India lacks the regulatory framework needed to expand the use of AI-driven components in the healthcare sector. Currently, the AI-related practices rely on general technology laws like the Information Technology Act, 2000[4] or the Digital Personal Data Protection Act, 2023 (DPDP)[5] and principles of medical negligence. The absence of AI-specific laws leaves a void in the Indian legal system and uncertainty for medical professionals and developers.

This paper contends that India is facing a legal vacuum in relation to AI in the healthcare sector, specifically in areas of accountability and ethical oversight. The lack of statutory guidance not only poses a threat to the patients but also to all professionals remotely related to such technology. The existing legal system struggles to address this complex interaction between human judgment and algorithmic decision-making in medical practice.

Accordingly, this study undertakes a comparative analysis of AI in regulations in healthcare. It examines international regulatory approaches and ethical frameworks in order to identify principles that can be adopted in the Indian practice. By analysing the foreign-based laws and the ones in the Indian regime, the paper seeks to highlight the existing regulatory gaps and suggest guiding principles for the formulation of a healthcare-specific AI regulatory framework.

RESEARCH OBJECTIVES

1. To study the role of Artificial Intelligence in the healthcare sector from a legal perspective.
2. To analyse ethical and accountability concerns associated with AI-based medical decision-making.
3. To assess the adequacy of the existing legal framework for the regulation of AI in healthcare.

[3] Kavitha Palaniappan, Elaine Yan Ting Lin and Silke Vogel, 'Global Regulatory Frameworks for the Use of Artificial Intelligence (AI) in the Healthcare Services Sector' (2024) 12 Healthcare 562.
[4] Information Technology Act 2000
[5] Digital Personal Data Protection Act 2023

4. To study comparative international legal approaches.
5. To give suggestions for building an AI-healthcare-specific regulatory framework

RESEARCH METHODOLOGY

This research mainly follows a doctrinal method and examines the legal and ethical challenges arising from the use of Artificial Intelligence (AI) in healthcare, with particular emphasis on accountability and regulatory gaps in the Indian legal framework. The review of current laws, court rulings, policy papers, regulatory guidelines, and academic literature pertinent to AI governance and healthcare regulation serves as the study's main foundation.

In addition to ethical and governance norms published by international organisations like the World Health Organisation, a comparative research technique has been used to analyse regulatory systems enacted across the globe by countries such as the United States or international organisations like the European Union. The goal of this comparative study is to find best practices and legal precepts that could be modified for the Indian setting.

The analysis has been supported by secondary sources, including government reports, journal articles, research papers, and reputable international publications. The study is restricted to a doctrinal analysis of legal frameworks and policy tools and does not collect statistical information. This paper does not include technical or clinical assessments of AI systems and is limited to the regulatory and accountability elements of AI in healthcare. Using this methodology, the study aims to identify current legal gaps and provide a methodical approach to the creation of an AI regulatory framework tailored to healthcare in India.

UNDERSTANDING ARTIFICIAL INTELLIGENCE IN HEALTHCARE

For this paper, the focus remains on AI systems that influence medical decision-making rather than purely administrative tools. AI technologies have been increasingly introduced to assist healthcare professionals in diagnosis, treatment planning, patient monitoring, and healthcare administration. AI systems often rely on machine learning algorithms that analyse large volumes of data to improve their performance over time.

The scope of AI in healthcare is broad and continues to expand with advancements in technology. Machine Learning (ML) is the backbone of most AI systems, where algorithms learn patterns from data to make accurate predictions. A more advanced form of this is Deep

Learning (DL), which uses neural networks to analyse complex data like medical images, making it very efficient for tasks like radiology analysis and cancer detection. Natural Discourse Processing (NLP) is an important AI technique that helps machines comprehend and interpret human language. It is frequently used to power virtual health assistants, automate recordkeeping, and assess clinical notes. X-rays, CT scans, and dermatological images are all interpreted using computer vision, a field that allows AI to analyse visual inputs. The delivery of healthcare is changing as a result of different AI kinds and technologies working together to make it more accessible, accurate, and data-driven.

Most national regulatory authorities around the world classify AI-based medical technologies as a type of medical device, more specifically under the category of Software as a Medical Device (SaMD). This classification recognises that certain software applications—despite not being part of any physical or hardware-based medical device—can have significant medical functions. SaMD refers to software solutions that are designed to carry out medical tasks such as diagnosing diseases, recommending treatments, monitoring health conditions, or assisting in clinical decision-making. These applications can include advanced diagnostic algorithms, treatment planning platforms, or even mobile health and wellness apps.[6]

What makes SaMD distinct is that it performs these functions independently, without being embedded in or dependent on specific hardware. While it can interact with physical medical devices (e.g., feeding data into a wearable or receiving outputs from diagnostic machinery), it does not need such devices to carry out its core function. In India, the Central Drugs Standard Control Organisation (CDSCO) has acknowledged the growing role of AI-driven Software as a Medical Device (SaMD) and issued guidance on how such software should be classified based on risk. However, despite this recognition, there is currently no detailed regulatory framework tailored specifically to the unique challenges posed by AI-based SaMDs. As a result, aligning AI-driven healthcare software with existing legal and regulatory requirements can be particularly complex. Developers and manufacturers often struggle to comply with outdated or non-specific regulations that were not designed with dynamic, learning-based AI systems in mind.

It's important to note that SaMD and AIMD (Artificial Intelligence as a Medical Device) are not the same. While SaMD refers broadly to standalone software intended for medical use,

[6] The National Institute for Health and Care Research HealthTech Research Centre in Devices, Digital and Robotics (NIHR HRC-DDR), UK, 'Software as a Medical Device (SaMD) Regulatory Pathway' (2023).

AIMD is a specific subset where AI or machine learning is the core driver of the software's function. Unlike traditional SaMDs, AIMDs often adapt over time through continuous learning, making their behaviour less predictable and posing additional regulatory challenges. These include the need for ongoing validation, risk monitoring, and mechanisms to prevent algorithmic bias or unintended harm to patients.

ETHICAL CHALLENGES OF ARTIFICIAL INTELLIGENCE IN HEALTHCARE

AI systems rely on already existing data sets, which might be incomplete or biased; this may give rise to an unconscious bias in the AI decision-making. This not only increases the bias faced by marginalised groups but also significantly raises ethical concerns regarding equality, fairness and access to healthcare services in the country, particularly relevant in India due to its socioeconomic disparity and large cultural region.

The increased reliance on AI may reduce the role of human judgment in healthcare and often cause damage to patient autonomy. AI recommendations may be treated as final rather than advisory, and patients may not be informed about the use of AI diagnosis or treatment. This limits the patient's ability to make informed choices, and ethical concerns arise when human oversight is absent.

An AI system requires data access, which raises concerns of data privacy and security risks of misuse and unauthorised access. Weak data protection measures can lead to data leaks and breaches of the privacy of the patients, thus undermining patient trust in the digital healthcare system and could result in a huge issue regarding confidentiality and privacy.

Problems raised due to faulty decisions by AI could harm doctor-patient relationships and the trust built over the years. A lack of clear ethical standards may discourage responsible innovation and thus hinder technological advancement. Thus, there is a clear need for ethical governance alongside legal regulation.

ACCOUNTABILITY AND LIABILITY IN AI-DRIVEN HEALTHCARE

With the significantly increasing influence of AI in the healthcare sector, several issues regarding accountability arise. Traditional healthcare accountability is based on human decision-making. When AI decision-making or AI tools are used to make a decision, the responsibility becomes unclear, and it becomes difficult in identifying upon who should be

liable or held accountable for a particular mishap. For example, if an AI tool makes a decision that significantly causes harm to the patient, who shall be held liable, the doctor under whose guidance it was performing, the hospital at which it was present, the developer who created such tool or the authority which approve the usage of the tool, the inclusivity of so many parties creates confusion and complexity in deciding accountability. Thus, the legal system needs to address this accountability gap and create provisions that help to address it.

Doctors usually owe a duty of care to their patients. It is a doctor's job to diagnose and treat the patient. It is necessary to understand how the use of AI tools would affect the doctor's liability in cases of medical negligence. The question arises whether reliance on AI tools would reduce a doctor's liability or further increase it. The ethical and legal dilemma follows when a doctor uses AI recommendations in good faith but fails to assess the complications that might follow by undertaking such a decision. Doctors may also lack a full understanding of the AI's functioning due to its complex nature and fail to understand its decisions or opinions.

Since essentially, it is hospitals that deploy and integrate AI systems into the infrastructure, they are also part of the liability circle. Institutional responsibility for training, supervision and system oversight lies upon them, and failure to ensure a safe deployment may attract vicarious liability in cases of AI-assisted medical errors. There is a need for internal governments and risk management mechanisms to avoid such heavy liabilities.

As mentioned earlier, the liabilities of AI developers and technology providers must also be considered, as AI systems are designed, trained and updated by such practitioners. The defects in data design or algorithm may cause significant harm to a patient, and thus, responsibility must be borne by these developers. Labour laws do not fully apply to adaptive AI systems and raise a question about shared or strict liability models.

As talked about earlier, the existing legal framework is limited and does not cover the extent of AI in healthcare. The medical negligence laws in India are based on human judgment, and not technological standards. The product liability law assumes static products are not evolving AI systems, thus struggles with causation and forceability in AI-related harm. The Indian legal framework lacks AI-specific liability provisions, which results in legal uncertainty for patients, doctors, and developers.

Absence of clarity under patient remedies, uncertainty, discouragement of responsible adoption of AI and healthcare and the importance of defining the accountability of doctors, hospitals and

developers are essential. This forms the basis for proposing a healthcare-specific AI framework.

COMPARITIVE REGULATORY APPROACHES TO AI IN HEALTHCARE

AI has been incorporated into the healthcare sector across the globe, and different jurisdictions have adopted different regulatory standards. A comparative analysis between different regions could help us analyse the best suggestions that India could adopt from these existing regulations.

United States of America: In the United States, the Food and Drug Administration (FDA) plays a central role in regulating AI technologies in the healthcare sector. The FDA classifies AI-driven medical software under the category of Software as a Medical Device (SaMD) and has actively developed guidance to keep pace with rapid advancements in AI. Recognising that traditional regulatory frameworks may not fully accommodate the dynamic nature of AI, the FDA has issued several targeted documents to provide industry-specific direction. In 2024, the FDA published a comprehensive report titled Artificial Intelligence and Medical Products: How CBER, CDER, CDRH, and OCP are Working Together, highlighting cross-departmental collaboration to responsibly advance AI applications in drug development and medical products.[7]

Further, in January 2025, it released a draft guidance document titled Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products, which outlines recommendations on how AI-generated data can be utilised to support regulatory evaluations concerning the safety, effectiveness, and quality of medical products.[8] Additionally, the FDA maintains an Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices database, which tracks authorised AI-powered medical devices in the U.S. These initiatives reflect the FDA's dual commitment to innovation and regulatory

[7] Kavitha Palaniappan, Elaine Yan Ting Lin and Silke Vogel, 'Global Regulatory Frameworks for the Use of Artificial Intelligence (AI) in the Healthcare Services Sector' (2024) 12 Healthcare 562.
[8] US Food and Drug Administration, 'Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products Guidance for Industry and Other Interested Parties DRAFT GUIDANCE' (2025).

oversight, ensuring that AI technologies are developed transparently and deployed safely in the healthcare ecosystem.[9]

United Kingdom: The United Kingdom has adopted a multi-agency and lifecycle-based approach to AI regulation in healthcare. In 2019, the National Institute for Health and Care Excellence (NICE), in collaboration with NHS England, released the Evidence Standards Framework for Digital Health Technologies, providing structured criteria for evaluating the clinical and economic impact of digital tools, including AI. In 2021, the Medicines and Healthcare Products Regulatory Agency (MHRA) launched the Software and AI as a Medical Device Change Programme, a robust initiative to address emerging challenges in AI medical regulation. This program emphasises regulatory clarity across the entire lifecycle of AI devices, encompassing cybersecurity, algorithmic change management, data privacy, post-market surveillance, and bias mitigation.[10] Further advancing its regulatory maturity, the Regulatory Horizons Council published a 2022 report titled The Regulation of AI as a Medical Device, which notably distinguishes AI as a Medical Device (AIMD) from SaMD and calls for a tailored regulatory framework that specifically addresses the complexities of AI.[11] These efforts signify the UK's commitment to inclusive governance, continuous oversight, and engaging stakeholders—including patients—throughout the development and deployment of AI-driven healthcare solutions.

European Union: The European Union has taken a risk-based approach to AI regulation. Initial efforts began in 2019 with the publication of non-binding instruments such as the Ethics Guidelines for Trustworthy AI.[12] and the Policy and Investment Recommendations for Trustworthy AI.[13] These laid the ethical foundation for future legal instruments. In terms of healthcare, the EU Medical Device Regulation (MDR) includes AI-based SaMD within its

[9] FDA, 'AI-Enabled Medical Devices' (*U.S. Food and Drug Administration*2025) <https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-enabled-medical-devices>.
[10] Kavitha Palaniappan, Elaine Yan Ting Lin and Silke Vogel, 'Global Regulatory Frameworks for the Use of Artificial Intelligence (AI) in the Healthcare Services Sector' (2024) 12 Healthcare 562.
[11] Government of UK, 'Regulatory Horizons Council: The Regulation of Artificial Intelligence as a Medical Device' (*GOV.UK*November 2022) <https://www.gov.uk/government/publications/regulatory-horizons-council-the-regulation-of-artificial-intelligence-as-a-medical-device>.
[12] European Commission, 'Ethics Guidelines for Trustworthy AI | Shaping Europe's Digital Future' (*European Commission*2019) <https://digital-strategy.ec.europa.eu/en/library/ethics-guidelines-trustworthy-ai>.
[13] European Commission, 'Policy and Investment Recommendations for Trustworthy Artificial Intelligence | Shaping Europe's Digital Future' (*digital-strategy.ec.europa.eu*2019) <https://digital-strategy.ec.europa.eu/en/library/policy-and-investment-recommendations-trustworthy-artificial-intelligence>.

scope when the software is intended for specific medical purposes like diagnosis, prevention, or treatment.[14]

In April 2021, the EU proposed the landmark AI Act,[15] aiming to establish a unified legal framework for AI technologies across member states. The Act classifies AI systems based on risk levels—from minimal to high—and imposes stricter regulatory requirements on high-risk applications such as biometric identification, clinical decision-support systems, and public health management tools. Articles 9 to 15 of the Act detail provisions on risk management, technical documentation, human oversight, and cybersecurity, while Articles 16 to 28 outline the obligations of providers, importers, and users of AI systems. The European Parliament also commissioned a study titled Artificial Intelligence in Healthcare, recommending policy interventions such as an AI "passport" for transparency, frameworks for accountability, education programs for clinicians, and mechanisms to bridge the digital divide in medical AI. While the AI Act has been lauded for its proactive stance, critics argue that its rigidity may limit adaptability to future innovations. Nevertheless, the EU remains a global leader in ethical AI regulation, particularly for high-stakes sectors like healthcare.

World Health Organisation: The World Health Organisation (WHO) has played a pivotal role in shaping the ethical, technical, and governance frameworks surrounding the use of AI in global healthcare systems. In 2021, the WHO released its landmark report titled Ethics and Governance of Artificial Intelligence for Health.[16], offering a comprehensive set of six guiding principles to support the development and application of AI in health while mitigating associated risks.

These principles are:

1. Protecting human autonomy,
2. Promoting human well-being and safety,
3. Ensuring transparency, explainability, and intelligibility,
4. Fostering responsibility and accountability,
5. Ensuring inclusiveness and equity, and

[14] THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION, 'REGULATION (EU) 2017/745 of the EUROPEAN PARLIAMENT and of the COUNCIL of 5 April 2017 on Medical Devices, Amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and Repealing Council Directives 90/385/EEC and 93/42/EEC' (2017).
[15] EU Artificial Intelligence Act
[16] WHO, *Ethics and Governance of Artificial Intelligence for Health* (World Health Organization 2021).

6. Promoting responsive and sustainable AI.

The report emphasises that AI should not replace human decision-making but rather augment the capabilities of healthcare workers, especially in low- and middle-income countries (LMICs) where resource constraints are significant. WHO also underscores the need for rigorous clinical validation, public engagement, and long-term monitoring of AI systems. Furthermore, the organisation has advocated for global collaboration to avoid the emergence of regulatory silos and to ensure that AI-driven healthcare technologies are equitably accessible, contextually relevant, and ethically aligned with public health objectives. By promoting a human-centric and equity-oriented approach, WHO's guidance serves as a global reference point for policymakers and regulators aiming to integrate AI into healthcare in a safe, inclusive, and ethically sound manner.

By assessing different regulatory standards undertaken, it can be inferred that there is a need for risk-based classification of AI-systems. It also highlights the importance of human oversight in medical decision-making. A clear substantive provision allocating the responsibility among the stakeholders is needed, along with a need to establish continuous monitoring of AI systems post deployment.

INDIAN LEGAL FRAMEWORK

India does not have a specific law regulating AI in healthcare; no current statute directly addresses AI-driven medical decision-making. A specific law related to AI in the healthcare sector is needed to address the liability and privacy concerns that arise due to the use of such AI-driven technologies in medical decision-making. However, there are a few existing statutes that are taken into consideration while dealing with AI in the healthcare sector.

The Medical Device Rules (MDR), 2017,[17] enacted under the Drugs and Cosmetics Act, 1940, form the cornerstone of India's regulatory framework for medical devices, including healthcare tools that qualify as Software as a Medical Device (SaMD). These rules classify devices into four risk-based categories—Class A (low risk) to Class D (high risk)—and mandate licensing, clinical investigation, quality assurance, and post-market surveillance based on the risk level. AI applications that aid in diagnosis, monitoring, or treatment fall under this regulation if they influence clinical decisions. However, the rules currently lack AI-specific provisions and do

[17] Medical Devices Rules 2017

not address continuous learning systems or algorithmic bias, posing regulatory gaps, nor do they address any of the liability concerns.

The Digital Personal Data Protection Act (DPDPA), 2023[18] and the Information Technology Act, 2000,[19] govern the processing of personal and sensitive data. It introduces stringent requirements on obtaining informed consent, limiting data usage to specified purposes, ensuring accountability, and enforcing data security measures. AI applications that handle electronic health records, genetic profiles, or real-time patient monitoring data must comply with the DPDPA's principles of data minimisation, transparency, and privacy-by-design. Until the DPDPA is fully implemented, the Information Technology Act, 2000, along with the SPDI Rules (Sensitive Personal Data or Information Rules, 2011), remains relevant. These rules regulate the collection, storage, and transmission of sensitive personal data, including health information. They mandate reasonable security practices such as encryption, access control, and breach notification. They emphasised consent, purpose limitation and data security, but do not regulate algorithmic decision-making or AI liability.

In India, Tort law and medical negligence are based on human standards of care. The courts have assessed the conduct of medical practitioners and not decisions made by a machine. The involvement of AI complicates causation and fault determination. There is no judicial clarity on AI-assisted medical negligence. The existing tort principles are insufficient for autonomous systems.

Though India does not have a specific authority for regulating AI in healthcare. The Central Drugs Standard Control Organisation (CDSCO) is India's national regulatory authority for pharmaceuticals and medical devices and has started to play an important role in overseeing AI-based tools classified as Software as a Medical Device (SaMD). Under the framework of the Medical Device Rules, 2017[20] CDSCO is entrusted with the risk-based classification of AI health tools (into Class A to D), reviewing clinical investigation data, and issuing licenses for manufacture, sale, and import. For AI systems that claim diagnostic or therapeutic utility, CDSCO conducts rigorous assessments to ensure safety, effectiveness, and compliance with quality standards. This includes evaluation of the algorithm's performance, accuracy, clinical validation, and intended use. As AI continues to evolve, CDSCO's responsibilities now extend

[18] Digital Personal Data Protection Act 2023
[19] Information Technology Act 2000
[20] Medical Devices Rules 2017

to keeping pace with innovations such as adaptive algorithms and continuously learning systems, which present new regulatory challenges.

Government discussions on AI governance are largely policy-driven and focus more on innovation and growth rather than regulation. Healthcare-specific AI risks remain under-addressed, and there are no binding standards or enforcement mechanisms.

SUGGESTIONS FOR FRAMEWORK IN INDIA

AI in healthcare directly affects life, health and body integrity. The general technology laws are insufficient for the medical context, due to the unique risk associated with autonomous decision-making systems. There is a need to balance innovation with patient safety and autonomy, and thus, there is an urgent need for sector-specific regulation. By assessing regulations undertaken by different geographical regions, it can be easily inferred that the need for risk-based classification is essential. Not all systems have the same level of risk, and thus, high-risk AI systems should face stricter regulations. The risk-based approach promotes proportional regulation without hindering technological advancement.

It is important to note that AI should exist to assist and not replace human decision-making. It is essential that human supervision is made mandatory in clinical decisions, and there is a clear allocation of responsibility among the stakeholders. Doctors should retain final decision-making authority. There must be accountability mechanisms to protect the rights of the patient. The patient should be informed about the involvement of AI in healthcare. It is essential to uphold patient autonomy. Informed consent must include disclosure of AI use and thus allow the patient to choose whether he or she wants involvement of such technology in their treatment process.

A strong safeguard for sensitive health data is essential since AI relies on existing data sets. There should be limitations on secondary use of patient data for air training, regular audits and security assessments are required, and provisions that protect patient dignity and confidentiality must be introduced. There are several authorities governing healthcare regulations in India, but there is a specific need for a designated regulatory Authority for AI in healthcare. This need arises from the rapid development of AI in the sector and is essential for coordination between health and technology regulators. This authority needs to focus on setting standards, monitoring, and enforcement of mechanisms. There must be a regular review of the AI system,

post-deployment and institutional accountability at the hospital and development levels are also addressed.

One key factor to keep in mind is that regulation should not stifle technological advancement. There should be clear rules that provide certain guidelines for developers and healthcare providers. Ethical compliance can coexist with innovation, and there should be support provided for a search within regulated boundaries. Authorities must ensure the long-term sustainability of healthcare, along with protecting the rights of the patients.

CONCLUSION

AI is increasingly shaping healthcare delivery and decision-making. While beneficial, it introduces serious, legal and ethical concerns. The existing legal framework in India is not designed for autonomous technologies and thus essentially leaves a vacuum in the Indian legal system. This paper attempts to compare regulatory standards adopted by different regions and how the legal vacuum in India could be filled by adopting such standards. Risk-based and human-centric models adopted in countries like the USA and international organisations like the WHO serve as guiding principles for establishing such laws in India. AI in healthcare is not a familiar technological issue, but a legal one and addressing the regulatory vacuum is essential for sustainable adoption. Timely legal intervention can ensure ethical and accountable use of AI, and thus, there is a growing need for specific regulations concerning AI in healthcare in India.