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REGULATING ARTIFICIAL INTELLIGENCE IN HEALTHCARE: A COMPARATIVE STUDY OF INDIA AND THE EU'S AI ACT

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ABSTRACT

As Artificial Intelligence (AI) continues to transform healthcare, particularly in diagnostics such as radiology, oncology, and predictive analytics, while the technologies promise greater accuracy, increased accessibility, and enhanced efficiencies, they raise complex legal and ethics concerns in regards to accountability, liability, transparency, and patient rights. India's regime of regulations, currently governed via general enactments such as the Information Technology Act, 2000, the Digital Personal Data Protection Act, 2023, and the Telemedicine Practice Guidelines, 2020, does not specifically cater to AI-driven diagnostics. Relatively, the European Union's AI Act (2024) provides a comprehensive, risk-based regime where healthcare AI has been designated a high-risk technology and imposes stringent requirements on transparency, conformity assessment, and human oversight.

This piece critically examines the Indian legal and regulatory readiness for handling healthcare diagnostics with artificial intelligence and places it in a comparative framework including the European Union's Artificial Intelligence Act and other foreign paradigms. Using a blend of doctrine and comparative law methods with interdisciplinary inputs from health ethics and health policy, the article considers areas of gap in liability, informed consent, and algorithmic responsibility in the Indian scenario. It also identifies policy evolution, such as implementing regulatory sandboxes and adaptive compliance frameworks.

The findings emphasize the abiding need for India to develop a specialized, locally applicable framework for artificial intelligence in healthcare. Through the drawing of lessons from the European Union's systematic approach and adapting it to its distinctive healthcare situations, India can ensure advanced and trustworthy AI-driven diagnostic equipment.

Key Words: Artificial Intelligence (AI); Healthcare Regulation; Diagnostics; EU AI Act; India; Comparative Law; Algorithmic Accountability; Patient Rights; Digital Health Law; Medical Liability; Data Protection

1. INTRODUCTION

Artificial Intelligence (AI) has become a dynamic force that can change healthcare, and its applications ranging from oncology to diagnostic imaging and predictive analytics and personalized medicine. Adoption of AI can ensure greater efficiency, accuracy, and

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accessibility in medical diagnosis. But the disruptive power of AI also poses acutely regulatory and ethical issues surrounding accountability, liability, transparency, patient consent, and protecting data. While countries compete to implement AI technologies, the test is to ensure that innovation is not at the cost of patient safety or of legal protection[1].

India has progressed fast in digital health policy through initiatives like the National Digital Health Mission and the Digital Personal Data Protection Act, 2023. However, its legal and regulatory infrastructure around AI in diagnosis is disjointed and nascent. Existing regulation is dispersed in the Information Technology Act, 2000, the Telemedicine Practice Guidelines, 2020, and sectoral ethics codes, without any specified provisions on AI-based decision-making for healthcare. Academics identify that this vacuum of regulation jeopardizes patient rights and clinical responsibility[2].

Conversely, the European Union's AI Act (2024) has already deemed AI systems employed in healthcare diagnostics as "high-risk," and has mandated risk management, transparency, and human oversight requirements[3]. Comparative research underscores the significance of harmonizing India's AI regulation with foreign models. For example, in their research paper, Francu and Ștefan (2025) illustrate how Romania and other EU member countries' digital and AI legislation prioritizes data protection and governance frameworks as conditions for implementing AI in the healthcare sector[4].

Whereas the EU and North America have gone wholeheartedly towards binding AI law, more than 60% of Global South nations—such as India—are still without enforceable regulatory systems for AI in health care. Such comparative findings support the conclusion that India stands at a regulatory crossroads[5].

[1] Singh, M.P., Keche, Y.N. and Keche, Y., 2025. Ethical Integration of Artificial Intelligence in Healthcare: Narrative Review of Global Challenges and Strategic Solutions. Cureus, 17(5).
[2] Vignesh, S. and Nagarjun, D.N., Legal Challenges of Artificial Intelligence in India's Cyber Law Framework: Examining Data Privacy and Algorithmic Accountability Via a Comparative Global Perspective.
[3] Bharal, S. and Sharma, R., 2025, April. AI Acts in Focus: Comparative Insights from the European Union and Canada for India's Policy Evolution. In International Conference on Advancements in Computing Technologies and Artificial Intelligence (COMPUTATIA-2025) (pp. 251-262). Atlantis Press.
[4] Francu, C.C. and Ștefan, S.A.V.A., 2025. Global Perspectives on Digital and AI Legislation: A Comparative Study of Data Protection, AI Governance, and Healthcare Innovations with a Focus on Romania. In Proceedings of the International Conference on Business Excellence (Vol. 19, No. 1, pp. 2469-2481). Sciendo.
[5] Busch, F., Geis, R., Wang, Y.C., Kather, J.N., Khori, N.A., Makowski, M.R., Kolawole, I.K., Truhn, D., Clements, W., Gilbert, S. and Adams, L.C., 2025. AI regulation in healthcare around the world: what is the status quo?. medRxiv, pp.2025-01.

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Aside from gaps in the law, ethical and business issues also arise. Researchers posit that algorithmic transparency erodes trust from patients, calling for high standards in transparency[6]. Others emphasize that accountability should be defined in explicit terms to avoid the dangers of deflecting liability for diagnostic mistakes across developers, clinicians, and hospitals[7]. India does not have innovative governance frameworks like regulatory sandboxes and adaptive compliance models that would provide a guarantee of responsible AI integration while promoting innovation[8].

A number of scholars encourage India to take lessons from global experience but develop its own context-specific framework. The need for a world AI regulatory framework and points to the EU AI Act as an example of harmonization. India needs to base its strategy not just on international best practices but also on its judicial and ethical heritage so that technological advances do not erode constitutional rights. As a whole, this scholarship highlights the imperative for India to adopt a clear, legally sound, and ethically defensible framework for the regulation of AI-based diagnostics.

2. LITERATURE REVIEW

Healthcare applications of artificial intelligence (AI), especially in diagnostics, have posed fundamental legal and ethical issues internationally. A survey of current scholarship sets out the promise and regulatory ambivalence in embracing AI, particularly in the Indian context compared to international models like the European Union's AI Act.

Bharal and Sharma (2025) offer a comparative analysis of the EU AI Act and Canada's AIDA to how their risk-based framework could frame India's emerging AI policies. They contend that India needs to adopt a hybrid model that balances innovation and preventing risks through adaptive regulation and sandboxing options[9].

[6] Lund, B., Orhan, Z., Mannuru, N.R., Bevara, R.V.K., Porter, B., Vinaih, M.K. and Bhaskara, P., 2025. Standards, frameworks, and legislation for artificial intelligence (AI) transparency. AI and Ethics, pp.1-17.
[7] Tiwari, Naresh. "Regulatory Responses to AI in Healthcare and Medical Diagnostics." Navigating Law and Policy in STM Enterprises: Ethical Governance, Regulation, and Innovation Strategy, edited by Hewa Majeed Zangana, et al., IGI Global Scientific Publishing, 2025, pp. 59-92. https://doi.org/10.4018/979-8-3373-4862-9.ch003
[8] Ghosh, A., Saini, A. and Barad, H., 2025. Artificial intelligence in governance: recent trends, risks, challenges, innovative frameworks and future directions. AI & SOCIETY, pp.1-23.
[9] Bharal, S. and Sharma, R., 2025, April. AI Acts in Focus: Comparative Insights from the European Union and Canada for India's Policy Evolution. In International Conference on Advancements in Computing Technologies and Artificial Intelligence (COMPUTATIA-2025) (pp. 251-262). Atlantis Press.

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Busch et al. (2025) provide a world map of AI health regulation, noting that while the EU has gone boldly with binding AI legislation, more than 60% of Global South nations have no enforceable framework in place. The research highlights India's regulatory crossroads role with a need for urgent establishment of clear rules governing AI diagnostics[10].

Francu and Ștefan (2025) continue the comparative discussion by examining AI regulation and health innovation focusing on Romania, comparing European models with international models more extensively. The findings are reflective of various paths of regulatory evolution and present lessons that India could capitalize on while harmonizing domestic law with international norms[11].

In the Indian setting, Vignesh and Nagarjun critically 6nalyse cyber law, privacy, and algorithmic responsibility, pointing out how India's current structures do not fully respond to AI-based diagnosis mistakes. Their comparative perspective identifies major gaps in the law when India is compared to international best practices, most notably in standards of liability[12]. In the same vein, PS (2024) calls for a global regulatory system of AI with the EU AI Act's impact as a reference point for harmonization. The report underscores that India not only needs to conform but actively shape the global AI norms[13].

From a healthcare-focused perspective, Singh, Keche, and Keche (2025) provide a narrative review of international challenges in integrating AI ethically in the healthcare field. They suggest methods for tackling transparency, bias, and accountability, which are essential for regulatory acceptance of AI diagnostics[14].

Lund et al. (2025) add to this discussion through an examination of AI transparency levels and frameworks. Although not exclusively focused on healthcare, their insistence on algorithmic

[10] Busch, F., Geis, R., Wang, Y.C., Kather, J.N., Khori, N.A., Makowski, M.R., Kolawole, I.K., Truhn, D., Clements, W., Gilbert, S. and Adams, L.C., 2025. AI regulation in healthcare around the world: what is the status quo?. medRxiv, pp.2025-01.
[11] Francu, C.C. and Ștefan, S.A.V.A., 2025. Global Perspectives on Digital and AI Legislation: A Comparative Study of Data Protection, AI Governance, and Healthcare Innovations with a Focus on Romania. In Proceedings of the International Conference on Business Excellence (Vol. 19, No. 1, pp. 2469-2481). Sciendo.
[12] Vignesh, S. and Nagarjun, D.N., Legal Challenges of Artificial Intelligence in India's Cyber Law Framework: Examining Data Privacy and Algorithmic Accountability Via a Comparative Global Perspective.
[13] PS, D.A., 2024. The Need for a Global Regulatory Framework for Artificial Intelligence: Implications of the European Union's Artificial Intelligence Act 2024.
[14] Singh, M.P., Keche, Y.N. and Keche, Y., 2025. Ethical Integration of Artificial Intelligence in Healthcare: Narrative Review of Global Challenges and Strategic Solutions. Cureus, 17(5).

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interpretability has direct implications for diagnostic AI, where decision-making within black boxes presents substantial medico-legal risk[15].

Ghosh, Saini, and Barad (2025) point to the regulatory and governance implications of AI implementation in India, such as algorithmic bias risks and insufficient accountability mechanisms. They propose new frameworks to facilitate the integration of AI without compromising patient rights[16].

Dhir and Verma (2024) extend the coverage by examining India's AI laws, policies, and ethical standards, as well as applicable judicial rulings. Their research illustrates the dispersed nature of India's legal environment at present, pointing to a unifying AI-specific regulatory framework for overseeing high-risk use areas such as diagnostics[17].

Lastly, Tiwari (2025) offers perhaps the most concentrated analysis of the topic, canvassing regulatory reactions to AI in medicine and medical diagnostics. The research investigates liability, transparency, and informed consent in a variety of jurisdictions and provides tangible takeaways India might implement to secure patient safety and technological advancement[18].

3. LEGAL FRAMEWORK IN INDIA

India's legal regime on digital health and AI has been developed in bits and pieces through general technology and data protection statutes, rather than any unified AI-specific regime. The lack of a dedicated legal framework governing AI-driven diagnostics has left many medico-legal questions open, especially on accountability, transparency, and patient safety. Indeed, the current approach toward cyber law and healthcare governance in India inherently adopts a reactive rather than proactive approach, leading to policy lag and uncertainty[19].

[15] Lund, B., Orhan, Z., Mannuru, N.R., Bevara, R.V.K., Porter, B., Vinaih, M.K. and Bhaskara, P., 2025. Standards, frameworks, and legislation for artificial intelligence (AI) transparency. AI and Ethics, pp.1-17.
[16] Ghosh, A., Saini, A. and Barad, H., 2025. Artificial intelligence in governance: recent trends, risks, challenges, innovative frameworks and future directions. AI & SOCIETY, pp.1-23.
[17] Dhir, M. and Verma, S., 2024. AI for good: India and beyond: Detailed analysis of AI & laws, policies, ethical frameworks and judgements. Notion Press.
[18] Tiwari, Naresh. "Regulatory Responses to AI in Healthcare and Medical Diagnostics." Navigating Law and Policy in STM Enterprises: Ethical Governance, Regulation, and Innovation Strategy, edited by Hewa Majeed Zangana, et al., IGI Global Scientific Publishing, 2025, pp. 59-92. https://doi.org/10.4018/979-8-3373-4862-9.ch003
[19] S. Vignesh & D.N. Nagarjun, Legal Challenges of Artificial Intelligence in India's Cyber Law Framework: Examining Data Privacy and Algorithmic Accountability Via a Comparative Global Perspective.

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3.1 *Information Technology Act, 2000*

The foundational statute regarding electronic data and cybersecurity in India remains the information technology act, 2000; sections 43A and 72A address compensation for data breaches and penalties for unauthorized disclosure of personal information, respectively. However, these remain important provisions related to data security but had been drafted long before AI became an integral part of medical decision-making.

The Act is silent on algorithmic decision-making, automated diagnostics, or even AI accountability in health. For this reason, it does not provide means of attributing liability whenever diagnostic tools yield erroneous outcomes. Scholars note that IT Act has taken a technology-neutral approach, which though allows flexibility, is inadequate to address sophisticated, high-risk applications like AI-driven clinical tools[20].

3.2 *Digital Personal Data Protection Act, 2023*

The DPDP Act, 2023, is a significant step for India toward privacy governance, inspired partly by the General Data Protection Regulation of the EU. It establishes data fiduciaries' obligations and grants individuals rights over their personal data.

This law applies to processing, storing, and cross-border transfers of patient data in healthcare AI systems. However, it does not explicitly regulate algorithmic profiling and bias and secondary use of anonymized data for training AI models. Data protection and AI regulation must be intertwined to ensure that digital health ecosystems are trustworthy[21]. India’s current privacy law lacks this integration, creating a gap between the circle of data protection and the circle of algorithmic governance.

3.3 *Telemedicine Practice Guidelines, 2020*

The Telemedicine Practice Guidelines, 2020, issued by the Medical Council of India-which is now known as the National Medical Commission-represented a milestone in legitimizing healthcare from a distance. These guidelines outline the scope of teleconsultation, consent, and doctor-patient responsibility.

[20] M. Dhir & S. Verma, AI for Good: India and Beyond: Detailed Analysis of AI & Laws, Policies, Ethical Frameworks and Judgements (Notion Press 2024).
[21] C.C. Francu & S.A.V.A. Ștefan, Global Perspectives on Digital and AI Legislation: A Comparative Study of Data Protection, AI Governance, and Healthcare Innovations with a Focus on Romania, Proceedings of the International Conference on Business Excellence, Vol. 19, No. 1, at 2469 (2025).

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However, AI-enabled telemedicine, particularly diagnostics, falls outside their explicit ambit. The guidelines assume a human clinician as the decision-maker, with no liability framework for either AI-assisted or AI-led clinical judgments. This omission creates ambiguity when AI outputs influence medical decisions or treatment planning without clear standards for validation and human oversight[22].

3.4 *National Digital Health Mission (NDHM) and Related Policies*

The NDHM, launched under the Ayushman Bharat Digital Mission, aims to create interoperable digital health infrastructure. This also includes a vision for the integration of AI into clinical analytics for decision support. Still, these are at the policy aspirations level rather than enforceable legal norms. The NDHM framework does not have statutory support on classification of risk associated with AI, ethical validation, or certification.

According to Busch et al.[23], emerging economies often develop digital health infrastructures faster than the building up of corresponding regulatory regimes, thus leaving ethical and legal vacuums that expose patients and practitioners alike to risks.

3.5 *Liability and Accountability Challenges*

Until now, the Indian legislative and judicial system has not addressed the question of liability when AI-driven diagnostics result in harm. The moot question remains, who is liable: the developer or the healthcare provider or the hospital that deployed the AI system?
In the absence of codified accountability norms, such cases can lead to protracted litigation and uneven jurisprudence[24].

Besides, AI's "black box" problem complicates the causation or even intent-the fundamental principles underlying tort and, therefore, medical negligence. Lack of a validation or certification mechanism for AI diagnostic tools further weakens accountability, echoing scholar's warning that transparency standards are necessary if AI regulation is to be trusted[25].

[22] Naresh Tiwari, Regulatory Responses to AI in Healthcare and Medical Diagnostics, in Navigating Law and Policy in STM Enterprises: Ethical Governance, Regulation, and Innovation Strategy 59 (Hewa Majeed Zangana et al. eds., IGI Global Scientific Publ'g 2025).
[23] F. Busch et al., AI Regulation in Healthcare Around the World: What Is the Status Quo?, medRxiv 2025-01 (2025).
[24] A. Ghosh, A. Saini & H. Barad, Artificial Intelligence in Governance: Recent Trends, Risks, Challenges, Innovative Frameworks and Future Directions, AI & SOCIETY 1 (2025).
[25] B. Lund et al., Standards, Frameworks, and Legislation for Artificial Intelligence (AI) Transparency, AI & Ethics 1 (2025).

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3.6 *Absence of AI Specific Legislation*

Although policy discussion papers like "Responsible AI for All" (2021) by India's NITI Aayog have advocated ethical AI governance and self-regulation, these remain non-binding. There is no statutory definition of "AI system," no risk-based classification (as seen in the EU AI Act), and no oversight body to ensure compliance or audit algorithms.

Scholars believe that India needs to take a cue from the EU's proactive stance by following a graded risk-based approach in which healthcare AI is classified as high risk, thus being subject to conformity assessments and continuous monitoring.

The existing legal ecosystem in India regulates AI indirectly through a compilation of general laws, privacy provisions, and medical guidelines. However, none provide a cohesive framework for regulating AI-driven healthcare diagnostics. Without explicit legislation, liability, consent, validation, and accountability remain decidedly ambiguous.

This regulatory gap places India in a category of countries whose urgent need for reform needs to balance innovation-friendly policy with patient-centered accountability, leveraging best practices from other international models such as the risk-based regulatory approach of the EU AI Act.

4. Comparative Analysis: The EU AI Act and Global Models

Comparative analysis is central to understanding how India can strengthen its regulatory environment for AI in healthcare diagnostics. Countries such as those in the European Union, Canada, and the United States have advanced structured or sector-specific regulatory regimes, while India continues to rely on fragmented, general laws. The EU's Artificial Intelligence Act (AI Act, 2024) represents the world's first comprehensive legislation on AI, establishing a risk-based regulatory framework. Scholars regard the Act as a landmark in global AI governance, one that offers valuable lessons for jurisdictions like India.

4.1 *Structure and scope of the EU AI Act*

The EU AI Act adopts a risk-based approach, classifying AI systems in a four-tier system of unacceptable risk, high risk, limited risk, and minimal risk. Because of their potential impact on life, safety, and patient rights, healthcare and medical diagnostics fall into the high-risk category.

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Articles 6 to 9 of the Act impose strict obligations on high-risk AI systems, including:

- Systems of risk management to continuously evaluate safety and performance;
- Data governance and quality standards to ensure that datasets are relevant, representative, and unbiased;
- Explainability and transparency requirements;
- Human oversight to prevent automation bias;
- Post-marketing monitoring and reporting requirements to ensure system performance.

These provisions address precisely the concerns of liability and accountability that are currently missing in India's legal framework. As Francu and Ștefan[26], state highlighting the EU's approach, this point underlines how data protection and the governance of AI are put together in one framework, ensuring coherence between technological innovation and ethical responsibility.

4.2 *Healthcare and AI Act under EU AI Act*

The EU AI Act categorizes AI applications in healthcare diagnostics as high-risk systems under Annex III. High-risk systems must undergo conformity checks by developers/deployers before being placed on the market to ensure that they meet requirements on safety, transparency, and fairness.

Also, the AI act demands the balance on the current MDR 2017/745, which the balance enables the AI diagnostic tool to serve as both a digital product and medical instruments. This is what makes the integration of AI with health care regulation give the EU a leading model for governance, even as budding economies like India have difficulties in the implementation process due to infrastructural and legal capacity hindrances.

4.3 *Canada's Artificial Intelligence and AI Act*

Canada's AIDA as cited by cited by Bharal and Sharma[27] in their study follows a similar model, but focuses on proportionality and innovation enablement. A system of graded compliance for developers and deployers of AI involves documentation, transparency, and mitigation of risk

[26] C.C. Francu & S.A.V.A. Ștefan, Global Perspectives on Digital and AI Legislation: A Comparative Study of Data Protection, AI Governance, and Healthcare Innovations with a Focus on Romania, Proceedings of the International Conference on Business Excellence, Vol. 19, No. 1, at 2469 (2025).
[27] S. Bharal & R. Sharma, AI Acts in Focus: Comparative Insights from the European Union and Canada for India's Policy Evolution, in Proceedings of the International Conference on Advancements in Computing Technologies and Artificial Intelligence (COMPUTATIA-2025) 251 (2025).

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when it comes to "high-impact systems," which include healthcare AI.

While the EU AI Act has adopted a more prescriptive approach, AIDA allows flexibility through regulatory sandboxes-in other words, controlled environments in which new AI applications can be tested under supervision. The innovation-friendly model of the sandbox may be an intermediate path to help India balance regulatory stringency with technological growth.

4.4 *The United States Approach*

Unlike the EU or Canada, the United States does not have a unified AI law. Indeed, instead, it adopts a sectoral approach where the U.S. Food and Drug Administration is responsible for regulating AI-enabled medical devices. The FDA's Software as a Medical Device (SaMD) framework has requirements for pre-market validation and post-market surveillance of AI-driven diagnostics. This model focuses on scientific validation and clinical safety rather than generalized AI ethics.

An evidence-based regulatory structure would ensure safety for patients without overregulation. However, India does not have a specific medical technology authority with similar jurisdiction, and there exists a gap between medical regulation and digital innovation.

4.5 *Comparative Insights for India*

India's policy, by contrast, is still largely reactive and piecemeal, the fact that India bases its policy on general information technology laws and soft-policy instruments, such as NITI Aayog's Responsible AI for All discussion paper, means compliance obligations will not be enforceable. The EU and Canada, in their approach, do the opposite, emphasizing binding accountability, transparency, and conformity mechanisms. Such legal ambiguity regarding AI-driven diagnostics may lead to disputes on medical negligence and product liability in India. It is further emphasize that only transparency and adaptive governance can help uphold patient trust and, therefore, accountability, principles inbuilt in the EU AI Act but not in the Indian law.

The EU AI Act represents the world's most advanced model, balancing innovation with patient safety through enforceable, risk-based regulation. Canada's AIDA allows for flexibility through sandboxing, while the U.S. FDA provides sector-specific oversight based on scientific

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validation. The current Indian framework lacks these structured mechanisms, relying instead on general laws not well-suited to high-risk technologies like AI diagnostics.

A hybrid approach that brings together the accountability mechanisms of the EU and innovation flexibility from Canada could enable India to design a robust, adaptive, and ethically grounded AI healthcare framework-one that protects patients while fostering technological growth.

5. Ethical and Medico – Legal Challenges

The introduction of AI in medical diagnostics opens an entire new dimension of ethical and medico-legal issues that go beyond traditional clinical and legal paradigms, including liability attribution, informed consent, algorithmic bias, data protection, professional accountability, and others. Even as AI-assisted medical systems offer better diagnostic accuracy and efficiency, they contradict fundamental medical ethics like autonomy, beneficence, non-maleficence, and justice. It is these ethical dilemmas that are further complicated by the lack of explicit regulatory provisions in India that have placed clinicians and patients in a state of uncertainty.

5.1 *Algorithmic Transparency and Accountability*

One of the most important concerns within the AI-based diagnosis is the opacity of algorithmic decision-making, sometimes referred to as the "black-box" problem. This opaqueness undermines the possibility for patients and doctors to understand or contest the results of diagnoses. Transparency is a cornerstone of trustworthy AI and needs to be enshrined legally. No such statute exists in India that requires algorithmic explainability or auditability. In the absence of legally binding transparency requirements, healthcare practitioners might be using systems whose logic in diagnosis cannot be independently checked. Conversely, the EU AI Act requires developers of high-risk AI systems to provide explainability and traceability to allow legal accountability and post-market surveillance.

5.2 *Informed Consent and Patient Autonomy*

Informed consent models traditionally consider the human-to-human interaction between the doctor and the patient. AI disrupts this dynamic by inserting an algorithmic intermediary in diagnostic processes. Indian law does not recognize the algorithmic participation of AI in medical decisions, thus creating an ethical vacuum regarding the consent of patients for AI

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involvement[28].

Rarely is the patient informed about the contribution of AI to diagnosis, the level of human oversight involved, or any limitations of the algorithms. On the other hand, the EU AI Act requires that users of high-risk AI systems be transparently informed that an AI tool is being used and that final decisions remain under human control. Adopting similar disclosure norms in India would bring consent practices in line with global ethical standards and reinforce patient autonomy.

5.3 *Liability and Professional Responsibility*

The question of who is liable when the AI-driven diagnosis goes wrong has not been addressed in India. Existing laws such as the Consumer Protection Act, 2019, and principles of medical negligence under tort laws, assume a human operator. They are not equipped to apportion liability between developers of AI, vendors, and healthcare providers.

While the EU's risk-based classification allows shared liability models and conformity assessments, thus accountability at each step of AI deployment, in contrast, India has no statutory mechanism to check whether an AI medical device meets all the criteria and standards nor does it adjudicate on fault in case an algorithm misdiagnoses a patient. Ghosh, Saini and Barad caution that, without such frameworks, disputes will result in lengthier litigation and greater inconsistency at the judicial level[29].

5.4 *Data Privacy and Ethical use of Medical Data*

AI diagnostics require large datasets, which often contain sensitive personal health information. The Digital Personal Data Protection Act, 2023, requires data fiduciaries to have wide-ranging responsibilities but does not specifically address the issue of secondary use of anonymized data for AI model training. The robust data governance must accompany AI regulation to ensure fairness, non-discrimination, and patient trust.

There are also ethical considerations relating to data ownership and cross-border data flows,

[28] Naresh Tiwari, Regulatory Responses to AI in Healthcare and Medical Diagnostics, in Navigating Law and Policy in STM Enterprises: Ethical Governance, Regulation, and Innovation Strategy 59 (Hewa Majeed Zangana et al. eds., IGI Global Scientific Publ'g 2025).
[29] A. Ghosh, A. Saini & H. Barad, Artificial Intelligence in Governance: Recent Trends, Risks, Challenges, Innovative Frameworks and Future Directions, AI & SOCIETY 1 (2025).

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particularly when Indian hospitals share data with AI developers from other countries. In contrast with the EU's GDPR, which interlinks algorithmic fairness and data protection, India's law keeps them as separate domains-an omission that weakens patient safeguards.

5.5 *Bias, Fairness and Inclusivity*

AI systems in healthcare are only as reliable as the data they are trained on. Biased or non-representative data sets can lead to perpetuation of inequality, especially when there is such socio-cultural diversity in a country like India. It is important to highlight the fact that ethical AI integration at all levels needs clear protocols for bias mitigation, coupled with data collection that represents cultural inclusivity.[30]

The European Union AI Act requires data-set quality standards and bias testing for all high-risk systems, provided for under Indian law. Without such requirements, algorithmic outputs risk being skewed toward urban or high-income populations, further deepening healthcare disparities rather than bridging them.

5.6 *The Doctor-AI Relationship and Professional Ethics*

AI-powered diagnostic tools redefine the relationship between doctor and patient. Caution that excessive reliance on AI could erode physicians' independent judgment, leading to "automation bias." At the same time, failure to use validated AI tools might itself be seen as negligence in the future. Thus, professional ethics must evolve to balance technological reliance with clinical discretion. Medical councils in India have not issued any binding ethical codes or professional conduct standards on AI-assisted practice, unlike the EU, where conformity with professional and ethical norms finds a place within the governance structure of the AI Act.

6. Policy Recommendation for India

India is at an important juncture in the regulation of AI-driven healthcare. The current framework of India, which is anchored in general laws like the IT Act, 2000, and the DPDP Act, 2023, will fall short of regulating the ethical and medico-legal dimensions of AI diagnostics. This section draws insights from the EU AI Act (2024), Canada's AIDA (2022), and U.S. FDA's SaMD framework to recommend a pragmatic, phased strategy for India.

[30] M.P. Singh, Y.N. Keche & Y. Keche, Ethical Integration of Artificial Intelligence in Healthcare: Narrative Review of Global Challenges and Strategic Solutions, Cureus 17(5) (2025).

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i. **Establish a Dedicated AI in Healthcare Law:** India should implement a "Health AI Regulation Act" or one similar in nature, drawing inspiration from the risk-based approach of the EU. The categorization for AI used in diagnostics falls under high-risk devices, which would include necessary conformity assessments, performance validation, and post-deployment monitoring. This will provide the legal clarity that the Indian ecosystem currently lacks[31].

ii. **Introduce Regulatory Sandboxes:** While drawing from Canada's AIDA, regulatory sandboxes should be implemented in India, providing a controlled environment for the testing of AI systems under ethical and technical oversight before general use. This will balance innovation with patient safety, permitting iterative policy learning.

iii. **Create an AI Oversight Authority:** This would involve a dedicated national AI Ethics and Regulation Authority in coordination with the Ministries of Health, IT, and Law. Its purview should extend to certification, compliance audits, and liability adjudication for AI tools in healthcare, filling the institutional vacuum currently identified by Ghosh, Saini & Barad.

iv. **Strengthen Ethical and Transparency Standards:** It is necessary to codify a legislative framework that makes transparency, explainability, and human oversight binding. Doctors will have to disclose the involvement of AI in diagnostics to the patients, obtain their consent, and ensure patient autonomy. This would bring India in line with EU demands for transparency and be in response to the concerns raised by Lund et al[32].

v. **Promote Inclusive and Bias Free AI:** India's diverse population dictates that dataset inclusion is a must, and one hopes that regulatory standards require this in demographics to minimize algorithmic bias, as suggested by Singh, Keche & Keche[33].

CONCLUSION

Artificial intelligence is transforming health diagnostics around the world with unparalleled accuracy and availability. However, its application in clinical practice is fraught with serious legal and ethical questions relating to liability, transparency, and protection of the rights of

[31] S. Bharal & R. Sharma, AI Acts in Focus: Comparative Insights from the European Union and Canada for India's Policy Evolution, in Proceedings of the International Conference on Advancements in Computing Technologies and Artificial Intelligence (COMPUTATIA-2025) 251 (2025).
[32] B. Lund et al., Standards, Frameworks, and Legislation for Artificial Intelligence (AI) Transparency, AI & Ethics 1 (2025).
[33] M.P. Singh, Y.N. Keche & Y. Keche, Ethical Integration of Artificial Intelligence in Healthcare: Narrative Review of Global Challenges and Strategic Solutions, Cureus 17(5) (2025).

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patients. India has a fragmented regulatory ecosystem based on the Information Technology Act, 2000; the DPDP Act, 2023; and Telemedicine Guidelines, 2020, with no express provision relating to AI-enabled diagnostics.

Comparative analyses show that the EU AI Act of 2024 goes to the extent of categorizing health AI as "high-risk," thus imposing duties of human oversight and transparency, and conformity assessment on it. The AIDA 2022 complements the foregoing by infusing regulatory flexibility in the form of innovation sandboxes, while the U.S. FDA ensures safety through sectoral validation. Collectively, they demonstrate that effective AI governance requires both certainty in law and ethical adaptability.

What works for India is the adoption of a risk-based, patient-centric framework. The model proposed here-combining statutory regulation, ethical standards, and institutional oversight-would strike a balance between accountability and fostering innovation. In so doing, India can position itself not merely as a technology adopter but as a global contributor to the responsible governance of medical artificial intelligence.

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