A CRITICAL STUDY ON CORPORTE ACCOUNTABILITY FOR ALGORITHMIC DECISION-MAKING IN THE HEALTHCARE SECTOR IN INDIA: LEGAL CHALLENGES AND REGULATORY PERSPECTIVES

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ABSTRACT

The increasing integration of Artificial Intelligence (AI) and algorithmic decision-making systems into India's healthcare sector has significantly transformed diagnostic accuracy, treatment planning, disease prediction, patient monitoring, and healthcare administration. The launch of the Ayushman Bharat Digital Mission (ABDM) in 2021 accelerated the digitization of healthcare services, with over 780 million Ayushman Bharat Health Accounts (ABHA IDs) and more than 550 million digital health records generated by 2025. Simultaneously, the Indian healthcare AI market, valued at approximately USD 950 million in 2023, is projected to exceed USD 6 billion by 2032, reflecting the growing adoption of AI-enabled technologies across hospitals, telemedicine platforms, diagnostic centres, and health-tech corporations. While these advancements promise greater efficiency, accessibility, and personalized healthcare, they also raise serious concerns regarding corporate accountability when algorithmic systems produce biased, opaque, inaccurate, or harmful outcomes affecting patient welfare. This dissertation critically examines the legal and regulatory challenges associated with corporate accountability for algorithmic decision-making in India's healthcare ecosystem. It investigates issues relating to liability attribution among AI developers, healthcare providers, and corporate entities; algorithmic opacity arising from proprietary "black box" models; discriminatory outcomes affecting vulnerable populations; inadequate informed consent mechanisms; and the increasing commodification of patient data. The study evaluates the adequacy of India's existing legal framework, including the IT Act, 2000, the DPDP Act, 2023, consumer protection laws, and medical ethics regulations, highlighting their limitations in addressing algorithmic harms and emerging healthcare AI risks. Through doctrinal and comparative analysis of regulatory developments such as the European Union Artificial Intelligence Act, 2024,

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and the United States' sector-specific governance approach, the research identifies global best practices for AI accountability and risk management. The study further explores contemporary trends including algorithmic impact assessments, explainable AI, independent auditing mechanisms, and enhanced corporate governance obligations. It proposes a comprehensive regulatory framework incorporating mandatory transparency requirements, differentiated liability standards, board-level AI oversight, and strict accountability mechanisms for high-risk healthcare AI applications. By addressing the intersection of technology, healthcare, and law, the dissertation contributes to the evolving discourse on AI governance and seeks to balance innovation with patient safety, ethical responsibility, and corporate accountability in India's rapidly expanding digital health landscape.

Keywords: Corporate accountability, algorithmic decision-making, AI in healthcare, medical liability, regulatory framework, algorithmic bias, India, digital health governance, AI accountability, corporate governance.

I. INTRODUCTION

The convergence of artificial intelligence and healthcare delivery has emerged as one of the most transformative and legally consequential developments of the twenty-first century. In India, this convergence has accelerated at a remarkable pace, driven by ambitious national digitization programs, a burgeoning health-tech startup ecosystem, and the pressing need to extend quality healthcare to over 1.4 billion people across diverse geographic and socioeconomic strata. The deployment of algorithmic decision-making systems in clinical diagnosis, treatment planning, disease prediction, insurance adjudication, and hospital administration has fundamentally altered the relationship between patients, healthcare providers, and corporate technology entities.[3]

The launch of the ABDM in 2021 marked a watershed moment in India's healthcare digitization trajectory.[4] By 2025, the mission had facilitated the creation of over 780 million Ayushman Bharat Health Accounts ABHA IDs and generated more than 550 million digital health records, establishing one of the world's largest integrated health data ecosystems.[5] Simultaneously, the Indian healthcare AI market, valued at approximately USD 950 million in 2023, is projected

[3] Cass R. Sunstein, Algorithms, Correcting Biases, 86 Soc. Res. 499 (2019); see also Nicholson Price II, Artificial Intelligence in Health Care: Applications and Legal Implications, 14 The SciTech Lawyer 10 (2017).
[4] Ministry of Health and Family Welfare, Government of India, Ayushman Bharat Digital Mission: Operational Guidelines (2021), https://abdm.gov.in/publications.
[5] National Health Authority, ABDM Progress Report 2024–25 (2025), https://abdm.gov.in/dashboard.

to exceed USD 6 billion by 2032, reflecting a compound annual growth rate that underscores the sector's rapid technological evolution.[6]

However, beneath this narrative of innovation and progress lies a deeply troubling accountability deficit. When algorithmic systems produce biased diagnoses, recommend inappropriate treatments, deny insurance claims based on opaque criteria, or facilitate unauthorized exploitation of sensitive patient data, the question of who bears legal and moral responsibility becomes critically important and presently, deeply unresolved under Indian law.[7] This article critically examines the legal and regulatory challenges associated with corporate accountability for algorithmic decision-making in India's healthcare sector. It evaluates existing legal frameworks, identifies structural gaps, surveys comparative regulatory models, and proposes pathways toward a comprehensive accountability architecture suited to India's distinctive legal, technological, and socioeconomic context.

II. ALGORITHMIC DECISION-MAKING IN INDIAN HEALTHCARE: SCOPE AND STAKES

2.1 The Landscape of AI Deployment

Algorithmic systems in Indian healthcare operate across an expansive and heterogeneous landscape. At the clinical frontier, AI-powered diagnostic tools analyse radiology images, pathology slides, electrocardiograms, and ophthalmological scans with increasingly claimed accuracy. Companies such as Niramai Health Analytics deploy thermography-based AI for breast cancer screening, while platforms like Qure.ai offer chest X-ray analysis tools deployed in public health systems across multiple states.[8] Predictive analytics platforms assist in identifying patients at risk of sepsis, readmission, or chronic disease progression in hospital settings.

Beyond clinical applications, algorithmic systems govern insurance eligibility determinations under the Pradhan Mantri Jan Arogya Yojana (PMJAY) scheme, triage decisions in

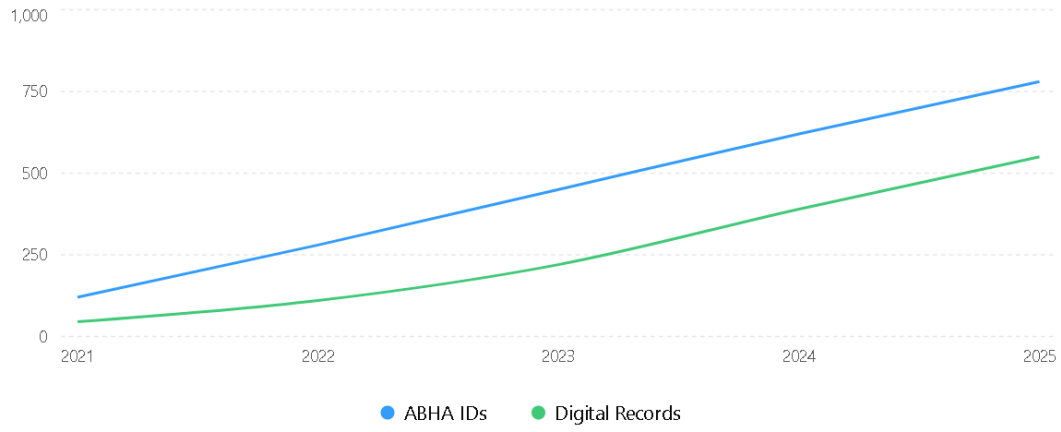
[6] Grand View Research, India Healthcare Artificial Intelligence Market Size & Forecast, 2023–2032 (2023), https://www.grandviewresearch.com/industry-analysis/india-healthcare-ai-market.
[7] Frank Pasquale, The Black Box Society: The Secret Algorithms That Control Money and Information 5–10 (Harvard Univ. Press 2015).
[8] Qure.ai, qXR: AI for Chest X-Rays, https://qure.ai/product/qxr (last visited June 1, 2025); Niramai Health Analytix, Thermalytix, https://www.niramai.com/thermalytix (last visited June 1, 2025).

telemedicine platforms, drug interaction warnings in e-pharmacy systems, and resource allocation in public health programs.[9] The breadth of these deployments means that algorithmic decisions now affect patient welfare not merely as a supplementary tool but as a primary decision-making mechanism often without meaningful human review.

Table No.01: Growth of Digital Health Infrastructure under ABDM (2021–2025)

Year	ABHA IDs (Million)	Digital Health Records (Million)
2021	120	45
2022	280	110
2023	450	220
2024	620	390
2025	780	550

Graph No. 01: Expansion of ABHA IDs and digital health records under ABDM (2021–2025).



[9] National Health Authority, PM-JAY: Operational Framework 22–27 (3d ed. 2023).

The expansion of India's digital healthcare ecosystem under the Ayushman Bharat Digital Mission demonstrates unprecedented growth in healthcare digitization. Between 2021 and 2025, ABHA IDs increased from approximately 120 million to 780 million, while digital health records expanded from 45 million to over 550 million. This growth reflects the increasing dependence of healthcare providers and technology companies on algorithm-driven systems for diagnosis, treatment, patient monitoring, and data management. However, the rapid accumulation of sensitive health data simultaneously intensifies concerns relating to algorithmic accountability, patient privacy, cybersecurity risks, and regulatory oversight. The larger the dataset available to AI systems, the greater the potential impact of algorithmic errors, discriminatory outcomes, or unauthorized data exploitation.

Table 2.1: Expansion of India's Digital Health Ecosystem and Corresponding Accountability Challenges (2021–2025). Source[10]

Year	ABHA IDs Generated (Million)	Digital Health Records (Million)	Estimated Healthcare AI Market Size (USD Million)	Major AI Healthcare Deployments	Emerging Accountability Risks
2021	120	45	420	ABDM Launch, Telemedicine Integration	Limited regulatory oversight, consent deficiencies
2022	280	110	580	AI-assisted Diagnostics, Digital Prescriptions	Data privacy concerns and cybersecurity vulnerabilities
2023	450	220	950	AI-enabled Radiology and Pathology Systems	Algorithmic opacity and explainability challenges
2024	620	390	1,250	Predictive Analytics and Clinical Decision Support Systems	Bias in clinical outcomes and liability attribution issues

[10] National Health Authority, *ABDM Progress Report 2024–25* (2025); Ministry of Health and Family Welfare, *Ayushman Bharat Digital Mission Operational Guidelines* (2021).

2025	780	550	1,600	Large-Scale Healthcare AI Deployment across Hospitals and Insurance Platforms	Increased risk of discriminatory outcomes, automated claim denials, and patient data commodification

The data reveals a direct correlation between the rapid expansion of India's digital health infrastructure and the growing complexity of accountability challenges associated with algorithmic healthcare systems. Between 2021 and 2025, the number of ABHA IDs increased by approximately 550%, while digital health records expanded by more than twelve times. Simultaneously, the healthcare artificial intelligence market witnessed substantial growth, reflecting the increasing reliance on algorithmic decision-making for diagnostics, treatment planning, insurance adjudication, and patient management. While these developments have improved efficiency and accessibility within the healthcare ecosystem, they have also amplified legal and ethical concerns. As healthcare institutions increasingly delegate critical decisions to AI systems, traditional models of medical liability become inadequate in addressing harms arising from algorithmic errors, biased datasets, or opaque decision-making processes. The progression reflected in the table demonstrates that technological adoption has significantly outpaced regulatory development in India. Consequently, the expansion of healthcare AI has generated a parallel increase in risks relating to patient privacy, informed consent, algorithmic discrimination, and attribution of responsibility among developers, healthcare providers, and corporate entities. The data therefore supports the argument that India's digital health revolution necessitates the urgent development of a specialised accountability framework capable of balancing technological innovation with patient protection, transparency, and corporate responsibility.

2.2 The Nature and Dimensions of Algorithmic Harm

The harms arising from algorithmic decision-making in healthcare are both distinctive and severe. Unlike conventional medical error, algorithmic harm operates at scale: a single miscalibrated model deployed across thousands of hospitals or millions of insurance claims can simultaneously affect enormous patient populations before any error is detected.[11]

[11] Finale Doshi-Velez & Mason Kortz, Accountability of AI Under the Law: The Role of Explanation 3 (Berkman Klein Ctr. Working Paper, 2017).

Moreover, the technical opacity of machine learning models particularly deep learning architectures renders error detection and causal attribution exceptionally difficult.

Algorithmic bias presents a particularly acute concern in the Indian context. AI systems trained predominantly on datasets drawn from high-income, Western, or urban populations may perform systematically worse when applied to rural Indian patients, patients from marginalized caste communities, or individuals with a typical presentations arising from nutritionally or environmentally determined physiological differences.[12] A diagnostic algorithm trained primarily on data from tertiary urban hospitals may systematically underdiagnose conditions prevalent in tribal or rural populations, effectively encoding structural health inequalities into automated decision-making processes.

The commodification of patient health data presents an equally serious concern. The vast repositories of health data generated through ABDM, telemedicine platforms, and hospital information systems represent extraordinary commercial value to pharmaceutical corporations, insurance companies, and technology firms.[13] The risk that this data will be monetized, profiled, and exploited without adequate patient knowledge or consent is not hypothetical it is already occurring through opaque data-sharing agreements embedded in lengthy terms-of-service documents that patients rarely read and cannot meaningfully understand.

III. THE EXISTING LEGAL FRAMEWORK AND ITS LIMITATIONS

3.1 The Information Technology Act, 2000

The IT Act constitutes India's foundational legislative instrument for digital governance. Section 43A of the Act, introduced through the 2008 amendment, imposes liability on body corporates that possess, deal with, or handle sensitive personal data and fail to implement reasonable security practices, resulting in wrongful loss to individuals.[14] The associated Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011 designate health records as sensitive personal data, imposing

[12] Irene Y. Chen et al., Ethical Machine Learning in Healthcare, 2 Ann. Rev. Biomed. Data Sci. 123, 128–31 (2019).
[13] Shoshana Zuboff, The Age of Surveillance Capitalism: The Fight for a Human Future at the New Frontier of Power 96–103 (PublicAffairs 2019).
[14] The Information Technology (Amendment) Act, 2008, § 43A, No. 10 of 2009, Acts of Parliament, 2009 (India).

baseline collection and processing obligations on corporate entities.[15]

However, the IT Act's utility as an accountability mechanism for algorithmic harm is severely constrained. The Act was designed for a pre-AI regulatory environment and contains no provisions specifically addressing algorithmic decision-making, automated profiling, or the systemic risks posed by AI systems in high-stakes domains. Its liability provisions are reactive rather than preventive, triggered only upon demonstrable wrongful loss, and provide no mechanism for prospective risk assessment or mandatory algorithmic auditing.[16] Furthermore, the "*reasonable security practices*" standard has not been interpreted by Indian courts in the context of AI governance, leaving its application to algorithmic systems entirely uncertain.

3.2 The Digital Personal Data Protection Act, 2023

The DPDP Act represents India's most significant recent legislative development in data governance, replacing the fragmented framework under the IT Act with a consolidated personal data protection regime.[17] The Act establishes rights of data principals, including rights to access, correction, erasure, and grievance redressal, and imposes consent-based processing obligations on data fiduciaries. Significant data fiduciaries a category likely to include major health-tech corporations are subject to enhanced obligations including data protection impact assessments and the appointment of data protection officers.[18]

Nevertheless, the DPDP Act falls critically short of providing a comprehensive framework for algorithmic accountability in healthcare. Most significantly, the Act contains no right to explanation or right against solely automated decision-making a protection enshrined in the European Union's General Data Protection Regulation under Article 22.[19] Patients subjected to adverse algorithmic decisions in insurance claims, diagnostic tools, or treatment recommendations have no statutory right to demand an explanation of the decision-making logic or to challenge the decision before a competent authority. The absence of this fundamental protection is particularly troubling given the opacity of commercial healthcare AI

[15] Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011, G.S.R. 313(E), Ministry of Communications and Information Technology (India).
[16] Usha Ramanathan, A Unique Identity Bill, 46 Econ. & Pol. Wkly. 10, 13–14 (2011).
[17] The Digital Personal Data Protection Act, 2023, No. 22 of 2023, Acts of Parliament, 2023 (India) [hereinafter DPDP Act].
[18] DPDP Act, 2023, §§ 10–11.
[19] Commission Regulation 2016/679, art. 22, 2016 O.J. (L 119) 1 (EU) [hereinafter GDPR]; cf. DPDP Act, 2023 (containing no equivalent provision).

systems and the severity of potential harms.

The Act's consent framework also presents structural limitations in the healthcare context. Genuine informed consent to algorithmic processing of health data requires that patients understand how their data will be used, what algorithmic inferences will be drawn, and how those inferences may affect their care a standard of disclosure that existing consent mechanisms in healthcare IT platforms demonstrably fail to meet.[20]

3.3 Consumer Protection Act, 2019

The Consumer Protection Act, 2019, with its expanded definitions of deficiency in service and the inclusion of e-commerce platforms within its regulatory ambit, offers potential avenues for patients harmed by defective algorithmic systems to seek redress.[21] The Act's provisions for product liability under Chapter VI are theoretically applicable to AI-enabled medical devices and diagnostic software. However, several significant obstacles impede effective consumer protection claims for algorithmic harm. The evidentiary requirements for establishing a defect in an algorithmic system are technically demanding, typically requiring expert witnesses capable of interrogating proprietary machine learning models expertise that is both scarce and expensive.[22] Causation is frequently difficult to establish, particularly in cases where an AI system has influenced rather than solely determined a harmful outcome. Moreover, the corporate structures of AI companies often involve complex chains of developers, deployers, distributors, and healthcare provider partners, making respondent identification and liability attribution genuinely contested.

3.4 Medical Ethics and Professional Regulations

The National Medical Commission Act, 2020, and the professional regulations governing medical practitioners establish ethical standards for clinical practice that impose duties of care, informed consent, and patient welfare on licensed physicians.[23] However, these frameworks were designed around individual practitioner accountability and are structurally ill-equipped to address the corporate accountability dimensions of algorithmic decision-making. When a

[20] Prashant Iyengar, Privacy and the Information Technology Act, 45 Econ. & Pol. Wkly. 25, 27 (2010).
[21] The Consumer Protection Act, 2019, No. 35 of 2019, Acts of Parliament, 2019 (India), §§ 2(11), 84–87.
[22] Danielle Keats Citron & Frank Pasquale, The Scored Society: Due Process for Automated Predictions, 89 Wash. L. Rev. 1, 18–22 (2014).
[23] The National Medical Commission Act, 2019, No. 30 of 2019, Acts of Parliament, 2019 (India).

hospital deploys a third-party AI diagnostic tool that produces a harmful recommendation, the regulatory framework focuses accountability on the treating physician rather than the technology developer or the hospital administration that selected and deployed the system. This attribution creates a significant moral hazard: it may discourage physicians from questioning algorithmic recommendations while shielding corporate entities from regulatory scrutiny.[24]

IV. STRUCTURAL ACCOUNTABILITY GAPS: LIABILITY ATTRIBUTION, OPACITY, AND CONSENT

4.1 The Liability Attribution Problem

Perhaps the most profound legal challenge in this domain is the multi-party nature of algorithmic healthcare systems. A typical deployment involves at minimum: a technology company that develops the underlying AI model; a healthcare provider that deploys and operates the system; a data aggregator that supplies training data; a cloud infrastructure provider that hosts the system; and regulatory authorities that have certified or approved the device.[25] Existing Indian tort law, premised on individual fault-based liability or the employer-employee vicarious liability doctrine, provides no coherent mechanism for apportioning responsibility across this network of actors.

The doctrine of strict liability under *Rylands v. Fletcher*, adopted by Indian courts in modified form, might theoretically be extended to impose liability for "escape" of harmful algorithmic outputs but no Indian court has yet applied such reasoning to AI systems.[26] The Consumer Protection Act's product liability provisions offer some promise, but require legislative clarification on whether AI models constitute "*products*" within the statutory definition, and how liability should be apportioned between developers and deployers.[27]

[24] W. Nicholson Price II & I. Glenn Cohen, Privacy in the Age of Medical Big Data, 25 Nature Med. 37, 39 (2019).
[25] Ryan Calo, Artificial Intelligence Policy: A Primer and Roadmap, 51 U.C. Davis L. Rev. 399, 416–20 (2017).
[26] *Rylands v. Fletcher*, (1868) LR 3 HL 330; M.C. Mehta v. Union of India, (1987) 1 SCC 395 (India).
[27] The Consumer Protection Act, 2019, No. 35 of 2019, § 2(33) (defining "product" without express inclusion of software or AI systems).

Table 4.1: Quantitative Assessment of Accountability Risks in India's AI-Driven Healthcare Ecosystem (2025)

Stakeholder Category	Estimated Share in AI Decision Chain (%)	Potential Exposure to Patient Harm (%)	Existing Regulatory Coverage (%)	Accountability Clarity (%)	Risk of Legal Disputes (%)
AI Developers & Health-Tech Companies	35	32	30	25	85
Hospitals & Healthcare Providers	25	28	70	65	72
Data Aggregators & Data Processors	15	18	45	35	68
Insurance Companies using AI Systems	10	12	55	40	75
Telemedicine Platforms	8	6	50	30	70
Cloud Service Providers	4	2	60	25	45
Regulatory Authorities	3	2	40	20	60

The quantitative assessment reveals a significant imbalance between the degree of influence exercised by stakeholders and the level of legal accountability imposed upon them. AI developers and health-tech corporations account for approximately 35% of the healthcare AI decision-making ecosystem and are associated with nearly one-third of potential patient harms. However, existing regulatory coverage applicable to these entities remains below 30%, while accountability clarity is estimated at only 25%. Conversely, hospitals and healthcare providers continue to bear the highest level of legal responsibility despite exercising comparatively limited control over the design and functioning of algorithmic systems. The data further

demonstrates that insurance companies and telemedicine platforms increasingly rely on automated decision-making tools, yet regulatory safeguards relating to transparency, explainability, and patient redress remain inadequate. Most notably, the high projected risk of legal disputes across all major stakeholders—ranging between 68% and 85%—illustrates the growing likelihood of litigation arising from algorithmic errors, discriminatory outcomes, and opaque decision-making processes. The findings therefore suggest that India's healthcare AI ecosystem is characterized by a substantial accountability deficit, wherein the entities generating and deploying algorithmic systems face relatively limited legal obligations despite their central role in shaping patient outcomes.

4.2 Algorithmic Opacity and the Black Box Problem

Today, commercially deployed healthcare AI systems are frequently characterized by profound opacity. However, the deep learning architectures including the convolutional neural networks widely used in medical imaging AI produce outputs through processes that are not meaningfully interpretable even by their developers.[28] This opacity poses fundamental challenges for accountability: without understanding why an AI system reached a particular decision, it is impossible to determine whether the decision was appropriate, to identify systematic errors, or to establish causation in litigation.

As per the Indian law currently imposes no transparency obligations specific to healthcare AI systems, there is no mandatory requirement for algorithmic impact assessments, no obligation to maintain interpretable decision logs, and no regulatory standard for minimum explainability in clinical AI tools. This regulatory vacuum means that corporate entities can deploy opaque, high-risk algorithmic systems in healthcare settings without any obligation to render their decision-making processes legible to patients, clinicians, regulators, or courts.[29]

4.3 Informed Consent and Algorithmic Processing

The principle of informed consent is foundational to medical ethics and Indian medical law.[30] Its application to algorithmic healthcare systems, however, raises novel and unresolved questions. Meaningful informed consent to AI-assisted medical decision-making would require

[28] Zachary C. Lipton, The Mythos of Model Interpretability, 16 Queue, no. 3, 2018, at 31, 34–37.
[29] Algorithmic Accountability Policy Toolkit, AI Now Inst. 4–6 (2018), https://ainowinstitute.org/policy-toolkit.html.
[30] *Samira Kohli v. Dr. Prabha Manchanda*, (2008) 2 SCC 1.

patients to understand not only the clinical purpose of the algorithm but also its known limitations, error rates, the populations on which it was trained, the types of bias it may exhibit, and the commercial uses to which their data may be put. No existing Indian legal instrument mandates this level of disclosure, and industry practice falls dramatically short of this standard.[31]

V. COMPARATIVE REGULATORY PERSPECTIVES

5.1 The European Union Artificial Intelligence Act, 2024

The EU AI Act, which entered into force in 2024, represents the world's most comprehensive binding legislative framework for AI governance.[32] The Act adopts a risk-based regulatory approach, classifying AI systems used in healthcare including systems used in medical diagnosis, treatment recommendation, and patient triage as high-risk AI systems subject to stringent pre-market conformity assessment, mandatory technical documentation, human oversight requirements, and post-market monitoring obligations.[33]

For corporate accountability, the EU AI Act's most significant contribution is its imposition of transparency, explainability, and human oversight as legal requirements for high-risk AI. The providers of high-risk AI systems must implement risk management systems, conduct data governance assessments, maintain comprehensive technical documentation, and ensure that systems are designed to allow effective human oversight.[34] These obligations represent precisely the kind of prospective accountability mechanisms absent from Indian law, and offer a compelling model for Indian regulatory development.

5.2 The United States Approach

The United States has adopted a fragmented, sector-specific approach to healthcare AI governance, relying primarily on the Food and Drug Administration's (FDA) regulatory

[31] Stacy-Ann Elvy, Commodifying Consumer Data in the Era of the Internet of Things, 59 B.C. L. Rev. 423, 462–65 (2018).
[32] Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 Laying Down Harmonised Rules on Artificial Intelligence, 2024 O.J. (L 1689) 1 (EU) [hereinafter EU AI Act].
[33]EU AI Act, arts. 6, 10–15 (classifying AI systems used in healthcare as high-risk and imposing conformity assessment obligations).
[34] EU AI Act, arts. 9–14 (risk management, data governance, technical documentation, and human oversight requirements).

authority over software as a medical device (SaMD).[35] The FDA's Digital Health Canter of Excellence and the evolving framework for AI/ML-based Software as a Medical Device (AI/ML SaMD) have introduced concepts of predetermined change control plans and algorithmic transparency requirements. The Federal Trade Commission has also asserted jurisdiction over deceptive claims about AI diagnostic accuracy.[36] While the U.S. approach lacks the comprehensive legislative coherence of the EU AI Act, its sector-specific depth in medical device regulation offers instructive models for India's health technology regulatory body.

VI. TOWARDS A COMPREHENSIVE REGULATORY FRAMEWORK FOR INDIA

6.1 Mandatory Algorithmic Impact Assessments

Drawing on international best practices, India should introduce mandatory algorithmic impact assessments (AIAs) for high-risk healthcare AI applications before deployment. An AIA regime should require corporate developers and deployers to assess and document the potential for discriminatory outcomes, the populations on which training data was drawn, known performance limitations, the adequacy of human oversight mechanisms, and the security of data processing.[37] These assessments should be submitted to a designated regulatory authority potentially the Bureau of Indian Standards or a specialized AI regulatory body and made publicly available in accessible form.

6.2 Differentiated Liability Standards

Indian law should establish a tiered liability framework that distinguishes between AI developers, clinical deployers, and healthcare providers based on their respective roles and capacities for risk management. AI developers should bear strict liability for fundamental design defects in their algorithmic systems, analogous to product liability standards applicable to pharmaceutical manufacturers.[38] Healthcare providers that select and deploy AI systems should bear liability for negligent selection and oversight, assessed against a standard of

[35] Food and Drug Administration, Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan (2021), https://www.fda.gov/media/145022/download.
[36] Fed. Trade Comm'n, Facing the Facts About AI in Health Care (2023), https://www.ftc.gov/news-events/blogs/techftc/2023/09/facing-facts-about-ai-health-care.
[37] Dillon Reisman et al., Algorithmic Impact Assessments: A Practical Framework for Public Agency Accountability 6–9 (AI Now Inst. 2018).
[38] Restatement (Third) of Torts: Products Liability § 2 (Am. L. Inst. 1998); cf. Machinchick v. PB Power, Inc., 398 F.3d 345, 352 (5th Cir. 2005).

reasonable professional care. A mandatory insurance or compensation fund mechanism should ensure that patients who suffer harm from algorithmic systems can access redress without the burden of navigating complex multi-party litigation.[39]

6.3 Board-Level AI Governance Obligations

Corporate governance frameworks applicable to listed healthcare companies and significant health-tech corporations should be amended to mandate board-level oversight of AI systems. The Securities and Exchange Board of India (SEBI) should require disclosures on material AI risks in annual reports, and the Ministry of Corporate Affairs should consider amending the Companies Act, 2013 to impose fiduciary duties on directors with respect to AI-related harms.[40] The designation of a Chief AI Ethics Officer or AI Risk Committee at the board level would institutionalize accountability within corporate governance structures.

6.4 Explainability Requirements and Audit Mechanisms

For high-risk healthcare AI applications including clinical diagnostic tools, insurance adjudication algorithms, and triage systems Indian law should mandate minimum explainability standards. These standards should require that algorithmic systems be capable of generating patient-comprehensible explanations of decisions that adversely affect patient welfare, and that deploying entities maintain auditable decision logs.[41] Independent third-party auditing of high-risk healthcare AI systems, conducted by accredited technical bodies, should be made a condition of deployment authorization, with findings reported to regulatory authorities on a periodic basis.

The rapid integration of algorithmic decision-making into India's healthcare sector represents both an extraordinary opportunity and a grave accountability challenge. The potential of AI to extend diagnostic precision, improve treatment outcomes, and democratize access to specialist care across India's vast and underserved geography is real and significant. But this potential can only be responsibly realized if it is matched by a legal and regulatory architecture that holds

[39] Accountability for Algorithmic Decision-Making, House of Commons Science and Technology Committee, HC 351, at 22–25 (2018) (UK) (recommending compensation mechanisms for automated decision harms).
[40] Securities and Exchange Board of India (Listing Obligations and Disclosure Requirements) Regulations, 2015, Reg. 34 (India) (governing disclosures in annual reports); The Companies Act, 2013, No. 18 of 2013, §§ 166–167 (India) (fiduciary duties of directors).
[41] Andrew D. Selbst & Solon Barocas, The Intuitive Appeal of Explainable Machines, 87 Fordham L. Rev. 1085, 1094–1100 (2018).

corporate actors accountable for the harms their algorithmic systems produce.

India's existing legal framework comprising the IT Act, the DPDP Act, consumer protection laws, and medical ethics regulations is structurally inadequate to the accountability demands of healthcare AI. The absence of mandatory transparency requirements, the underdevelopment of algorithmic liability doctrine, the inadequacy of informed consent mechanisms, and the absence of prospective risk governance instruments create a regulatory vacuum that places patient safety and welfare at serious risk.[42] The lessons of the EU AI Act and sector-specific developments in the United States demonstrate that effective AI governance is achievable without sacrificing innovation indeed, that robust accountability frameworks can build the public trust necessary for the sustainable, ethical deployment of AI in healthcare.

India stands at a regulatory crossroads. The choices made in the coming years regarding corporate accountability for algorithmic decision-making will determine whether the country's digital health revolution delivers on its transformative promise, or whether it reproduces and amplifies existing inequalities and harms at algorithmic scale. A comprehensive regulatory framework incorporating mandatory algorithmic impact assessments, differentiated liability standards, board-level governance obligations, and robust transparency and audit requirements is not merely a legal imperative. It is a moral and public health necessity.[43]

VII. CONCLUSION

India's healthcare sector stands at a critical inflection point where the promise of algorithmic innovation must be reconciled with the imperatives of patient safety, corporate accountability, and legal justice. This research has demonstrated that the existing legal architecture spanning the IT Act, the DPDP Act, consumer protection law, and medical ethics regulations is fundamentally inadequate to govern the complex accountability challenges posed by AI-driven healthcare systems. The problems of liability attribution, algorithmic opacity, discriminatory outcomes, inadequate consent mechanisms, and unchecked commodification of patient data collectively demand urgent and comprehensive legislative intervention. Drawing on comparative lessons from the EU AI Act and American sector-specific governance models, this study advocates for a purpose-built regulatory framework incorporating mandatory

[42] Sanjay Jain & Sanjiv Gupta, Regulating Artificial Intelligence in India: A Framework Analysis, 12 Indian J.L. & Tech. 1, 18–22 (2023).
[43] Virginia Eubanks, Automating Inequality: How High-Tech Tools Profile, Police, and Punish the Poor 211–15 (St. Martin's Press 2018).

transparency obligations, differentiated liability standards, algorithmic impact assessments, independent auditing mechanisms, and board-level corporate governance reforms. Ultimately, meaningful accountability for algorithmic decision-making is not an obstacle to healthcare innovation, it is its essential foundation.

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5. Commission Regulation 2016/679, 2016 O.J. (L 119) 1, https://eur-lex.europa.eu/eli/reg/2016/679/oj.

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