The Indian Journal for Research in Law and Management

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Editor-in-Chief – Dr. Muktai Deb Chavan; Publisher – Alden Vas; ISSN: 2583-9896

LEGAL ASPECTS OF ARTIFICIAL INTELLIGENCE IN HEALTHCARE IN INDIA: REGULATING THE UNSEEN DOCTOR

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INTRODUCTION

Artificial intelligence (AI) is revolutionizing healthcare worldwide, promising more accurate diagnostics and personalized treatment plans. Forbes estimates the global healthcare AI market will reach nearly **$200 billion by 2025**.[i] In India, thousands of digital health startups (over 10,000 companies) are already reshaping patient care.[ii] Government figures show India has only about *1 doctor per 1,457 people*, far below the WHO-recommended 1:1,000 ratio.[iii] AI tools—such as mobile apps, imaging algorithms, and remote-monitoring devices—hold special promise for both public hospitals and private clinics. For example, Indian innovators use AI-powered retinal scanners to detect diabetic eye disease in rural camps,[iv] and corporate hospitals employ AI "chatbots" and wearables for chronic-care management[v]. This blog examines India's evolving legal landscape for healthcare AI—especially in diagnostics and treatment—and focuses on liability, data protection, informed consent, bias, and the status of AI as a regulated medical device.

MEANING OF AI

AI broadly refers to computer systems that perform tasks normally requiring human intelligence, such as diagnosing disease or recommending treatment[vi]. Key AI techniques include machine learning (ML) and neural networks, which train on large datasets (e.g. medical images or electronic health records) to "learn" patterns. In healthcare, AI applications range from deep□learning imaging tools that detect tumours to natural-language processors that review clinical notes[vii]. There is no single formal definition of AI, but experts agree it involves "systems that interpret data, learn, and make decisions" much like a human clinician would[viii].

For our purposes, "AI in healthcare" encompasses software or devices (including robotics) that assist in medical diagnostics, treatment or monitoring without requiring direct human guidance for every decision.

LEGAL FRAMEWORK (DOMESTIC AND INTERNATIONAL)

Domestic (India). India currently has no comprehensive AI-specific law, so regulators rely on existing healthcare and technology statutes. Health data privacy is addressed in part by the *Information Technology Act, 2000* and proposed data protection legislation. The draft *Digital Personal Data Protection Bill (2022)* – recently enacted as a law – defines "sensitive personal data" to include health records[ix]. The Ministry of Health's *Electronic Health Record Standards (2016)* set norms for capturing and sharing patient data, and affirm patients' control over their data (including requiring specific consent for secondary uses). Crucially, the Supreme Court held in *K.S. Puttaswamy v. Union of India* that privacy is a fundamental right under the Constitution, anchoring patients' right to data confidentiality[x].

Medical devices (broadly defined) are regulated under the Drugs and Cosmetics Act, 1940. The *Medical Devices Rules, 2017 (MDR)* treat AI software with a medical purpose as a "medical device." In 2020, India's drug regulator explicitly expanded the MDR definition to cover software for diagnosis, prevention, monitoring or treatment of disease[xi]. This means many AI diagnostic tools (e.g. imaging algorithms) require registration or approval through the Central Drugs Standard Control Organization (CDSCO) before use. In January 2024 the government launched a "single window" portal to streamline device approvals, reflecting efforts to modernize regulation[xii]. However, there is still no dedicated agency or statute focused solely on medical AI. Health tech practitioners must navigate a patchwork of laws (IT Act, consumer safety laws, clinical norms, etc.) in the absence of AI-specific rules.

International. Globally, governments and agencies are developing AI governance principles that influence Indian policymaking. For example, the European Union's *General Data Protection Regulation (GDPR)*—enacted in 2018—imposes strict rules on processing health data and has inspired India's data protection laws[xiii]. International bodies like the World Health Organization (WHO) have emphasized safety, transparency and fairness in health AI. A recent WHO report (Oct. 2023) stressed that AI systems must be safe and effective, with rigorous testing and documentation throughout their lifecycle[xiv]. It specifically warns of privacy and bias risks, noting that health AI may access sensitive personal information and should therefore be

subject to robust regulatory frameworks[xv]. Similarly, the OECD and the UN have issued non-binding AI ethics guidelines (e.g. on algorithmic bias and accountability) that inform national policies.

LEGAL ISSUES

Liability for Errors: A central concern is medical malpractice and product liability when AI errs. If an AI diagnostic tool misses a tumor or recommends the wrong treatment, who is legally responsible? Traditional tort law focuses on the doctor's duty of care, but experts note that assigning fault is "legally ambiguous" when an opaque AI system is involved[xvi]. Current Indian law does not clearly cover AI harms. Under the Consumer Protection Act (2019), AI software might fall under the product liability regime (Section 2(34)), but this is untested in court. Scholars argue that it is illogical to hold only the physician liable for a machine's unexplained decision[xvii]. Instead, leading commentators suggest joint liability: developers (and possibly institutions) should share responsibility alongside clinicians when an AI error causes injury.[xviii]

Data Protection and Privacy: AI systems require huge amounts of personal health data, raising serious privacy issues. Indian law classifies health records as "sensitive personal data," which receives the highest protection under the new data law[xix]. Any unauthorized use or breach of such data can incur heavy penalties (up to ₹5 crore or 2% of global turnover for businesses)[xx]. Importantly, patients (as data owners) retain ongoing control: they must be informed about how their records are used, and must consent explicitly before their data are used for non-care purposes. Proposed legislation (the *Digital Information Security in Healthcare Act*, or DISHA) would strengthen this by treating individual health data as a trust belonging to the patient.[xxi]

Informed Consent: The integration of AI transforms what informed consent means in healthcare. Traditionally, patients consent to a doctor's treatment plan, but it is far less common for them to consent to an AI's involvement or data use. Scholars argue that AI should be disclosed to patients: patients ought to know if an AI is assisting diagnosis or if their data is being used to train algorithms[xxii]. Legal experts recommend new guidelines specifically for medical AI: doctors should explain (in simple language) the role and limits of any AI system used, and must obtain consent if patient data will be analyzed beyond immediate care.

Algorithmic Bias and Fairness: AI can inadvertently encode and amplify societal biases. If the data used to train an AI reflects historical discrimination (gender, race, socio-economic status), the AI's outputs will mirror those patterns. Experts warn this risk is acute with "black-box" AI models that lack explainability.[xxiii] Without transparency, bias can go undetected. Mitigating bias requires deliberate steps: developers should use diverse training datasets, conduct regular bias audits, and involve stakeholders (e.g. community representatives and ethicists) in design and testing[xxiv].

CONCLUSION

AI promises significant benefits for India's public and private healthcare, especially in diagnostics and patient monitoring. Yet reaping those benefits safely requires robust legal guardrails. Policymakers face difficult trade-offs: on one hand, India needs flexible rules to encourage innovation; on the other, patients must be protected against AI-related harms. Key priorities include ensuring strong data privacy and consent regimes, clarifying liability so victims can be compensated, and enforcing standards that prevent discriminatory AI outcomes. Although India lacks bespoke AI healthcare laws today, recent steps (like PDPA, digital health missions, and device rule updates) indicate growing momentum. Moving forward, stakeholders must collaborate to innovate responsibly, ensuring that AI in diagnostics and treatment improves health for all Indians without compromising ethics or the rule of law.

ENDNOTES

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[ii] Ibid
[iii] Press Information Bureau, *Health Infrastructure in India*, Press Release, Ministry of Health and Family Welfare, PIB (2022), https://pib.gov.in/
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[v] Ibid
[vi] Supranote - 1
[vii] Ramneek Kaur, Privacy in the Age of Artificial Intelligence: An Indian Perspective, 17.2 UILS (2023) 114
[viii] Ibid
[ix] Ibid
[x] Justice K.S. Puttaswamy v. Union of India, (2017) 10 SCC 1 (India)
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[xxii] Rose Angelique Dizon, A New Way of Healing: Regulating Healthcare AI, 64 ATENEO L.J. 1127 (February 2020).
[xxiii] Ramneek Kaur, Privacy in the Age of Artificial Intelligence: An Indian Perspective, 17.2 UILS (2023) 114
[xxiv] Ibid