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Legal Certainty in the Use of Artificial Intelligence for Healthcare and Medical Diagnosis

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Abstract

The integration of artificial intelligence into healthcare promises to revolutionize medical diagnostics and service delivery. However, rapid technological advancement has outpaced the development of a specific legal framework, creating significant legal uncertainty. This study aims to examine Indonesia's legal framework for medical artificial intelligence, identify key regulatory gaps, and propose an adaptive legal model to ensure safe and ethical artificial intelligence adoption. Using a normative juridical approach with statutory, conceptual, and comparative analyses, the study finds that current regulations, including Law Number 17 of 2023 on Health and Law Number 11 of 2008 on Information and Electronic Transactions, provide general but insufficient guidance. Critical issues such as liability for artificial intelligence-induced errors, data governance, algorithmic transparency, and patient consent remain unresolved. This regulatory gap poses risks to patients, healthcare providers, and technology developers. The absence of a robust, adaptive legal framework undermines legal certainty and patient protection, limiting trust and safe adoption of artificial intelligence in healthcare. The study proposes a tiered regulatory model based on international best practices to ensure accountability and foster confidence in artificial intelligence-driven medical services.

Keywords

Artificial Intelligence, Healthcare, Legal Certainty, Medical Diagnostics, Patient Protection.

1. Introduction

The global healthcare sector is undergoing a digital transformation, where human intuition and machine precision increasingly converge. At the core of this change is Artificial Intelligence (AI), which has the potential to redefine patient care and medical discovery (Davenport & Kalakota, 2019; Ahuja, 2019; Fauziah et al., 2024). Through machine learning and deep learning, AI can analyze complex medical data from genomic sequences to radiological images to detect patterns beyond human cognition. This enables hyper-personalized treatments, predictive diagnostics, and unprecedented optimization of healthcare resources (Topol, 2019; Akzatria, 2023; Caesar, 2025).

For Indonesia, an archipelago with significant healthcare disparities, AI offers urgent potential. The country faces a chronic shortage of medical experts, especially in rural and remote areas (Wenang et al., 2021). AI can act as a "force multiplier," providing expert-level diagnostic support in community health centers (*Puskesmas*) and empowering general practitioners and nurses to make accurate decisions (Habibi & Haryati, 2021). This democratization of expertise could reduce health inequities between urban and remote regions (Syam, 2019; Lamem et al., 2025). Early studies show AI's high accuracy in diagnosing cardiovascular conditions using local data, highlighting its promise as a vital clinical ally (Ghassemi et al., 2021; Rayyan & Simarmata, 2025).

However, this promise is overshadowed by significant legal challenges. AI development has far outpaced legal reform, creating uncertainty that threatens the healthcare system. The introduction of autonomous and semi-autonomous systems in high-stakes medical diagnosis raises complex legal and ethical issues that Indonesia's current framework cannot address (Librianty & Prawiroharjo, 2023). Misdiagnoses caused by AI, especially when algorithms reflect systemic biases, create ambiguity over liability, whether it lies with the physician, the hospital, the developer, or potentially the AI itself as a novel legal entity.

This state of ambiguity is the direct result of a legal framework that is reactive, fragmented, and inadequate. The new omnibus Law Number 17 of 2023 concerning Health, while mandating a digital transformation, speaks in the broad, aspirational language of policy rather than the precise, enforceable language of regulation. Its implementing regulation, Government Regulation Number 28 of 2024, gestures toward innovation by permitting technologies "in accordance with the development of science and technology." This phrase, while intended to be future-proof, functions as a regulatory vacuum, offering no specific standards, validation requirements, or safeguards for high-risk medical AI.

Attempts to apply existing laws to AI have proven futile. Law Number 11 of 2008 concerning Information and Electronic Transactions (*Undang Undang Informasi dan Transaksi Elektronik*/UU ITE) defines an "Electronic Agent," but this concept, designed for deterministic e-commerce processes, cannot accommodate the probabilistic and adaptive logic of AI, leaving accountability unclear (Firza et al., 2024). Similarly, Law Number 27 of 2022 concerning Personal Data Protection (*Undang Undang Perlindungan Data Pribadi*/UU PDP) mandates transparency and informed consent, yet the "black box" nature of AI makes truly informed consent practically impossible (Vayena et al., 2018; Ermita et al., 2024).

This legislative patchwork creates a landscape of profound legal uncertainty a state where laws are ambiguous, conflicting, and incapable of providing predictable guidance, thereby chilling innovation and endangering patients (Simbolon & Sh 2022; Juang et al., 2025). This regulatory gap has been identified as a critical barrier globally but in Indonesia, the silence of the law is particularly hazardous (Price et al., 2019). Previous analyses have highlighted these fragmented concerns, Mutiah et al. (2025) on telemedicine liability, Rayyan and Siregar (2025) on technology-

induced error, but a holistic, narrative analysis of the cumulative failure of legal certainty remains a critical research gap.

This article aims to address this gap by providing a comprehensive normative-juridical analysis of Indonesia's legal ambiguity surrounding medical AI. The study aims to examine the adequacy of existing laws, identify critical regulatory gaps affecting liability, data governance, and patient rights, and propose an adaptive legal framework to support safe and ethical AI adoption. It evaluates how Indonesia's current regulations are insufficient in governing AI in healthcare, identifies key legal gaps that compromise accountability and patient protection, and explores how international best practices can inform the development of a robust and adaptive legal framework for AI in medicine. By dissecting this legal vacuum and benchmarking it against emerging international regulatory philosophies, this research will demonstrate the urgent and unavoidable necessity for a *sui generis*, adaptive, and robust legal framework. Without such a framework, Indonesia's healthcare system will be navigating its intelligent future without a map, a compass, or an anchor.

2. Methods

To dissect the intricate layers of this legal ambiguity, this research employs a normative juridical (doctrinal) research methodology. This approach is anchored in the hermeneutic analysis of legal texts, focusing on the law as a system of norms, principles, and doctrines as they are written (*das sollen*). The primary objective is not to measure empirical outcomes but to construct a coherent legal argument, interpreting and synthesizing legal sources to expose internal contradictions, logical fallacies, and, most critically, regulatory gaps (*rechtsvacuüm*) (Marzuki, 2017).

The investigation is conducted through a multi-pronged analytical strategy. First, the statutory approach forms the core of the analysis, involving a meticulous inventory and hierarchical interpretation of Indonesia's laws. This approach systematically deconstructs the content of relevant legal instruments to map their intended scope and, more importantly, to identify their limitations in addressing AI. Second, the conceptual approach moves beyond the black-letter law to examine foundational legal concepts that AI destabilizes. It explores how doctrines of legal certainty, liability, standard of care, and informed consent are stretched, altered, or undermined by the introduction of AI into medical practice. Third, the comparative approach provides an essential external benchmark, critically juxtaposing Indonesia's framework with emerging regulatory architectures such as the European Union's AI Act and the United States' FDA Software as a Medical Device (SaMD) framework. This comparison highlights international best practices and exposes both the philosophical and practical deficits of Indonesia's current legal framework.

Data for this doctrinal study are drawn exclusively from secondary sources. Primary legal materials include the 1945 Constitution of the Republic of Indonesia; Law Number 17 of 2023 on Health; Government Regulation Number 28 of 2024; Law Number 11 of 2008 on Information and Electronic Transactions (as amended); Law Number 27 of 2022 on Personal Data Protection; and associated Minister of Health regulations. Secondary legal materials comprise a comprehensive corpus of peer-reviewed journals in law, technology, and bioethics; foundational legal textbooks; government policy documents such as Indonesia's National AI Strategy; and official guidelines from international bodies like the World Health Organization (WHO). The analytical process is qualitative and descriptive-analytical, involving the narration of legal norms, systematic analysis of conflicts between them, and the application of legal reasoning to develop a prescriptive argument for fundamental regulatory reform.

3. Results and Discussion

3.1. The Normative Legal Framework: A Tapestry of Ambiguity

To lay the foundation for understanding Indonesia's regulatory challenges in medical AI, this study first examines the principle of legal certainty (*rechtssicherheit*). As articulated by legal theorists like Hadjon (1987), this principle is the bedrock of the rule of law, demanding that legal norms be clear, consistent, and predictable. It is this predictability that allows individuals and institutions, in this case, doctors and hospitals, to structure their conduct with confidence in the legal consequences (Prawiroharjo & Librianty, 2017). The introduction of a disruptive technology like AI, which is inherently probabilistic and dynamic, shatters this stability, introducing novel scenarios that existing legal doctrines were never designed to contemplate. This ambiguity is intensified by the precautionary principle, a core tenet of health and environmental law, which posits that in the face of uncertain but potentially catastrophic risk, preventative measures are not just justified but required (Foster et al., 2000).

A granular examination of Indonesia's legal architecture reveals not a coherent framework, but a precarious tapestry of generalist laws, each failing in its own way to govern the specific challenges of medical AI (Mutiah et al., 2025). This is not a simple gap but a systemic failure of provision. The journey begins with the new omnibus Law Number 17 of 2023 concerning Health. This law, celebrated for its modernizing agenda, champions a "digital transformation" and formally legitimizes telemedicine. However, it remains a document of broad policy aspirations rather than granular legal control (Wijayanti et al., 2024). Its implementing regulation, Government Regulation Number 28 of 2024, exemplifies this problem. It vaguely permits telemedicine services that are "in accordance with the development of science and technology." (Dalimunthe et al., 2024) This clause, intended to be flexible, instead operates as a void. It provides no technical standards, no validation requirements, no auditing mechanisms, and no specific prohibitions. It essentially green-lights a high-risk technology with no safety manual, leaving the crucial details of patient safety entirely to the discretion of developers and providers, rather than the mandate of the law.

Searching for more specific rules, the legal analyst naturally turns to Law Number 11 of 2008 concerning Information and Electronic Transactions (*Undang Undang Informasi dan Transaksi Elektronik*/UU ITE). The "Electronic Agent" concept, a legal construct for an automated device that performs an action on specific electronic information automatically, is organized by a person (Article 1). Some scholars have attempted to force AI into this box, but the analogy is deeply flawed (Firza et al., 2024). An electronic agent, in the context of UU ITE, is a deterministic tool, like an e-commerce checkout system, which executes a pre-programmed command. Its "organizer" is clearly and fully liable. A medical AI, particularly a deep learning model, is the antithesis of this. It is a probabilistic, adaptive system. It learns from new data and can generate outputs that were not explicitly programmed. It is not a simple tool; it is a predictive partner. To apply the "Electronic Agent" model is to fundamentally misunderstand the technology, and in doing so, it creates a loophole for accountability, as the developer can argue the AI's decision was not one they organized.

Finally, we encounter Law Number 27 of 2022 concerning Personal Data Protection (*Undang Undang Perlindungan Data Pribadi*/UU PDP). This law is modern and robust, correctly identifying the need for informed consent as the bedrock of data processing. Yet, it inadvertently creates an insurmountable barrier for AI. The law demands that consent be based on a clear understanding of the data processing's purpose and logic. This directly conflicts with the "black box" problem, a core attribute of many advanced AI models, where the path from input (patient data) to output (diagnosis) is mathematically so complex that it is non-interpretable,

even to its designers, raising the issue of how physicians can obtain legally valid consent for a process they cannot explain and how patients can provide informed consent to a logic they cannot understand. The UU PDP, while well-intentioned, fails to provide a legal pathway for this new technological reality, placing physicians in a state of perpetual legal jeopardy: either they violate the UU PDP by using the tool, or they fail their patient by not using the best tool available. This composite failure, a health law that is too vague, an ITE law that is irrelevant, and a data law that is too rigid, creates the perfect storm of legal uncertainty.

3.2. Identification of Critical Regulatory Gaps

Building on this understanding of the limitations of existing law, the study next identifies the critical regulatory gaps, particularly concerning liability. Traditional medical malpractice law is built upon a human-centric "standard of care." AI detonates this model by inserting a non-human agent into the chain of causation. Legal scholars are now in a vigorous debate, attempting to map old doctrines onto this new terrain. Some explore vicarious liability, arguing that a hospital "employs" an AI in the same way it employs a human doctor and should thus be liable for its errors. Others turn to product liability, treating the AI algorithm as a "defective product" (Pasquale, 2019; Gerke, 2020). This debate reveals that our existing legal tools are imperfect, struggling to assign fault in a system where decision-making is diffuse and opaque.

Frontline physicians are among the most exposed to legal and professional risk, as traditional malpractice law is grounded in the concept of the "standard of care," which establishes what a reasonable and prudent medical professional would be expected to do under comparable circumstances. AI shatters this benchmark. Imagine a physician presented with an AI's diagnostic recommendation. If the physicians follow the AI's advice and it turns out to be wrong, is the physician negligent for "blindly" trusting a machine? The plaintiff will argue that a reasonable doctor would have used her own judgment. But what if the physicians ignore the AI's correct advice, rely on their own intuition, and the patient is harmed? The plaintiff will now argue that she was negligent for failing to heed a diagnostic tool. The law provides no guidance, trapping the physician in a state of legal checkmate. This uncertainty fosters a culture of "defensive medicine," where clinical decisions are dictated not by the patient's best interest, but by a rational fear of litigation (Price et al., 2019).

The institution's exposure arises because the healthcare institution, whether a hospital or clinic, faces a different but equally potent threat under the doctrine of vicarious liability. By procuring and deploying an AI system, the hospital is not merely providing a tool but also making an implicit promise to its patients that the tool is safe and effective (Ghassemi, 2021). When that tool fails, the institution is on the hook. The hospital becomes liable for the "actions" of its AI "employee." This exposure is amplified by the fact that the institution often lacks the deep technical expertise to independently validate an algorithm. They must trust the developer's claims, making them financially and legally vulnerable to failures they cannot predict or control (Gerke, 2020).

The developer's shield arises because the AI developer, who is arguably the most responsible for the product's logic, is paradoxically the most protected. Under a product liability claim, a patient would have to prove the AI was "defective." But in a "black box" system, this is a near-impossible burden of proof (Price et al., 2019). The developer can argue the "defect" was not in their code, but in the biased hospital data it was trained on, or in the physician's interpretation of its probabilistic output. This opacity acts as a powerful legal shield. The result is a system where the party with the most control has the least liability, while the party with the least control, the physician, has the most. This diffusion of responsibility is not only unjust; it is a

direct threat to patient safety, as it removes the primary incentive for creating safer, more transparent, and more accountable AI.

3.3. Proposing a Legal Framework for Safe and Ethical AI Adoption

This brings us to the third and most crucial discourse: the search for a new regulatory paradigm. Recognizing the failure of old laws, jurisdictions globally are architecting sui generis (unique) frameworks. The European Union's AI Act stands as a landmark proposal, pioneering a risk-based philosophy. It classifies medical AI as "high-risk," subjecting it to a gauntlet of pre-market conformity assessments, post-market surveillance, and stringent demands for human oversight and transparency (European Commission, 2021). In parallel, the U.S. Food and Drug Administration (FDA) is developing a "Software as a Medical Device" (SaMD) framework, adopting a total product lifecycle approach. This model is uniquely adaptive, allowing AI to learn and evolve post-deployment through a "predetermined change control plan" that ensures safety is maintained as the algorithm grows "smarter" (Brown, 2021). These international models are not mere academic exercises; they are the first drafts of the legal future, providing an essential comparative lens through which to analyze the profound emptiness of Indonesia's current legal stance. The challenges facing Indonesia, while profound, are not insurmountable. A cohort of nations is already charting a course through this uncharted legal territory, and their efforts provide a crucial blueprint for reform. The regulatory philosophies emerging from the European Union and the United States are particularly instructive, as they reject a one-size-fits-all approach in favor of a nuanced, risk-based framework.

The European Union's AI Act is a lesson in structured governance. It meticulously categorizes AI systems based on their potential for harm. An administrative scheduling AI is "low-risk," but a medical diagnostic AI is designated "high-risk" (European Commission, 2021). This high-risk designation triggers a cascade of stringent legal obligations: pre-market conformity assessments to prove safety and accuracy, robust post-market monitoring systems to catch real-world errors, and a non-negotiable requirement for human oversight. This model provides clarity, telling developers exactly what standards they must meet. In contrast, the US FDA's "Software as a Medical Device" (SaMD) framework is a lesson in adaptive governance (Brown, 2021). It embraces the fact that AI is not a static product but a dynamic one that learns and evolves. The FDA's "predetermined change control plan" allows a developer to get pre-approval for future updates to its algorithm. This brilliant solution fosters innovation by allowing AI to improve, while ensuring safety by requiring the developer to prove that its "learning" will stay within safe and validated boundaries.

From these international models, a clear path for Indonesia emerges. The solution is neither to ban AI nor to continue with the current *laissez-faire* ambiguity; rather, it lies in building a *sui generis* regulatory architecture that is both structured and adaptive. This study proposes the urgent formulation of a new Government Regulation (*Peraturan Pemerintah*/PP) dedicated specifically to AI in healthcare, built upon a three-tiered risk-based model. Tier 1, low-risk, covers AI used for non-clinical tasks such as billing, patient scheduling, or general wellness apps, which pose minimal risk to patient safety; regulation here should be light-touch, focusing primarily on data privacy and security under the existing mandate of the UU PDP (Mökander et al., 2021). Tier 2, medium-risk, encompasses the majority of medical AI as clinical decision support tools that assist, but do not replace, human experts for example, algorithms that flag suspicious nodules on CT scans for radiologists' review. Regulation for this tier must be robust, mandating clinical validation overseen by the Ministry of Health, algorithmic transparency including intended use, limitations, training data, and known biases, post-market surveillance through a national registry for adverse events, and a defined standard of care clarifying that

final legal and ethical responsibility rests with the licensed human clinician (Amann et al., 2020). Tier 3, high-risk, governs autonomous AI capable of making final diagnoses or directing treatment with minimal human oversight (Shneiderman, 2020). These systems require stringent controls, including rigorous clinical trials equivalent to those for new pharmaceuticals or high-risk medical devices, mandatory human-on-the-loop oversight, and clear liability mechanisms such as mandatory insurance for developers or a no-fault compensation fund to ensure patient protection. This tiered architecture would finally provide the legal certainty that Indonesia's healthcare system desperately needs. It would create clear rules for innovators, provide a safe harbor for physicians, and build a foundation of public trust, allowing Indonesia to finally and safely harness the immense, life-saving potential of artificial intelligence.

4. Conclusion

Indonesia's current legal framework for medical AI is fragmented and insufficient, leaving critical issues such as liability for AI-induced errors, data governance, and patient protection unresolved. This legal ambiguity diffuses accountability, exposes healthcare providers to risk, and undermines public trust in AI-driven healthcare services. To address these gaps, this study proposes a risk-stratified, tiered legal framework: at the foundational level, responsibilities, data protection, and patient consent should be clarified under existing laws; at the operational level, sector-specific guidelines should establish validation standards, algorithmic transparency, and human oversight; and at the strategic level, an adaptive oversight body should monitor AI innovation, ensure compliance with international standards, and update regulations as technology evolves.

This research contributes to understanding the interplay between legal certainty, technology governance, and patient rights, demonstrating how normative legal analysis can inform policy design in emerging technological domains. This research provides policymakers with a structured model to establish clear standards for validation, algorithmic transparency, human oversight, and liability, thereby protecting patients, supporting physicians, and fostering public trust in AI-driven healthcare.

This study has certain limitations. As normative-juridical research based on secondary sources, it does not empirically evaluate real-world implementation challenges of AI in Indonesian healthcare institutions. Further research could include empirical studies examining stakeholder readiness, the effectiveness of proposed regulations, and comparative analyses with jurisdictions that have already implemented AI-specific legal frameworks. Such studies would complement the normative foundation established in this research, helping to ensure that Indonesia's regulatory landscape for artificial intelligence is practical, effective, and capable of safely harnessing AI's life-saving potential in healthcare.

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The data that support the findings of this study are available from the corresponding author upon reasonable request.