



LEGAL ASPECTS OF THE USE OF ARTIFICIAL INTELLIGENCE FOR MEDICAL DIAGNOSIS UNDER LAW NO. 17 OF 2023 ON HEALTH AND LAW NO. 27 OF 2022 ON THE PROTECTION OF PERSONAL DATA

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ABSTRACT

Health is a fundamental human right guaranteed by various international and national legal instruments, including the 1945 Constitution and Law No. 17 of 2023 on Health. The state has a responsibility to provide adequate health facilities and services to achieve the optimal level of public health. With the development of information technology, innovations such as Artificial Intelligence (AI) are beginning to be utilized in the health sector, particularly in medical diagnosis, as they can improve the accuracy and efficiency of services. The use of AI in medical diagnosis is supported by regulations that encourage health technology innovation, yet it also poses various challenges, particularly regarding ethical considerations, trust, accountability, and the protection of patients' personal data as stipulated in Law No. 27 of 2022. Additionally, the use of AI requires proper risk management to uphold the principles of fairness, transparency, and security. Although regulatory frameworks related to health, technology, and data protection are in place, specific regulations regarding the use of AI in medical diagnosis remain unclear and incomplete. This creates legal uncertainty, particularly regarding liability in the event of a misdiagnosis. Therefore, the development of more detailed regulations is necessary to provide legal certainty and ensure that the use of AI in healthcare services is safe, ethical, and responsible. This study aims to explore the legal aspects of the use of Artificial Intelligence (AI) in medical diagnosis, in light of Law No. 17 of 2023 on Health and Law No. 27 of 2022 on Personal Data Protection. Patient data is a valuable asset that is not only sensitive but also vulnerable to misuse. The integration of AI in diagnosis requires access to large amounts of patient data to train algorithms and improve diagnostic accuracy. This study falls under the category of normative legal research, which focuses on legal norms found in legislation, legal doctrine, and other relevant regulations. It analyzes the legal framework, expert opinions, and relevant case studies to assess how AI can be integrated into the healthcare system while ensuring compliance with data protection regulations and safeguarding patients' rights. This study investigates the implications of these laws on AI applications in medical diagnostics, with a focus on data security, patient consent, and the ethical use of AI in healthcare. It also examines how AI developers and healthcare providers must navigate these regulations to ensure privacy and transparency. The findings reveal that while this legislation provides a strong foundation for data protection in AI-based healthcare, challenges remain in its implementation.

Keywords: artificial intelligence; data protection; legal aspects

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INTRODUCTION

Artificial Intelligence (AI) has demonstrated significant potential in the medical field, particularly in diagnosing and treating patients (Ambar et al., 2024). This technology enables the analysis of large volumes of medical data, such as electronic health records, laboratory results, and medical imaging, to generate rapid and accurate diagnoses (Abdillah, 2024). AI not only improves diagnostic efficiency but also drives the development of more precise medical methodologies. Schuett (2023) emphasizes that AI regulation should not rely on general definitions but must adopt a risk-based approach, focusing on specific risks associated with technical methodologies, applications, or capabilities. This approach ensures that regulations are targeted without hindering technological progress. The integration of AI into healthcare offers substantial benefits, including faster patient management and a reduction in diagnostic errors (Christine & Kansil, 2023).

The rapid development of AI has introduced ethical issues and challenges in gaining public trust. AI-generated diagnoses significantly influence medical decisions, which require patient trust in the technology. Accuracy, transparency, and fairness are key factors in fostering trust (Asadi, 2024). According to the Financial Services Authority (2023), the responsible and trustworthy implementation of AI must adhere to the principles of fairness, accountability, transparency, and security. These principles aim to ensure that AI applications not only enhance operational efficiency but also reduce inequality, promote inclusion, and uphold ethical values rooted in Pancasila. However, concerns regarding errors or excessive reliance on AI remain major obstacles that require comprehensive risk mitigation through a clear regulatory framework before AI can be widely adopted in the medical field (Jingga & Mufidi, 2024).

The use of AI in medical diagnosis raises concerns regarding privacy and data security. Patient data is highly sensitive and vulnerable to misuse (Adelaja & Alkattan, 2023). AI-based diagnostics require access to extensive patient data to train algorithms and improve diagnostic accuracy, posing challenges in ensuring the ethical and secure use of data. The increasing risk of privacy breaches in the digital age further complicates this issue (Indina, 2024). Legal frameworks play a crucial role in addressing these issues, protecting patients, medical professionals, and technology developers by ensuring compliance with medical standards and patient rights. The involvement of various stakeholders, including healthcare providers and regulators, adds to the complexity of AI governance (Sastria et al., 2024). The European Commission's EU AI Act aims to regulate risks related to health, safety, and fundamental rights, ensuring that the adoption of AI aligns with the values of democracy, the rule of law, and environmental protection (European Commission, 2024).

The Indonesian government has taken steps to regulate AI in healthcare through various laws and policies. Health Law No. 17 of 2023 establishes a legal framework to support medical innovation and technology, ensuring high-quality and safe healthcare services (Disemadi, 2021). Additionally, Regulation of the Minister of Communication and Information Technology No. 9 of 2023 outlines guidelines for non-tax state revenue in the digital sector, reflecting efforts to manage information and communication technologies that impact health (Minister of Communication and Information Technology, 2023). The Personal Data Protection Act No. 27 of 2022 mandates data controllers to safeguard individual privacy, particularly in AI-based diagnostics that require access to sensitive patient data. Despite existing regulations, challenges remain in enforcement and oversight, particularly regarding technical and operational standards for healthcare providers and technology developers (Bajwa et al., 2021).

This study aims to examine how Law No. 17 of 2023 on Health supports the use of AI in medical diagnosis in Indonesia and to analyze patient data protection in AI-based diagnostics under Law No. 27 of 2022 on Personal Data Protection. Identifying regulatory gaps and proposing policy recommendations will help establish a robust legal framework that ensures the adoption of AI in healthcare is safe, responsible, and aligned with legal principles that protect patients' rights.

METHOD

This study employs a normative legal research approach, which focuses on the study of legal norms found in legislation, legal doctrine, and other relevant regulations (Muhaimin, 2020). The purpose of this approach is to understand, analyze, and interpret existing legal provisions. Specifically, this study examines Law No. 17 of 2023 on Health and Law No. 27 of 2022 on Personal Data Protection, particularly regarding the use of artificial intelligence in medical diagnosis. The normative legal method allows for an in-depth exploration of legislation to assess its implications and application in the healthcare sector.

The legal sources in this study are categorized into primary and secondary sources (I Made, 2016). Primary sources consist of official legal documents, specifically Law No. 17 of 2023 and Law No. 27 of 2022, which serve as the fundamental legal framework for analyzing the use of artificial intelligence in medical diagnosis and patient data protection. Secondary sources include books, articles, scientific journals, and previous studies discussing artificial intelligence in healthcare, personal data protection, and relevant regulatory frameworks. These secondary sources provide a theoretical foundation and broader contextual insights to support the interpretation of legal provisions.

The data collection techniques involve systematic documentation and a literature review (Sugiyono, 2019). The documentation method requires the collection of legal regulations and related documents regarding the advancement of artificial intelligence in healthcare policy and personal data protection. Meanwhile, the literature review involves examining academic sources that outline legal theories, expert opinions, and analyses related to the application of artificial intelligence in medical diagnosis. This method ensures a comprehensive understanding of the legal framework governing artificial intelligence in the healthcare industry.

The data analysis in this study follows a normative approach, which involves the interpretation and discussion of legal material based on legal definitions, norms, theories, and doctrines relevant to the research problem. Legal norms serve as the major premise, while legal facts act as the minor premise. Through the process of legal reasoning, particularly syllogism, conclusions regarding the legal implications of artificial intelligence in medical diagnosis and data protection can be formulated. This analytical method provides a structured way to evaluate the legal status and potential regulatory challenges surrounding artificial intelligence in healthcare.

RESULT

Based on a normative legal analysis of Law No. 17 of 2023 on Health and Law No. 27 of 2022 on Personal Data Protection (PDP Law), this study identifies two primary pillars regarding the legality and governance of Artificial Intelligence (AI) in medical diagnostic systems in Indonesia.

Legal Framework for Medical AI under Law No. 17 of 2023 on Health

The integration of AI technology into medical scanning and diagnostic practices is normatively supported by the Health Law as part of modernizing public healthcare services. This regulation emphasizes that the application of AI aims to enhance diagnostic accuracy, operational efficiency, and minimize the rate of medical errors. Nevertheless, its implementation is governed by several substantive legal provisions

1. **Clinical Testing and Validation**, Any software or AI algorithm utilized as a diagnostic decision-support tool is categorized as healthcare technology that must undergo rigorous clinical trials, quality standard validation, and receive official approval from competent health authorities prior to deployment in healthcare facilities.
2. **Professional Accountability (Human Oversight)**, The Health Law explicitly stipulates that AI operates strictly as a decision-support tool rather than a replacement for medical professionals. Consequently, ultimate responsibility for diagnostic interpretations and final clinical decisions remains fully with medical practitioners (physicians).
3. **Legal Liability Framework**, Should a misdiagnosis occur as a result of AI implementation, the Health Law establishes a framework for shared liability among executing healthcare practitioners, healthcare facilities, and technology developers.

Patient Personal Data Protection under Law No. 27 of 2022 (PDP Law)

Given that AI models rely on processing vast volumes of medical data (big data), the PDP Law enforces stringent standards to protect patient rights

1. **Informed Consent for Data Processing**, The collection, processing, and training of algorithms using patient medical records require explicit consent from patients after they receive transparent information regarding the specific purposes of data usage.
2. **Data Minimization and Purpose Limitation**, Data controllers are restricted to collecting and processing only health data that is relevant and strictly necessary for specific diagnostic purposes, thereby preventing data exploitation.
3. **Cybersecurity and Data Encryption**, Providers operating AI systems in healthcare facilities are obligated to implement high-level technical safeguards—such as encryption, anonymization/pseudonymization, and strict access controls—to prevent data breaches within cloud infrastructures.
4. **Data Subject Rights and Audit Obligations**, Patients possess the legal right to access, rectify, and request the deletion of their personal data from AI systems. Conversely, service providers and developers are required to conduct periodic data protection audits and promptly report any data breach incidents to authorities.

DISCUSSION

The integration of Artificial Intelligence (AI) into the national healthcare system offers a significant technological leap forward by analyzing high-value clinical data—such as medical imaging (radiology/pathology), electronic health records, and laboratory results—with remarkable speed and precision. However, the adaptation of this technology introduces complex legal discourses, particularly when confronted with operational regulatory gaps in Indonesia.

Dialectics of Legal Liability and the "Human-in-the-Loop" Doctrine

A fundamental issue arising under Law No. 17 of 2023 is the determination of legal liability when medical malpractice occurs due to an erroneous AI diagnostic recommendation. Doctrinally, health law in Indonesia adopts the "Human-in-the-Loop" approach, holding that artificial intelligence lacks legal personhood and cannot be held legally accountable.

Challenges arise from the inherent nature of deep learning algorithms, often described as the "black box problem," where the internal reasoning behind an AI-generated decision remains opaque. When a diagnostic error occurs, disentangling whether the fault stems from physician negligence (medical negligence), an algorithmic/software defect from the developer, or biased historical training data becomes exceptionally complex. Consequently, medical practitioners are legally required to exercise due diligence by re-verifying all AI outputs before executing clinical actions. Existing legal frameworks necessitate detailed implementing regulations to clearly delineate the boundaries of liability among physicians, healthcare institutions, and technology developers.

The Dilemma of Healthcare Big Data and Patient Privacy Protection

The operationalization of diagnostic AI heavily depends on access to massive health datasets (big data). Under Law No. 27 of 2022, health data is classified as specific/sensitive personal data, thereby requiring the highest level of legal protection.

Conventional informed consent models prove insufficient when patient health data is continuously processed for future AI model retraining and algorithmic updates. A dynamic and transparent consent mechanism is required, granting patients revocable consent rights without compromising their access to healthcare services. Furthermore, because AI diagnostic processing extensively

utilizes cloud computing, the risk of cyberattacks and unauthorized access increases substantially. Healthcare providers must balance innovation with cybersecurity by conducting continuous Data Protection Impact Assessments (DPIA) and security audits to ensure big data integration does not breach patient confidentiality.

Urgency of Risk-Based Implementing Regulations

Although Law No. 17 of 2023 and Law No. 27 of 2022 establish solid macro-level foundations, regulatory gaps persist regarding technical operational standards for medical AI in Indonesia. Aligning with global regulatory developments—such as the EU AI Act—and academic perspectives (e.g., Schuett, 2023), Indonesia needs to adopt a risk-based regulatory framework.

Under this approach, diagnostic AI systems that handle critical health conditions posing high risks to patient safety must be subjected to stringent regulatory oversight, including digital medical device certification and algorithmic transparency (explainable AI). Technical implementing regulations—such as Government Regulations or Minister of Health Regulations—are urgently needed to prevent diagnostic bias and discrimination in care delivery, ensuring that medical AI is deployed safely, ethically, transparently, and in harmony with national values.

CONCLUSION

In conclusion, the integration of Artificial Intelligence (AI) into medical diagnosis holds significant potential for improving healthcare delivery, but it also presents various legal challenges. Based on Law No. 17 of 2023 on Health and Law No. 27 of 2022 on Personal Data Protection, it is important to ensure that AI applications in the healthcare sector comply with legal requirements regarding patient rights, privacy, and data security. These regulations emphasize the need to obtain explicit consent from patients before using their data, implement robust security measures, and adhere to the principle of data minimization to prevent misuse and ensure that patient data is used only for legitimate medical purposes. Additionally, healthcare providers and AI developers must continuously update their practices to align with the evolving legal framework and technological advancements.

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