West Science Law and Human Rights
Vol. 4, No. 03, October 2026, pp. 406~414

Artificial Intelligence in Healthcare: Assessing Patient Protection Under Law No. 17 of 2023 and Article 28H, Paragraph (1) of the 1945 Constitution

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Article Info

Article history:

Received Oct, 2026
Revised Oct, 2026
Accepted Oct, 2026

Keywords:

Artificial Intelligence
Patient Protection
Healthcare Law
Constitutional Rights
Legal Accountability

ABSTRACT

The integration of artificial intelligence (AI) into healthcare presents significant legal challenges concerning patient safety, data protection, and medical accountability. This study examines the adequacy of Indonesia's constitutional and statutory frameworks in protecting patients receiving AI-assisted healthcare services and identifies regulatory measures necessary to strengthen legal certainty. Employing a normative juridical approach, the research analyzes Article 28H(1) of the 1945 Constitution, Law No. 17 of 2023 concerning Health, and Law No. 27 of 2022 concerning Personal Data Protection through statutory, conceptual, and doctrinal legal analysis. The findings demonstrate that existing regulations provide a substantive foundation for patient rights, informed consent, professional responsibility, and medical data confidentiality. However, significant regulatory limitations remain regarding algorithmic transparency, clinical validation, continuous performance monitoring, human oversight, and the allocation of liability among healthcare professionals, institutions, and technology providers. The study argues that these limitations reflect insufficient operational specificity rather than a complete legal vacuum. Accordingly, it proposes an integrated, risk-based regulatory framework incorporating AI-specific clinical safeguards, transparent decision-making, strengthened data governance, and clearly defined accountability mechanisms. This research contributes to the development of Indonesian healthcare law by demonstrating how existing constitutional guarantees and statutory obligations can be operationalized to ensure patient protection while supporting responsible AI innovation.

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1. INTRODUCTION

The rapid integration of artificial intelligence (AI) into healthcare has transformed clinical decision-making, diagnostic procedures, patient monitoring, and medical information management, creating substantial opportunities to improve

healthcare efficiency, diagnostic accuracy, and service accessibility. AI-driven technologies, including machine learning algorithms, predictive analytics, and automated diagnostic systems, increasingly influence medical judgments that have traditionally depended on professional expertise. However, these technological advancements also introduce significant legal and ethical concerns regarding patient safety, algorithmic bias, informed consent, medical confidentiality, and professional accountability. The World Health Organization [1] emphasizes that the responsible implementation of AI in healthcare must safeguard human autonomy, transparency, accountability, and equitable access to medical services. These considerations demonstrate that technological performance alone cannot determine the legitimacy of AI-assisted healthcare; its implementation must also be evaluated against legal frameworks capable of protecting patients from foreseeable risks. In particular, the increasing involvement of automated systems in clinical decisions requires closer examination of whether established healthcare regulations adequately address the legal consequences of algorithmic errors and technologically mediated medical interventions.

The legal complexity of AI-assisted healthcare becomes particularly evident in determining responsibility for medical errors and protecting sensitive patient information. Unlike conventional medical practices, AI-supported clinical decisions may involve interactions among healthcare professionals, medical institutions, software developers, and technology providers, complicating the attribution of responsibility when adverse outcomes occur. [2] identify substantial challenges in determining medical liability when diagnostic algorithms contribute to clinical decisions, while [3] demonstrate that AI technologies introduce distinctive liability risks arising from the interaction between software performance and professional judgment. [4] similarly emphasize the difficulties of establishing causation and professional accountability in technologically mediated healthcare. Furthermore, AI systems depend extensively on sensitive medical datasets, raising concerns regarding data confidentiality, unauthorized processing, discriminatory profiling, and the secondary use of patient information. International regulatory discussions increasingly recognize these challenges. The [5] identifies clinical validation, algorithmic transparency, risk management, data quality, privacy protection, and continuous regulatory oversight as essential safeguards, while [6] highlights the importance of sustained monitoring throughout the operational lifecycle of medical AI systems. Nevertheless, these international principles require contextual interpretation within national legal systems to establish enforceable patient protections.

Within Indonesia, patient protection in AI-assisted healthcare is grounded in the constitutional right to health and the statutory framework governing medical services. [7] of the Republic of Indonesia guarantees the right to obtain healthcare services, establishing a constitutional foundation for state responsibility in ensuring accessible, safe, and accountable medical care. This constitutional protection is further implemented through [8] concerning Health, particularly Article 276, which recognizes patients' rights to medical information, appropriate healthcare services, informed consent, and access to medical records. In addition, Article 274 establishes professional obligations, while provisions concerning healthcare quality and patient safety provide standards relevant to clinical services supported by emerging technologies. The protection of medical information is further regulated under [9] concerning Personal Data Protection, which classifies health, biometric, and genetic information as specific personal data requiring legal safeguards. Although these provisions establish important normative protections, they do not comprehensively specify the operational requirements for AI-assisted clinical decision-making, particularly concerning algorithmic explainability, disclosure of AI involvement, continuous clinical validation, and the distribution of

legal responsibility among medical professionals, healthcare institutions, and technology providers. Consequently, the central legal issue is not the absence of patient-protection legislation but the extent to which existing constitutional and statutory provisions can effectively accommodate the distinctive risks associated with AI-based medical practices.

Existing scholarship has provided valuable insights into the ethical governance, regulatory oversight, and liability implications of AI in healthcare; however, an important normative issue remains insufficiently addressed within the Indonesian legal context. [2], [3], and [4] primarily examine questions surrounding medical negligence, causation, and professional liability, whereas [1], [5], [6] emphasize broader principles of responsible AI governance and regulatory supervision. Although these contributions establish important analytical foundations, they do not specifically explain how Indonesia's constitutional guarantee of healthcare under Article 28H(1) should be operationalized through the patient-protection provisions of [8] when clinical decisions are substantially influenced by AI technologies. The research gap therefore concerns the relationship between constitutional healthcare guarantees, statutory patient rights, and the operational accountability mechanisms required for AI-assisted medical services. Addressing this gap, the present study develops an integrated constitutional–statutory analysis that conceptualizes patient protection not merely as professional compliance or technological risk management but as a constitutional obligation requiring effective legal implementation. Its intended contribution lies in systematically connecting patient autonomy, informed consent, algorithmic transparency, healthcare quality, medical data protection, and legal accountability within Indonesia's existing regulatory framework.

Accordingly, this study examines the adequacy of Indonesia's legal framework in protecting patients receiving AI-assisted healthcare services and identifies regulatory measures necessary to strengthen legal certainty, patient safety, and institutional accountability. Specifically, it addresses two research questions: (1) How do [7], [8] establish and protect patients' constitutional and statutory rights in AI-assisted healthcare? (2) What normative limitations and regulatory improvements are necessary to address algorithmic risks, informed consent, data protection, and liability arising from AI-supported medical decisions? To answer these questions, the study employs normative juridical research using statutory and conceptual approaches, supported by relevant legal scholarship and international regulatory guidance. The analysis examines the interaction between constitutional obligations, healthcare legislation, personal data protection, and professional accountability to identify areas requiring more specific regulatory interpretation. By integrating these dimensions, the study seeks to advance the doctrinal understanding of patient protection in technologically mediated healthcare and provide a normative foundation for developing proportionate, risk-based regulatory safeguards in Indonesia. Ultimately, the research contributes to ongoing discussions on the governance of medical AI by demonstrating how existing constitutional and statutory protections can be translated into more coherent legal standards without undermining healthcare innovation.

2. METHODS

This study employs a normative juridical research method using statutory and conceptual approaches to examine patient protection in artificial intelligence (AI)-assisted healthcare in Indonesia. The statutory approach analyzes [7], [8], [8] concerning Health, and [9] concerning Personal Data Protection, supported by Government Regulation No. 28 of 2024 and Minister of Health Regulation No. 24 of 2022. The conceptual approach examines constitutional rights, patient autonomy, informed consent, professional accountability, algorithmic transparency, and legal certainty. These

approaches are integrated to assess the adequacy of existing legal safeguards in addressing technological risks and protecting patients' rights.

Legal materials were collected through library-based research and documentary analysis, encompassing primary, secondary, and tertiary legal sources. Primary materials include constitutional provisions, legislation, and implementing regulations, while secondary sources consist of scholarly publications, legal literature, and authoritative institutional reports. International guidance from the World Health Organization [1], [5] was examined as a non-binding normative reference. Materials were selected based on their legal authority, relevance, and contribution to the research objectives. The analysis focuses on five dimensions of patient protection: constitutional healthcare rights, patient safety, informed consent, medical data protection, and legal accountability for AI-related medical harm.

The collected materials were examined through qualitative doctrinal analysis, employing grammatical, systematic, and teleological legal interpretation. These techniques were used to interpret statutory provisions, assess regulatory coherence, and evaluate their applicability to AI-assisted healthcare. A limited normative comparison with WHO regulatory principles was conducted to identify potential improvements in algorithmic transparency, clinical validation, human oversight, and accountability. Conclusions were developed through deductive legal reasoning, distinguishing existing legal obligations from regulatory limitations requiring further clarification. As a normative study, the research focuses on legal interpretation and regulatory recommendations rather than empirical assessments of healthcare practices or medical outcomes.

3. RESULT AND DISCUSSION

3.1 Constitutional Foundations of Patient Protection in Artificial Intelligence-Based Healthcare

The normative legal analysis demonstrates that patient protection in artificial intelligence (AI)-assisted healthcare is fundamentally grounded in [7] of the Republic of Indonesia, which guarantees the right to healthcare services, physical and spiritual well-being, and a healthy environment. This constitutional provision establishes the state's responsibility to ensure accessible, safe, and equitable healthcare while safeguarding human dignity and fundamental rights [10]. Although AI technologies enhance diagnostic accuracy, clinical decision-making, and healthcare accessibility, their implementation must remain consistent with constitutional guarantees and existing professional obligations. Accordingly, AI should function as a supporting instrument rather than replace medical professionals' legal responsibilities, particularly regarding patient autonomy, safety, and accountability [1].

The integration of AI into healthcare presents significant constitutional and regulatory challenges, particularly concerning algorithmic reliability, discriminatory outcomes, and medical accountability. Algorithmic bias resulting from unrepresentative datasets may undermine equitable healthcare access and expose patients to inaccurate medical recommendations, emphasizing the importance of clinical validation and regulatory oversight [11]; [12]. Although [8] establishes general patient protections, the absence of comprehensive AI-specific provisions creates legal uncertainty regarding professional liability, diagnostic errors, and personal data protection [13], [14]. Furthermore, insufficient technical standards for AI-based medical decision-making complicate the determination of legal responsibility when technological errors affect patient outcomes [14], [15].

From a constitutional perspective, the state is responsible for establishing appropriate legal safeguards, institutional supervision, and effective remedies against foreseeable risks associated with AI-assisted healthcare. Strengthening these protections requires coordinated efforts among

government authorities, healthcare institutions, medical professionals, and patients to ensure ethical implementation, algorithmic transparency, and professional accountability [12]. Nevertheless, Article 28H(1) provides general constitutional guarantees rather than detailed technical requirements for AI development, validation, and clinical deployment. Therefore, its effective implementation depends on [8] and complementary regulations that translate constitutional obligations into enforceable standards for patient safety, technological reliability, and legal accountability within Indonesia's evolving healthcare system.

3.2 Patient Protection Under Law No. 17 of 2023 Concerning Health

[8] concerning Health establishes the principal statutory framework for patient protection in Indonesia, including healthcare services supported by artificial intelligence (AI). Article 276 guarantees patients' rights to medical information, appropriate healthcare services, informed consent, and access to medical records, while Article 293 regulates consent for medical procedures, emphasizing patient autonomy and adequate disclosure when AI influences clinical decisions [16]. Furthermore, Article 274 requires healthcare professionals to maintain professional standards and exercise appropriate clinical judgment when utilizing AI technologies [17]. Article 303 provides a legal foundation for patient safety and healthcare quality, reinforcing institutional responsibilities in technologically assisted medical services [18]. These provisions demonstrate that integrating AI into healthcare does not diminish existing patient rights or professional obligations, although their practical application requires careful consideration of algorithmic complexity and technological risks.

Nevertheless, Indonesia's healthcare regulations have not comprehensively addressed AI-specific governance, particularly algorithmic transparency, clinical validation, continuous performance monitoring, and the allocation of legal liability. The absence of explicit transparency requirements creates uncertainty regarding the disclosure of AI involvement in medical decision-making [19], while limited AI-specific clinical validation standards raise concerns about diagnostic reliability and patient safety [15]. Continuous monitoring and professional oversight are therefore essential to maintaining the safety of AI-supported clinical practices [17]. Moreover, determining responsibility among healthcare professionals, medical institutions, and technology developers remains legally complex when algorithmic errors contribute to patient harm [19]. Although Government Regulation No. 28 of 2024 strengthens the operational implementation of [8], additional regulatory clarification is necessary to establish proportionate technical safeguards, institutional accountability, and legal certainty without undermining healthcare innovation.

3.3 Legal Protection of Patient Data and Confidentiality in AI-Based Healthcare

The protection of personal health information constitutes a fundamental aspect of patient rights in artificial intelligence (AI)-assisted healthcare, particularly as extensive data processing increases risks of unauthorized access, privacy violations, and discriminatory profiling. [9] concerning Personal Data Protection, particularly Article 4, classifies health, biometric, and genetic information as specific personal data requiring legal safeguards [20]. Article 10 further recognizes individuals' right to object to decisions based solely on automated processing when such decisions produce legal consequences or significantly affect them, reinforcing the importance of human oversight in healthcare [20]. Minister of Health Regulation No. 24 of 2022 strengthens medical record confidentiality and information security. Nevertheless, consent to medical treatment does not automatically authorize secondary data processing, particularly for AI development and commercial applications. Limited regulatory

guidance concerning data sharing, automated decision-making, and third-party access creates potential risks to patient privacy and legal certainty [21].

Despite these statutory protections, effective implementation remains challenging due to limited public awareness, institutional resources, and regulatory enforcement [22]. AI-assisted healthcare therefore requires comprehensive data governance encompassing lawful processing, access controls, cybersecurity safeguards, and accountability throughout the data lifecycle. Strengthening collaboration among government authorities, healthcare institutions, technology providers, and civil society is essential to improving regulatory compliance and protecting patient confidentiality [23]. Furthermore, technological innovations, including blockchain-based systems, may support data integrity, security, and transparency when appropriately implemented [22]. Accordingly, integrating healthcare confidentiality obligations with personal data protection regulations and establishing clearer operational standards for AI model training, secondary data use, and external data sharing are necessary to strengthen patient rights, institutional accountability, and legal certainty within Indonesia's evolving digital healthcare system.

3.4 Medical Liability and Legal Accountability for AI-Assisted Healthcare Errors

Determining legal liability in artificial intelligence (AI)-assisted healthcare presents significant challenges due to the involvement of medical professionals, healthcare institutions, and technology providers in clinical decision-making. Under [8], Articles 274 and 303 establish professional obligations and patient safety standards, requiring healthcare professionals to exercise appropriate clinical judgment and institutions to maintain effective supervision. However, algorithmic defects, inadequate clinical validation, and insufficient institutional oversight complicate the attribution of responsibility for medical errors [24]. Existing legal frameworks do not comprehensively address the distribution of liability among healthcare professionals and AI developers, highlighting the need for clearer accountability mechanisms and proportionate responsibility based on legal duties and causal relationships [25]. Although technology providers may bear contractual or civil liability for defective systems, their responsibility cannot be presumed solely from the occurrence of patient harm. Consequently, determining liability requires examining professional conduct, technological reliability, institutional obligations, and evidence establishing causation.

Indonesia's healthcare legislation provides mechanisms for addressing professional misconduct and medical disputes through Articles 304, 305, and 308 of [8]. Nevertheless, AI-related disputes introduce evidentiary challenges, particularly when patients lack access to algorithmic documentation, system logs, and technical performance records necessary to establish causation. Regulatory adaptation is therefore essential to accommodate technological developments and strengthen patient protection [26]. Greater emphasis on algorithmic transparency, risk management, and continuous oversight can further reduce medical risks and improve accountability [27] An effective legal framework should distinguish professional negligence, institutional failures, and technological defects while ensuring appropriate allocation of responsibility among relevant actors [25]. Strengthening digital evidence preservation, institutional governance, and access to legal remedies is essential to achieving legal certainty and protecting patients within Indonesia's evolving AI-assisted healthcare system.

3.5 Regulatory Gaps in the Implementation of AI for Healthcare Services

The analysis of [7], [8], and [22] reveals that Indonesia has established a

general legal foundation for patient protection, yet significant regulatory gaps remain in AI-assisted healthcare. These gaps primarily concern risk-based classification, clinical validation, algorithmic transparency, and continuous performance monitoring. The World Health Organization [5] emphasizes the importance of risk management, data quality, clinical validation, and ongoing evaluation to ensure responsible AI implementation. Although Articles 276 and 293 of [8] protect patient information and informed consent, existing provisions lack specific requirements for disclosing AI involvement in clinical decisions. Furthermore, clearer standards for meaningful human oversight and post-deployment monitoring are necessary to address algorithmic errors, technological changes, and patient safety risks.

Additional regulatory challenges involve medical data governance, institutional accountability, and access to legal remedies. [9] and Minister of Health Regulation No. 24 of 2022 provide safeguards for sensitive health information, but greater regulatory clarity is needed regarding secondary data use, third-party processing, and AI model development. Similarly, Articles 303–308 of [8] establish relevant accountability mechanisms without comprehensively addressing the allocation of responsibility among healthcare professionals, institutions, and technology providers. These limitations do not indicate a complete regulatory vacuum but highlight the need for coordinated, AI-specific operational standards concerning transparency, clinical oversight, digital evidence preservation, and liability. Strengthening these safeguards through proportionate regulation would enhance legal certainty, patient protection, and responsible healthcare innovation in Indonesia.

3.6 Strengthening Patient Protection Through an Integrated Legal Framework

Strengthening patient protection in AI-assisted healthcare requires an integrated legal framework that aligns [7], [8] concerning Health, and [9] concerning Personal Data Protection with AI-specific regulatory safeguards. Key priorities include risk-based clinical validation, algorithmic transparency, informed consent, meaningful human oversight, institutional accountability, and secure patient data governance, consistent with [5] recommendations. Healthcare institutions and technology providers should also establish clear responsibilities, continuous performance monitoring, and digital evidence preservation to facilitate legal remedies for AI-related medical harm. Rather than replacing existing legislation, regulatory improvements should strengthen its implementation through coordinated oversight, proportionate technical standards, and effective accountability mechanisms, ensuring patient safety and legal certainty while supporting responsible healthcare innovation in Indonesia.

3.7 Implications for the Constitutional Right to Health and the Development of Indonesian Healthcare Law

The findings demonstrate that [7] Constitution and [8] provide a fundamental legal basis for protecting patients' rights in AI-assisted healthcare, including access to quality medical services, informed consent, and professional accountability. Their implementation must be integrated with [9] concerning Personal Data Protection to safeguard sensitive health information and patient autonomy. However, AI-related medical decisions introduce regulatory challenges concerning algorithmic transparency, clinical reliability, institutional responsibility, and liability allocation among healthcare professionals and technology providers. These findings emphasize the need to translate existing constitutional and statutory guarantees into enforceable AI-specific operational standards through clinical validation, meaningful human oversight, data governance, and effective legal remedies. Such regulatory improvements would strengthen legal certainty and patient protection while

supporting responsible technological innovation within Indonesia's healthcare system.

4. CONCLUSION

This study concludes that Indonesia's existing constitutional and statutory frameworks provide a fundamental legal basis for protecting patients in AI-assisted healthcare, particularly through [7] Constitution, [8] concerning Health, and [9] concerning Personal Data Protection. These provisions establish essential safeguards for healthcare access, patient autonomy, informed consent, professional responsibility, and medical data confidentiality. However, the findings identify regulatory limitations concerning algorithmic transparency, clinical validation, continuous performance monitoring, meaningful human oversight, and the allocation of liability among healthcare professionals, institutions, and technology providers. These limitations indicate a need for more specific operational standards rather than the establishment of an entirely new legal framework. Strengthening patient protection therefore requires an integrated, risk-based regulatory approach that clarifies institutional responsibilities, reinforces data governance, establishes appropriate AI evaluation and oversight mechanisms, and ensures access to effective legal remedies. The study contributes to legal scholarship by connecting constitutional healthcare guarantees with statutory patient protections and emerging requirements for AI governance. Given its normative juridical scope, the research does not assess actual institutional compliance or clinical outcomes. Future studies should examine the practical implementation of AI-related safeguards and accountability mechanisms within Indonesian healthcare institutions. Ultimately, effective regulatory coordination is essential to ensuring that healthcare innovation advances without compromising patient safety, fundamental rights, and legal certainty.

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