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Legal Protection of Electronic Medical Records in Artificial Intelligence: A Comparative Study of Indonesia and the Netherlands

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Abstract

Electronic Medical Records (EMRs) are increasingly used beyond clinical treatment, including in Artificial Intelligence (AI) training, validation, and clinical decision-making, raising questions about patient protection when data purposes change. This study compares the legal protection of EMRs used in AI development and implementation in Indonesia and the Netherlands. It uses normative legal research with a prescriptive orientation, drawing on statutory, conceptual, and comparative approaches. The study analyzes legal materials qualitatively through grammatical and systematic interpretation, guided by Hadjon's theory of preventive and repressive legal protection. The findings show that both jurisdictions protect patient privacy, confidentiality, health data, and medical records but differ in how they integrate regulations. The Dutch/EU framework connects data protection, medical records, medical devices, AI safety, and secondary health data use. Indonesia's framework provides fundamental safeguards but lacks operational links among privacy impact assessments, clinical safety evaluation, model-version traceability, human oversight, and accountability for AI-assisted decisions. The study concludes that Indonesia should strengthen health AI governance through risk-based requirements, integrated privacy and clinical safety assessments, traceable model documentation, secure data-processing environments, and clear accountability standards. Implementation should consider regional infrastructure disparities and healthcare facilities' technical capacities.

Keywords

Artificial Intelligence, Comparative Law, Electronic Medical Records, Health Data, Legal Protection.

1. Introduction

Electronic medical records are no longer confined to serving as clinical archives. Diagnoses, laboratory results, radiology images, prescriptions, and procedure histories can now be incorporated into Artificial Intelligence (AI) training, testing, and operational processes. In clinical practice, AI can help healthcare professionals identify patterns and prioritize care (van Leeuwen et al., 2024; Hermawan & Jamaludin, 2025). These benefits are real, but their value depends on data quality and how effectively healthcare facilities control data use. Legal issues arise when data are used for purposes beyond those for which they were initially collected. Patients provide information because they require medical treatment. Later, healthcare facilities or developers may use the same information to test models, improve products, or develop new services. This change in purpose is not simple, as it determines the lawful basis for processing, the entities responsible for controlling data, access restrictions, retention periods, and the information disclosed to patients.

Data breaches are easily visible, but they are not the sole risk. Incomplete data can produce erroneous clinical recommendations, non-representative data can reinforce bias, and unrecorded model updates can disrupt the chain of evidence. The core legal problem lies in the continuity of protection: whether patient rights established during the creation of medical records remain enforceable when the data enter AI systems. Indonesia is expanding electronic medical records and health data integration, creating significant opportunities for AI development (Rinaldi & Sulistiadi, 2025). However, studies by Hossain et al. (2025) across hospitals indicate that infrastructure readiness, digital capability, and record-keeping culture remain uneven. This condition is critical because AI systems cannot independently correct inaccurate or incomplete source data.

The Netherlands is selected as a comparator because of its documented digital health practices and clinical AI applications. The adoption of AI in hospital radiology has grown in recent years, yet some applications have been discontinued, and integration barriers persist (World Health Organization, 2021; van Leeuwen et al., 2024; van Kolfschooten & van Oirschot, 2024). Research on Dutch medical records and health portals also shows that workload, system design, and user acceptance still heavily influence technology adoption (van Poelgeest et al., 2021; van der Smissen et al., 2025). Existing literature addresses healthcare AI ethics, data protection, medical liability, and the EU AI Act (Bottomley & Thaldar, 2023; Cestonaro et al., 2023; Konnoth, 2024). Although these studies provide a valuable foundation, they generally treat medical records as one component of broader discussions on AI (Mita et al., 2024; Palmieri, 2024; Schmidt et al., 2024). This article focuses specifically on the trajectory of medical records from their initial use in care relationships to their subsequent use in AI training, validation, and clinical decision-making.

This study's novelty lies in comparing the functional roles of legal frameworks rather than simply counting regulations. It evaluates whether existing rules effectively prevent unauthorized data use, provide evidence during disputes, and facilitate the restoration of patient rights. This functional approach enables comparison across jurisdictions with different legal terminology and institutional structures. The comparison also considers the implications of legal transplantation. Successful mechanisms in the Netherlands cannot simply be transferred to Indonesia without adaptation. Although functional objectives can be compared, institutional arrangements and technical standards must reflect Indonesia's healthcare structure, facility capacities, and patterns of technology adoption across an archipelagic nation. According to BPS, national internet access reached 72.78% in 2024, although spatial disparities remain (Badan Pusat Statistik, 2025).

Medical records also represent value-generating assets beyond clinical documentation. Longitudinal and continuously updated data support disease

research, AI model validation, quality evaluation, risk prediction, and patient safety monitoring. Their economic value lies in the lawful reuse of data to generate knowledge, improve efficiency, and develop services while ensuring purpose limitation, data minimization, security, and fair benefit sharing. Against this background, this study addresses one central research question: how do Indonesia and the Netherlands provide preventive and repressive legal protection for electronic medical records used in AI development and implementation? The analysis is limited to patient medical records and excludes general consumer health device data and social media data.

2. Methods

This study employs normative legal research with a prescriptive orientation to examine legal protection for electronic medical records in AI development and implementation in Indonesia and the Netherlands. This design is appropriate because it evaluates the adequacy, coherence, and practical application of existing legal provisions rather than measuring empirical behavior. Statutory, conceptual, and comparative approaches are applied to identify regulatory gaps, assess preventive and repressive safeguards, and evaluate the transferability of Dutch/EU legal mechanisms to Indonesia. The analysis is grounded in Hadjon's (1987) theory of legal protection to formulate contextually appropriate recommendations for strengthening patient protection.

The legal materials consist of primary and secondary legal materials. Indonesian primary legal materials include the 1945 Constitution of the Republic of Indonesia, Law Number 27 of 2022 concerning Personal Data Protection, Law Number 17 of 2023 concerning Health, Government Regulation Number 28 of 2024, and Minister of Health Regulation Number 24 of 2022 concerning Medical Records. The comparative analysis examines relevant Dutch and European Union legal instruments, including the Dutch Constitution (Grondwet), Book 7 of the Dutch Civil Code concerning medical treatment agreements (WGBO), the Dutch Implementation Act of the General Data Protection Regulation (UAVG), the Medical Data Act (Wabvpz), the Quality, Complaints and Disputes in Healthcare Act (Wkkgz), the General Data Protection Regulation (GDPR), the Medical Device Regulation (Regulation (EU) 2017/745), the Artificial Intelligence Act (Regulation (EU) 2024/1689, as amended by Regulation (EU) 2026/1744), and the European Health Data Space Regulation (Regulation (EU) 2025/327) (Kingdom of the Netherlands, 2008). Secondary legal materials include scholarly books, peer-reviewed journal articles, and relevant academic publications addressing health data protection, AI governance, medical liability, and comparative legal protection.

Legal materials were collected through document-based research by identifying, selecting, and examining legislation, regulatory instruments, and relevant scholarly literature. The collected materials were analyzed qualitatively through grammatical and systematic legal interpretation to determine the scope, coherence, and implications of the applicable provisions. The analysis then classified legal safeguards as preventive or repressive and compared the functions of the Indonesian and Dutch/EU frameworks regarding lawful data processing, purpose limitation, patient rights, data security, traceability, human oversight, and legal remedies. A functional comparison assessed the transferability of relevant Dutch and EU mechanisms to Indonesia based on legal compatibility, institutional capacity, digital infrastructure, and clinical practice. The findings provide the basis for prescriptive recommendations to strengthen legal protection throughout the lifecycle of electronic medical records used in AI development and implementation.

3. Results and Discussion

The comparison reveals differences in the regulatory structures governing electronic medical records in Indonesia and the Netherlands/EU. Indonesia distributes legal protection across general data protection legislation and sector-specific health regulations. In contrast, the Netherlands/EU adopts a more interconnected framework integrating national healthcare laws with multiple European regulations governing data protection, electronic health records, medical devices, and AI governance.

Table 1. Comparison of Legal Foundation and Protective Functions

Dimension	Indonesia	Netherlands / European Union
Fundamental Rights	1945 Constitution: protection of health and personal security (Republic of Indonesia, 1945).	Grondwet: protection of privacy and public health (Kingdom of the Netherlands, 2008).
Medical Records	Health Law and Minister of Health Regulation Number 24 of 2022 concerning Medical Records (Republic of Indonesia, 2022a).	Medical treatment agreements under Book 7 of the Dutch Civil Code (WGBO).
Data Processing	Personal Data Protection Law and sector-specific health regulations (Republic of Indonesia, 2022b).	GDPR and UAVG (Autoriteit Persoonsgegevens, 2026; European Union, 2016).
Electronic Access	Minister of Health Regulation Number 24 of 2022 and the SATUSEHAT ecosystem (Kementerian Kesehatan RI, 2026).	Wabvpz and European Health Data Space Regulation (European Union, 2025).
AI and Safety	General data protection, health, and medical device regulations.	Medical Device Regulation (MDR) and the risk-based AI Act (European Union, 2017; European Union, 2024).
Redress and Remedies	Personal Data Protection Law, Health Law, and applicable civil, administrative, and criminal law.	GDPR, WGBO, and Wkkgz (European Union, 2016).

Table 1 compares the legal foundations and protective functions governing electronic medical records in Indonesia and the Netherlands/European Union. Both jurisdictions recognize the importance of protecting privacy, health information, and patient rights through constitutional and statutory provisions. However, their regulatory structures differ. Indonesia relies on a combination of the 1945 Constitution, the Personal Data Protection Law, the Health Law, and sector-specific regulations, particularly Minister of Health Regulation Number 24 of 2022. This framework establishes the legal basis for medical record management, personal data processing, and electronic access through the SATUSEHAT ecosystem (Kementerian Kesehatan RI, 2026).

In contrast, the Netherlands operates within an interconnected framework combining national healthcare legislation and European Union regulations. The WGBO governs medical treatment relationships and medical records, while the GDPR and UAVG regulate personal data processing. Electronic access is supported by the Wabvpz and the European Health Data Space Regulation (European Union, 2025). Regarding AI-related safety, the MDR and AI Act provide more specific regulatory instruments for medical devices and risk-based AI governance (European Union, 2017; European Union, 2024). Both jurisdictions also recognize legal remedies for violations, although the Dutch/EU framework provides a more integrated regulatory structure connecting data protection, healthcare accountability, and emerging AI-related risks.

Previous studies by Bottomley and Thaldar (2023) have examined healthcare AI from the perspectives of medical liability, data protection, and regulatory

governance. Other research by van Kolfschooten and van Oirschot (2024) has explored the implications of the EU AI Act for healthcare and the development of digital patients' rights. In Indonesia, Mita et al. (2024) examined AI regulation in healthcare, while Rinaldi and Sulistiadi (2025) discussed the optimization of AI-based electronic medical records.

Research on digital health implementation has also highlighted the importance of institutional readiness and practical implementation. Hossain et al. (2025) examined electronic medical record implementation and record-keeping culture in Indonesian hospitals. In the Netherlands, van Leeuwen et al. (2024) investigated clinical AI applications in radiology, van Poelgeest et al. (2021) explored medical specialists' perspectives on electronic medical records, and van der Smissen et al. (2025) examined personal health record adoption. Although these studies provide valuable insights into healthcare AI governance and digital health implementation, further analysis is needed to explain how legal protection operates when medical records collected for treatment are subsequently reused for AI training, validation, and clinical decision-making. This study addresses that gap by comparing preventive and repressive legal protection in Indonesia and the Netherlands, focusing on lawful processing, purpose limitation, patient rights, data security, traceability, human oversight, and remedies. Drawing on Hadjon's (1987) theory of legal protection, it evaluates the functional adequacy of both legal frameworks and formulates recommendations for strengthening patient protection throughout the AI lifecycle.

Table 2. Application of Legal Rules According to Processing Scenario

Scenario	Indonesia	Netherlands / European Union	Core Finding
Clinical Decision Support	Healthcare service obligations under the Health Law (Republic of Indonesia, 2023).	GDPR and WGBO; MDR and AI Act where applicable.	AI supports clinical decisions but does not displace professional responsibility.
Training and Validation	Changes in processing purposes must be assessed under the Personal Data Protection Law and medical record regulations (Republic of Indonesia, 2022a; Republic of Indonesia, 2022b).	GDPR, UAVG, WGBO, and EHDS (European Union, 2016).	Data collected for treatment are not automatically available for AI training.
Vendor Processing	Responsibilities depend on the parties' actual roles and control over personal data (Republic of Indonesia, 2022b).	GDPR establishes requirements concerning processing roles, contracts, security, and international data transfers (European Union, 2016).	Vendor contracts do not eliminate statutory responsibilities.
Significant Decisions	The Personal Data Protection Law provides safeguards concerning decisions based solely on automated processing (Republic of Indonesia, 2022b).	GDPR restricts certain solely automated decisions, while the AI Act establishes human oversight requirements for applicable high-risk AI systems.	Clear standards are needed for decisions materially influenced by AI.

Table 2 presents the application of legal provisions to four scenarios involving electronic medical records in AI development and implementation. In clinical decision support, Indonesian healthcare regulations establish obligations for healthcare professionals to provide services in accordance with applicable standards, whereas the Netherlands/EU framework combines the GDPR and WGBO with the Medical Device Regulation and AI Act where applicable. These provisions indicate that AI functions as a supporting instrument rather than a substitute for professional judgment and responsibility. In training and validation, both jurisdictions require the legal basis and purpose of data processing to be assessed before medical records are reused. Data initially collected for treatment are not automatically available for AI training, as subsequent processing must comply with applicable data protection and medical record requirements.

In vendor processing, Indonesia determines responsibilities according to the parties' actual roles and control over personal data, while the GDPR provides more explicit requirements concerning processing arrangements, contractual obligations, security measures, and international data transfers. Consequently, outsourcing data processing does not release healthcare institutions or other responsible parties from their statutory obligations. Regarding significant decisions, Indonesia's Personal Data Protection Law and the GDPR establish safeguards against certain decisions based solely on automated processing. The EU AI Act further requires human oversight for applicable high-risk AI systems. These findings demonstrate that legal protection must cover the entire data-processing lifecycle, including secondary data use, third-party involvement, AI deployment, and decisions affecting patients. Accordingly, Indonesia needs more operational standards governing AI-related medical record processing, particularly regarding accountability, human oversight, and clinical responsibility.

Table 3. Transferability of Dutch/EU Legal Elements to Indonesia

Element	Function in Dutch/EU Framework	Adoption Status	Adaptation Requirement for Indonesia
Primary vs Secondary Purpose Separation	Distinguishes healthcare delivery from research, innovation, and secondary data use (European Union, 2016; European Union, 2025).	Adoptable	Establish clear purpose categories, lawful processing bases, retention periods, patient rights, and restrictions on data reuse.
Access Logging and Traceability	Supports data security, patient rights, auditability, and evidentiary accountability (European Union, 2016; European Union, 2024).	Adoptable	Link electronic medical record logs with user identification, processing purposes, model versions, AI outputs, human reviews, and final decisions.
Secure Processing Environments	Restricts uncontrolled data copying during secondary use (European Union, 2025).	Adaptable	Develop national or regional secure computing environments with appropriate output filtering.
Health Data Access Body	Authorizes and oversees access to health data for secondary use	Adaptable	Establish a single-window access function within national health data governance, coordinated

Element	Function in Dutch/EU Framework	Adoption Status	Adaptation Requirement for Indonesia
	(European Union, 2025).		with the personal data protection authority.
Continuous Online Interoperability	Facilitates continuous digital data exchange across healthcare systems.	Not directly transferable	Implement offline-first systems, store-and-forward mechanisms, edge processing, and delayed synchronization in areas with limited connectivity.
High-Cost Uniform Compliance Standards	Establishes technical requirements and conformity assessment for applicable medical devices and AI systems (European Union, 2017; European Union, 2024).	Not directly transferable	Establish baseline national security requirements with tiered obligations based on risk levels and healthcare facility capacity.

Table 3 presents the potential adaptation of Dutch and European Union legal mechanisms to strengthen electronic medical record protection in Indonesia. Separating primary and secondary data use, implementing access logging, and establishing secure processing environments could improve accountability and prevent unauthorized data reuse. Previous studies emphasize the importance of data protection and responsible governance when medical information is used for AI development and implementation (Konnoth, 2024; Schmidt et al., 2024). However, these mechanisms require adaptation to Indonesia's healthcare conditions, particularly differences in digital infrastructure, institutional readiness, and healthcare facility capacity. Research on electronic medical record implementation in Indonesia highlights challenges related to implementation and recordkeeping culture, underscoring the importance of aligning regulatory improvements with institutional capabilities (Hossain et al., 2025).

The findings also reveal structural differences between Indonesia and the Netherlands/European Union. Indonesia relies primarily on general data protection and health legislation, whereas the Dutch/EU framework connects data protection, medical records, medical devices, AI safety, and secondary health data use (Schmidt et al., 2024; van Kolfschooten & van Oirschot, 2024). Despite Indonesia's existing safeguards concerning patient rights, confidentiality, and data security, operational gaps remain in healthcare AI governance. These include insufficient integration between data protection impact assessments and clinical safety evaluations, limited traceability of model versions and clinical decisions, and uncertainty concerning decisions materially influenced by AI recommendations. Such gaps may complicate accountability and dispute resolution.

Accordingly, Indonesia should prioritize functional adaptations rather than wholesale regulatory transplantation. Clearer requirements for secondary data use, clinical validation, model-version traceability, and human oversight could strengthen preventive legal protection. Risk-based security requirements, offline-capable systems, and phased implementation would also accommodate regional infrastructure disparities. These measures could improve patient protection while supporting responsible AI development and ensuring that regulatory obligations remain proportionate to healthcare facilities' institutional and technical capacities (Konnoth, 2024; van Kolfschooten, 2025).

4. Conclusion

This study finds that Indonesia and the Netherlands/European Union recognize obligations to protect patient privacy, health data, and EMRs, but differ in regulatory integration. Indonesia's legal framework provides fundamental safeguards but lacks operational connections between privacy assessments, clinical safety, model traceability, human oversight, and accountability for AI-assisted decisions. The Dutch/EU framework offers mechanisms that could inform Indonesia's regulatory development. Accordingly, Indonesia should strengthen health AI governance through risk-based classifications, integrated privacy and clinical safety assessments, traceable model documentation, meaningful human oversight, secure processing environments, and clear accountability requirements. Implementation should consider regional infrastructure disparities and healthcare facilities' technical capacities.

This study is limited by its normative legal approach and reliance on legislation and secondary literature, without empirical assessment of regulatory enforcement or clinical implementation. Therefore, its findings concern legal adequacy and potential regulatory adaptation rather than demonstrated practical effectiveness. Future research should investigate how healthcare institutions implement EMR protection throughout AI training, validation, and clinical deployment. Empirical studies involving patients, healthcare professionals, regulators, and technology providers could examine barriers to secondary data use, clinical oversight, and accountability. Further research should also assess the feasibility of regulatory sandboxes, secure data processing environments, and integrated privacy and clinical safety assessments in Indonesia. These investigations could support evidence-based regulations that protect patients while enabling responsible healthcare AI innovation.

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



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