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Legal and Ethical Challenges in Regulating the Use of Health Technology

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Abstract

Advances in digital technology have driven transformation in healthcare systems through innovations such as telemedicine, artificial intelligence, and electronic medical records. While offering efficiency and accessibility, the use of these technologies raises complex legal challenges that are not yet fully accommodated in positive law, particularly in Indonesia. The purpose of this study is to analyze the legal issues of health technology use in Indonesia and provide recommendations for legal reform to ensure patients' rights are protected ethically and fairly. This study uses a normative-conceptual approach to examine legal issues arising in the context of health technology, including personal data protection, liability for technological errors, the validity of informed consent, and jurisdictional conflicts in telemedicine. The results of the study indicate an urgent need to reform existing regulations, establish technology audit mechanisms, improve legal literacy among medical personnel, and strengthen cross-regional cooperation. Thus, legal reform is an important prerequisite for ensuring the ethical and fair use of health technology and protecting patients' rights.

Keywords

Artificial Intelligence, Electronic Medical Records, Health Technology, Legal Issues, Patient Rights, Telemedicine.

1. Introduction

Advances in information and communication technology have been a major catalyst in the transformation of the global healthcare sector, including in Indonesia. Various innovations such as telemedicine, Artificial Intelligence (AI), the Internet of Medical Things (IoMT), and Electronic Medical Records (EMR) have changed the paradigm of healthcare services from conventional to more modern, faster, and more affordable (Hanifa & Wicaksono, 2025; Prabowo, 2025). These innovations have proven to improve service efficiency, accelerate diagnosis and clinical decision-making, and expand patient access to healthcare services, especially in remote areas or those lacking medical personnel.

However, the development of health technology also presents very complex legal issues that are not fully anticipated by the current legal framework. The use of advanced technology in healthcare processes poses various challenges, including the protection of patients' personal data recorded and stored in digital systems, the clarity of legal responsibility for losses resulting from algorithmic errors or AI systems that replace the clinical role of humans, jurisdictional boundaries in cross-regional or even cross-border telemedicine practices, and issues related to algorithm transparency as well as the validity of informed consent given by patients to technology-based systems that are often not fully understood by lay users (Gerke et al., 2020; Naik et al., 2022; Mutiah et al., 2025).

In the Indonesian context, although Law Number 27 of 2022 on Personal Data Protection (PDP Law) exists, this regulation is still general in nature and does not specifically regulate issues specific to the digital health sector (ELSAM, 2021). For example, there are no regulations that specifically detail how patient health data may be collected, processed, stored, shared, or destroyed, nor who is responsible in the event of a data breach. Additionally, the legal responsibility for AI-based medical decisions lacks a clear legal basis, whether the fault lies with the algorithm developer, the healthcare institution, or the technology platform provider (WHO, 2021; Annan, 2024; Hermawan & Jamaludin, 2025). This legal vacuum creates legal uncertainty and has the potential to violate patients' fundamental rights, such as the right to privacy, information security, and legal certainty. On the other hand, healthcare providers also face undefined legal risks, especially in the event of technological failures that harm patients. Without an adequate legal framework, the implementation of technology in the healthcare sector could backfire on patient safety and the accountability of medical institutions (Santhi, 2025).

Therefore, an in-depth and comprehensive assessment of these legal challenges is urgently needed. This study aims to identify and critically analyze various legal issues arising from the integration of technology into the healthcare system, as well as to develop conceptual proposals for national legal reforms that are adaptive to the times. In line with this objective, the study focuses on how the protection of patients' personal data is managed and regulated within digital health systems in Indonesia, how legal responsibility is defined in cases of losses resulting from AI errors or algorithm-based clinical decisions, how jurisdictional issues are addressed in cross-regional and cross-border telemedicine practices, and how Indonesia's national legal framework can be adaptively reformed using a multi-sectoral approach to ensure ethical, safe, and rights-based use of health technology. These focal points guide the analysis of legal challenges and the formulation of recommendations to enhance the governance of digital health services while protecting patient rights.

Furthermore, legal reform also needs to consider a multi-sectoral approach, in which the health, legal, technology, and civil society sectors collaborate in formulating comprehensive and inclusive policies. The new regulatory framework must be able to bridge the needs of innovation with public protection, as well as provide clear guidelines for businesses and health workers in using technology

safely, ethically, and responsibly. Thus, the urgency to update health technology regulations in Indonesia is not merely a response to technological advances, but also a preventive measure to ensure that digital transformation in the health sector is sustainable, fair, and in the interests of the wider community.

2. Methods

This study uses a normative juridical approach as the main basis for examining regulations on the use of technology in health services. This approach aims to systematically analyze legal norms contained in national legislation, general legal principles, and relevant legal doctrines and theories. The focus of the analysis is directed at positive legal provisions applicable in Indonesia, especially those governing the use of information and communication technology in the health sector, such as the Medical Practice Law, the Personal Data Protection Law, and technical regulations from the Ministry of Health and other relevant agencies. In addition, a legal comparison is made with the international regime, particularly the General Data Protection Regulation (GDPR) and the Artificial Intelligence Act of the European Union, to see the extent to which national regulations are in line with or lag behind in responding to contemporary legal challenges posed by innovations in health technology.

In addition to normative studies, this research also applies content analysis methods to various legal sources, including legislation, public policy, ethical guidelines, and academic literature discussing technological developments such as artificial intelligence, electronic medical records, and telemedicine. This method is used to identify regulatory patterns, prominent legal issues, and legal evolution trends in response to these technological dynamics. To deepen the understanding of the legal norms analyzed, this study also uses a legal hermeneutics approach, which is a method of legal interpretation that considers not only the literal text of the law but also the historical, social, and ethical context in which the norm applies. This approach is important in the context of health technology, which is fraught with moral dilemmas and technical complexities, so that legal interpretation should not be purely legalistic, but should also reflect the values of humanity, justice, and protection of patient rights. With a combination of these three approaches, normative juridical, content analysis, and legal hermeneutics, this study is expected to produce results that are not only descriptive and comparative but also analytical and reflective, in order to contribute to the development of a regulatory system that is adaptive and responsive to current and future developments in health technology.

3. Results and Discussion

3.1. Patient Data Protection and Legal Responsibility in Digital Health

Law Number 27 of 2022 concerning Personal Data Protection (PDP Law) is an important milestone in Indonesia's efforts to protect the digital rights of its citizens, including in the health sector. However, the effective implementation of this law still faces various obstacles. Substantively, the PDP Law does not specifically regulate the protection of health data, which is sensitive and highly personal. There are no detailed provisions on how patient data should be collected, stored, used, and shared in the context of digital health services (Judijanto et al., 2024). In comparison, the General Data Protection Regulation (GDPR) in the European Union sets high standards for the processing of health data, including the principles of data minimization, the right of patients to access and transfer their data, and the obligation of system developers to conduct Data Protection Impact Assessments (DPIA) (European Commission, 2021). In this context, there is a significant normative gap between Indonesia and more advanced jurisdictions (Georgiou & Lambrinoudakis, 2021). This normative vacuum or ambiguity risks violating patient

rights and potential data leaks that could be misused by third parties, including technology providers and insurance companies. As Meskó et al. (2017) and Stoumpos et al. (2023) note, the digitization of health services requires structural and regulatory adjustments to ensure patient data protection aligns with technological transformation. Similarly, Price and Cohen (2019) emphasize that patient privacy is a fundamental concern in digital health systems, highlighting the need for proactive legal oversight.

The development of artificial intelligence technology in diagnostic services and clinical decision-making poses a major challenge to the principle of legal responsibility in the medical world. McDougall's (2019) study highlights that when AI produces an incorrect diagnosis, there is ambiguity as to who should be held legally responsible, the doctor who relied on the AI, the algorithm developer, the hospital as an institution, or even the AI itself. In Indonesian positive law, the concept of legal responsibility is still based on human and corporate entities. The legal accountability system, both in the civil (medical malpractice) and criminal frameworks, does not yet provide a place for non-human entities such as AI as legal actors. This creates a legal vacuum in the aspect of medical professional responsibility, which in turn can hinder the adoption of technology due to fears of uncertain legal risks. In an ideal scenario, the legal system should be able to develop a doctrine of shared liability or a protection scheme based on the principle of prudence regarding the use of high technology in health services. Gellert and Gutwirth (2013) underline that patient data protection is part of human rights obligations, suggesting that legal frameworks should account for both technological complexity and fundamental patient rights.

3.2. Incompatibility of the Informed Consent Process with AI Systems

The informed consent process is an ethical and legal pillar in medical practice that guarantees the patient's right to make informed and free decisions regarding medical interventions. However, this study found that in the context of the use of artificial intelligence in healthcare services such as diagnostic prediction systems, therapy recommendations, or health chatbots, there is a degradation of the essence of informed consent. Patients are often only given administrative explanations in the form of checkboxes or standard documents without detailed explanations about how the algorithm works, potential data bias, model accuracy levels, and the limitations of the AI system (Rose & Shapiro, 2024). Mittelstadt et al. (2016) and Nebeker et al. (2019) note that traditional ethical principles like informed consent, fairness, and transparency become more complex when AI-driven systems participate in medical decision-making. Shaw et al. (2019) further emphasize that AI's autonomous recommendations challenge clinicians' ability to fully inform patients.

This practice has the potential to violate the principle of patient autonomy as stated in international bioethics principles and Article 56 of Law Number 29 of 2004 concerning Medical Practice (Beauchamp & Childress, 2001). In the Indonesian legal system, informed consent must include a comprehensive explanation that is understandable to the patient, not merely administrative or legal-formal in nature. Without transparency regarding the role of AI systems in the medical decision-making process, patients do not have the full capacity to assess the risks and benefits, so that the decisions made cannot be considered legally and ethically valid consent. By comparison, Article 22 of the General Data Protection Regulation (GDPR) contains specific provisions on automated decision-making, whereby individuals have the right not to be subject to decisions based solely on automated processing, including profiling, unless there are adequate legal safeguards. These provisions have not been explicitly accommodated in Indonesian regulations, leaving a gap in the protection of patient rights in the digital age. Tehrani et al. (2025) highlight the diffusion of responsibility in AI-assisted care, which further complicates ensuring legally valid informed consent.

3.3. Regional Regulatory Inconsistencies in Telemedicine

Telemedicine, as a form of digital health service that has grown rapidly in the wake of the COVID-19 pandemic, brings new challenges to the national legal system, particularly regarding jurisdiction and the legal validity of cross-regional medical practices. In Indonesia, the implementation of telemedicine has been regulated through Minister of Health Regulation Number 20 of 2019 concerning the Implementation of Telemedicine Between Health Service Facilities and reinforced by Minister of Health Regulation Number 24 of 2022. However, these regulations do not comprehensively regulate aspects of cross-border jurisdiction in virtual medical practices, both between provinces and across countries (Kuntardjo, 2020; Heriani & Adina, 2024). Floridi and Cowls (2022) and Nikolinakos (2023) argue that principles such as justice and explicability should guide digital health regulation, which includes harmonizing telemedicine rules across regions.

This lack of synchronization raises several legal implications. First, regarding medical practice licenses, doctors registered in one region can provide services to patients in other regions without clarity on the applicable licensing authority. This creates ambiguity regarding supervisory authority, dispute resolution, and legal protection in the event of ethical violations or malpractice. Second, the mechanism of legal responsibility becomes unclear when telemedicine practices involve foreign-based digital platforms, making it difficult to enforce national laws and protect domestic patients (Bonsapia, 2025).

In comparison, the United States has an interstate licensure compact approach, which allows doctors to practice in several states with mutually recognized licenses. Meanwhile, the European Union, through Directive 2011/24/EU on patients' rights in cross-border healthcare, establishes a legal framework that facilitates and protects cross-border healthcare services. Indonesia still lags behind in this aspect, and existing regulations are inadequate in addressing the complexity of digital medical services that transcend administrative boundaries. This situation highlights the urgency of establishing a synchronized and interoperable national legal framework, not only between central and regional regulations, but also with relevant international legal systems. Without this, the potential for legal conflicts, access inequalities, and patient vulnerability to unethical practices will continue to increase as the adoption of digital technology in healthcare services accelerates (Marinelli et al., 2022). Lodge and Wegrich (2012) emphasize that institutional capacity and understanding of complex regulations are crucial for the effective implementation of multi-jurisdictional telemedicine.

3.4. Adaptive Legal Reform and Multi-Sectoral Approaches in Digital Health

Advances in health technology require a more complex and structured system of ethical oversight and assessment. Unfortunately, Indonesia does not yet have a specific audit mechanism or ethics committee tasked with assessing the use of technology in daily healthcare practices. Existing ethics committees tend to only function in the context of biomedical research or clinical trials, not in the operationalization of technology such as the use of AI for diagnosis, the use of big data in disease prediction, or medical chatbots. According to Floridi and Cowls (2022), every healthcare technology that is widely used must adhere to ethical principles such as fairness, transparency, and accountability. Without routine audits and oversight based on ethical principles, health technology systems are prone to algorithmic bias, discriminatory automated decisions, and violations of patient rights. Even in developed countries such as the United Kingdom, audit systems for AI in health services have begun to be integrated into the structure of the National Health Service (NHS), while Indonesia is still in the early stages of normative discussion. Lam et al. (2024) highlight the difficulties of auditing black box AI systems, emphasizing the need for adaptive and multi-stakeholder oversight mechanisms to ensure accountability and transparency in clinical decision-making.

Furthermore, audits should not only cover the technical aspects of algorithms, but also verify the system's compliance with patient rights, such as the right to explanation, the right to refuse automation (right to human review), and the right to data security and integrity. Without a robust audit system and ethics committee, the integrity of Indonesia's digital healthcare system is at risk of being compromised, damaging public trust. Lodge and Wegrich (2012) and Muzam (2023) stress that the effectiveness of regulations heavily depends on institutional competence and literacy, including digital and legal literacy among health professionals. Meskó et al. (2017) also note that structural and operational adaptation is necessary for safe digital health transformation.

Digital transformation in healthcare requires increased digital literacy and legal understanding, both on the part of service providers (health workers) and users (the public/patients). However, recent surveys and studies show that this gap in understanding is still very large in Indonesia. Most medical personnel have not received adequate training on the safe and legal use of digital systems, such as the use of EMR AI-based health applications or telemedicine platforms. Many doctors, for example, do not understand how digitally collected patient data should be stored, processed, and shared in accordance with the principles of personal data protection as stipulated in Law Number 27 of 2022. This can lead to practices that unknowingly violate the law, such as sharing patient data through unencrypted applications or storing medical records on personal devices (Jubaidi & Khoirunnisa, 2025).

From the public's perspective, digital and legal literacy levels are also major obstacles. Many patients do not understand the consequences of agreeing to the terms and conditions in health applications, or are even unaware that their data is being processed and stored by third parties. This reduces patients' capacity to exercise control over their personal data and weakens their right to individual autonomy in medical decision-making. Lodge and Wegrich (2012) emphasize that effective regulation must be accompanied by the capacity for understanding and implementation by all parties involved. In Indonesia, investment in legal and digital literacy programs in the health sector is still very minimal. Without this capacity building, technology that is supposed to be a solution has the potential to become a source of even greater legal and ethical problems. Ozair et al. (2015) highlight the high potential for privacy violations in EMR systems, reinforcing the need for education and literacy programs to prevent misuse. Gellert and Gutwirth (2013) also stress that digital health adoption must integrate patient rights and human-centric data protection.

4. Conclusion

The integration of digital technologies such as electronic medical records, artificial intelligence, and telemedicine has transformed healthcare services in Indonesia, improving efficiency, clinical accuracy, and patient access. However, the rapid adoption of these innovations has also introduced significant legal and ethical challenges due to the lack of a comprehensive regulatory framework. Key issues include the protection of patient data, unclear legal responsibility for AI-related errors, lack of transparency in clinical algorithms, licensing ambiguities in cross-regional telemedicine, and limited legal and digital literacy among healthcare professionals. Addressing these challenges requires a multi-pronged approach. Specific regulations for health technology should be developed to govern data management, security standards, liability, algorithm transparency, and mandatory reporting. Such measures provide legal certainty for medical personnel and institutions while fostering public trust. Additionally, independent health technology ethics and audit committees are essential to evaluate technologies, develop operational ethical guidelines, safeguard patient rights, and conduct regular audits, ensuring technological innovation aligns with ethical and legal norms.

Strengthening legal and digital literacy among healthcare providers through formal education and ongoing training is crucial to ensure responsible use of technology. In parallel, informed consent mechanisms must be adapted to digital platforms, guaranteeing that patients understand the role, risks, and limitations of AI-assisted clinical decisions. Furthermore, international cooperation is necessary to harmonize telemedicine regulations, recognize professional licenses, clarify cross-border liability, and establish global standards for data security and patient protection.

Implementing these measures has important implications for protecting patient rights, promoting ethical technology use, and enhancing accountability and trust in healthcare systems. This study is limited by its normative-conceptual approach, which does not empirically assess the effectiveness of the proposed strategies. Future research should investigate the real-world impact of regulatory reforms, auditing frameworks, digital literacy programs, informed consent processes, and cross-border telemedicine practices on patient safety, legal accountability, and ethical compliance.

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