The Law Reform Regarding the Regulation of Medical Use of Artificial Intelligence and the Protection of Patient Privacy in the Utilization of Artificial Intelligence in Health Care

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Abstract. The use of artificial intelligence as a form of development is becoming increasingly common. Artificial intelligence is causing significant changes, including in the health sector. Further research is needed to determine the protection of patient privacy in the context of the use of artificial intelligence in the health sector and the need for legal reform related to the use of artificial intelligence in the health sector. This type of research is normative jurisprudence, using legal and conceptual approaches. The results of this study indicate the need for legal reform related to the use of artificial intelligence in the health sector. This reform should include restrictions on the use of artificial intelligence in the health sector, as well as guarantees of confidentiality of patient data.

1 Introduction

Artificial intelligence (AI) technology in healthcare has brought new capabilities for machines and computer algorithms to mimic the functions of the human brain in terms of learning, reasoning, and independent decision making. Computers in healthcare are designed to perform medical analysis and make healthcare decisions and actions. The process of decision making and health actions can be done quickly thanks to the integration of comprehensive and in-depth knowledge of various health issues obtained from medical experts [1]. Article 1 point 8 of Law No. 11 of 2008 on Electronic Information and Transactions (UU ITE) defines an electronic agent as a device of an electronic system designed to perform actions on certain electronic information automatically organized by humans. This definition includes various types of entities or computer programs that operate within an electronic system to perform pre-programmed tasks without direct human intervention.

In the context of artificial intelligence (AI), this definition is relevant because AI is often implemented as electronic agents in electronic systems. AI can be designed to automatically perform various actions and decisions based on pre-programmed data analysis. For example, in healthcare, AI can act as an electronic agent in a medical data management system that performs data processing, diagnosis, or even treatment recommendations based on the

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analyzed information. It is important to understand that this definition also includes legal aspects related to responsibility and protection in the use of AI technology. The applicable regulations must be able to accommodate the development of this technology so that the use of AI can be carried out safely, ethically and effectively in various areas of life, including electronic transactions and information management [2].

The development of artificial intelligence (AI) technology in healthcare has had a significant transformative impact. AI has revolutionized the way disease is diagnosed by leveraging its ability to quickly and accurately analyze data. Through sophisticated algorithms, AI is able to identify complex patterns in medical data, helping physicians make more informed and faster decisions. In addition, AI has made great strides in patient care by developing systems that can monitor patient conditions in real time and make recommendations for optimal treatment. Healthcare data management has also been transformed by AI. The technology enables the integration and analysis of data from many different sources, providing a detailed, holistic view of population health and epidemiological trends. AI is also being used in medical research to accelerate the discovery of new drugs and therapies, and to facilitate the development of personalized therapies for each patient. These advances include improving the accuracy of disease diagnosis, especially in the analysis of medical images such as CT scans and MRIs; drug development; and health data management, organizing electronic medical records and helping healthcare providers make better decisions [3].

The link between artificial intelligence (AI) and health technology, as defined in Health Law No. 36 of 2009, highlights the evolution of approaches to the diagnosis, prevention and treatment of health problems. This law defines health technology as a tool that supports medical efforts to improve health resources and the overall effectiveness of health efforts. In this context, AI serves as a tool that expands diagnostic capabilities by analyzing medical data deeply and thoroughly, helping to identify patterns that are not easily visible to humans.

The application of AI in diagnosis, especially through the use of machine learning algorithms, allows physicians to make faster and more accurate decisions based on massive analysis of patient data. AI also plays an important role in disease prevention by predicting disease risk based on factors related to patient data, enabling earlier and more targeted interventions. origin 334 paragraph (1) of the Health Act states that the use of health technology should focus on improving health resources. In the context of AI, this includes the development and implementation of technologies that not only improve the ability of health professionals to deliver services, but also expand access to quality health services.

Privacy is the right of every individual to live his or her private life without interference, and one of its manifestations is personal information. Personal information is any information about an individual. Over time, the form of personal information has evolved with the rapid development of technology.[4] Personal information in medical records is very important because it is the basis for providing appropriate and effective treatment to patients. The information contained in medical records, such as medical history, test results, and previous treatments, provides a detailed picture of an individual's health. This enables physicians and healthcare professionals to make informed clinical decisions based on solid evidence. The importance of this data cannot be separated from the need to maintain the privacy and security of patient information. Because of its highly sensitive nature, information in medical records can be an attractive target for hackers or unauthorized parties. Medical data breaches can have direct negative consequences for patients, including misuse of personal information, discrimination, or identity theft.

Protecting patient data is a critical aspect of medical practice and is governed by various privacy regulations and standards around the world, such as the General Data Protection Regulation (GDPR) in Europe and the Health Insurance Portability and Accountability Act (HIPAA) in the United States. While the adoption of electronic health records improves the

availability of patient health and care information, it also increases the risk of cybersecurity threats and data breaches. Keeping up with technological developments and addressing cybersecurity concerns requires constant monitoring, improving security measures, and implementing robust privacy policies. This is to prevent the loss of personal information.

In fact, one of the most critical aspects of AI integration in healthcare is patient privacy. Medical data collected and processed by AI systems often contain highly sensitive information such as medical history, medical test results, and other personal details. Therefore, data protection is essential to prevent potential misuse, unauthorized access, or privacy breaches, which can have both personal and societal negative impacts on patients. Effective regulations should be able to set strict standards for the collection, processing, and storage of medical data by AI systems. This includes the need for the use of strong encryption techniques, strict access arrangements, and stringent data security procedures to ensure that patient health information is well protected from cyber threats and unauthorized use. By maintaining the integrity and confidentiality of medical data, patients can feel more confident in using AI-based healthcare services, while supporting the development of safe and ethical technologies in the healthcare sector.

Comprehensive legal reforms in the regulation of the medical use of artificial intelligence (AI) and the protection of patient privacy in healthcare are crucial steps to integrate rapid technological innovation with strong protection of patients' rights and safety. In this context, the importance of adequate regulation is immense, as AI has brought about significant changes in diagnosis, treatment and health data management. Through an approach based on ethics, transparency and careful data security, we can ensure that the development and use of artificial intelligence not only improves the efficiency of healthcare, but also strengthens public trust and respects human values in the use of technology in this digital age. Therefore, there is an urgent need for legal reforms on the use of AI to improve oversight and accountability in the use of AI in the healthcare sector, in particular to protect patient privacy and strengthen data security and guarantee the confidentiality of patient data.

2 Methods

This research employs a normative jurisprudence approach with two main methods: a legal approach and a conceptual approach. The legal approach is used to analyze various relevant laws and regulations, such as Indonesia's Health Law Number 36 of 2009, which governs the use of health technology. The conceptual approach is applied to explore the legal principles underlying the protection of patient privacy.[5] The research aims to provide a comprehensive overview of how laws can be adapted or updated to address the challenges and maximize the benefits of integrating AI technology into healthcare. By analyzing current legal frameworks and exploring the underlying principles of patient privacy protection, the study seeks to identify gaps and propose necessary legal reforms. These reforms are intended to ensure that regulations keep pace with technological advancements and effectively safeguard both patient rights and the potential of AI innovations in improving healthcare outcomes.

3 Discussion and Analysis

3.1 Protecting Patient Privacy In The Context Of The Use Of Artificial Intelligence In Healthcare

Technology has played a very important role in the progress of various fields of human civilization today. Technological innovations have fundamentally changed the way people

perform daily tasks that previously relied on human labor and took a long time, making them more practical, efficient, and integrated. The development of artificial intelligence (AI) is one of the most prominent results of advances in information technology, providing more intelligent and adaptive solutions to various complex problems. AI technology has great potential to transform various sectors, including healthcare, education, industry, and financial services. In healthcare, AI has enabled more accurate and faster disease diagnosis, more accurate epidemic prediction, and more efficient health data management. In industry, AI is being used to automate manufacturing processes and supply chain management, improving efficiency and significantly reducing production costs.

AI is artificial intelligence or artificial intelligence is a part of computer science that makes machines (computers) do work like and as well as humans do [6]. The word "intelligence" comes from the Latin "intelligo," which means "I understand". Essentially, intelligence refers to the ability to understand and act. In general, intelligence can be defined as something that is created or produced by humans, either naturally or artificially. The term "artificial intelligence" refers to the development of systems that can mimic or display human intellectual abilities through machines or computers.

Creating AI requires a knowledge-based database containing facts, theories, ideas, and relationships, alongside inference engines capable of drawing conclusions from experience. AI presents significant opportunities for addressing complex problems and improving various sectors, but it also raises ethical and legal issues, such as the framework for liability if errors occur in AI-driven diagnostics or treatment.

Health is a resource that all people have, not a goal to be achieved. Health is not focused on being physically fit, but includes a healthy mind where individuals can be tolerant and accepting of differences [7]. According to the Law of the Republic of Indonesia. No. 23 of 1992 on Health, health is a state of physical, mental and social well-being that enables everyone to live a productive social and economic life. According to WHO, health is a dynamic state that includes physical, mental, and social health and is not only free from disease, disability, and weakness. A person is said to be physically healthy when he or she has no clinical disorders, his or her organs function properly, and he or she is not ill. Meanwhile, mental or psychological health includes a person's mental, emotional, and spiritual health [8].

In the healthcare context, medical records play a vital role. According to the Indonesian Health Law No. 44 of 2009, medical records are documents containing patient identity, examination results, treatment information, and other services provided. This information is considered confidential and must be protected from unauthorized disclosure according to medical ethics and legal regulations [9]. In Indonesia, privacy and security of electronic medical records (EMRs) are regulated by the Electronic Information and Transaction Law (ITE) and Regulation of the Minister of Health No. 269 of 2008. However, existing laws are limited to the legal aspects of electronic health records (EHRs) and do not fully address privacy concerns specific to AI-enabled medical records. Recent breaches in patient data at institutions like the University of Chicago Hospitals highlight the need for improved data security measures.

An electronic medical record is a patient's medical record maintained by a healthcare provider over time that contains clinical information relevant to the patient's care at a particular healthcare facility. This includes information about the patient's progress, health problems, treatments received, vital signs, previous treatment history, immunizations, laboratory test results, and radiology reports [10]. However, people are often worried about leaking information about this data.

The patient's examination report is part of the medical record data that must be kept confidential because it contains the patient's personal information. According to Article 32 (i) of Law No. 44 of 2009 on Health, patients have a fundamental right to privacy and

confidentiality regarding their illness. Article 1 paragraph 1 of the Regulation of the Minister of Health of the Republic of Indonesia No. 269 of 2008 states that medical records are documents that contain the patient's identity, examination results, information about treatment, measures and other services provided to patients. All information contained in medical records is considered confidential information, as it reflects the special relationship between patients and doctors, and must be protected from unauthorized disclosure in accordance with the medical code of ethics and applicable legal regulations [11].

In Indonesia, the laws that regulate privacy security under the legal umbrella are the Electronic Information and Transaction Law (ITE) in Articles 5 and 6, and Regulation of the Minister of Health Number 269 of 2008 concerning Medical Records Article 2 [12]. However, this existing law is still limited to the legal aspects of EHRs and has not addressed the privacy issues of these EHR data, so the current development of RME is still limited to replacing EHRs from paper to AI-enabled digital form. Hospital patient data breaches have occurred at one of the University of Chicago Hospitals and Wilcox Memorial Hospital.

Patient data leaks in electronic medical records have highlighted the need for improved data security techniques and information systems, especially in the context of AI-enabled medical records. One of the primary solutions to this problem is the implementation of data encryption. Encryption ensures that sensitive data in EHRs is mathematically scrambled so that it can only be read by a party in possession of the correct decryption key. Sophisticated cryptographic methods, such as the Advanced Encryption Standard (AES) algorithm, are used to protect patient information from unauthorized access. AI security is also important to consider in this context. AI used in medical records must be protected with the same rigor as data security. The use of strong usernames and passwords is the first step in preventing security breaches. In addition, access control should be tightened by implementing two-factor authentication systems or biometric techniques.

It is also important to develop good authentication and authorization mechanisms. This includes implementing systems to ensure that only authorized users have access to certain health information. Two-factor or more authentication technologies can be used to increase the security of access to sensitive patient information. Transparency is also key to protecting patient privacy. Healthcare providers and artificial intelligence developers must provide patients with clear information about how their data will be collected, used and protected. Patients should be given choice and control over the use of their data, including the right to withdraw consent at any time.

Ensuring that patient privacy is protected requires strong policies and regulations. These policies should include clear and firm guidelines for data collection, use, storage, and disclosure. In addition, policies should address technical security issues such as data encryption, strict access control, and appropriate authorization mechanisms. Privacy risk management requires regular auditing and monitoring of artificial intelligence systems used in healthcare. These audits are designed to ensure compliance with established privacy policies and to detect potential data leaks or unauthorized use. Protecting patient privacy in the context of artificial intelligence requires collaboration among governments, regulators, healthcare providers, and technology developers. This collaborative effort is necessary to create a safe and reliable environment for the use of artificial intelligence to improve healthcare without compromising individual privacy.

3.2 The Need for Legal Reform Regarding the Use of Artificial Intelligence in Healthcare

The development of artificial intelligence (AI) technology has had a major impact on the healthcare sector. In recent years, AI applications have significantly changed the way diagnosis, treatment, and health data management are performed. This article provides an

analysis of the progress of AI technology in healthcare, covering some of the key innovations [13]. Analyzing the evolution of AI in healthcare refers to understanding and evaluating how AI technologies have impacted and continue to impact the healthcare sector. It involves monitoring the trends, impacts, and changes brought about by the use of AI in diagnosis, treatment, data management, and various other aspects of healthcare [14].

The regulation and oversight of the use of artificial intelligence (AI) technologies in healthcare, particularly in the context of medical records as patient data, is critical to ensuring that their use in medical practice is safe, ethical, and effective. These regulations include requirements for certification of AI technologies in the diagnosis and treatment of disease. This certification often includes an evaluation of the safety, quality, and effectiveness of AI systems before they are implemented in clinical practice. The purpose of these certification requirements is to ensure that AI technologies are reliable and safe when used to diagnose and treat patients.

The need for legal reforms related to the use of artificial intelligence (AI) in the health sector arises from the rapid development of technology, which is deepening the integration of AI in various aspects of health care [15]. The development of artificial intelligence (AI) technology has brought about significant paradigmatic changes in health data management. AI is not only capable of quickly and accurately analyzing large-scale medical data to support more precise disease diagnosis and epidemic forecasting, but it is also a catalyst in the advancement of medical research. Despite its great benefits, the use of AI in the healthcare context also raises a number of serious challenges related to the privacy and security of patient data. This technology presents risks that are not yet fully regulated by existing laws, especially in the face of cyber security threats and the protection of highly sensitive medical data.[16] To address these challenges, an appropriate regulatory framework is needed that not only regulates the ethical and effective use of AI in clinical practice, but also strictly protects patients' personal data. This includes extending existing regulations to cover cybersecurity aspects specific to AI technologies in the healthcare context. The updated regulation should be able to cope with the rapid dynamics and complexities of the use of AI technologies in different areas of healthcare, from diagnosis to complex medical data management.

Ethics are also an important consideration in the use of AI in healthcare. AI can be used to make complex medical decisions that previously could only be made by human physicians or health professionals. Ethical questions arise about how AI should be programmed to handle complex moral situations and how to ensure that AI decisions are consistent with universally accepted ethical values. There is also a need to clarify the legal liability associated with the use of AI in medical diagnosis and treatment. If an error occurs in the diagnosis or treatment provided by an AI system, who is liable? Legal reforms are needed to establish a clear framework for liability in medical decision-making by AI.

Another aspect to consider is the regulation and certification of AI in healthcare. It is important to develop strong regulations and certifications for the use of artificial intelligence (AI) technologies in healthcare. This is necessary to establish clear guidelines on how to test, evaluate, and certify AI applications used in clinical practice. Strong regulations will ensure that applied AI technologies can be trusted to deliver safe, effective, and high-quality healthcare services to patients. Build a strong technological infrastructure and train sufficient human resources to support the integration of AI across the health system. This includes considering adequate funding for the development, implementation and maintenance of AI technologies, as well as providing the necessary training for health professionals to use these technologies appropriately.

A comprehensive legal reform should also cover these aspects to ensure that the implementation of AI in healthcare is not only effective in improving medical services, but also meets high safety and ethical standards [17]. As such, these actions will not only support

the wider adoption of AI technologies in clinical practice, but also secure and strengthen the future of AI integration in sustainable healthcare.

Some jurisdictions may require healthcare providers or medical institutions to obtain a special license before using AI technologies in their practice. This is to ensure that the use of AI technologies in the healthcare context not only meets established safety and ethical standards, but also complies with applicable legal requirements. These licenses may include requirements such as specific training for healthcare professionals using AI technologies, as well as procedures to ensure that their use does not pose additional risks to patients. In addition, regulations also aim to address patient privacy issues, which are becoming increasingly relevant in the context of AI use in healthcare. Sensitive and confidential medical data must be kept confidential in accordance with applicable data protection regulations. This includes ensuring that AI technologies used to manage or analyze medical data can protect patients' personal information from unauthorized access or inappropriate use.

Legal reforms related to the use of artificial intelligence in health care are also important to address new challenges that may arise as the technology develops. This includes regulating legal liability in cases where medical decisions are made with the help of AI, as well as clarifying the limits and authority of healthcare professionals in using this technology in their daily practice.[18] In a global context, regulatory harmonization is also an important consideration. Creating uniform standards for the use of AI technologies in healthcare can help reduce legal uncertainty for healthcare providers operating across borders. This will facilitate faster adoption of the technology and harmonize patient protection and data security expectations around the world. Overall, appropriate and comprehensive legal reforms governing the use of artificial intelligence in healthcare not only support responsible and safe innovation, but also protect patients' interests and build public trust in this rapidly evolving technology.

4 Conclusion

The advent of technology, particularly artificial intelligence (AI), has brought about significant advances in various sectors, including healthcare. AI has the potential to facilitate faster disease diagnosis and more efficient health data management. However, it also raises concerns about data security and privacy. While existing laws provide protections, they are insufficient for the complexity of AI-powered electronic medical records. To protect patient privacy, robust encryption, rigorous access controls, and transparent data practices are essential. Effective protection necessitates a collaborative approach between governments, healthcare providers, and technology developers to balance innovation with privacy.

The advent of artificial intelligence (AI) has had a profound impact on the healthcare sector, transforming the manner in which diagnosis, treatment, and health data management are conducted. The application of AI in healthcare has the potential to enhance the accuracy and efficiency of diagnosis and medical research. However, it also presents unique challenges related to the protection of patient data privacy and security. It is imperative that adequate regulation and oversight be established to ensure the safe, ethical, and effective use of AI. It is imperative that legal reforms be enacted to address these challenges, including the necessity for more comprehensive regulations pertaining to cybersecurity, legal liability, and the certification of AI technologies. Furthermore, the establishment of consistent global regulations is crucial to mitigate legal ambiguity and facilitate accelerated technological integration. Appropriate legal reforms will facilitate responsible innovation, safeguard the interests of patients, and foster public trust in this evolving technology.

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