

LEGAL ASPECTS OF THE USE OF ARTIFICIAL INTELLIGENCE IN TELEMEDICINE-BASED DIAGNOSIS: BETWEEN AID TOOLS MEDICAL AND CLINICAL DECISION MAKING

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Abstract

The development of Artificial Intelligence (AI) technology in healthcare has encouraged its use in telemedicine-based diagnosis. In Indonesia, the application of AI in telemedicine raises legal questions regarding the status of AI: whether it is merely a medical aid or has become a determinant of clinical decisions. This study aims to analyze the legal aspects of the use of AI in telemedicine by examining the legal framework, the principles of legal responsibility of medical personnel and healthcare facilities, and the ethical implications for the doctor-patient relationship. The research method used is normative juridical with a limited statutory, conceptual, and comparative approach. The results show that based on Law Number 17 of 2023 concerning Health, Law Number 29 of 2004 concerning Medical Practice, and the Minister of Health Regulation concerning the implementation of telemedicine, AI is not yet normatively recognized as a legal subject, but rather as an instrument or aid in the healthcare process. Clinical decisions remain with the physician as the primary person responsible for medical services. However, the high degree of autonomy of AI systems and doctors' reliance on AI recommendations creates a gray area of legal liability, particularly in the case of misdiagnosis or delayed diagnosis. This study recommends the need for specific regulations (*lex specialis*) regarding medical AI, standards for AI-assisted medical practice, mechanisms for the feasibility and certification of AI devices, and strengthening informed consent that explicitly includes the use of AI in telemedicine services. This will ensure legal certainty, patient protection, and professional accountability in the era of digital transformation in healthcare services.

Keywords: artificial intelligence, telemedicine, legal liability, medical practice, medical aids

INTRODUCTION

Law plays a vital role in human life, as legal norms are used to regulate human behavior to achieve happiness. Indonesia is a country based on the principle of law (*rechtsstaat*). Therefore, every action taken by citizens must comply with and follow applicable laws. According to Gustav Radbruch, law has three main objectives: ensuring certainty, justice, and benefit. Therefore, legal norms must be established to create order in society. The previous industrial revolution focused on the use of technology and electronics to automate production. However, in the current era of Industrial Revolution 4.0, humans, machines, and data are increasingly connected. These technologies support efficiency, intelligence, and accelerate human performance.

In today's digital era, the need for fast, efficient, and responsive healthcare services is increasing. Artificial Intelligence (AI) presents an innovative solution to address these challenges by automating various processes within the healthcare system. The use of AI is not limited to the clinical field but also encompasses managerial and administrative aspects, helping to improve the operational efficiency of hospitals and primary healthcare facilities. In Indonesia, the use of AI in healthcare has begun to be implemented in various forms, from chatbots for medical consultations, electronic medical record management systems, to algorithms for patient medication reminders. This transformation paves the way for more integrated and adaptive healthcare services to meet the needs of modern society. Accurate diagnosis is a key foundation for effective healthcare. Misdiagnosis, including missed, delayed, or incorrect diagnoses, is a major source of preventable harm worldwide. Numerous cases demonstrate that adult

patients in outpatient settings experience misdiagnosis each year, with consequences including morbidity, mortality, and a significant economic burden. The complexity of disease manifestations, increasing multimorbidity, fragmentation of care pathways, and the explosion in clinical data volume have collectively increased the cognitive load faced by healthcare professionals. Traditional diagnostic processes rely heavily on human ability to recognize patterns, perform clinical reasoning, and utilize prior clinical experience. While experienced clinicians are capable of nuanced assessments, human performance still has limitations, including fatigue, cognitive biases, and information overload.

Artificial Intelligence (AI) operates by collecting large amounts of data, which is then analyzed algorithmically using the mathematical capabilities of AI. The results of this analysis are then recorded and stored as knowledge within the AI system, which is used to make decisions. The decisions produced by AI are similar to those made by the human brain. What distinguishes AI from other computer programs is its ability to complete complex tasks even better than humans, leading people to believe that AI possesses human-like intelligence.³ AI-based disease diagnosis does not necessarily mean autonomous clinical decision-making. Instead, AI systems can play a role in various stages of the clinical workflow, such as screening and triage by identifying normal cases or prioritizing high-risk patients, disease detection and classification, assessment of disease severity or staging, and diagnostic decision support through probabilistic outputs or differential diagnosis lists. Diagnostic AI research has focused largely on areas with abundant data availability, clear labeling standards, and well-defined diagnostic endpoints. Key areas include medical imaging (radiology, ophthalmology, dermatology), whole-slide imaging-based computational pathology, biosignal analysis such as ECG and EEG, structured and unstructured HER utilization, and genomic and multi-omics diagnostics.

In the context of healthcare, AI is widely used to improve operational efficiency, assist nurses in decision-making, and simplify administrative processes. AI applications such as chatbots and virtual assistants can provide initial medical information, answer health-related questions, and screen patients for priority services. Developments in information and communication technology have brought significant changes to healthcare delivery, one of which is through telemedicine. Telemedicine allows medical services to be delivered remotely using electronic devices and internet networks. The COVID-19 pandemic has further accelerated the adoption of telemedicine in Indonesia as an effort to maintain continuity of healthcare services while reducing the risk of disease transmission. AI has also been applied in electronic medical record systems and patient data analysis, including real-time monitoring of vital signs and providing early warnings. This technology supports modern nursing practice by assisting with scheduling, documentation, and information management, allowing healthcare professionals to focus more on clinical aspects and patient empathy.

The rapid development of digital technology, particularly artificial intelligence (AI), has given rise to various legal regulatory issues encompassing conceptual aspects, development conditions and features, functions and scope of application, integration with other systems, and control mechanisms for the use of such technology. Numerous cases in various countries demonstrate that the application of AI in healthcare is not free from controversy. For example, algorithmic bias has the potential to lead to discrimination in the provision of medical services, as well as the use of AI systems that are unable to transparently explain the basis for their decision-making (the black-box problem). This situation emphasizes the importance of comprehensive oversight and regulation to ensure that technology is used fairly, accountably, and responsibly.

Therefore, a robust legal and ethical framework is needed to support the development of AI technology in the healthcare sector. This framework aims not only to protect the rights of patients and medical personnel but also to build public trust in the use of technology in healthcare. Taking into account the characteristics of their respective legal systems, various countries have developed their own regulatory approaches, ranging from developing national AI strategies to formulating principles for the application of AI in the pharmaceutical, medical device, and healthcare industries, covering all stages, from research and development to patient care.

In practice, the application of AI in healthcare encompasses various aspects, such as drug development, medical imaging and diagnostics, clinical decision support systems for doctors, health risk analysis and prediction, lifestyle management and monitoring, data processing from wearable devices, chronic disease monitoring, the use of virtual assistants, and emergency management and surgical procedures. From clinical applications to optimizing hospital management and the use of digital-based health applications, many believe AI will significantly revolutionize the healthcare system. Accordingly, various economic projections indicate rapid growth in the AI market in the healthcare sector in recent years. However, this development also presents complex challenges, so the implementation of AI in healthcare systems must always be based on ethical principles and legal compliance to ensure optimal benefits are realized without compromising the protection of human interests.

The application of AI in disease diagnosis raises fundamental ethical questions related to clinical responsibility, informed consent, and accountability. When AI contributes to diagnostic decisions, the lines of responsibility between developers, institutions, and healthcare professionals become blurred. From a medical ethics perspective, diagnostic AI must adhere to the principles of beneficence, non-maleficence, autonomy, and justice. This includes protecting patient data, preventing algorithmic discrimination, and human involvement in clinical decisions with significant impact.

Ethics in digital health primarily concerns the impact of digitalization (the use of information and communication technologies) on society and the environment, with a particular focus on healthcare workers. Many societies are undergoing a digital transformation, which has significant implications for ethics. The principles of equality, privacy, confidentiality, Ownership, personal respect, responsibility, accountability, and informed consent are fundamental ethics in digital health. Advances in AI impact existing legal systems in society, particularly regarding criminal liability. In Indonesia, there is no law specifically regulating AI. In Indonesia, there are no regulations that explicitly govern AI, and this could become a legal issue if AI technology commits acts that violate Indonesian law. Given AI's ability to commit acts and crimes, it cannot be ignored that AI could commit legal acts that harm others, just as humans do.

Yolanda Simbolon with the research title "Civil Liability for Artificial Intelligence Causing Losses According to Law in Indonesia" which in conclusion there are no regulations that specifically regulate Artificial Intelligence.⁹ Currently there are no specific regulations governing artificial intelligence. Responsibility for losses caused by artificial intelligence can only be based on Article 1367 of the Civil Code. In Indonesia, the health legal framework is still centered on the concept of a professional relationship between doctors and patients, where doctors as legal subjects bear professional responsibility for the medical actions provided.

Meanwhile, AI is not yet recognized as a legal subject, but functions as an information technology product that falls within the scope of medical device and data protection regulations.

This phenomenon raises a number of research questions, including:

- 1) What are Indonesia's positive legal regulations regarding the use of AI in telemedicine services?
- 2) What is the position of AI in telemedicine-based diagnosis from a legal perspective—as a medical aid or a clinical decision maker?
- 3) How is legal liability constructed if patient harm occurs due to the use of AI in telemedicine?

Based on this background, this research aims to:

- a) Analyzing the normative framework for the use of AI in telemedicine in Indonesia;
- b) Examining the position of AI in telemedicine-based diagnostic processes; and
- c) Examining the construction of legal responsibilities of medical personnel, health facilities, and AI developers.
- d) Theoretically, this research contributes to the development of digital health law studies in Indonesia, while practically it can provide input in the formulation of medical AI regulatory policies and guidelines for telemedicine-based medical practices.

This research uses a normative legal research method. This method collects secondary data, such as primary legal materials, indirectly. This data is obtained through document or library data collection techniques, based on the legal materials used in this research. The data is then analyzed using qualitative data analysis techniques.

LITERATURE REVIEW

The development of artificial intelligence (AI) in the healthcare sector has received significant attention in various scientific literature, particularly regarding its role in improving diagnostic accuracy, improving the efficiency of medical services, and optimizing clinical decision-making. In the healthcare context, AI is generally used as a clinical decision support system (CDSS), which assists medical personnel in analyzing patient data and providing diagnostic and therapeutic recommendations. However, the literature reveals a fundamental debate regarding the role of AI, whether it is merely an assistive tool or has shifted to become an entity that plays a role in clinical decision-making.

Numerous studies confirm that the use of AI in telemedicine-based diagnostics offers significant benefits, such as expanding access to healthcare services, especially in remote areas, and accelerating medical analysis through big data analytics. In this context, telemedicine is a strategic medium that integrates digital technology with medical practice, enabling remote interactions between doctors and patients. However, on the other hand, various studies also highlight the legal and ethical risks arising from the use of AI. One key issue is the lack of transparency in algorithms (the "black-box problem"), which makes it difficult for medical professionals to understand the basis of AI decision-making. This has implications for legal accountability, particularly in cases of misdiagnosis or patient harm. The

literature also highlights the potential for algorithmic bias, which can lead to inequities in healthcare, particularly for certain groups. From a legal perspective, liability for the use of AI in medical practice remains a matter of debate. Some approaches in the literature suggest that responsibility remains with medical personnel as those with professional authority (professional liability). Meanwhile, other approaches are beginning to consider the possibility of sharing responsibility between physicians, technology developers, and healthcare providers (shared liability), especially when AI has a high degree of autonomy.

Furthermore, a literature review shows that regulations related to AI in healthcare remain fragmented and unable to fully accommodate the complexity of this technology. Several countries have developed regulatory frameworks covering security, transparency, and patient data protection, but there is no uniform global standard. In the context of telemedicine, the issue of personal data protection and informed consent are crucial aspects that must be addressed, given that medical interactions are conducted through digital platforms. Thus, based on the existing literature review, it can be concluded that the use of AI in telemedicine-based diagnostics lies at the intersection of technological innovation and the need for legal certainty. Therefore, a legal framework is needed that not only positions AI as a medical aid but also anticipates the potential shift in its role as part of the clinical decision-making process. This study is crucial for formulating a legal liability model that is adaptive, equitable, and capable of ensuring protection for all parties in the technology-based healthcare system.

METHOD

This study uses a qualitative approach with a normative (doctrinal) research approach that focuses on examining legal norms, principles, and doctrines related to the use of Artificial Intelligence (AI) in telemedicine-based diagnosis. The method used is a literature review, examining various relevant primary, secondary, and tertiary legal sources. Primary legal materials include laws and regulations related to medical practice, telemedicine, personal data protection, and regulations related to health technology. Secondary legal materials consist of textbooks, national and international scientific journal articles, and previous research discussing artificial intelligence in healthcare and the legal responsibilities of medical personnel. Tertiary legal materials include legal dictionaries, encyclopedias, and other reference sources that support conceptual understanding.

The approaches used in this research include a statutory approach, a conceptual approach, and a comparative approach to compare regulations in various countries regarding the use of AI in healthcare services, particularly in the context of telemedicine. The legal material collection technique was conducted through documentation studies by searching scientific journal databases such as Google Scholar, PubMed, and accredited national journal portals, as well as official documents from international institutions related to health and technology. The legal material analysis was conducted descriptively and analytically, systematically outlining and reviewing various literature findings to then draw conclusions regarding the legal aspects of using AI as a medical aid or as a clinical decision-maker in telemedicine practice. Through this method, research is expected to provide a comprehensive understanding of the limits of legal responsibility, the position of AI in medical practice, and the need for legal regulations that are adaptive to developments in health technology.

RESULTS AND DISCUSSION

1. Legal Basis for Health Services and Patient Diagnosis Using AI

Although Indonesia currently does not have specific regulations explicitly governing AI in the healthcare sector, a number of existing laws and regulations provide a general legal basis for regulating the use of this technology. One form of technology utilization in the medical world that is increasingly popular is telemedicine. This service allows patients to consult with a doctor without having to be in the same location. Consultations are conducted through communication media such as apps, telephone, or the internet. While this method is very helpful in increasing access to healthcare services, especially for people in remote areas, concerns remain regarding diagnostic accuracy. This is because doctors do not perform a direct physical examination of the patient, which can lead to inaccurate medical decisions. As a result, patients may receive inappropriate medication, potentially causing allergic reactions or dangerous side effects. Furthermore, if a medical error occurs, it is difficult to determine legal responsibility because the interaction is indirect.

The legal principle of *de minimis non curat lex* does state that the law does not deal with matters that are considered trivial, but when the error has a serious impact on the patient's life, it can be categorized as a form of gross negligence. Regulations on the use of medical software in Indonesia are currently still limited and spread across several regulations. Law Number 17 of 2023 concerning Health, Law Number 11 of 2008 concerning Electronic Information and Transactions (ITE) as last amended by Law Number 1 of 2024, Law Number 27 of

2022 concerning Personal Data Protection (PDP), Minister of Health Regulation Number 20 of 2019 concerning the Provision of Telemedicine Services Between Health Service Facilities as well as Regulation of the Minister of Health Number 23 of 2020 concerning Amendments to Regulation of the Minister of Health No. 20 of 2019 Law No. 17 of 2023 concerning Health recognizes the digitalization of healthcare services, including the development of health information systems and technology, as part of national healthcare reform efforts. While the term "Artificial Intelligence" is not explicitly mentioned, the articles governing the provision of technology-based healthcare services, including telemedicine and electronic medical records, can serve as a starting point for implementing AI. Article 1 Paragraph (3) of Law Number 17 of 2023 concerning Health explains that health services include all forms of activities carried out directly to individuals or community groups, whether to prevent, treat, or restore health conditions. Therefore, if health services are carried out online or remotely, such as through telemedicine, these activities must still comply with applicable legal provisions. This means that a doctor's professional responsibility remains attached even if medical procedures are carried out virtually. Doctors are still required to comply with professional standards, medical procedures, and pay proper attention to patient needs, just as if the service were carried out in person.

However, in practice, there is still a legal vacuum regarding the use of third-party applications or technologies, including those based on Artificial Intelligence (AI). If the AI used to assist in diagnosis turns out to produce incorrect results and harms the patient, then the question arises as to who should be held responsible, whether the doctor who uses the system, or the technology developer. Currently, there are no specific regulations that clearly regulate the distribution of legal responsibility in the context of the use of AI in medical practice, thus creating a gray area in digital health regulations. In traditional medical practice, responsibility can be directed at health workers, but in AI-based systems, especially those that are automated and based on black-box algorithms, determining the responsible party becomes more difficult. Another risk is the violation of patient privacy and data security, because AI systems require access to large amounts of health data to train and optimize their algorithms. Without a strong security system and regulations, this data is vulnerable to misuse, leaks, or even being traded without the patient's consent. Furthermore, in Article 260 Paragraph (1) and Article 263 Paragraph (1) of Law No. 17 of 2023 stipulates that healthcare workers must possess a practice permit, in the form of a Registration Certificate (STR) and a Practice Permit (SIP), to legally carry out their professional duties. This emphasizes that medical practice must be carried out by competent and officially licensed individuals, including in the context of online medical services. However, because remote medical services lack direct physical contact, this has the potential to violate ethical and legal aspects of medical practice, which should be conducted in person and in real time, in accordance with applicable standard operating procedures.

The Medical Practice Law (Law No. 29 of 2004) stipulates that medical practice may only be carried out by licensed physicians and dentists. Clinical decisions are the authority and responsibility of licensed medical personnel, not technological devices. Therefore, AI is positioned as a tool to support medical practice. The Minister of Health Regulation concerning the provision of telemedicine services stipulates that remote healthcare services must be provided by qualified healthcare facilities, while ensuring quality standards and patient safety. AI used in telemedicine must meet at least the following criteria:

- a. Classified as a medical device/medical software where relevant;
- b. Through functional and security testing;
- c. Comply with data protection and electronic medical records provisions.

2. The Use of Artificial Intelligence in Medical Practice

The use of artificial intelligence (AI) in medical practice has significant potential to improve medical diagnostics and healthcare. AI can analyze large amounts of complex medical data, identify patterns, and help doctors make more accurate and faster decisions. Accurate and timely diagnoses are crucial elements of medical care. Unfortunately, this process is often hampered by time constraints, complex data, and high workloads for medical personnel. Artificial intelligence (AI) is a powerful tool in overcoming these challenges. With its ability to analyze large amounts of data and recognize complex patterns, AI can accelerate the diagnostic process and improve accuracy. One significant opportunity for using artificial intelligence in medical diagnostics lies in the interpretation of medical images.¹⁰ AI can be trained to analyze radiological images such as CT scans, MRIs, and mammograms, and identify abnormalities and diseases. Through deep learning techniques, AI can learn patterns in medical data and provide accurate diagnoses. AI is capable of achieving the same or better accuracy than human physicians in differentiating and classifying lesions or tumors.¹¹ AI can enable physicians to recommend the most appropriate treatment based on each patient's individual characteristics, including specific medications and the risk of side effects. This can assist in making informed clinical decisions and improving

patient care in key nursing areas. The use of AI can also increase the efficiency of healthcare services overall.¹² Furthermore, AI can be used in drug development and clinical research.¹³ In Indonesia, the use of AI in diagnostic processes is growing, particularly in medical imaging such as MRIs, CT scans, and ECGs. This demonstrates that AI is not merely a supplement, but has the potential to become a strategic element in improving the quality of diagnosis and comprehensive patient care. The use of techniques such as deep learning and neural networks enables computers to recognize patterns in imaging data such as MRIs and ECGs with high accuracy. For example, studies on the application of AI in analyzing ECGs show that the system can help detect heart disease earlier and more accurately than manual methods.

AI can assist in the identification of therapeutic targets, the design of drug molecules, and the analysis of clinical data to accelerate the process of discovering new drugs. AI can also be used to analyze data from clinical studies and identify patterns or trends that can aid clinical decision-making. Furthermore, AI can be used in Electronic Health Records (EHRs) to improve patient safety and the efficiency of the care process, particularly in addressing errors and financial risks.¹⁴ AI's ability to rapidly process large amounts of data allows medical personnel to obtain more comprehensive information in a shorter time, minimizing the possibility of misdiagnosis. With AI support, doctors can focus more on clinical interpretation and communication with patients. However, it is important to note that not all AI models can be directly implemented in a clinical context without validation. Testing and certification processes from official institutions are required to ensure the reliability and security of the system. Furthermore, the presence of AI should be seen as a support, not a replacement, in the medical decision-making process, which still requires ethical considerations and human empathy.

Although AI has the potential to surpass human capabilities, concerns and mistrust remain about its use. Some physicians may feel that AI algorithms are not as accurate as human subjective reasoning in clinical diagnosis.¹⁵ The use of AI requires adaptation and training for healthcare professionals. Healthcare professionals need to understand and use AI algorithms correctly, as well as understand the limitations and weaknesses of this technology. Collaboration between healthcare professionals and AI is also needed to ensure that AI-driven decisions are understandable and accepted by both healthcare professionals and patients. To address this challenge, healthcare developers and policymakers must be able to collect behavioral data from clinicians to help tailor AI algorithms.¹⁶

The principle of informed consent is crucial in telemedicine services that utilize AI. Patients have the right to know that the services they receive involve the use of an AI system in symptom screening or data analysis, the limitations of the AI's capabilities, including the potential risk of error or inaccuracy, that the final decision remains with the doctor (unless there are regulatory changes), and the personal data management policies used to train and operate the AI. Medical consent forms and data use agreements should be updated to explicitly include the use of AI. Without this transparency, patients' right to self-determination may be violated. Furthermore, patients have the right to receive an explanation of the basis for their diagnosis, including the extent of AI involvement, to refuse the use of AI if they find it uncomfortable, provided such refusal is technically feasible and does not endanger patient safety, and to seek compensation if negligence in the use of AI is proven.

3. Legal Accountability for the Use of Artificial Intelligence in Medical Practice in Indonesia

The use of Artificial Intelligence (AI) in digital healthcare presents significant opportunities to improve the quality, efficiency, and accessibility of medical services in Indonesia. This technology enables faster diagnostic processes, comprehensive patient data processing, and expanded healthcare coverage, particularly through telemedicine systems. However, despite this potential, AI developments also raise complex legal and ethical issues. From a legal perspective, Indonesia already has a general regulatory framework that can serve as a foundation, including Law Number 17 of 2023 concerning Health, the Electronic Information and Transactions (ITE) Law and its amendments, and the Personal Data Protection Law. These three legal instruments govern the provision of digital health services and the protection of patient data in general. However, to date, there are no specific regulations that comprehensively govern the use of AI in the healthcare sector, particularly regarding algorithm validation, determining legal responsibility, and audit and accountability mechanisms for AI systems.

From an ethical perspective, the application of AI in healthcare must remain grounded in the fundamental principles of bioethics: beneficence, non-maleficence, autonomy, and justice. These principles are crucial to ensuring that the use of technology does not compromise the rights, safety, and dignity of patients as the primary subjects of healthcare. Furthermore, a number of risks inherent in the use of AI also require serious attention, including the potential for misdiagnosis, violations of patient data privacy,

algorithmic bias that can lead to discrimination, and a lack of transparency in the decision-making process (black-box problem). If not adequately regulated, these risks could compromise fairness and integrity in digital healthcare systems. In the context of legal accountability, responsibility essentially arises as a consequence of actions that give rise to legal consequences. However, to date, there is no explicit definition of AI within Indonesia's positive legal framework, particularly the Electronic Information and Transactions (ITE) Law. Consequently, various interpretations have emerged linking AI to existing concepts within the regulation.

Referring to the provisions of the ITE Law, AI can be qualified as part of an electronic system and/or electronic agent. This is based on the conformity of AI's characteristics with the definition of an electronic system as stipulated in Article 1 number 5 of the ITE Law, namely the ability to collect, process, analyze, store, and convey electronic information. Furthermore, AI also has similarities with the concept of an electronic agent as referred to in Article 1 number 8 of the ITE Law, namely a system that operates automatically based on human commands in an electronic system. Thus, from the current perspective of Indonesian law, AI cannot yet be categorized as a legal subject with independent rights and obligations, but rather is positioned as a legal object or tool used by humans. Consequently, legal responsibility for the use of AI remains with humans, whether medical personnel, system developers, or healthcare providers, depending on their role and contribution in the use of the technology.

In this case, the legal entity responsible for the implementation of the electronic system is the electronic system administrator. Legal responsibility for losses caused by AI depends on the party deemed responsible, whether the developer, provider, or medical personnel. If AI is viewed as a medical product, then responsibility refers to the principle of product liability, while for doctors the principle of medical negligence applies if the service does not meet standards. Therefore, clear and adaptive regulations are needed to ensure legal certainty and patient protection in the use of AI in the medical field. The theory of liability in the use of artificial intelligence in medical practice is that those who create and use AI are fully responsible under criminal law for the actions and behavior of AI. In this context, AI is not subject to the law and does not consciously determine its will in carrying out actions.

Simons argues that an agent must be conscious, aware, and able to determine their own will to act. In this case, artificial intelligence is unaware of its behavior and can only rely on commands, with limited ability to determine its own will. Medical activities involving AI technology are subject to legal regulations, but also raise psychological, ethical, and moral issues related to patient care. The work performed by AI is considered a genuine part of medical practice and emerging legal customs, equivalent to the work of human physicians. Responsibility for activities related to the use of AI rests with the person using the intelligence. Existing legal structures assume that the hospital or the AI administrator, whether a doctor, operator, or other party, sets the parameters for its work or behavior.²¹ The role of the AI creator must be considered in terms of accountability. The use of AI in medical practice also rests with the AI creator and the AI user, as AI is not categorized as a legal subject, but rather as a legal object.

Some of the key challenges in regulating AI for telemedicine include:

a. Normative gap (regulatory gap)

There are no specific regulations governing the classification, feasibility testing, and certification of AI as a medical device, particularly for ever-evolving machine learning-based software (adaptive systems).

b. Certainty of legal responsibility

The division of responsibility between doctors, healthcare facilities, and AI developers in cases of patient harm remains unclear.

c. New ethical and professional standards

Medical and health professional organizations do not yet have comprehensive guidelines on the use of AI in clinical practice.

d. Data protection and algorithmic bias

The risk of data leakage and bias in algorithms (e.g. bias against certain demographic groups) can result in inequities in service.

Based on the analysis, several recommendations can be put forward:

a. Establishment of special regulations (lex specialis) for medical AI

- 1) The government needs to draft regulations that specifically regulate:
- 2) Definition and classification of medical AI;
- 3) Clinical feasibility and safety testing procedures;

- 4) Certification and post-market surveillance mechanisms;
- 5) AI-related safety incident reporting obligations.

b. Strengthening professional standards and practice guidelines

Professional organizations (IDI, PERSI, and others) need to develop ethical guidelines on the use of AI, including the principle of “human in the loop” and limits on reliance on AI recommendations.

c. Clear contractual arrangements between stakeholders

The contract between the healthcare facility and the AI provider should detail the division of responsibilities, including obligations for algorithm updates, data security, and technical support obligations.

d. Strengthening informed consent mechanisms and patient education

Standard consent forms and processes should clarify the use of AI and the associated risks, to ensure patient autonomy.

e. Capacity development of law enforcement officers

Judges, prosecutors, and investigators need to receive training on the technical characteristics of AI so they can assess AI-based medical dispute cases proportionately.

CLOSING

Based on the research results and discussions that have been described, several main conclusions can be drawn as follows:

Artificial Intelligence (AI) is a manifestation of human culture evolving towards modern life. AI, as artificial intelligence, essentially helps and facilitates human work. AI has penetrated various aspects, from education and economics to even the medical world. In the medical world, AI is used in various fields, such as therapeutic target identification, drug molecule design, and clinical data analysis to accelerate the process of discovering new drugs. It also serves as a medium for communication between doctors and people separated by distance and geography. In addition, there are many other uses of AI in the medical world. The ethical aspects of using AI in the medical field are crucial and inseparable from legal considerations. The principles of informed consent, patient autonomy, and the moral responsibility of physicians remain valid even when the diagnostic process is assisted by technology. The principles of beneficence and nonmaleficence remain the guiding principles in medical decision-making. Therefore, even when AI provides diagnostic advice, the final decision must still be made by the physician, the party with the professional and ethical competence and responsibility.

As AI advances, Indonesia, as a nation governed by the rule of law, needs to take swift action to regulate its development. To date, there are no regulations specifically addressing the role of AI in the medical world. After reviewing the regulations, principles, and positive aspects in Indonesia, it can be concluded that AI is a medical aid used to determine clinical decisions, and responsibility for its use in medicine rests with both the AI creator and the AI user. This review concludes that AI is a legal object, not a legal subject capable of legal accountability.

Suggestion

Based on the conclusions above, the researcher makes several suggestions as follows:

The government needs to immediately develop specific regulations regarding medical AI and telemedicine, including technical standards, certification procedures, and a clear legal liability framework. Medical professional organizations should develop ethical guidelines and standards for AI-assisted medical practice, emphasizing the role of physicians as the final decision-makers. Healthcare facilities and AI developers need to strengthen contractual arrangements and mechanisms for regular evaluation of AI performance. Education for healthcare workers and patients regarding the potential, limitations, and risks of AI use must be enhanced to create a safe, ethical, and equitable telemedicine ecosystem.

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