

## **The Role and Legal Responsibility of Using Artificial Intelligence (AI) In Medical Sector**

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### **Abstract**

*Artificial Intelligence has brought significant transformations to the healthcare sector, ranging from disease diagnosis, medical data management, to drugs development. While it offers efficiency and accuracy, the implementation of Artificial Intelligence also raises challenges related to legal responsibilities and regulations. In the context of legal responsibility, issues such as disease diagnosis, medical data management, and drugs development become key concern. Legal responsibility for potential harm caused by Artificial Intelligence in this sector arises from the availability of information for medical professionals as well as electronic agents that manage patient data during registration in hospitals or online healthcare services, along with healthcare provision and policy formulation. This article aims to analyze the relationship between the application of Artificial Intelligence in healthcare and the legal framework and regulations in Indonesia, such as the Electronic Information and Transactions Law No. 19 of 2016 and the Health Law No. 17 of 2023. It also offers recommendations to address potential legal gaps. The conclusion of this study emphasizes the importance of developing adaptive regulations and fostering collaboration among technology experts, healthcare professionals, and policymakers to ensure the safe, fair, and responsible implementation of Artificial Intelligence.*

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### **1. INTRODUCTION**

In this incredible digital era, human created technology and started into working area is artificial intelligent (AI). Artificial intelligent (AI) is a system that allow computer to do obligation related by human intelligent in many types. In medical context, AI is using to analyzed medical file, clinical determination, supporting and increasing operational efficiency. AI has been applied in medical area for service area and also information resource for medical worker and electronic agent that handle file each patient who registered from the hospital or medical health service by online. There are two types of AI, virtual AI and physical AI, example of the Virtual is Electronic Medical Record system, and the physical is a Robot that help in surgery action. (Trenggono & Bachtiar, 2023).

In AI there is a feature that collect information automatically, so that could be as same as with electronic agent that valid in Indonesian Law. In Article 1 Law about Electronic Information and Transaction Number 19 Year 2016, the definition of electronic agent is 'an electronic device system that made for doing an action toward the Electronic

*Information that automatically provide by person*’. If we refer to Article 1 Law Electronic Information and Transaction Number 19 Year 2016 means the rule that organize about electronic agent is valid to AI. There is correlation between AI as electronic agent from the definition AI as electronic agent as itself is, someone who give mandatory to operate electronic device system AI is understood as an electronic agent, which refers to a person who is given the ability to operate an electronic system to carry out an activity of collecting and organizing electronic information automatically. The person who carries out this activity is a legal subject who has legal responsibility. This means that the person using the electronic agent agrees for their personal data to be processed again by the operator of the electronic agent. (PM & Priancha , 2021).

The use of AI is not only limited to systems like "Electronic Agents" that store patient data, but it can also serve as a system that supports and helps medical staff in treating patients.

One example is robotic surgery, often referred to as Robot-assisted surgery (RAS), which is commonly used during operations (Misel, 2023).

The use of AI technology in the healthcare field is not only used for diagnosing diseases through accurate medical image analysis, but also includes remote patient condition monitoring using Internet of Things (IoT) devices like sensors and cameras. This technology allows nurses to monitor patients' vital signs and activities in real-time from a distance, offering significant benefits especially for elderly patients, those with chronic illnesses, and post-operative patients. However, there are several legal aspects that need to be considered. The use of machines, medical staff, and hospital administration each have legal responsibilities.

In other words, if an error occurs that leads to a legal court case, it becomes a platform where the involved parties blame each other. Since the court views the use of robots as tools assisting surgeons, whose role is to help the surgeon only. The surgeon and the relevant hospital must still wisely use their authority regarding the actions proposed by the robot, with strict oversight by the involved parties on the proposed actions of the robot, because there is still unclear regulation that clearly defines the legal responsibility of the surgeon regarding malfunctions of the surgical robot (Pai dkk., 2023) .

As time goes on and modern technology develops, remote healthcare has become common through online platforms that use apps. The rules for telemedicine are set out in Article 1, paragraph 22 of Law No. 17 of 2023 on Health. It says that telemedicine is the provision and facilitation of clinical services through telecommunications and digital communication technology. In today's modern era, one of the health services that uses AI is Halodoc. When it comes to legal responsibility for using AI in the health sector, it is connected to the Health Law, which is Law No. 17 of 2023 on Health, and also the Electronic Information and Technology Law, which is Law No. 19 of 2016.

Therefore, although AI offers efficiency and accuracy, its use comes with very high legal risks. We know that legal subjects (*rechts persoon*) can be individuals (*natuurlijk persoon*) or legal entities (*rechtspersoon*). However, AI itself is an object that has no feelings or conscience; it only works when it is used, and when it is not used, it is just a dead object. With this understanding, the author is interested in examining the role and legal responsibility of using Artificial Intelligence (AI) in the health sector.

## 2. METHOD

This research uses a normative legal method, which involves looking at laws and regulations, also known as the statute approach. This approach studies all relevant laws and regulations related to the legal issues discussed. The author uses several legal sources in writing this journal, including both primary and secondary legal materials. The author refers

to several regulations, such as Law No. 17 of 2023 on Health, Law No. 11 of 2008 on Electronic Information and Transactions (ITE) and its amendment through Law No. 19 of 2016, Law No. 27 of 2022 on Personal Data Protection, and the Minister of Health Regulation No. 20 of 2019 concerning the Implementation of Telemedicine. In addition, the author uses relevant secondary legal materials, secondary legal sources are basically additional data sources that support the author's writing of this journal.

### 3. RESULTS AND DISCUSSION

#### **Regulations or legal rules about Artificial Intelligence and its impact on the health sector**

So far, Indonesia does not have a specific law that directly regulates Artificial Intelligence.

This is because AI is not considered a legal entity (*rechts persoon*) and only humans (*natuurlijk persoon*) and legal entities (*rechtspersoon*) are recognized as such. However, some existing regulations do cover aspects related to AI. One of these is the Electronic Information and Transactions Law (ITE), numbered 11 of 2008, and its amendment through Law Number 19 of 2016. The ITE Law regulates the use of information technology, including aspects related to data security, privacy, and electronic transactions, which are highly relevant to the use of AI. For example, in the data processing process by AI, this law emphasizes the importance of protecting personal data, ensuring the authenticity of information, and holding parties involved in using technology accountable legally.

Using AI is a modern and up-to-date strategy that uses developing technology to support health professionals. Legal rules regarding AI in the health sector in Indonesia still refer to several broader regulations, such as Law Number 17 of 2023 on Health, Minister of Health Regulation Number 20 of 2019 on the Implementation of Telemedicine Services across Health Facilities, and Law Number 27 of 2022 on Personal Data Protection. Law Number 17 of 2023 on Health regulates the basics of health services, including the use of technology to improve the quality of service. Although it does not specifically mention AI, the principles within this law can be applied in the context of health technology. This law sets the goal of improving the health status of the community, which can be achieved through the use of health technology, including AI. The use of AI in diagnosis, treatment, and health data management can contribute to achieving this goal.

The Health Act of 2023 emphasizes the importance of safe and high-quality healthcare services, which includes using technology like AI for diagnosing and treating patients. Also, the Personal Data Protection Law is very relevant in the healthcare context because AI often processes sensitive medical data. The use of AI must follow principles of transparency, accountability, and patient consent to ensure that health data is not misused and patient privacy is maintained. Although there is no specific law regulating AI use in healthcare, these two laws provide an important legal framework to ensure that AI is used ethically and safely, and to protect patients' rights.

One way AI is being used in the health sector in Indonesia is through telemedicine. According to Article 1, point 22 of Law Number 17 Year 2023 on Health, telemedicine refers to the provision and facilitation of clinical services through telecommunications and digital communication technology (Pemerintah Pusat, 2023). *Telemedicine* is described as a form of remote healthcare that uses information and communication technology. The services covered include the exchange of information about diagnosis, treatment, disease prevention, injury management, research and evaluation, and the delivery of health service education. The regulation of telemedicine is also outlined in the Minister of Health Regulation Number 20 Year 2019 on the Implementation of Telemedicine Services Between

Health Service Facilities. The role of artificial intelligence in healthcare has greatly expanded in Indonesia, especially during the time of the COVID-19 pandemic.

During that period, to minimize the spread of the virus, the government encouraged the public to use telemedicine as the main alternative. The benefits of telemedicine, as regulated by the Health Law Number 36 Year 2009 and the Minister of Health Regulation Number 20 Year 2019 on Telemedicine, are significant in improving access and the quality of health services. Telemedicine allows patients, especially those in remote or underserved areas, to get medical consultations without having to travel long distances to health facilities. Therefore, telemedicine is expected to improve the quality of health services, speed up patient care, and support a more efficient national health system. However, its implementation must follow existing guidelines and regulations to ensure the services provided remain high quality and safe.

### **Perlindungan data pribadi pasien**

Some challenges related to protecting personal data in AI-based healthcare services include effectiveness and security, responsibility, data privacy, cybersecurity, and legal aspects of copyright. Patient confidentiality is a key concern in the relationship between doctors and patients. This is because providing healthcare based on data and AI requires a wide and comprehensive variety of personal patient information. As data owners, when patients use AI-based healthcare services, they must give permission for their personal data and medical records to be accessed by the information system so that it can be processed further to provide the most suitable recommendations.

It is important to inform patients about the purpose and use of their data, including who has access to it and what kind of data can be shared. Service providers must ensure that patient data is managed properly and not shared or used for other purposes without the patient's knowledge. Managing data includes its use, storage, access, and sharing, including for research, publication, or other purposes. On the other hand, service providers must also make efforts to protect patients' personal data to prevent it from being leaked or used for harmful purposes. This is covered under the Health Act, which requires all healthcare facilities to protect patients' personal health data and to refuse to disclose any information related to personal health secrets to the public, unless allowed by law.

Patients can give permission (*informed consent*) to their doctor and healthcare facility to access and use their medical records. This allows healthcare providers to decide the best course of action for the patient. The consent must be properly documented to make sure the data is not used for purposes outside of agreed-upon healthcare services. The right to give consent is entirely up to the patient. Patients should have the choice to agree or not agree to the handling, processing, and sharing of their data. Patients have the right to access their electronic health records. (Primasatya, 2024).

However, this brings to light the need for the government to create official regulations on AI to ensure the security of user data and to provide legal accountability in case of data leaks that cause harm to patients, although AI is very helpful, system failures can happen, and it's important to prepare for legal issues if they arise. Legal accountability can be pursued against the corporation or developer of the AI system if there is a system failure. In the case of a data leak due to a doctor's negligence (*human error*), legal responsibility can be addressed under Article 67 (2) of Law No. 27 of 2022 on Personal Data Protection and medical ethics guidelines. There is therefore a connection between Law No. 27 of 2022 on Personal Data Protection (UU PDP) and the registration process for telemedicine (Indonesia, 2022). Article 15 (1) letters d and e of the Personal Data Protection Law emphasize that data must be collected with the individual's consent for the purpose of electronic agent

operations. In the registration process for telemedicine, service providers must comply with this requirement by obtaining patients' consent before collecting their health data.

In addition, Article 27 and Article 29 (2) of the Personal Data Protection Law state that data owners have the right to access, edit, and delete their personal data. This aligns with the transparency principle in telemedicine services, where patients should be informed about how their data is used. By following the Personal Data Protection Law No. 27 of 2022 (PDPA), telemedicine service providers can ensure their practices not only meet legal requirements but also build patient trust through proper data protection. Therefore, it is very important for the government to create specific regulations for AI itself and include AI within the legal framework, considering that AI is already part of various work areas.

#### 4. CONCLUSION

The use of AI technology in the healthcare sector, especially in telemedicine, has had a major impact on the quality of medical services. AI plays a key role in improving healthcare through telemedicine, as seen in apps like Halodoc. However, while AI brings efficiency and accuracy, it also creates legal challenges that need to be addressed, especially regarding legal responsibility and the protection of patients' personal data.

Existing regulations in Indonesia, such as the Health Law No. 17 of 2023 and the Electronic Information and Transactions Law No. 19 of 2016, provide a legal basis for applying AI in healthcare, even though there is no specific law that regulates AI itself.

Patient personal data must be managed with transparency and clear consent to ensure the security and confidentiality of patient information. Therefore, developing flexible regulations and collaboration between technology experts, medical professionals, and legal experts are essential to ensure the safe, fair, and responsible implementation of AI in the healthcare sector.

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