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REVIEW

A Juridical Analysis on the Usage of Artificial Intelligence in Medical Instruments from the Perspective of the Indonesian Law No. 17 of 2023

Análisis jurídico del uso de la inteligencia artificial en instrumentos médicos desde la perspectiva de la Ley n.º 17 de 2023 de Indonesia

Arief Budiono[1,2], Onnie Wira Tama[1], Naeem Allahrakha[3], Aminuddin Mustaffa[2], Abdullah Al Mamun[4], Rizka[1], Nur Aida Ikrima[5]

[1]Faculty of Law, Universitas Muhammadiyah Surakarta, Surakarta, Indonesia.
[2]Faculty of Law and International Relations, Universiti Sultan Zainal Abidin, Kuala Nerus, Terengganu, Malaysia.
[3]Department of Cyberlaw, Tashkent State University of Law, Tashkent, Uzbekistan.
[4]Knowledge Dynamics, Rangpur, Bangladesh.
[5]Turner High School, Kansas City, Kansas, USA.

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Corresponding author: Arief Budiono

ABSTRACT

Introduction: the quick development of artificial intelligence (AI) has spread to various sectors of health, including health technology. However, in line with the development of AI in the medical sector, complex medicolegal (legal and ethical) issues that health professionals, researchers, and policymakers must face start to emerge, such as the lack of legal regulations that govern AI, the issue of patient security and privacy, as well as who must take legal responsibility in case a certain issue occurs. This research aims to analyze how AI is used in health instruments from the perspective of Indonesian Law No. 17 of 2023 using a juridical analysis. Specifically, it aims to analyze the legal position of AI; telehealth and telemedicine in the Indonesian Health Law; the importance of data in the usage of AI in the health sector; risks in Using AI in the medical field; regulations on the use of AI in the medical field; and the implementation of telesurgery with the help of AI.
Method: this research employed the normative juridical research method with a doctrinal characteristic. It employed the statute approach. It means research based on previous research data, library data, systematic reviews and laws and regulations.
Results: Law No. 17 of 2023 on Health has not regulated the use of artificial intelligence (AI). These unclear regulations may endanger the position of doctors and patients. The lack of regulations that govern medical services between doctors and patients via AI may lead to legal uncertainty. This will certainly lack providing AI service scope for patients and doctors, especially on the safety of utilizing telesurgery in long-distance surgeries. Telesurgery offers certain benefits for patients and doctors but its practice must consider the legal and ethical aspects.
Conclusions: There should be regulations that govern the use of AI based on the medical ethical code and the ethical values that apply in society so that its use may always prioritize human interests.

Keywords: Artificial Intelligence; Medical Sector; Law; Indonesia.

RESUMEN

Introducción: el rápido desarrollo de la IA se ha extendido a diversos sectores de la salud, incluyendo la tecnología sanitaria. Sin embargo, a medida que la IA avanza en el sector médico, comienzan a surgir complejos

problemas médico-legales (legales y éticos) que los profesionales de la salud, investigadores y legisladores deben afrontar, como la falta de regulaciones legales que rijan la IA, la seguridad y privacidad del paciente, y la responsabilidad legal en caso de incidente. Esta investigación busca proporcionar un análisis jurídico sobre el uso de la inteligencia artificial en instrumentos de salud desde la perspectiva de la Ley de Salud de Indonesia n.º 17 de 2023.
Método: esta investigación empleó el método de investigación jurídico normativo con un componente doctrinal. Se empleó el enfoque estatutario. Se empleó el enfoque estatutario. Esto significa investigación basada en datos de investigaciones previas, datos bibliográficos, revisiones sistemáticas y leyes y reglamentos.
Resultados: la Ley de Salud n.º 17 de 2023 no ha regulado el uso de la inteligencia artificial (IA). Estas regulaciones poco claras pueden poner en peligro la posición de médicos y pacientes. La falta de regulaciones que rijan los servicios médicos entre médicos y pacientes a través de la IA puede generar inseguridad jurídica. Sin duda, esto carecerá de la capacidad de proporcionar servicios de IA a pacientes y médicos, especialmente en lo que respecta a la seguridad en el uso de la telecirugía en cirugías a distancia. La telecirugía ofrece ciertos beneficios para pacientes y médicos, pero su práctica debe considerar los aspectos legales y éticos.
Conclusiones: deben existir regulaciones que regulen el uso de la IA, basadas en el código ético médico y los valores éticos vigentes en la sociedad, para que su uso priorice siempre los intereses humanos.

Palabras clave: Inteligencia Artificial; Sector Médico; Derecho; Indonesia.

INTRODUCTION

Technological advancement has created a blend that blurs the boundaries between physical and digital media, which either directly or indirectly influences various sectors, starting from the economic, political, social, international relations, and law enforcement, up to the health sectors. Medical technologies play an increasingly important role in the development of health and medical treatment systems. Advancements in various fields such as artificial intelligence, genetic engineering, sophisticated medical instruments, and digital medical records have opened doors to significant improvements in health diagnosis, treatment, and research.

Artificial intelligence (AI) is part of computer science that allows machines (computers) to carry out tasks with capabilities that are similar and as good as human beings.[1] The sophistication of AI technologies in the health sector may increase the capabilities of machines and computer programming algorithms in copying the human brain, namely how to independently learn, think, and make decisions.[2]

Computers' capabilities in the health sector are designed to carry out medical analysis which are then followed up with health decisions and actions. The taking of health decisions and actions are carried out very quickly as they are supported with complete and more profound knowledge of all health issues obtained from health experts. In health science, AI plays a crucial role as an instrument that helps human beings check their health status.

The quick development of AI has spread to various sectors of health, including health technology. It concerns the aspects of the service system, clinical services, and treatment. AI has some roles in the medical world. In the cardiovascular sector, it can predict heart failure quickly and analyze electrocardiogram waves. In the pathological sector, it enforces pathological diagnosis, detects cancer metastasis, and determines patients' prognosis. In the oncological sector, it helps diagnose and determine the administration as well as decreases the chance of human error. Next, in the ophthalmological sector, it carries out an early detection of diabetic retinopathy using a smartphone.

In its application, patient diagnosis using AI technology brings positive impacts in the establishment of inclusive health services (house visits). One of the regulations in AI that is often used is the Evidential Reasoning (ER) rule. AI is needed to carry out long-distance diagnosis using the main medical data. AI is also applied to diagnose diseases from medical images by extracting images of acute lymphoblastic leukemia.[3]

Then, AI is used to support the basic research process to determine medicine, pre-clinical phase, clinical phase, and post-marketing phase. They are urgent actions that must be carried out using AI technology. It can be concluded that AI is created like so with the goal of becoming similar to or even better than human beings to help or to substitute human beings in carrying out a certain task.[4]

However, in line with the development of AI in the medical sector, complex medicolegal (legal and ethical) issues that health professionals, researchers, and policymakers must face start to emerge, such as the lack of legal regulations that govern AI, the issue of patient security and privacy, as well as who must take legal responsibility in case a certain issue occurs.

The use of inaccurate health technologies, especially health instruments, may lead to the malfunction of those technologies in their use.[5] Health technologies are inseparable from economic factors. In general, the more sophisticated a health technology is, the more expensive the cost that must be spent for its procurement

or application.[6]

The existence of AI technological advancement cannot be separated from legal regulations that apply in a certain country. AI's technological sophistication that is able to carry out people's jobs may lead to several legal issues related to its actions and/or activities. AI is artificial intelligence that is limited by codes that become the basis of its capabilities in carrying out certain tasks.[7]

Indonesia does not yet have any legal regulations that specially govern AI but there are some legal regulations that may be applied on the application of AI in the medical industry. AI that can carry out legal actions cannot be categorized as a legal object but it may be categorized as legal subjects that have an equal degree as other legal subjects.

Legally, one of the sources of the legal basis that specially regulates technologies is Law No. 19 of 2016, which was formed under certain considerations, including to respond to technological development and advancement. This law is entrusted to resolve various issues related to technology.[8] Even so, it does not provide a significant definition of AI. If AI is linked to Law No. 19 of 2016, AI will only be categorized as electronic information, as regulated in Article 1 number 1 of this law.

Indonesia has previously enacted a law that regulates health, i.e., Law No. 36 of 2009 on Health. However, in line with the development of information and technology, old laws need to be revoked and/or revised.[9] Therefore, through its legislative house, the Republic of Indonesia's government carried out an initiative to conduct changes or revisions to the Law on Health. The legislative house created a bill on the Law on Health using the omnibus law method as a strong and comprehensive regulatory basis to resolve various health issues.

It is hoped that the choice of using the omnibus law method on this law as carried out in Law No. 11 of 2020 on Job Creation may fix the required regulations in the health sector to make sure that the legal structure in this sector does not overlap or counter each other. In the end, on August 8th, 2023, the Republic of Indonesia's president signed Law No. 17 of 2023 on Health that has been validated in the Legislative House Plenary Meeting on July 11th, 2023. Meanwhile, the derivative regulations of Law No. 17 of 2023 on Health namely in the form of Governmental Regulations were to be completed by the end of 2023.[10]

It is hoped that with the application of the omnibus law, Law No. 17 of 2023 on Health may provide a solution to the various issues in the health sector, such as health services that are still dominated by curative approaches;[11] the lack of availability and equal distribution of human resources; the lack of readiness in facing health crises; as well as the independence aspect of pharmacies and health instruments.[2]

It is also hoped that Law No. 17 of 2023 on Health may provide legal protection for health service actors. It is known that health workers face many legal cases or actions but there is not yet any legal protection to shield them from such issues. The regulations in the Law on Health may advance Indonesian people's health through the provision of the best health services, including through the usage of AI.

Based on the description above, this research aims to provide a juridical analysis of the usage of artificial intelligence in health instruments from the perspective of Law No. 17 of 2023 on Health. This paper's research problem are:

- What is the legal position of AI?
- How are telehealth and telemedicine regulated in the Indonesian Health Law?
- What is the importance of data in the usage of AI in the health sector?
- What are the risks in using AI in the medical field?
- What are the regulations on the use of AI in the medical field?
- How is telesurgery with the help of AI implemented?

METHOD

The specification in this research was that it utilized the normative juridical research method with a doctrinal characteristic. Doctrinal research means research based on previous research data, library data, systematic reviews and laws and regulations. The object of this research was the usage of artificial intelligence in health instruments from the perspective of Law No. 17 of 2023 on Health. This research employed the statute approach as it analyzed and reviewed regulations on the usage of AI in health instruments from the perspective of Law No. 17 of 2023. Researchers also use previous research as references and systematic reviews of similar research. It also utilized the conceptual approach which departed from perspectives and doctrines that develop in legal studies as a footstep to build legal argumentations in resolving the analyzed legal issue.

In this study, the authors analyzed secondary data, i.e., data which were indirectly obtained through the literary study technique. The secondary data used were primary legal materials, such as regulations on the usage of AI technologies and Law No. 17 of 2023. It also employed secondary data in the form of previous research, journal articles, and papers related to the research theme. In this study, the authors employed the descriptive-qualitative analysis where data from legal materials that were written in the form of orderly sentences were analyzed.

RESULTS

The Legal Position of AI

The Society 5.0 Era is characterized by the existence of very rapid technological development which is more and more blended into daily life. It is hoped that technological usage may increase people's efficiency in carrying out their tasks. Technological usage is also required to decrease the prevalence of a product's failure and decrease the negative impacts on the environment. Various technologies have provided human beings with facilities that they may use to help with their daily activities.

In general, sophisticated technologies exist to help all activities related to human beings' tasks. One of the sophisticated technology trends is as artificial intelligence, which has started to be applied in almost all sectors, especially in Southeast Asia. AI develops very rapidly and becomes a positive trend in Indonesia. AI technology is one of the results of technological development in the computer science and technology sectors that is designed to resolve certain issues with a thinking capability that is similar to that of human beings in general. To make sure that AI functions as expected, it requires a huge amount of data related to a certain sector and its own algorithm. From this definition, it can be understood that AI is a technological machine whose work method adapts human beings' patterns of thought and learning.

AI offers various advantages and its existence may help human beings more quickly and accurately carry out their tasks. For instance, if a worker must process a huge amount of data, it will take a long time to analyze such data one by one. Fortunately, with the help of AI in processing the data, this task may be completed in a quicker manner with fewer errors. AI brings tremendous help related to finding and analyzing the required data.

AI's capability in to help human beings resolve their tasks may bring positive impacts by increasing the productivity of those human beings. For instance, a task that requires two hours for a human being to complete may only require thirty minutes to finish with the help of AI. In doing so, that person may use the remaining one and a half hours to carry out other tasks. Nowadays, AI has been developed in various scientific disciplines, including in the field of legal studies.

However, aside from the tremendous benefits that AI offers to human beings, it also brings negative impacts. Because AI can carry out tasks much quicker and much more accurately compared to human beings, there is a concern that people's jobs may slowly be substituted with AI. Therefore, it can be said that AI has carried out legal actions that cannot be categorized as legal objects but rather as legal subjects. However, theoretically, in Indonesian positive law, legal subjects only encompass human beings (*natuurlijke persoon)* and legal entities (*rechtspersoon*).[13]

Legal subjects are people who have rights and responsibilities that create legal authority.[14] Then, according to Sudikno,[15] legal subjects are anything that has rights and responsibilities according to the law. Next, according to Subekti,[16] legal subjects bring rights and obligations.

To determine whether or not something can be categorized as a legal subject, there is a need to see the legal protection that becomes its basis. In this case, AI in the discourse of legal subjects must see the perspective of the legal state. As an anthropocentric legal state, Indonesia focuses on the protection and welfare of human beings as the main subject of the legal system.

At a glance, Indonesia's anthropocentric tendencies show that AI is a series of legal subjects that still prioritize the interests of human beings. Up to now, one of the sources of legal subjects that specially regulate technologies is Law No. 19 of 2016 on Electronic Information and Transaction which has not significantly regulated AI.

In the explanation of Article 1 number 1 of Law No. 19 of 2016, it is explained that artificial intelligence (AI) is limited to a legal object and is not perceived as a legal subject. This is because Law No. 19 of 2016 states that legal subjects are: senders, recipients, people, business entities, and the government. However, AI's position as a legal subject is not far-fetched and it can truly be achieved based on the progressive legal theory.

The progressive legal theory that Rahardjo stated declares that the law will always have a "law-making" status[17] as it is never final and always develops according to the development of the era. The position of AI as a legal subject is a breakthrough of change that is possible in law. Apart from the progressive legal theory, there are many experts who opine that the rationing of AI as a new legal subject in the current digital era may use the same rationing as the legal entity theory.

There are two legal theories on legal subjects that can be transplanted to become the basic perspective for the development of AI as a legal subject, namely the fiction theory and the concession theory. The fiction theory was proposed by Von Savigny in the 19th century which states that legal entities are abstract rather than concrete. In essence, laws grant rights and responsibilities to legal subjects. Thus, legal entities are represented by human beings in carrying out their tasks (the entity theory).

The background to the birth of the fiction theory is inseparable from the school of thought that he embraces, namely the understanding of the function of law that only follows the changes that occur in society. The law validates changes that occur in society. In the context of this theory, AI becoming a legal subject can be deemed

a change that happens in society that may be validated by the law in the future. The concession theory which was founded by Gierke emerged to complete the fiction theory. In essence, this theory opines that legal entities in a state do not have legal personality unless it is given by the law.

The manifestation of corporations (legal entities) originates from sources that give it legal strength (the state in the context of the concession theory). Based on these two theories, one can obtain the perspective that apart from human beings, AI can be engineered to become legal subjects such as by imitating the legal entity model or others solely for the interest of human beings. The development of AI encourages the creation of a new era that brings tremendous impacts to human life. Therefore, the law becomes one of the most important instruments in life in the future.

Telehealth and Telemedicine in the Indonesian Health Law

The Indonesian nation is currently suffering a law enforcement crisis. In its practice, law enforcing apparatuses tend to ignore and neglect legal justice, losing society's trust. The society's lack of trust in law enforcement occurs as legal instruments fail to reflect social justice. Judicative institutions are not yet independent and impartial. Aside from that, law enforcement is inconsistent and discriminative. Even worse, there is a failure to give legal protection to all of society.

The health law becomes a legal instrument that determines regularity, orderliness, and obligatory behavior in the health sector. The health law, norms, and ethics apply as guidelines to whether or not an activity is acceptable. The health law also regulates the rights and obligations of the related parties as well as their legal relationships in the health sector. The health law has juridical consequences in case of negligence and malpractice as well as the right for legal protection for the parties in the field of health.[18]

There are some regulations that differentiate between the new Health Law (Law No. 17 of 2023 on Health) and the previous Health Law (Law No. 36 of 2009 on Health). In the newer version, health service facilities may provide telehealth and telemedicine services. Telemedical services are carried out by health service facilities (polyclinics, supporting community health centers, and public hospitals, both state-owned and private-owned) to society.

Meanwhile, telehealth is the provision of health services and health service facilities, including community health, health information services, and independent services through telecommunication and digital communication technologies. Then, telemedicine is the provision of clinical services and clinical service facilities through communication and digital communication technologies.[19]

Meanwhile, in the previous Health Law, there was no regulation on telehealth and telemedicine services. Telehealth and telemedicine services are comprehensively regulated in the Regulation of the Republic of Indonesia's Minister of Health No. 20 of 2019 on the Establishment of Telemedicine Facilities Between Health Service Facilities. Telemedicine services comprise the following services:

- Teleradiology: It is a radiology service using electronic transmission from all radiology modalities from the health service facility demanding consultation to the health service facility providing consultation to obtain expertise (analysis results and conclusion from specialist doctors/sub-specialist doctors and/or experts) in terms of diagnosis determination.
- Teleelectrocardiography: It is an electrocardiography service that utilizes electronic transmission from all electrocardiography modalities from the health service facility demanding consultation to the health service facility providing consultation to obtain expertise (analysis results and conclusion from specialist doctors/sub-specialist doctors and or experts) in terms of diagnosis determination.
- Teleultrasonography: It is an ultrasonography service using electronic transmission from all ultrasonography modalities from the health service facility demanding consultation to the health service facility providing consultation to obtain expertise (analysis results and conclusion from specialist doctors/sub-specialist doctors and or experts) in terms of diagnosis determination.
- Clinical teleconsultation: It is a long-distance clinical consultation service to help determine diagnoses and or provide consideration/suggestions for administration. It can be carried out using a written manner or via voice or video. Clinical teleconsultation must be recorded and written in the medical records according to the stipulations of legal regulations.

Table 1. Some examples of telemedicine services

No.	Type of Service	How It Works	Objective
1	Teleradiology	It uses electronic transmission from all radiology modalities.	
2	Teleelectrocardiography	An electrocardiography service that utilizes electronic transmission from all electrocardiography modalities.	It is used to ask for consultation to obtain expertise in determining a diagnosis.
3	Teleultrasonography	It is an ultrasonography service using electronic transmission from all ultrasonography modalities.	

4	Clinical teleconsultation	It is a long-distance clinical consultation service using a written manner or via voice or video.	It is used to help determine diagnoses and or provide consideration/suggestions for administration.

Article 174 clause (2) of Law No. 17 of 2023 states that in emergency conditions, health service facilities are prohibited from rejecting patients, asking for a down payment, and prioritizing any administrative affairs which lead to the postponement of health services.

- In emergency conditions, health service facilities, both state-owned and privately-owned, must prioritize providing health facilities to save the lives of patients and prevent disabilities.
- In emergency conditions, health service facilities, both state-owned and private-owned are prohibited from rejecting patients and/or asking for a down payment.
- The head of a hospital can be medical workers, health workers, or professional workers who have the competency to manage hospitals. This is regulated in Article 186 of Law No. 17 of 2023. Meanwhile, Article 32 of Law No. 36 of 2009 does not regulate a hospital's organizational structure, i.e., the people who are categorized as leaders in managing the organization in a hospital.
- Hospitals must apply a hospital information system that is integrated with the National Health Information System. Every health data and information must be available in this system. The National Health Information System is management of health information and regulation that encompasses the management and storage of patient data and information.

The Importance of Data in the Usage of AI in the Health Sector

Artificial intelligence may be entrusted to decrease biases in the health service system, such as by decreasing human error and doctors' cognitive biases in determining the decision for the best treatment. However, AI's algorithm may also yield biased results. In the development of AI, the confounding variables that occur in the collection of the datasets may also lead to a selection bias.

For instance, the face recognition accuracy in people with dark skin may be less than that in people with lighter skin. This leads to biases in the association data collection algorithm. Other biases may also happen as most of AI's data sources for health services originate from referral health facilities. This may lead to biases when used in primary health facilities.

Algorithm biases may occur due to underestimation or overestimation in diagnosing patients' diseases due to a lack of representative data. Therefore, there is a need for large amounts of representative data. There must be variety and each group must be represented so that AI can generalize patients across race, geography, gender, and all health service facilities. The AI system used highly depends on the source of data that becomes its reference. There is a quote in the computer world which states "garbage in, garbage out."

This quote means that AI absorbs whatever information is available to them, which originate from various sources that are not always reliable. Even though information originating from experts in medical fields are available, they are often mixed with data from unreliable sources that lacks accountability. Therefore, the AI may yield unreliable and misleading information that may bring more harm than good. Such a condition is especially dangerous in the medical field, as medical decisions impact people's health. A wrong decision made based on "garbage information" may be detrimental to patients, which in turn will affect their long-term health and future.

Data related to the medical sector is varied and originates from various sources, such as literary data, clinical examination data, real data, and hypothetical data. Data may be sourced from health applications. As a consequence, the quality of AI will be equivalent to the quality of the data that becomes its source. In the past, there has been a report that AI committed some errors in the oncological sector. IBM's Watson for Oncology System has been reported to be insecure and unsafe for treating cancer as the data used for the algorithm did not originate from real patients.

On the contrary, the data originated from virtual patients, hypothesis results, as well as administration recommendations originating from experts' arguments rather than being sourced from reliable guidelines or evidence. These data do not illustrate actual clinical situations, influencing the accuracy and generalization of the algorithm model.

The data collection quality is also influenced by the accuracy of data assessment, which will influence the data collection quality. Even if the data are accurate and representative, issues in the data assessment process will make the results meaningless. Risks in data annotation exist, especially in the consistency aspect. For instance, the golden standard for lung nodule clinical diagnosis is biopsy.

However, not all patients with lung nodules will carry out a biopsy. CT scan examinations are usually used to evaluate lung nodules. Images of the lung nodule CT must be assessed by clinically experienced doctors. The lung nodule CT imaging, includes nodule size, solidity (CT value), characteristic (soft/hard nodule), and signs

(lobar sign, burr sign, concave umbilical sign, and vascular cluster sign). However, because each hospital and software development institution has different instruments, there may be biases in doctors' assessments. The different standards, qualities, and formats will lead to assessment deviations which will result in differences and controversies.

Another issue with the use of AI in the oncological sector is data colonization. Usually, the data originating from oncology center institutions create algorithms to be used in primary service facilities, making it difficult to generalize them in an application. When AI algorithms are used in oncology compared to standard treatment, most research does not obtain a significant difference. A wide variety is shown in the usage of technologies for cancer screening and diagnosis with sensitivity (75-100 %), specificity (71-100 %), and accuracy (61-100 %). Even though the development of AI is very rapid in diagnosis just like doctors, AI is not immune from errors. It may bring dangerous risks to patients as well as doctors.

Risks in Using AI in the Medical Field

The security issue in the use of AI in the medical sector is the risk of adverse events or dangers in medical practices, such as program errors, cybersecurity, the need for adequate software certification tests, etc., encompassing legal and ethical issues. No technology is 100 % safe. For instance, there were cases where AI is used to accelerate hacking. In this case, AI may be used to obtain patients' medical data that are confidential.[20] AI has also been used to create deepfake videos to create propaganda.[21] AI can also be used to create highly convincing fake accounts that can be used to spread lies in society. Using such a method, deepfake accounts may spread misinformation related to the medical sector, which will in turn feed the AI with false infromation. Such a case may make medical workers make wrong diagnostic decisions when using AI to help them analyze medical cases.[22] The first thing that must be considered when using AI in the medical field is guaranteeing security as the AI must be dedicated to protecting and increasing human health. When AI commits errors, it may endanger human beings.

Surgery robots may commit an error and cause deaths, both in major surgery such as robotic laparotomy as well as in minumum invasive endoscopy surgery such as robotic bronchoscopy. In the United States, from 2000 to 2013, surgery robots were responsible for causing 1391 incidents and 144 deaths. The AI system must be designed with certain minimum conditions. Several systems have the potential to become dangerous for public safety. They must have an information and a prevention system in case of accidents as well as carry out a certain action in case of adverse and unpredictable events.[23]

In the medical sector, AI's algorithm poses the greatest risk. *First*, the black box algorithm makes modules that lack the capability to explain and are difficult to correct. If the algorithm is defective or wrong, the output will lead to a greater danger, such as diagnostic errors that endanger human life. In 2015, England used a medical robot to carry out a heart valve improvement surgery.

This robot not only committed a serious operational error but also disturbed the correct operation of a doctor, leading to the patient's death. It is impossible to develop codes that can encompass all adverse events. Therefore, AI's security weakness may endanger more patients compared to a single diagnosis error by a doctor as the automatic system will replicate more errors. In 2019, the FDA revoked Zimmer Biomet's ROSA Brain 3.0 robotic surgery system which faced an error in its software, placing the robot's arm in a wrong position.

Second, most of AI's algoritms in the medical sector is currently trained using historical data from retrospective studies. When facing data in the real world that is different from the data which existed in the training datasets, the AI may show a bad performance which directed towards clinical errors.[24]

Third, there are also risks related to the AI application's function that may potentially become autonomous. For instance, medical chatbots may give diagnostic recommendations and treatments to decrease unneeded doctor visits. However, this medical chatbot may also endanger patients if they are not frequently updated, checked, and controlled.

There are also potential risks when treatment robots are involved in treating patients and the elderly. When the treatment standard for cancer patients changes, such as adapting the medicine dosage so that it is more beneficial for certain patients and the treatment robots fail to update that information, this may endanger the patient's health. Due to the limitations in the internal program algorithms, treatment robots may limit patients' autonomy, such as limiting the patients' movements to protect their safety. Apart from that, they may also violate patient privacy.

It is crucial for AI technology to be specifically programmed to carry out good actions. For instance, if a certain action, "X" may endanger human beings, this "X" action must be defined as wrong. Through this method, it is hoped that AI with a learning machine can be safer. AI's predictability feature is crucial in legal issues as the main point of the justice system is to give environmental support so that society may develop.[25]

Another important thing is that the AI needs to have a strong prevention feature against invalid reprogramming and manipulation. Ethical guidelines and moral values may be different in each region as different ethnicities, nations, and countries have different norms. However, there is an agreement on the values of honesty, truth,

transparency, virtue, non-malevolence, and respect for autonomy.

There are efforts to strive for medical ethical theories that apply human ethical values in technologies/machines. This is to make sure that machines do not endanger humans. The process of creating AI that is smarter than human beings must guarantee that its use is only for goodness. There are four ethical principles related to medical practices and patient treatment, namely non-maleficence, beneficence, autonomy, and justice.

These four principles should be integrated into AI before having it applied to health service systems to avoid issues that may occur. Some ethical issues that may happen are related to consent, patient confidential data, trust, empathy, etc.

The Technological Application and Analysis Agency has issued the National Strategy for Artificial Intelligence in Indonesia 2020-2045 which regulates the use of AI in Indonesia. However, it is merely in the form of an outline of policy direction steps rather than providing detailed regulations. The characteristic of AI in the automatization of information processing may be juxtaposed with an "Electronic Agent" in the Indonesian legal regulations. Article 1 of the Law on Electronic Information and Transaction, an "Electronic Agent" is defined as a "device of an electronic system that is created to automatically carry out actions on a certain electronic information and is established by people."

Article 21 of the Law on Electronic Information and Transaction contains regulations on electronic agents in the implementation of electronic transactions. Every electronic system/agent establisher must guarantee that the system it uses has been established in a secure, reliable, and responsible manner. All legal impacts carried out through electronic agents become the responsibility of electronic agent establishers although it is important to note that errors or failures in the operation of this electronic system must not be caused by user negligence.

Regulations on the Use of AI in the Medical Field

So far, there are not yet any official regulations that specially govern the use of AI by doctors in Indonesia. Just like in using social media, it is hoped that doctors utilize AI by considering ethical aspects contained in the Indonesian Medical Code of Ethics, especially professionalism, honesty, and secret of office. The use of AI in the medical field has started to be published in several countries, governments, and organizations in the world with the aim of regulating and limiting the development and application of AI technologies.

The goal of the application of these ethical principles is that the use of technologies must always prioritize human interests. In other words, the development and use of AI must prioritize the good of humankind. Apart from following ethical principles, AI must also holistically fulfill medical ethics. The four principles are autonomy, non-maleficence, beneficence, and justice and they must be ingrained in the algorithms. AI ethical values and medical ethics have the same orientation, namely to increase human health and welfare in manners that do not endanger humankind.

In Europe, there are the Ethical Guidelines for Trustworthy AI and Asilomar AI Principles which regulate the use of AI. In 2017, European countries enacted the Barcelona Declarations which contain principles and values in the correct development and use of AI in Europe, consisting of the values of reliability, policy, accountability, responsibility, autonomy, and human role. This declaration guarantees the need for the human role in AI usage and public protection as well as data privacy. China has also enacted the Next Generation AI Governance Principles-Developing Responsible AI. Then, the UK Ministry of Health and Social Service has issued a Guide to Good Practice for Digital and Data-Driven Health Technologies which contains recommendations on the use of technologies in patient treatment for doctors. Then, Australia has the Therapeutic Goods Administration (TGA) as an AI regulator before it is widely used.

AI has great benefits and potentials in the medical sector. it must be guaranteed that AI technologies are compatible with human beings, especially in terms of human ethical principles and moral values. The IEEE Global Initiative for Ethical Considerations in AI and Autonomous Systems recommend that the development of technologies should insert ethics as a crucial and inseparable part so that ethics and human rights become a natural part of the designing process.

Then, the World Health Organization published Ethics and Governance of Artificial Intelligence for Health: WHO Guidance as a guideline for AI in the medical sector. There are six ethical principles that are recommended in the usage of AI in the health sector, namely protecting autonomy; increasing human welfare and safety; guaranteeing transparency, responsibility, and accountability; guaranteeing inclusivity and equality; as well as promoting a responsive and sustainable AI. These six principles should be implemented by all stakeholders, including designers, programmers, providers, and patients.

Then, the Ministry of Health and the Ministry of Health Information Technologies must cooperate to integrate ethical norms in every stage of technological design, development, and dissemination. These guidelines also regulate the importance of data protection, patient autonomy to reject the use of AI technologies in his/her treatment, and compensation for patients in case they experience negative effects due to AI's errors.

So far, there are yet any special regulations that govern the use of AI in the medical field, making doctors exert extra care when applying AI in their daily clinical activities. They place AI as an instrument to help in the diagnosis and handling of diseases. However, the clinical decisions are still in the hands of doctors based on anamneses and the existing physical and supporting examinations.[26] It is hoped that health facilities, both primary services and hospitals, choose AI with an evaluated system that can be taken accountable for. However, there should be recommendations from health agencies which state that it is safe to use AI technology in health services.

Health is crucial for the human life. Health is defined as a healthy condition in the physical, mental, spiritual, and social aspects, which allows people to productively live their lives in the economic and social aspects.[27] Health is essential for human life to achieve (and strive for) their goals and hopes. In Indonesia, health is a human right and the welfare element must be achieved according to Indonesia's national goals and ideals as written in Pancasila (The Five Principles that make Indonesia's ideals) and the Preamble of the Republic of Indonesia's 1945 Constitution.[23]

Considering the importance of health for human beings, there is a need for health development that encompasses all aspects of life by placing the role of the government and society at the same and equal level. Every person has the right to obtain health services as in any societal order, it is the task and obligation of doctors through health services.[26] Health development also aims to increase society's awareness, advancement, and capabilities. There is a need to achieve the highest possible degree of health for society, considering that it is an investment in developing effective human resources.

All activities that aim to maintain and increase public health to the highest level possible are carried out based on the principles of non-discrimination, participation, and sustainability. It is crucial to train Indonesian human resources to increase the state's resilience and competitiveness in fulfilling national needs. The Law on Health contains principles and goals that become a basis and guideline to health development that are achieved through health efforts that aim to increase the society's health, readiness, and capability to live healthily to achieve an optimum degree of public health. This should be achievable without differentiating social status.

Law No. 17 of 2023 on Health regulates that health development is carried out under the basis of humanity, balance, benefit, protection, respect to rights and responsibilities, justice, gender, non-discrimination, and religious norms. The Law on Health is also based on the goal of health development to increase the awareness and capability to live healthily. This is so that society can achieve the highest level of health services as an investment in the health sector. It is also to develop human resources that are efficient in the economic and social sectors. Based on the above goals, society's access to health services in isolated areas often becomes a challenge for the government. Therefore, there needs to be a solution to serve public health in isolated Indonesian territories.[28]

Telesurgery

By utilizing sophisticated technology in the form of artificial intelligence (AI), telesurgery may be carried out. Telesurgery is long-distance surgery using communication technologies combined with medical expertise to provide medical services, starting from consultation, temporary diagnosis, and planning up to medical procedures without being limited to space or is carried out from a long-distance.

Another definition of telesurgery is the provision of medical services using a long-distance surgery system by doctors using robot technologies. Up to now, there are yet any special regulations on telesurgery in Law No. 17 of 2023. However, in daily practices, there are some regulations that are appropriate to be used as guidelines in the usage of surgrical technologies.

Robotic telesurgery is the spearhead of medical services. Some factors must be considered in the practice of conducting telesurgery. Quoting Article 274 letter (1) of Law No. 17 of 2023, it is explained that when carrying out their tasks, medical workers must provide medical services according to the professional standard, the standard of professional services, the standard of surgery procedures, professional ethics, and patients' health needs.

Doctors must realize that the system on the use of telesurgery has a limitation in providing comprehensive services on patients' clinical conditions. Doctors must consider that the information presented in the telesurgery system is enough to develop a strong professional trust that may be followed in medical treatments and in determining patient management.

Just like in the patient-doctor relationship, the utilization of telesurgery must fulfill the requirements determined in Law No. 29 of 2004 on Medical Practices. Article 39 of Law No. 29 of 2004 regulates that medical practices are carried out based on an agreement that is made based on mutual trust between doctors and patients with the aim of maintaining health, preventing diseases, and recovering health. This agreement is one of the maximum efforts to serve the medical industry that doctors must carry out to treat and maintain patients' health according to the service standard, professional standard, standard operational procedures, and medical needs of patients in hospitals.[29]

Law No. 17 of 2023 only regulates medical services for patients that fulfill professional service standards and do not specifically regulate the use of long-distance surgery. This shows that the use of telerobotics in telesurgery has not fully been regulated. There is a lack of regulations that govern medical services between doctors and patients through telesurgery, which may lead to a lack of legal certainty.

This certainly lacks in giving the scope of telesurgery services between doctors and patients, especially concerning the safety of utilizing telesurgery in long-distance surgical operations. Long-distance surgery depends on wireless and robotic technologies which may lead to failure during surgery. It must be known that up to now, there are no legal regulations which specially govern the use of telesurgery in general medical practices and telesurgery services.

The term telesurgery originates from Greek, consisting of two words, namely *tele* meaning long-distance and *cheirourgia* meaning working with the hand. Telesurgery is a new surgical instrument that utilizes robotic technologies and wireless networks to connect patients and surgeons who are geographically located far away from each other. Telesurgery utilizes a form of tissue robot control. Robots carry out surgical actions under the direct control of surgeons using a robotic system from a faraway location.[30]

Surgery using robots was first developed by the North Atlantic Treaty Organization Ministry as it was needed to provide support in the form of surgery for troops in the warzone. Phil Green was the first person to create a system consisting of two cameras and a telerobot in California. It is a system that is placed on the operation table on the battlefield. The camera sends surgical images to a long-distance computer, i.e., the place where a surgeon controls the surgrical telerobot.

Telesurgery is defined as a long-distance surgrical procedure that is carried out by surgeons or surgrical teams from any distance from the patients and the operation room. This new treatment and diagnosis technique is a branch of telemedicine which involves the use of medical instruments in a location other than where the patient is located using robotic and electronic devices with the aim of providing the best quality medical treatment.

The determining factor in surgery with the help of robots is the distance between the patient and the surgeon, without real interaction. This may lead to a two-way scepticism. The application of telemedicine must be based on the same ethical principles that have become the basis of medical science before the use of this new technology. However, the specification of this medical innovation leads to the emergence of a series of new ethical questions which start to emerge a few years after its application. This issue includes the impacts on the patient-doctor relationship, including the loss of direct physical contact between professional workers and patients, which may lead to depersonalization.

Traditionally, surgery is carried out at a distance which is only limited to centimeters or milimeters from the patient. In many cases, there is physical contact between surgeons and patients if it is carried out online. With the development of laparoscopic surgery, this distance increases while yielding better surgrical results. In telesurgery or surgery with the help of robots, the principle of medical practice ethics is still the same. It encompasses privacy, device security, as well as data collection and storage.

Legal and ethical aspects need to be strengthened to guarantee professional accreditation medical qualifications as well as unify practical standards to prevent patients' limited access to robotic surgery services. The medical code of ethics is part of the general ethics that applies in society. Thus, in the implementation of its practice, it cannot violate the medical code of ethics and the ethical code that applies in society.

Referring to Article 8 of the 2012 Indonesian Medical Code of Ethics, it is explained that in any medical activity, doctors must competently provide services with full freedom in technique and morality. It must be completed with compassion and respect for human dignity and honor. The explanation of this article explains that a doctor must carry out treatment in a competent manner as well as give freedom and show compassion to his/her patient. In this case, doctors must respond to patient's needs in a positive manner as well as give emergency help based on humanity and have the capability to put themselves in other people's shoes.

Various countries have ethical codes that explain the basic principles and tasks of doctors. The code of ethics shows the morality of doctors and guarantees moral quality in society. These regulations are based on the principles of ethics and doctors' obligation to protect the life, health, physical integrity, and psychological state of patients across geographic locations by prioritizing treatment for patients and respecting human dignity.

In conducting telesurgrical practices, doctors do not carry out direct contact with patients. In this case, it does not become an obstacle to the application of ethical principles and other responsibilities that doctors have over patients, such as safety, quality, and security. In the medical sector in general and especially in the field of telesurgery, there need to be actions to evaluate medical service quality to guarantee that the diagnostic and treatment services fulfill the highest standard applied and given to patients. The usage of the electronic system may endanger confidentiality and special actions must be taken to prevent inaccurate medical data transmission.

In situations such as transmission of test results, especially if the ultrasonography shows the gender of the child, disorders, or diseases, additional actions must be taken. Doctors that provide telesurgrical services must make sure that patients agree to carry out surgrical treatment process from a long-distance using a

robot. Telesurgery offers certain benefits for patients and doctors but in line with the ever rampant usage of this practice, there must be consideration of the legal and ethical aspects. Ideally, the standardization and regulation of these aspects must be applied so that similar considerations may be considered in every country that provides or obtains benefits from the telesurgery service.

CONCLUSION

- Regarding the legal position of AI, in the Indonesian law, AI is still positioned as a legal object rather than a legal subject. Law No. 19 of 2016 on Electronic Information and Transaction does not significantly regulate AI.
- Indonesia's new health law, i.e., Law No. 17 of 2023 on Health, regulates that health service facilities may provide telehealth and telemedicine services which comprise Teleradiology, Teleelectrocardiography, Teleultrasonography, and Clinical teleconsultation.
- There is a need for large amounts of representative data in diagnosing patients' diseases with the use of AI. A lack of appropriate data may make the AI yield unreliable and misleading information that brings more harm than good.
- A great risk in the use of AI in the medical sector is the security issue. AI can also be used to spread misinformation that bring risks to people's health. AI-made errors may endanger human health. AI needs to have a strong prevention feature against invalid reprogramming and manipulation.
- There are not yet any regulations that specially govern the use of AI by medical workers in Indonesia. The usage of AI in the medical field should consider the ethical aspects contained in the Indonesian Medical Code of Ethics. Several regions have enacted guidelines on the use of AI, such as Europe, China, UK, etc.
- This long-distance surgery using communication technologies combined with medical expertise can provide medical services. Doctors must realize that the system on the use of telesurgery has a limitation in providing comprehensive services on patients' clinical conditions. Article 8 of the 2012 Indonesian Medical Code of Ethics explains that in any medical activity, doctors must competently provide services with full freedom in technique and morality. This must be considered in conducting telesurgery with the help of AI.

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AUTHORSHIP CONTRIBUTION

Conceptualization: Arief Budiono, Onnie Wira Tama, Naeem Allahrakha, Aminuddin Mustaffa, Abdullah Al Mamun, Rizka, Nur Aida Ikrima.

Data curation: Arief Budiono, Onnie Wira Tama, Naeem Allahrakha, Aminuddin Mustaffa, Abdullah Al Mamun, Rizka, Nur Aida Ikrima.

Formal analysis: Arief Budiono, Onnie Wira Tama, Naeem Allahrakha, Aminuddin Mustaffa, Abdullah Al Mamun, Rizka, Nur Aida Ikrima.

Research: Arief Budiono, Onnie Wira Tama, Naeem Allahrakha, Aminuddin Mustaffa, Abdullah Al Mamun, Rizka, Nur Aida Ikrima.

Methodology: Arief Budiono, Onnie Wira Tama, Naeem Allahrakha, Aminuddin Mustaffa, Abdullah Al Mamun, Rizka, Nur Aida Ikrima.

Project management: Arief Budiono, Onnie Wira Tama, Naeem Allahrakha, Aminuddin Mustaffa, Abdullah Al Mamun, Rizka, Nur Aida Ikrima.

Resources: Arief Budiono, Onnie Wira Tama, Naeem Allahrakha, Aminuddin Mustaffa, Abdullah Al Mamun, Rizka, Nur Aida Ikrima.

Supervision: Arief Budiono, Onnie Wira Tama, Naeem Allahrakha, Aminuddin Mustaffa, Abdullah Al Mamun, Rizka, Nur Aida Ikrima.

Validation: Arief Budiono, Onnie Wira Tama, Naeem Allahrakha, Aminuddin Mustaffa, Abdullah Al Mamun, Rizka, Nur Aida Ikrima.

Display: Arief Budiono, Onnie Wira Tama, Naeem Allahrakha, Aminuddin Mustaffa, Abdullah Al Mamun, Rizka, Nur Aida Ikrima.

Drafting - original draft: Arief Budiono, Onnie Wira Tama, Naeem Allahrakha, Aminuddin Mustaffa, Abdullah Al Mamun, Rizka, Nur Aida Ikrima.

Writing - proofreading and editing: Arief Budiono, Onnie Wira Tama, Naeem Allahrakha, Aminuddin Mustaffa, Abdullah Al Mamun, Rizka, Nur Aida Ikrima.