

Legal Responsibility For Operational Failures Through Robotic Telesurgery

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ABSTRACT

The rate of technological advancement is currently accelerating at an extremely quick pace, particularly in the field of medicine. Robotic telesurgery, also known as remote surgical robots, is anticipated to become a technology that can bring about health equality in Indonesia. However, it is unfortunate that the progression of technology is not comparable to the relevant regulations that regulate it. It is feared that this will not guarantee legal certainty, which could result in malpractice. The strategy that was utilized in this research was a normative legal research method. This is due to the fact that the objective of the study was to move away from the ambiguity of norms by utilizing the following approaches: the statute approach, the conceptual approach, and the analytical approach. The method of searching for legal materials makes use of document study techniques, whereas the method of study analysis makes use of qualitative analysis. Based on the findings of this study, it has been determined that there is a gap in the norms that are included in Law Number 17 of 2023 concerning Health. This law does not control the legal liability for unsuccessful procedures that are performed by robotic surgeries. As a result, it is essential to enact legislation that controls the duties that are explicitly assigned to medical professionals.

Keywords: Legal Responsibility, Robotic Telesurgery, Health Sector

1. INTRODUCTION

Technological developments have changed human civilization. This development is not only in one or two fields, but technological developments have become part of humans themselves. The development of science collaborated with technology has given rise to advances in technology-based science, so that in its development it has produced innovations that help humans and can have a big impact on human life. Technological developments in the health sector have produced findings that can help in organizing hospitals, treatment, and research into the development of health science itself. Technological advances in the world of health, especially as tools that can help doctors, have become an opportunity that can improve the quality of human life [1]. According to Rogowski, technology in the world of health is divided into 5 types, namely:

- 1) Drugs, which include chemicals and biological substances used in food, are injected into the human body for medical purposes;
- 2) Tools, which include special tools with diagnostic and therapeutic purposes;
- 3) Surgical and medical procedures or combinations thereof are often very complex;
- 4) Supporting systems are technology used to provide medical services in hospitals;
- 5) The organizational system is the technology used to ensure the delivery of health services becomes more efficient and effective [1].

Currently, one of the products resulting from sophisticated technology in the world of health is Robotic Telesurgery. Robotic Telesurgery or Remote surgical robot is a tool that can help doctors, especially surgeons, in carrying out operations remotely. Telesurgery or remote surgery is a new

surgical tool that utilizes robotic technology and wireless networks to connect geographically distant patients and surgeons.

Telesurgery utilizes a form of network-mediated robotic control, the word comes from the Greek 'a lot' which means far away, 'cars' means hand, and 'result' which means work.¹ Robotic Telesurgery himself is one use case innovative use of 5G network technology supported by leading network solutions and services that enable surgeons to perform operations on patients remotely real-time [2]. The way of surgery through the help of tools robotic surgery operated using console in the hands of the surgeon, as well remote control long distance. Robotic surgery, the machine will translate every movement of the surgeon's hand to the robot arm on the patient's body. There are several benefits obtained from surgical operations using robotic telesurgery compared to conventional surgery, namely: (1) the benefits of robot-assisted surgery can increase precision and stability for the surgeon, thereby reducing the risk human error. (2) Shorter recovery time, (3) reduced pain, (4) improved surgeon's ability to identify and treat complex structures. (5) Patients do not need to travel long distances, (6) Health equality is implemented

Medical practitioners are mandated by Article 274, letter a, of Law Number 17 of 2023 concerning Health (hereinafter referred to as the Health Law) to deliver health services in accordance with professional standards, service protocols, operational procedures, and ethical guidelines, as well as to address patient health requirements. This implies that physicians must utilize their expertise to the fullest extent when providing care to patients. Nonetheless, any action undertaken by a physician inherently involves medical hazards. One of the risks of surgery is failure of the surgical operation which causes injury to the patient. Data from 2000 – 2013 recorded 144 deaths due to robot surgery, 1,391 injuries and 8,061 equipment failures out of 1.7 million operations performed in America [3].

Development robotic telesurgery in Indonesia has now entered its third year roadmaps of center robotic surgery in Indonesia. In May 2023, the Ministry of Health (Kemenkes) of the Republic of Indonesia (hereinafter referred to as the Indonesian Ministry of Health) first conducted trials robotic telesurgery in Indonesia using the 5G network. The Ministry of Health conducted trials with 2 Central General Hospitals (RSUP) which have pilot projects for telesurgery, namely RSUP Dr. Hasan Sadikin (Bandung) and RSUP Dr. Sardjito (Yogyakarta). In this trial, the surgeon was at RSUP Dr. Hasan Sadikin (Bandung), while the patient is at RSUP Dr. Sardjito (Yogyakarta). The two hospitals are connected to a 5G network which has been tested previously [4].

Robotic Telesurgery which is expected to be a hope for realizing equal distribution of health and improving the quality of life in Indonesia, unfortunately this progress is not accompanied by the relevant legal regulations that govern it. This is certainly a concern regarding the certainty of use robotic telesurgery. In the Health Law there is no regulation regarding responsibility for use robotic telesurgery as a combination or tool to assist doctors in carrying out surgical operations on patients, if an accident occurs.

Based on the explanation above, there is a legal problem, namely the absence of norms in the Health Law which does not explain the legal regulations related to failed operations by Robotic Telesurgery Therefore, it is important to regulate legal responsibility for failed patient operations by Robotic Telesurgery when in the future there is a failure of the operation on the patient.

Kaspar Rosager Ludvigsen and Shisgir Nagaraja did prior research titled "Dissecting Liabilities in Adversarial Surgical Robot Failures: A National (Danish) and EU Law Perspective," published in the *Computer Law & Security Review (CLSR)*. The study analyzes accountability for surgical robot failures within the framework of national legislation in Denmark and the European Union. The author's research investigates the regulation of accountability for patients who do not comply with robotic telesurgery and pertinent future rules. This study seeks to analyze and address the obligations of physicians to patients who experience surgical failure.

2. METHODS

This study employs normative legal research methodologies, as the research focus arises from the lack of norms, utilizing a statutory approach and conceptual approaches. The utilized legal materials comprise main legal materials such as legislation, secondary legal materials including various books, journals, and articles, along with tertiary legal elements in the form of legal dictionaries. Techniques employed in legal material analysis encompass descriptive techniques, evaluative techniques, and argumentative strategies [5], [6]

3. RESULTS AND DISCUSSION

3.1 Concept of Legal Responsibility for Operation Failure Through Robotic Telesurgery in Indonesia

Surgical procedures are procedures that are performed by a physician in an effort to save the patient's life. In order to establish a legal relationship with the patient, doctors, as members of the medical staff, are required to obtain the patient's or the patient's family's agreement prior to performing surgical procedures. Because it is built on the patient's trust in the physician, this relationship is a very personal relationship. This type of interaction is referred to as a therapeutic transaction. An agreement between a physician and a patient that takes the shape of a legal relationship and gives birth to the rights and obligations of both parties is referred to as a therapeutic transaction. As a result of this agreement, an attempt or therapy to cure the patient is the aim of the agreement. Contrary to what many people believe, the beginning of the contractual legal relationship that exists between a patient and a doctor does not occur when the patient enters the doctor's practice. Rather, the beginning of the relationship occurs when the doctor expresses his or her willingness, either verbally or implicitly by demonstrating an attitude or action that concludes willingness [7], [8]

It is inevitable that duties will emerge as a result of the interaction between patients and their doctors, which involves rights and obligations. Acceptance of responsibility If it is related to the notion of legal responsibility, as stated by [9] in the book *Pure notion of Law*, which was translated by [10] in the book *Pure Legal Theory, Basics of Normative Legal Science*, then responsibility is closely tied to obligation, but it is distinct from obligation. The existence of obligations can be attributed to the existence of legal regulations, which contain provisions that control and provide obligations to legal subjects. As a type of order derived from the rule of law, legal subjects who are charged with obligations are obligated to carry out their commitments. It is inevitable that sanctions will be imposed on those who fail to meet their duties. In this context, the sanction in question refers to an act that imposes legal regulations in order to ensure that legal subjects fulfill their obligations in an appropriate manner. Kelsen considers the legal subject who is subject to sanctions to be "responsible" or legally liable for the infraction. This is according to Kelsen's interpretation of the term. Titik Triwulan then stated that in order for a person to be held legally responsible, there must be a foundation for that responsibility. This basis must be something that gives birth to a legal right for someone to sue another party, as well as something that gives rise to a legal obligation for another party to provide accountability [1].

On the basis of this theory, it is possible to assert that responsibility is a consequence of the existence of legal rules that impose responsibilities on legal subjects and expose them to the possibility of punishment in the event that these obligations are not fulfilled. Responsibility can also be understood as legal responsibility due to the fact that it originates from legal commands or laws, and the punishments that are communicated are also sanctions that are imposed by law; hence, the responsibility that is carried out by legal subjects is considered to be legal responsibility [2].

Relates to conditions where legal responsibility for failure of operations by robotic telesurgery This is different from ordinary surgery or conventional surgery performed by doctors. Conventional surgery is carried out directly by the doctor on the patient directly in the same place without using the help of a robot, whereas surgery is assisted robotic telesurgery This is assisted by medical equipment technology where this technology will carry out direct surgery on patients in different places remotely by translating every movement of the surgeon's hand into a robotic arm on the patient's body, so that the connection can be seen that the concept of legal responsibility in this case can divided into 2, namely:

1. Circumstances for which the doctor is responsible.
2. Circumstances for which the equipment provider is responsible telesurgery.

3.2 Relevant Regulations Regarding Responsibility for Failure to Use Operations Robotic Telesurgery

Robot-assisted remote surgery has excellent advantages with assistance robotic telesurgery in this way, doctors can reach patients in areas far from the doctor's location without the patient needing to travel long distances to see a doctor so that doctors can carry out operations without restrictions on distance and travel time. There is Robotic Telesurgery This can create equal distribution of health in Indonesia. The lack of surgeons in Indonesia is no longer an obstacle in realizing this equality. However, in order to make this happen, there needs to be regulations that can guarantee patients.

Legal certainty is necessary to guarantee legal protection for patients. In fact, the Health Law does not yet regulate liability due to failed operations by robots Telesurgery This. If in the future an accident occurs caused by this assistive device, it is certain that the law will not be able to provide protection. However, if we examine that tool robotic telesurgery operated by a doctor using the help of technology so it needs to be studied that legal responsibility is not only limited to the burden on the doctor if an error occurs in the operation process, but the responsibility can also be borne by the equipment provider. robotic telesurgery.

When a physician is able to be held accountable for certain circumstances, those circumstances can be construed as either carelessness or malpractice. In the third edition of the Big Indonesian Dictionary, the term "malpractice" is defined as "medical practice that is wrong, inappropriate, violates the law or code of ethics." This definition is included in the definition of "malpractice." A definition of malpractice can be found in Black's Law Dictionary as follows:

"professional misconduct or unreasonable lack of skill" or "failure of one rendering professional services to exercise that degree of skill and learning commonly applied under all the circumstances in the community by the average prudent reputable member of the profession with the result of injury, loss, or damage to the recipient of those services or to those entitled to rely upon them" are both examples of professional misconduct.

Whether it is due to errors or negligence committed by doctors or other health workers, whether it originates from consent or not, medical malpractice is defined as an improper practice that takes place during or as a result of providing professional medical services in accordance with their expertise and abilities. If this practice is violated and results in injury or loss to the patient, the patient is obligated to provide compensation. Gunawan Widjaja is the author of this definition. In

the event that an activity satisfies the following requirements, it is considered to be medical malpractice;²

- 1) The medical operations that are carried out do not adhere to the standards that have been established;
- 2) The medical procedures that are carried out do not comply with the standards that have been established.
- 3) The cautious principle is not put into practice when performing medical treatments;
- 4) The medical procedure was carried out in a manner that was either inadequate or negligent;
- 5) The patient is subjected to direct injury as a result of these medical procedures

As a result, one interpretation of the term "misconduct" is that it refers to any inappropriate attitude or a lack of abilities at an excessive degree. "The failure to provide professional services and to perform at a level of skill and intelligence that is reasonable in the community by average colleagues in that profession is what is meant by the term "malpractice." This failure can result in injury, loss, or damage to those who receive such services and who have a tendency to place their trust in doctors. This encompasses any and all instances of professional misconduct, unjustifiable lack of skill or lack of due care or legal duties, poor practice, or attitudes that are illegal or ethically questionable." states that a doctor's actions can be classified as malpractice if they fulfill:

1. There is no negligence if there is an obligation to treat, there must be a legal relationship so the doctor's attitude must comply with professional standards (duty to use due care)
2. If there is an agreement, there is an obligation, the doctor must act according to professional standards, if there is a deviation the doctor can be legally blamed. (Dereliction/breach of duty)
3. If as a result of the doctor's negligence the patient suffers injury, injury, loss or serious mental disorders then the doctor can be legally blamed (Damage)
4. To carry out legal blame, there must be a reasonable causal relationship. (Direct Causation/Proximate Causes)

Regarding Malpractice, there are 2 types of malpractice, including:

1. Ethical Malpractice, also known as Ethical Malpractice, occurs when health practitioners engage in behaviors that are in direct opposition to the professional ethics that they are expected to uphold as health workers. There are violations of the rules of the Code of Medical Ethics that are considered to be solely ethical violations; however, there are also violations of ethics and at the same time legal offenses, which are referred to as ethical violations. Ethical malpractice is divided into two types, namely:
 - a. Pure ethical violations include: (1) Extracting unreasonable compensation or remuneration for services from the family of fellow doctors and dentists; (2) Taking over a patient without the consent of his colleagues (violating Article 16 of the Code); (3) Praising yourself in front of the patient (violating Article 4 letter a Kodeki); (4) The doctor ignores his own health (violation of Article 17 of the Code)
 - b. The following are examples of ethical violations: (1) providing substandard medical services; (2) issuing a fake certificate (which is a violation of Article 7 of the Code as well as Article 267 of the Criminal Code); (3) disclosing the secret of a doctor's position or work (which is a violation of Article 13 of the Code and Article 322 of the Criminal Code); (4) never having participated in education and training in the development of science and technology; (5) provocatus abortion; (6) sexual

- harassment; (7) failing to provide emergency assistance to people who are suffering (which is a violation of Article 14 of the Code and Article 304 of the Criminal Code).
2. Judicial malpractice, also known as civil malpractice and criminal malpractice, is a sort of malpractice that can be broken down into two categories: civil malpractice and criminal malpractice:
 - a. Civil malpractice (also known as civil malpractice), which arises when there are circumstances that result in the non-fulfillment of the provisions of the agreement (also known as default) in therapeutic transactions carried out by health workers, or when unlawful acts take place (also known as unlawful act), consequently causing harm to the patient civil malpractice.
 - b. Criminal malpractice (criminal malpractice), Criminal malpractice occurs when a patient dies or becomes disabled as a result of health workers being careless. Or not being careful in carrying out care efforts for patients who die or are disabled.

When it comes to malpractice in civil law, it is stated that there are two (2) different categories of liability, which are error and risk. The concept of responsibility for errors, also known as liability without fault, and accountability without fault, also known as liability without fault, or what is commonly referred to as risk responsibility (risk liability) or absolute responsibility (strict liability), are sometimes used interchangeably. Meanwhile, negligence is the term that is used to describe malpractice in the Criminal Code, which will be referred to in the following paragraphs as the Criminal Code. Article 359 and Article 360 of the Criminal Code provide an explanation of the idea of negligence in the Criminal Code. The explanation is presented as follows:

- a. Article 359 of the Criminal Code stipulates that "Any individual who, through negligence, causes the death of another person is subject to a maximum imprisonment of five years or a minimum of one year."
- b. Article 360, paragraph (1) of the Criminal Code states, "Any individual who, through negligence, inflicts serious injuries upon another person is subject to a maximum imprisonment of five years or a minimum of one year."
- c. Article 360, paragraph (2) of the Criminal Code states: "Any individual who, through negligence, inflicts injury on another person resulting in illness or hindrance to employment or activities for a specified duration, faces a penalty of up to nine months of imprisonment, six months of imprisonment, or a maximum fine of three hundred rupiah."

Based on Regulation (EU) 2017/745 Of The European Parliament And Of The Council Of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC Pada Article (66) bahwa: "Where, in the course of a clinical investigation, harm caused to a subject leads to the civil or criminal liability of the investigator or the sponsor being invoked, the conditions for liability in such cases, including issues of causality and the level of damages and sanctions, should remain governed by national law." "If, during the course of a clinical investigation, harm is caused to a subject that gives rise to the civil or criminal liability of the investigator or sponsor requested, the terms of liability in that case, including issues of causation and the extent of harm and sanctions, shall remain regulated by national law," is the translation of the phrase."

From this regulation it is explained that if losses occur as a result of its implementation, those responsible civilly and criminally must be determined based on national law, which in this case is Indonesian national law.

When we consider operational failures that are brought on by situations that may fall under the purview of the equipment provider, we find that telesurgery is a good example. Surgical operations using robots as assistive devices are included in medical devices, as regulated in article 1

point 1 of the Regulation of the Minister of Health of the Republic of Indonesia Number 15 of 2023 concerning Maintenance of Medical Devices in Health Service Facilities which states that the definition of medical devices is instruments, apparatus, machines and/ or implants that do not contain drugs that are used to prevent, diagnose, cure and relieve disease, treat sick people, restore health to humans, and/or form structures and improve body functions, so that from this article robotic telesurgery can be categorized as a health device.

According to the findings of this investigation, there are no specific regulations that have been discovered in either the Health Law or its derivative regulations. However, damage to equipment can be linked as one of the responsibilities of business actors, as regulated in Law Number 8 of 1999 concerning Consumer Protection (hereinafter referred to as the Law Consumer Protection). This is the case because the Health Law and its derivative regulations have not yet been found to contain any special regulations. According to the first paragraph of Article 19, business actors are obligated to provide compensation for any damages, pollution, or services that are created or transferred. It is further explained in paragraph two of article 19 of the Consumer Protection Law that compensation as was intended in paragraph one can take the form of a refund or return of goods and/or services of the same or equivalent value, or it can take the form of health care and/or the provision of compensation in accordance with the provisions of applicable laws and regulations. At the same time, it is highlighted in paragraph four of article 19 that the provision of compensation does not remove the potential of criminal prosecution based on additional information concerning the existence of an element of error.

So that by not regulating this responsibility, Indonesian national law, especially the Health Law, should regulate in more detail regarding legal responsibility due to failure of operations using Robotic Telesurgery. So, it can be interpreted that the doctor's responsibility in the event of a failed operation by robotic telesurgery This can be related to the doctor's professionalism. The doctor who performs surgery on the patient and if a problem occurs that causes injury, injury or even death which can be proven to be due to negligence or negligence on the part of the doctor as a medical personnel, then the doctor is responsible in this case, whereas if the error occurs in the equipment produced then the equipment provider can be charged responsibility so that the principle of abuse robotic telesurgery Even though the operation is carried out by a doctor, if an accident occurs then the burden of responsibility needs to be studied further. So, it is necessary to immediately create special regulations related to robotic telesurgery This is to create legal certainty.

CONCLUSION

Robotic Telesurgery is one of the advances in technology in the world of medicine. Use robotic telesurgery This is a medical tool used by doctors by utilizing network technology. There are several advantages to using this surgical robot compared to conventional surgery, one of which is that doctors can carry out operations on patients without the patient having to come face to face with the doctor. However, in line with its very rapid development, regulations governing it are not followed robotic telesurgery This is especially true of the Health Law. This of course has an impact on the lack of legal certainty regarding legal responsibility if something happens that could cause harm, injury or death to the patient in the future. Relates to conditions where legal responsibility for failure of operations by robotic telesurgery This is different from ordinary surgery or conventional surgery performed by doctors. Conventional operations are carried out directly by doctors on patients directly in the same place without using robots, while operations with the help of robotic telesurgery are assisted by medical equipment technology where this technology will carry out direct operations on patients in different places remotely by translating each the movement of the surgeon's hand to the robotic arm on the patient's body, so that the relationship can be seen that the concept of legal responsibility in this case can be divided into 2, namely: Conditions that are responsible for the doctor and conditions that are responsible for the equipment provider. The doctor's responsibility in

the event of a failed operation by robotic telesurgery This can be related to the doctor's professionalism. The doctor who performs surgery on the patient and if a problem occurs that causes injury, injury or even death which can be proven to be due to negligence or negligence on the part of the doctor as a medical personnel, then the doctor is responsible in this case, whereas if the error occurs in the equipment produced then the equipment provider can be charged responsibility and principles of use robotic telesurgery Even though the operation is carried out by a doctor, if an accident occurs then the burden of responsibility needs to be studied further. Thus, it is necessary to establish regulations related to robotic telesurgery this is in Indonesia. Regulatory policies related to legal responsibility for patients whose operations fail robotic telesurgery It should be immediately formulated in the Health Law in order to create legal certainty that provides justice and benefits to doctors, patients and the government.

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