



## Legal Responsibility for Medical Risks and Medical Negligence in The View of Health Law

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### ABSTRACT

This research examines legal aspects related to medical risk and negligence in the context of health law in Indonesia, especially after the ratification of Law Number 17 of 2023 concerning Health. Normative research methods are used, with a focus on examining legal principles, statutory regulations, relevant cases, and conceptual approaches in legal science related to medical negligence. The research results highlight that in criminal law, liability for medical acts deemed negligent depends on clear evidence of fault, in accordance with the principle "No punishment if there is no fault". This law specifically regulates criminal sanctions for health workers who are proven to have committed negligence that causes serious injury or death to patients, as regulated in Article 440. Medical risk is an inherent part of the practice of medicine, but medical negligence is defined as a deviation from the expected standard of care. This research also highlights the obligations of hospitals in providing safe and effective services in accordance with established standards, and their accountability for negligence that occurs, as regulated in Articles 189 and 193. Law Number 17 of 2023 also introduces a risk management system to prevent medical negligence, as well as the formation of a special assembly by the Minister of Health to resolve medical disputes, including allegations of negligence. This research underlines the importance of a comprehensive understanding of health law in medical practice and handling of medical negligence cases in Indonesia.

**Keywords :** Medical Risk, Negligence, Negligence and Crime

### Introduction

A condition of complete physical, mental and social well-being, and not just the absence of disease or disability (Hermien Hadiati Koeswadji, 1992: Page 17). Loosely, this statement means that health is not only related to the absence of disease or weakness, but rather to a healthy physical, mental and social state. Health is a comprehensive state of well-being, including physical, mental, spiritual and social aspects that enable a person to live a productive life in a social and economic context. As a valuable asset, efforts to improve the quality of health continue to be fought for. The main goal of state health initiatives is to improve the quality of life, which in turn will improve well-being. According to Article 28A of the 1945 Constitution of the Republic of Indonesia, "every person has the right to live and the right to defend his or her life and living", which means that every individual has the right to have the same opportunity to maintain their health. This includes the right to receive adequate health services. Therefore, improving the quality of health services is the main focus. Government policies in the health sector must cover all levels of society, because health is a human right protected by the state, as emphasized in Article 28H of the 1945 Constitution of the Republic of Indonesia. In an effort to improve the quality of health, the government must develop regulations that support increasing the capabilities of doctors and medical personnel as well as the development of medical technology. This regulation must also regulate the provision of better health services and

protect medical personnel and patients, ensuring they can carry out their obligations and rights optimally. The relationship between doctors and patients, which has existed since the time of Hippocrates, continues to evolve with advances in technology, science, and social change. These changes have resulted in an evolution in the way health services are provided and the medical procedures taken by doctors. This poses a challenge to the concepts and moral obligations faced by medical personnel and society when dealing with patients who are sick or face medical risks. Suprpti Samil (2007, pp. 60-61) states that human relations, especially between doctors and patients, are regulated by the values of politeness (*mores*), which means customs, behavior, character, character, morals and ethics (*ethica*). According to KODEKI 1980 mentioned by Suprpti Samil, ethics comes from two terms "mores of a community" and "ethos of the people". This means that the doctor-patient relationship must be based on good values and morals to provide effective and sustainable health services.

The doctor-patient relationship, which was previously paternalistic and based on trust (trust, *vertrouwen*, fiduciary relationship), is now experiencing changes. This belief is starting to waver, where people are now more critical of the results of treatment, especially if it results in serious disability or death (Guwandi: 2009, pp. 1-2). In the doctor-patient relationship, there is the concept of a therapeutic agreement, namely an agreement between the doctor and patient which gives the doctor the authority to provide health services according to his expertise and abilities (Anny Isfandyarie: 2006, p. 57). Komalawati applies the contract law regulated in book III of the Civil Code to therapeutic agreements, as stated in Article 1320 of the Civil Code which reads: "*All agreements, whether they have a specific name or are not known by a specific name, are subject to the general regulations contained in this and the previous chapters.*" But *agreement Therapeutic* is different from agreements in general because it has a different agreement object from agreements in general. Therapeutic agreements or therapeutic transactions are included in *inspanningverbinten* or effort agreements, because doctors cannot possibly promise healing to patients, what doctors do is provide health services as an effort to cure patients. Therapeutic agreements are binding like law for both doctors and patients. As regulated in Article 1338 of the Civil Code which reads: "*All agreements made legally apply as law for they made it.*" The medical profession also has medical ethics. Medical ethics are the norms and principles that apply to doctors as a basis for carrying out their profession. In practice, medical ethics, which has two interrelated aspects, includes: First, professional ethics or medical ethics, which relates to doctors' attitudes towards colleagues, assistants, society and the government. Second, ethics of medical care, which concerns the actions and attitudes of a doctor towards patients under his responsibility (Bahder Johan Nasution: 2013, p. 9). Currently, cases often arise in health services that raise doubts about doctors' competence and have the potential to threaten their careers. For example, the case of a caesarean section carried out by doctor Dewa Ayu Sasiary Prawan, which resulted in the patient's death. The case underwent a series of different decisions at various levels of court, illustrating the complexity of assessing medical practice.

The concept of medical risk has not been defined explicitly in statutory regulations, but is implied in several statements regarding the risks of medical procedures (Anny Isfandyarie: 2005, p. 38). Risks in medical services are difficult to predict, because medical personnel can only do their best to handle them as optimally as possible. Although medical risks can be anticipated, there is no certainty regarding the specific risks a patient may experience. Cases of risk that lead to death often give rise to allegations of error or negligence by medical personnel. We often hear via electronic media or social media about cases of suspected malpractice by the patient's family regarding the health care results of medical personnel. For example, the case of Mrs. H, who died after a caesarean section operation at a hospital in Medan City, and other similar cases that we are following. This situation creates confusion in the community, whether this incident is a risk or complication of medical procedures, or whether it is true negligence on the part of medical personnel which causes undesirable results for patients and their families. So, what steps should the patient or patient's family take to ensure this? Based on the explanation above, the scope of this research includes problem formulation, including: What categories of medical actions are included in medical risks and medical negligence, and how criminal liability for medical risks leads to medical negligence by doctors.

## Research Methodology

The type of research used is normative research, namely an approach method through the study of legal principles and legal systematics contained in applicable laws and regulations. So this normative research can focus on positive legal inventory and legal findings in *inconcreto cases* in case handling. In preparing and writing this thesis the author used a problem approach with several existing methods, namely; legal approach method ( *statute approach* ), case approach ( *case approach* ), and conceptual approach ( *conceptual approach* ). Peter Mahmud Marzuki (2013:33) describes the approach used in the research above as follows: The statutory approach is carried out by reviewing all laws and regulations that are related to the problem being discussed. A conceptual approach is an approach that is carried out using the views and doctrines that have developed in legal science related to medical negligence.

## Results and Discussion

### *Draft Negligence Medical And The Proof*

Negligence in criminal law is also called negligence. Langemeyer "Negligence is a very gecompliceerd structure. It contains, on the one hand, errors in external actions and refers to the existence of a certain inner state, and on the other hand, the inner state itself" (Moeljatno: 1993, p. 200). Van Hammel said that negligence contains two conditions, namely: (1) Failure to make assessments as required by law (2) Failure to exercise caution as required by law. The concept of negligence in the Criminal Code (KUHP) is explained in Article 359 and Article 360 of the Criminal Code:

Article 359 of the Criminal Code

"Anyone who, through negligence, causes the death of another person is threatened with imprisonment for a maximum of five years or imprisonment for a maximum of one year."

Article 360 paragraph (1) of the Criminal Code

"Whoever, through his negligence, causes another person to suffer serious injuries, is threatened with imprisonment for a maximum of five years or imprisonment for a maximum of one year."

Article 360 paragraph (2) of the Criminal Code

"Anyone who, through negligence, causes injuries to another person in such a way that they cause illness or are prevented from carrying out official duties or searches for a certain period of time, is threatened with imprisonment for a maximum of nine months or imprisonment for a maximum of six months or a fine of a maximum of three hundred rupiah."

Medical negligence or in everyday language known as *malpractice* is an event or phenomenon that has recently emerged and has become the public's spotlight. This is because some patients experience medical risks in the form of death or disability and this results in many lawsuits being filed by patients against doctors. Negligence in medical law is often called *Negligence*. *Negligence* is a human thing that humans often experience because humans are not perfect. According to Guwandi (2004:29) a person is said to be negligent if he acts indifferently or not caring. Not paying attention to the interests of other people as is common in social life. According to Hermien Hadiati Koeswadi, the definition of medical negligence literally means *bad practice* or bad practice related to the practice of applying medical science and technology in carrying out the medical profession which contains special characteristics. Because *malpractice* is related to " *how to practice the medical science and technology* ", which is closely related to health facilities or places of practice and people who carry out the practice, then Hermien's opinion is more likely to use the term " *maltreatment* " (Syahrul Machmud: 2008, p. 13). The Black Law Dictionary as quoted by HM. Soedjatmiko, formulates malpractice as: " *any profesional misconduct, unreasonable lack of skill or fidelity in professional or judiary duties, evil practice, or illegal or immoral conduct* " (evil acts of an expert, deficiencies in skills that are below standard, or carelessness of an expert in carrying out his legal obligations, bad or illegal practices or immoral acts).

Anny Isfandyarie, concluded that it was the doctor's mistake for not using knowledge and skill levels in accordance with professional standards, which ultimately resulted in the patient being injured or physically disabled or even dying. R. Hariadi, malpractice is bad practice: doing what should not be done or not doing what is actually done. The term malpractice applies to all types of professions including doctors, accountants, lawyers and so on. In the medical field, if a doctor commits malpractice, it is called medical malpractice or medical *malpractice* ). J Guwandi, citing several judges' opinions in several cases that have occurred or dictionaries express the meaning of malpractice as follows:

- a) The case of *Valentin v. Society se Bienfaisance de Los Angeles*, California, 1956 formulated:  
Malpractice is the negligence of a doctor or nurse to apply the level of skill and knowledge in providing treatment and care services to a patient that is usually applied in treating and caring for sick or injured people in the same area. " *Malpractice is the neglect of a physician or nurse to apply that degree of skill and learning on treating and nursing a patient which is customary applied in treating and caring for the sick or wounded similarly in the same community* ".
- b) *Steadman's Medical Dictionary*  
Malpractice is a wrong way to treat an illness or injury, because it is caused by actions that are indifferent, careless or based on criminal motivation. " *Malpractice is mistreatment of a disease or injuries throught ignorance, carelessness of criminal intent* ".
- c) *Coughlin's Dictionary of Law*  
Malpractice is "wrong professional attitudes from a person in a profession, such as a doctor, lawyer, accountant, dentist, veterinarian. Malpractice can be caused by careless attitudes or negligence. Or lack of skill or care in the performance of professional obligations; wrongful actions or unethical practices". " *Professional misconduct on the parts of a professional person, such US a physician, engineer, lawyer, accountant, dentist, veterinarian. Malpractice may be the results of ignorance, neglect, or lack of skills or fidelity in the performance of professional duties; intentional wrongdoing or unethical practice* ".

d) Black's Law Dictionary

Malpractice is any wrong attitude, lack of skill to an unreasonable degree. This term is generally used for the attitudes of doctors, lawyers and accountants. Failure to provide professional service and perform to appropriate skill levels and standards reasonable intelligence in the community by average colleagues from that profession, resulting in injury, loss or damage to recipients of said services who tend to place their trust in them. This includes any professional misconduct, unreasonable lack of skill or lack of due care or legal obligations, bad practice, or illegal or immoral attitudes. *"Any professional misconduct, unreasonable lack of skill. This term is usually applied to such conduct by doctors, lawyers, and accountants. 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 entitled to rely upon them. It is any professional misconduct, unreasonable lack of skill or fidelity in professional or judiciary duties, evil practice, or illegal or immoral conduct"*.

e) The Oxford Illustrated Dictionary, 2nd ed., 1975

Malpractice = wrong attitudes; (law) improper provision of services to patients by the medical profession; illegal actions to gain one's own advantage while in a position of trust. *"Malpractice = wrongdoing; (law) improper treatment of patient by medical attendant; illegal action for one's own benefit while in position trust"*. So it can be concluded that what is meant by malpractice is: (1) Doing something that a health worker should not do (2) Not doing what should be done or neglecting obligations (negligence) (3) Violates a provision according to or based on statutory regulations - invitation.

M Yusuf Hanafiah (1999:87) , malpractice is a doctor's negligence in using the level of skill and knowledge that is commonly used in treating patients or injured people according to measures in the same environment. From several expert opinions, a statement can be drawn that medical negligence is a condition where a doctor or medical personnel deviate from the code of medical ethics, professional standards for doctors and standard operating procedures (SOP) when carrying out medical procedures on their patients, resulting in losses suffered by the patient as a result. from the medical procedure. Benchmarks and conditions for proving medical negligence (Guwandu, Jakarta: 2009 p. 11) in *Anglo countries Saxon* is the "4D" concept of *Negligence* which consists of:

1. *Duty*  
There must be a doctor-patient relationship, so that there is a doctor's obligation to treat the patient
2. *Dereliction of that duty*  
There is a deviation from " *duty* " on the part of the doctor because apparently he is does not carry out his obligations according to professional standards.
3. *Direct causation*  
So a loss arises
4. *Damage*
5. However, there must be a direct link between the actions taken by the doctor and the losses incurred.

### *Linkages Risk Medical And Negligence Medical*

The definition of medical risk is not explained in detail and clearly in existing laws and regulations. Therefore, many people misunderstand medical risks, resulting in many lawsuits against doctors in court. Medical risks are implicitly mentioned in several statements as follows:

1. *Informed Written consent is one way that needs to be done* to protect doctors from patient demands, this is due to being *informed consent*, the patient has agreed to receive medical treatment that will be carried out by a doctor. From this agreement, the patient will not make any claims to court in the future. Apart from that, the statement also states that the doctor has explained the nature, purpose and possible consequences (risks) of the medical action to the patient or his family. The doctor concerned must also sign the Approval form for the Medical Action in question.
2. IDI (Indonesian Doctors Association) statement regarding *Informed Consent* in IDI SKB Attachment No. 319/P/BA/88 point 33 which reads: *"Every action medical Which contain risk Enough big require exists agreement written Which signed by patient, after previously patient That obtain information Which adequate about necessity action medical Which concerned as well as risk Which related with him."*
3. The applicable laws and regulations are explicitly stated in Article 2 paragraph (3), Article 3 paragraph (1) and Article 7 paragraph (2) Regulation of the Minister of Health of the Republic of Indonesia Number: 585/Men.Kes/Per/IX/ 1989 concerning Approval of Medical Procedures states the term risk explicitly and implicitly, including:
  - a. Article 2 paragraph (1): Consent as intended in paragraph (1) is given after the patient has received adequate information about the need for the medical action in question and the risks it may cause.

b. Article 3 paragraph (1): Every medical procedure that carries a high risk must have written approval signed by the person wishing to give approval.

c. Article 7 paragraph (2): Unforeseen expansion of surgery can be carried out to save the patient's life.

From the statements above, the definition of medical risk can be drawn, namely as follows:

1. That in medical procedures there are possibilities (risks) that can occur which may not be in accordance with the patient's expectations. The patient's lack of understanding of the risks he faces can result in the patient filing a lawsuit in court.
2. That in medical procedures there are actions that contain high risks.
3. That this high risk is related to the safety of the patient's life.

So it can be said that medical risk is a result that is not optimal from a medical action carried out by a doctor. Medical risks can occur because the risk of a medical procedure arises suddenly beyond the doctor's expectations and cannot be avoided by the doctor and there are also those that arise because the medical action is prohibited or limited by law because the medical action contains a large risk. The risks of medical procedures carried out by doctors vary in size and scale. Doctors are asked to carry out medical procedures that are appropriate to the patient's condition even though the risks associated with these medical procedures are large. In the Indonesian Medical Code of Ethics, doctors who are obliged to provide assistance to their patients must meet professional standards as guidelines that must be used in carrying out their profession properly. This is to avoid harm to other people as a risk from medical procedures carried out, which often results in the patient suing legally. It has long been known that one of the traditional principles of medical ethics is *primum non nocere*, meaning the important thing is not to cause harm. Medical negligence itself is caused by the doctor's lack of knowledge of the patient's illness or the doctor's lack of knowledge of medical science. Medical negligence occurs because doctors do not follow standard operational procedures, professional standards, and according to professional circles, doctors believe they violate the code of medical ethics, resulting in patients suffering harm in the form of physical disability or death. The following is a comparison table between medical risks and medical negligence:

Medical Risks	Medical Negligence
1. In accordance with standard operating procedures	1. not in accordance with standard operating procedures
2. There is caution	2. There is no element of caution
3. There is no element of negligence	3. There is an element of negligence
4. There are prevention efforts	4. There are no prevention efforts
5. There is a <i>Contributory Negligence</i>	5. There is no <i>contribution Negligence</i>

From the explanation above, it can be seen that the benchmark for determining whether a failed treatment outcome is categorized as medical risk or medical negligence is standard operating procedures, professional standards and the opinions of the medical profession itself. These three benchmarks can also be seen from the court decision regarding the case that befell Doctor Ayu and were taken into consideration by the panel of judges in acquitting Doctor Ayu and his team of doctors.

#### *Accountability In Law Criminal*

Criminal acts only refer to prohibited and punishable acts with a crime. Whether the person who commits the act is then also sentenced to a crime, as has been threatened, depends on the question of whether in committing this act he made a mistake. Because the principle of responsibility in criminal law is: Not to be punished if there is no mistake ( *Geen straf zonder schuld; Actus non facit reum nisi mens sit rea* ). In the doctor's responsibility for medical risks, the element of error used is negligence or negligence or in health law terms it is called *Negligence*. In the context of health law, the importance of understanding the legal implications of medical risks and medical negligence cannot be underestimated. Especially in Indonesia, with the enactment of Law Number 17 of 2023 concerning Health, the legal responsibilities of medical personnel in practice have been emphasized. This law specifically regulates medical negligence which can result in criminal sanctions for health workers. Article 440 of the Law is the legal foundation that regulates crimes related to medical negligence that causes serious injury or death to patients.

#### Chapter 440

1. Every Power Medical or Power Health Which made a mistake that resulted in the patient being injured heavy convicted with criminal prison most long 3 (three) year or criminal fine most Lots Rp. 250,000,000.00 (two hundred five tens million rupiah).
2. If negligence as intended on paragraph (1) result death, every Power Medical or Power Health convicted with criminal prison most long 5 (five) year or criminal fine most Lots IDR 500,000,000.00 (five hundred million rupiah).

Medical risks are often an integral part of the practice of medicine, given the complexity and uncertainty involved in diagnosis and treatment. While the risk may result in a less favorable outcome, medical negligence is different because it involves neglect of a required standard of care. Negligence, as regulated in Article 440 of the Health Law, emphasizes this neglect which can cause serious injury or death to the patient. In determining negligence, an important aspect to consider is whether the health worker has deviated from accepted standards of care. This includes an assessment of the skill, care and reasonable care expected of a health professional. Article 440 confirms that negligence that results in serious harm to patients can result in criminal sanctions, reflecting the serious legal consequences of reckless actions in medical practice. The Health Law also stipulates obligations for hospitals, as stated in Article 189. Hospitals are required to provide safe, quality and effective services, and meet certain service standards. A hospital's failure to meet these obligations, particularly regarding standards of care, can result in significant legal risks. Article 193 adds that hospitals are legally responsible for losses incurred due to negligence by health human resources.

#### Chapter 189

1. Every House Sick have obligation:
  - a. give information Which Correct aboutservice House Painful to public;
  - b. give Service Health Which safe, quality, anti-discrimination, And effective with Prioritize the interests of the patient in accordance with standard service Hospital;
  - c. give service Bad Emergency to Patient in accordance with ability the service;
  - d. role active in give ServiceHealth on disaster in accordance with ability the service;
  - e. provide means And service for public unable or poor;
  - f. carry out function social between other with give facility service for Patient Nocapable or poor, service Bad
  - g. Emergency no down payment, free ambulance, sharing services victim disaster And KLB, or devotion social formission humanity;
  - h. make, carry out, And guard standard Quality of Health Services in Hospitals as reference in serving Patient;
  - i. maintain medical records;
  - j. provide means And infrastructure general Which worthy, between other means worship, place parking, room Wait, means For disabled person disabilities, breastfeeding women, children, and the elderlyage
  - k. carry out referral system;
  - l. reject desire Patient Which contradictory with professional and ethical standards and provisions regulation legislation;
  - m. provide correct, clear and honest information about right And obligation Patient;
  - n. honor And protect rights Patient;
  - o. carry out ethics House Sick;
  - p. own system prevention accident Andcountermeasures disaster;
  - q. carry out program government in field Health, Good in a way regional nor national;
  - r. make list Power Medical Which do medical or dental practice and EnergyHealth other;
  - s. compile And carry out regulation internal House Sick;
  - t. protect and provide legal assistance for all hospital staff in carrying out task; And
  - u. applies to the entire hospital environment as area without cigarettes.
2. Violation of obligations as referred to in paragraph (1) charged penalty administrative in accordance with provision regulation legislation.

#### Chapter 190

Hospitals are required to implement a Health Information System House Sick Which integrated with System Information Health National.

To prevent medical negligence, it is important for hospitals and healthcare practitioners to implement effective risk management systems. This includes ongoing training for health workers, monitoring and evaluation of medical practices, as well as the use of health information technology as regulated in Article 190. An integrated information system can help detect and prevent medical errors. In the context of Indonesian health law, especially with Law Number 17 of 2023, the legal responsibility of health workers for medical risks and negligence has been clearly regulated. Negligence that results in serious injury or death of a patient not only results in criminal sanctions for health workers, but also affects the reputation and trust in the health system as a whole. Therefore, it is important for hospitals and healthcare professionals to understand and comply with established standards of care, and actively manage risks in their medical practices. However, every time there is an allegation of negligence a health worker is immediately punished in accordance with the provisions of Article 440. That is the big benefit of the presence of Law no. 17 of 2023 concerning health which replaces 14 laws relating to health. Namely, providing extra protection

to health workers if medical negligence is indicated, the Government through its Ministers forms a panel to handle the case, if mediation efforts are unsuccessful at the hospital management level. Which of course all begins with investigation and examination. The presence of a special assembly formed by the minister of health to resolve medical disputes including allegations of negligence is a clear example of the government's concern in protecting comfort, peace and criminalization of medical personnel. It is located under the ministry, no longer under professional organizations. Apart from that, the presence of Law Number 17b of 2023 concerning health makes it increasingly clear that *lex specialis derogat lex generalis* (specific laws override general laws). That any errors, allegations or negligence in health are resolved based on the health law. Trial and punishment are the last resort in health cases.

## Conclusion

The conclusions of this research emphasize the importance of accountability in criminal law, especially in the context of medical and health practice. Based on Law Number 17 of 2023 concerning Health, health workers in Indonesia can face criminal sanctions in cases of negligence that results in serious injury or death of patients. However, implementing these laws requires a cautious approach, taking into account the inherent risks and complexities in medical practice. Article 440 of this Law forms the legal basis governing medical negligence, emphasizing that there is only legal error if there is evidence of negligence or neglect. Hospitals also have an obligation to provide safe and effective services, in accordance with established standards, as regulated in Article 189. The importance of an effective risk management system and the implementation of an integrated health information system (Article 190) is emphasized as a preventive measure against medical errors. Law Number 17 of 2023 also regulates the formation of a special council by the Minister of Health to handle medical cases, including allegations of negligence, which shows the government's efforts to protect health workers and patients and prevent inappropriate criminalization. This conclusion underlines the principle of *lex specialis derogat lex generalis*, where specific health law overrides general law, and that trials and punishment are the last resort in resolving health cases.

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