Journal of Social Science Studies Vol. 3, No. 2, July 2023, pages 209 – 214

Informed Consent as a Fundamental Right of Patients: The Law and Medical Ethics Perspective

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ARTICLE INFO

Article history:
Received 16 August 2023
Revised 29 August 2023
Accepted 13 September 2023

Key words:
Patient rights,
Medical risks,
Informed consent,
Health law,
Lawful protection,
Doctor accountability,
Law sanctions.

ABSTRACT

In the era of globalization, the health sector has undergone significant changes, especially in providing information on medical service risks to patients. This information is a basic right of patients to understand their health conditions and make appropriate medical decisions. Practices in the field show that this right is often not fulfilled, resulting in physical, psychological, and economic losses for patients. The right to information about medical risks has a strong law basis and is the foundation for patients in providing informed consent, which is an important element in medical treatment. A doctor's negligence in providing information can have serious law consequences, both through civil lawsuits based on Article 1365 of the Civil Code and criminal charges under Articles 351 and 359 of the Criminal Code. This research aims to examine how patients' rights to information about medical risks are regulated and implemented, as well as to analyze the law sanctions that can be imposed on doctors who do not fulfill these obligations. With a normative approach, this research seeks to contribute to strengthening lawful protection for patients and increasing the accountability of doctors in meeting applicable ethical and law standards.

INTRODUCTION

In the era of globalization, the dynamics of the health sector show significant changes, especially in the context of providing information on medical service risks to patients. In reality, patients' rights to obtain information about medical service risks are often not properly fulfilled. This reflects a shift in the orientation of health institutions from a social function to a business function, which has the potential to reduce the human values and social interests in health services. This condition raises serious issues because medical risk information is a basic right of patients to understand their health conditions and make appropriate medical decisions.

The government has emphasized that health is a human right that must be guaranteed and protected. Health efforts must be carried out through a comprehensive, integrated, and continuous promotive, preventive, curative, and rehabilitative approach. In this case, medical practice as the core of health services must be carried out by medical personnel who have high competence, ethics, and moral responsibility. Doctors are obliged to continuously improve the quality of their services through continuing education, certification, and strict supervision in order to provide services in accordance with applicable standards (Sarif & Issalillah, 2022). One of the important obligations that doctors must fulfill is to provide clear and transparent information about medical risks to patients, as this is a fundamental right of patients (Lestari, 2021).

Risk is often defined as uncertainty and the probability or possibility of loss. In the context of health, medical risk refers to the possibility of patients experiencing physical, psychological, or economic losses. Physical losses can be temporary or permanent, while psychological losses include emotional impacts such as depression or shame. Economic harm can include loss of livelihood or additional costs due to longer treatment periods (Passat & Israhadi, 2021; Aziz et al., 2023). Risks in medical services, although they can be problematic, also have the potential to provide opportunities for individuals, doctors, hospitals, and related institutions (Waluyo, 2022).

The patient's right to obtain information about the risks of medical services is not only ethical but also has a strong legality. This information forms the

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basis for patients to provide informed consent for medical procedures, which is a key component of any medical treatment. The relationship between informed consent and medical procedures shows that patients have the right to know the potential risks and benefits of the procedures they will undergo (Conti et al., 2010). Doctors therefore have a moral and legally binding responsibility to fulfill this right as part of their professional duties.

The reality on the ground, however, shows that there are various obstacles to fulfilling this right. It is not uncommon for patients to receive inadequate information or even no information at all about the medical risks they will face (Baulin et al., 2019). As a result, patients do not have sufficient understanding to make appropriate medical decisions, which in turn can cause harm to patients, both in terms of health and law. From a law perspective, a doctor's negligence in providing medical risk information can have serious consequences, both in the form of civil lawsuits based on Article 1365 of the Civil Code concerning unlawful acts, as well as criminal charges based on Articles 351 and 359 of the Criminal Code related to abuse or negligence that causes harm to patients. The importance of fulfilling patients' rights to obtain information about medical service risks is therefore a highly relevant issue for further research. This topic not only has implications for the laws and regulations governing the relationship between doctors and patients, but also contributes to improving the overall quality of healthcare services. This research aims to examine and understand how patients' rights to obtain information about medical service risks are regulated and applied in healthcare practice. The main focus is to explore the extent to which these rights are protected by law, both from the perspective of medical ethics and applicable regulations, so as to provide a comprehensive picture of efforts to fulfill patients' rights.

This research also aims to analyze the law sanctions that can be imposed on doctors who fail to fulfill their obligation to provide information about medical service risks to patients. The analysis was conducted to explore the application of sanctions in various law aspects, including civil law, criminal law, and administrative law, as well as their implications for the legal relationship between doctors and patients. By understanding these two aspects, the research is expected to contribute to strengthening lawful protection for patients and increasing the accountability of doctors in providing medical services that comply with ethical and lawful standards.

RESEARCH METHOD

This research uses library research methods with the aim of obtaining results that are as objective as possible within the scope of law, particularly criminal law. This approach is carried out through the process of reading and learning theories and the law principles relevant to the subject matter being studied. This approach aims to analyze in depth the normative aspects that form the basis of the law issues raised.

According to Soerjono Soekanto and Sri Mamudji (2013), normative law research or the law library research covers various aspects, such as the study of law principles, systematic law research, vertical and horizontal law synchronization, comparative law, and law history. This approach provides a structured conceptual framework for analyzing the law in depth based on applicable law.

The data collected in this research was processed using normative law methods. This method focuses on adding to and developing analysis by adhering to applicable law norms. In this way, the research aims to produce a comprehensive and objective understanding of the law issues that are the focus of the research. The normative law approach not only ensures compliance with law rules but also facilitates systematic and relevant analysis of the law issues discussed.

RESULT AND DISCUSSION

In Indonesia, the definition of medical risk is not explicitly formulated in existing laws and regulations. The concept is, however, implicitly reflected in several regulations and official documents. One of the most relevant is informed consent, or consent for medical treatment. Informed consent is defined as a written document signed by the patient, giving permission for certain medical procedures after the patient has received complete information about the procedure to be performed. This document only has law force if it is signed after the patient clearly understands the medical procedure to be performed (Rizka et al., 2023).

Article 297 paragraph (1) of Law No. 17 of 2023 concerning Health explains that medical records are the property of Health Care Facilities. Article 297(2) of the Health Law further explains that every patient has the right to access the information contained in medical records. This means that while medical records are indeed the property of Health Care Facilities, the contents of these records and all the information contained therein belong to the patient themselves. Healthcare Facilities are therefore obligated to maintain the security, integrity, confidentiality, and availability of the data contained in medical records (Amir, 2020). Apart from the patient, are other parties allowed to access the information contained in the medical records? Minister of Health Regulation No. 24 of 2022 concerning Medical Records regulates who is allowed to access the information contained in medical records other than the patient themselves, with certain conditions and requirements (Ayurini & Mufidi, 2023).

Lawful protection for patients is an effort aimed at ensuring that patients' rights are protected and that the obligations of medical personnel are properly fulfilled. In realizing this protection, it is important for all parties involved, including doctors as healthcare providers and patients as recipients, to understand their respective rights and obligations. This understanding forms the basis for creating a harmonious and responsible relationship in healthcare practice (Gustina et al., 2022).

Patients' Rights to Obtain Information on Medical Service Risks

The patient's right to obtain information about the risks of medical services has a strong basis in protecting the interests of patients (Senjaya, 2007). Fundamentally, this right aims to ensure that patients clearly understand their illness, determine the medical actions to be taken, and receive appropriate health services in accordance with applicable standards (Khayru & Issalillah, 2022). The decision-making process regarding medical actions is carried out after patients receive adequate information. This information forms the basis of an agreement between doctors and patients to minimize the risks of the medical actions to be taken (Amir, 2020).

The relationship between doctors as providers of medical services and patients as recipients of services is often paternalistic. According to Isfandyarie (2006), this relationship pattern reflects a vertical relationship in which doctors are considered to know everything related to health, while patients are in a position where they do not fully understand their own condition. This places patients in a position where they completely surrender medical decisions to doctors, making it important for doctors to provide clear, transparent, and responsible information (Passat & Israhadi, 2021).

Article 276 letter e in conjunction with Article 297 paragraph (2) of the Health Law explicitly stipulates that every patient has the right to access the information contained in their medical records. Medical records are documents belonging to the patient that must be disclosed to them, either directly or through another party that meets certain requirements (Mubarak et al., 2023). Disclosure of medical records to immediate family members is permitted in special circumstances, such as when the patient is under 18 years of age or in an emergency. The immediate family members who have the right to access medical records include the patient's spouse, adult children, biological parents, and siblings, as stipulated in Article 34 paragraph (4) of Minister of Health Regulation Number 24 of 2022 concerning Medical Records.

Under certain conditions, consent to disclose medical records may be given by heirs if the immediate family is unable to give consent due to absence, lawlessness, or other conditions (Cahya & Muhtaddin, 2022). If no one is able to give consent, however, medical records may be disclosed without consent, in accordance with applicable laws. The disclosure of medical records to parties other than the patient or immediate family requires the patient's consent, except in certain situations as stipulated in Article 35 of Minister of Health Regulation No. 24 of 2022.

Medical records may be disclosed to other parties without the patient's consent if used for the purposes of law enforcement, ethical or disciplinary enforcement, medical audits, handling of extraordinary events, education and research, or protection against threats to the safety of others (Kholis et al., 2023). This disclosure is done without revealing the patient's identity, except in certain situations involving the handling of an outbreak or a threat to public safety, where the patient's identity may be disclosed to the relevant authorities in accordance with the law (Passat & Israhadi, 2021).

The confidentiality of medical records is an obligation that must be upheld by all parties who have access to patient health data and information, including health workers, health facility managers, students, and other related parties (Amir, 2020). This obligation remains in effect even after the patient has passed away. This provision emphasizes the importance of maintaining the privacy and confidentiality of patient health information as an integral part of professionalism and ethics in health services.

With a clear national law framework and strict protection of medical records, the right of patients to access and maintain the confidentiality of their medical information has become one of the main pillars in realizing transparent, high-quality health services based on the principle of respect for human rights (Cahya & Muhtaddin, 2022). This not only reflects a lawful commitment to patients but also contributes to increasing public trust in the healthcare system in Indonesia.

The importance of fulfilling these patient rights is also related to moral responsibility in the relationship between patients and medical personnel. These rights not only protect patients, but also maintain the independence and professionalism of medical personnel (Passat & Israhadi, 2021). The patient's rights and the doctor's obligations function within a social contract that strengthens the relationship of mutual respect between both parties.

Fulfilling patients' rights to obtain medical risk information has a significant impact on the quality of healthcare services. Medical risk information provides a basis for patients to determine actions that are appropriate to their needs and circumstances. In this case, patients have the right to ask for details of the medical treatment plan, request additional explanations from other doctors for comparison, and even refuse medical treatment plans that they feel are inappropriate. This right position patients as active subjects in the decision-making process, not just as objects of service (Amir, 2020).

Juridically, the importance of medical risk information is reflected in the laws and regulations that can be imposed on doctors in the event of negligence in the delivery of information. Medical risks can arise due to negligence, carelessness, or unavoidable factors (Shreekrishna & Kumar, 2022). Doctors are therefore obliged to ensure that all medical procedures are carried out in accordance with professional standards, clearly communicating risk information to prevent malpractice claims.

Public health is an integral part of development itself. Quality health services, including the provision of medical risk information, are a strategic investment to improve public health and reduce economic losses due to health problems. The responsibility for providing medical risk information is therefore not only the duty of doctors but also part of a collective effort between the government, medical personnel, and the community.

Fulfilling patients' rights to obtain medical risk information is an indicator of healthcare quality. Patient dissatisfaction with inadequate information can lead to a law suit, while patient satisfaction indicates the success of the services provided (Cahya & Muhtaddin, 2022). Providing transparent and accurate medical risk information is not only a legal obligation, but also a moral responsibility of medical personnel to maintain good relationships with patients and improve the overall quality of healthcare services. Effective communication and honesty in conveying medical risks are essential components in building patient trust and ensuring patient centered healthcare (Issalillah & Khayru, 2023).

Lawful Sanctions Against Doctors Who Fail to Provide Information on Medical Service Risks

In the law relations between the provider and user of medical services, namely doctors and patients, both parties act as law subjects that have rights and obligations. Medical services function as law objects that are valuable and beneficial to law subjects. This relationship creates law actions that are regulated by law, whether performed unilaterally or by both parties. In the context of medical risk information, doctors as providers of medical services have an obligation to provide information related to the risks of medical procedures to patients. This obligation is not only regulated by the Indonesian Medical Code of Ethics (KODEKI), but also subject to civil, criminal, and administrative law provisions.

In civil law, the benchmark used is culpa levis (minor negligence), so that if a doctor makes a minor mistake that harms a patient, law liability can be sought based on the principle that “anyone who harms another person must provide compensation.” For example, if medical treatment is performed without the informed consent of a patient who is conscious and capable of giving consent, the doctor may be considered to have committed an unlawful act (onrechtmatige daad) as stipulated in Article 1365 of the Civil Code. This article states that any unlawful act that causes harm to another person obliges the perpetrator to provide compensation (Mahmud et al., 2023).

In criminal law, medical risk information is also an absolute obligation. Article 351 of the Criminal Code on maltreatment stipulates that invasive action, such as surgery or radiology procedures, performed without the patient's consent can be considered a criminal act of maltreatment. Article 359 of the Criminal Code further states that “anyone whose negligence causes the death of another person shall be punished with a maximum imprisonment of fifteen years or a maximum confinement of one year.” Negligence in providing medical risk information may therefore result in criminal charges against doctors (Sasanthi, 2019).

From a law of obligations perspective, the obligation to provide medical risk information is related to informed consent. Based on Article 1320 of the Civil Code, the validity of an agreement requires four conditions: agreement between the parties, competence to enter into an agreement, a clear object, and a lawful purpose. In the context of the doctor-patient relationship, failure to provide sufficient information can be considered a violation of these basic principles of contract law. There are challenges, however, in determining whether the information provided by doctors is adequate. Theoretically and juridically, the standard for providing medical risk information does not yet have strong certainty and is often relative (Passat & Israhadi, 2021). For these reasons, further research is needed to establish clear standards regarding the obligation to provide medical risk information.

In the law relationship between doctors and patients, medical risk information is an integral part of creating a balance of rights and obligations for both parties (Cahya & Muhtaddin, 2022). This relationship also forms the basis of the law protection for patients and doctors. By providing clear medical risk information, doctors not only fulfill their ethical and law obligations but also prevent possible law suits due to patient dissatisfaction. Conversely, failure to fulfill this obligation can result in lawsuit consequences, both in the form of criminal charges and civil lawsuits. As a step forward, strengthening regulations and understanding of medical risk information is necessary to ensure law certainty and optimal protection for patients as users of medical services.

CONCLUSION

The conclusion of this research confirms that the patient's right to obtain information about the risks of medical services is an important part of ensuring that patients clearly understand their illness. This right also gives patients the freedom to decide on the medical treatment to be taken for the cure of their illness, as well as ensuring that patients receive adequate health services according to their needs. If doctors do not provide information about the risks of medical services to patients, they may be subject to sanctions stipulated in various laws, including the Civil Code, Criminal Code, and other administrative laws.

As a suggestion, in an effort to fulfill patients' rights to medical services, doctors as providers of medical services are advised to provide detailed and clear information about the risks of medical procedures regardless of the patient's economic background. This is important considering that in practice, information about the risks of medical services is often not conveyed clearly, mainly due to the shift in the orientation of health institutions from a social function to a business function. Law enforcement officials are also advised to impose sanctions on doctors who do not provide information about the risks of medical services as they should. This step will create better protection for patients, so that no party feels aggrieved.

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