

Legal Review of the Implementation of Informed Consent in High-Risk Medical Procedures in Indonesia Based on Health Law No. 17 of 2023

Revelino Pangaribuan^{*1}, Tamaulina Br. Sembiring^{*2}

E mail : pangaribuanrevelino@gmail.com tamaulina@dosen.pancabudi.ac.id

Universitas Pembangunan Panca Budi

Abstract

This study examines the implementation of informed consent in high-risk medical procedures in Indonesia based on the provisions of Law No. 17 of 2023 concerning Health. Informed consent is a basic patient right that ensures that consent to medical procedures is given consciously after receiving complete information from health workers regarding the benefits, risks, and alternative actions available. This study uses a normative legal method with a legislative approach to analyze the legal protection provided to patients and health workers. The results of the study indicate that although the existing legal framework is quite comprehensive, its implementation in the field still faces obstacles, especially in emergency situations and low health literacy in the community. Increased education for health workers and patients is needed, as well as affirmation of regulations related to therapeutic privilege to address gaps in the implementation of informed consent in high-risk medical procedures.

Keywords: *Informed Consent, High-Risk Medical Procedures, Legal Protection*

INTRODUCTION

The development of the medical world in the digital and modern era has brought many advances in health technology, but also presents new challenges related to the implementation of ethical and legal standards in medical practice. One of the main challenges faced by health workers, especially doctors, is the implementation of informed consent, or approval of medical procedures after the patient is given complete information about the benefits, risks, and alternatives to the medical procedures to be carried out. Informed consent is a patient's basic right that must be respected, but on the other hand it is also a legal protection for health workers. This becomes increasingly important especially in high-risk medical procedures, where decisions taken can have major consequences for the health and safety of patients.(Rahmadsyah and Sidi 2023)

Law No. 17 of 2023 concerning Health provides a more comprehensive legal framework in regulating health practices, including in terms of informed consent. However, in reality, the implementation of informed consent in the field often faces various challenges. One of them is the complexity of high-risk medical procedures that often involve urgent decisions and do not always provide enough time for patients to understand the information provided. This creates a dilemma for health workers who must choose between providing detailed explanations but requiring time, or immediately taking action that is considered urgent to save the patient's life. Thus, a legal study of informed consent is very important to see the extent of legal protection provided to health workers in carrying out their duties, especially in the context of high-risk medical procedures.(Sidi 2020)

In general, informed consent is a concrete manifestation of respect for the patient's right to decide for themselves what medical action will be taken on them. This right is related to the principles of patient autonomy, which means that patients must be given sufficient information and be free to

choose to accept or reject medical action. In this context, the law requires medical personnel to ensure that patients fully understand the risks, benefits, and alternatives of the proposed medical action. However, in some cases, especially those involving high-risk medical actions such as major surgery or life-threatening interventions, the implementation of informed consent becomes more complicated.

In Indonesia, the implementation of informed consent is regulated by several legal regulations, such as Law No. 36 of 2009 concerning Health, Regulation of the Minister of Health No. 269 of 2008 concerning Medical Records, and is now further strengthened by Law No. 17 of 2023 concerning Health. Law No. 17 of 2023 contains more specific provisions regarding the legal responsibilities of health workers, including the obligation to obtain consent from patients before medical procedures are carried out. However, even though regulations exist, their implementation in the field still faces obstacles, especially in emergency situations or when patients are in critical condition and unable to provide direct consent.(Risdawati and Zarzani 2023)

One of the crucial issues often faced in practice is when patients or their families do not have sufficient knowledge about the medical procedures to be performed. In some cases, patients or their families may feel forced to sign informed consent without fully understanding the risks and benefits. This situation often occurs in high-risk medical procedures such as heart surgery, organ transplants, or other invasive procedures. In such conditions, doctors are in a difficult position between maintaining patient safety and ensuring that informed consent has been carried out in accordance with applicable legal regulations.

Another challenge that arises in the implementation of informed consent is the communication gap between health workers and patients. Health workers, especially specialist doctors, often use medical terms that are difficult for lay patients to understand. In fact, a clear understanding of the information provided is very important so that patients can make the right decisions. On the other hand, it is not uncommon for patients to be in a state of stress or fear so that it is difficult to digest information rationally. This further complicates the informed consent process and poses legal risks for health workers if they are deemed not to have provided adequate information.

Law No. 17 of 2023 provides legal protection for health workers by requiring them to carry out their duties in accordance with professional standards and codes of ethics. However, it is undeniable that the situation in the field is often not as ideal as stipulated in the law. For example, in an emergency situation, doctors may not have enough time to explain in detail the risks and benefits of the actions to be taken. On the other hand, there are also situations where patients refuse medical treatment even though they have been given a full explanation of the risks if medical intervention is not carried out. In conditions like this, health workers are faced with a dilemma between respecting the patient's decision and carrying out their duties to save lives.(Sidi and Putra 2022)

Another issue that is often debated is the boundary between informed consent and therapeutic privilege, which is the right of a doctor to withhold certain information from a patient if it is considered to cause excessive anxiety or harm the patient's condition. Although in some situations therapeutic privilege is legally recognized, its boundaries are often unclear and give rise to potential legal disputes. Physicians must be careful in deciding what information to provide, as failure to provide sufficient information can be considered a violation of the patient's rights and lead to malpractice lawsuits.

From a legal perspective, informed consent not only serves as protection for patients, but also as an important instrument to protect health workers from potential lawsuits. In high-risk medical procedures, complete and clear documentation of patient consent can be evidence that health workers have carried out their duties according to the correct procedures. Thus, informed consent also serves as a form of preventive legal protection for doctors and other health workers.

Given the importance of informed consent in medical practice, a more in-depth study is needed regarding its implementation in the field, especially in high-risk medical procedures. This study aims to analyze the extent to which Law No. 17 of 2023 provides legal protection for health workers in implementing informed consent, as well as identifying the obstacles faced in its implementation. By understanding the existing problems, it is hoped that this study can provide recommendations for improving the quality of health services and strengthening legal protection for health workers in Indonesia.(Situngkir, Fauzan, and Sidi 2023)

In a global context, informed consent is an international standard recognized by various world health organizations, including the World Health Organization (WHO) and the World Medical Association (WMA) through the Declaration of Helsinki. This standard requires that every medical intervention must be carried out with the patient's consent based on an adequate understanding of the action to be taken. In many countries, informed consent has become an integral part of everyday medical practice, and neglect of this principle often results in serious lawsuits. Indonesia, with Law No. 17 of 2023, has demonstrated its commitment to maintaining international standards in the implementation of informed consent. However, the challenges faced in the field require more attention from the government and relevant stakeholders.

Thus, it is important for all stakeholders, including the government, health workers, and the community, to have the same understanding of the importance of informed consent. Legal protection for health workers does not only depend on existing laws, but also on continuous efforts to improve the quality of communication between health workers and patients. Educating the community about their rights as patients is also a key factor in reducing the potential for legal disputes. This study is expected to be a real contribution to the development of better policies in the health sector, especially in the implementation of informed consent in high-risk medical procedures in Indonesia.

METHOD

The research methodology used in this study is the normative legal method with a statute approach and legal concept analysis. This study analyzes the application of informed consent in high-risk medical procedures based on the provisions of Law No. 17 of 2023 concerning Health. The data used in this study consists of secondary data, including laws and regulations, legal journals, textbooks, and other relevant documents. The data analysis technique is carried out descriptively-analytically by examining various legal provisions governing the implementation of informed consent, as well as identifying and examining legal issues that arise in its implementation in the field.(Indra Utama Tanjung 2024)

RESULTS AND DISCUSSION

Basic Concepts of Informed Consent in Indonesian Health Law

Informed consent, or consent to medical action given after the patient has received adequate information, is one of the important principles in health law. This concept is based on respect for human rights, especially the patient's right to determine the medical action taken against him. In Indonesian health law, informed consent is regulated through various regulations, including Law No. 17 of 2023 concerning Health, which updates previous regulations by adjusting to developments in modern medical practice.

In general, informed consent is the consent given by a patient after receiving clear, complete, and adequate information from a health worker regarding the diagnosis, purpose of the medical action, the procedure to be performed, the risks that may arise, the benefits of the action, and other available medical action alternatives. This right ensures that every patient has full control over the actions to be taken on his/her body and guarantees the patient's autonomy as an individual. In this context, informed consent is not just an administrative formality, but part of the ethical and legal medical decision-making process.(Gemilang, Ismaidar, and Zarzani 2024)

In Law No. 17 of 2023, informed consent is recognized as one of the important instruments in maintaining a healthy and professional relationship between health workers and patients. The articles in this law emphasize the obligation of medical personnel to provide transparent and comprehensive information to patients before medical procedures are carried out, especially for invasive or high-risk procedures. Failure to provide adequate information and obtain valid consent from patients can result in legal consequences, either in the form of malpractice lawsuits or disciplinary sanctions against the medical personnel involved.(RAMADANI 2016)

In line with applicable regulations, the informed consent process involves several important elements that must be met so that the consent given by the patient can be considered legally valid. First, the patient must have the capacity or competence to give consent. This means that the patient must be conscious and have sufficient mental capacity to understand the information given by the doctor. In cases where the patient does not have capacity, such as children or individuals with mental disorders, consent can be given by a guardian or closest family member. Second, consent must be given voluntarily without coercion or pressure. Patients must be given the freedom to make decisions based on the information received, without any intervention that could influence their decisions. Third, the information given by health workers must be clear enough and cover all aspects relevant to the medical action to be taken, including the risks that may arise.

In medical practice, informed consent becomes more complicated in the context of high-risk medical procedures, where the decisions a patient makes can affect his or her life. Medical procedures such as heart surgery, organ transplants, and other surgical procedures often involve significant risks and uncertain outcomes. In these situations, doctors are obligated to provide more detailed and comprehensive information to patients, ensuring that they understand all the risks involved before giving consent. However, the patient's condition, which may be experiencing a serious health problem or an emergency situation, can hinder the ideal informed consent process. This presents a challenge for medical personnel who must balance the need to immediately perform medical procedures to save the patient's life with the legal and ethical obligation to obtain valid consent from the patient.

In addition, in the legal context in Indonesia, informed consent is also an important tool to protect health workers from potential lawsuits related to alleged malpractice. With informed consent, medical personnel have proof that the patient has been given adequate information and has agreed to the medical action taken. This is important in cases where the results of medical action do not meet the expectations of the patient or his/her family, so that medical personnel can show that they have carried

out their duties in accordance with applicable professional standards.(Dachban, Sidi, and Saragih 2023)

Law No. 17 of 2023 also pays special attention to emergency situations where the implementation of informed consent may not be fully possible. In life-threatening emergencies, this law allows medical personnel to perform medical procedures without the patient's consent, provided that the action is taken to save a life or prevent greater harm to the patient. However, this provision must still be carried out carefully, and medical personnel are expected to immediately seek consent from the patient's family or guardian after the patient's condition is stable.

In addition to laws and regulations, ethical aspects also play an important role in the implementation of informed consent. The Indonesian Code of Medical Ethics stipulates that doctors must always maintain integrity and professionalism in providing information to patients. Violation of the principles of informed consent not only has the potential to cause legal problems, but also violates the doctor's professional ethics. Therefore, it is important for every health worker to ensure that the informed consent process is carried out properly and correctly, not only to comply with legal provisions, but also to maintain trust and harmony in the relationship between health workers and patients.

However, in the field, the implementation of informed consent does not always go as expected. One of the main challenges is the low level of public health literacy. Many patients, especially in remote areas, do not have an adequate understanding of medical terms or the risks associated with certain medical procedures. This makes it difficult for doctors to provide information that can be easily understood by patients. In addition, the paternalistic culture in health services in Indonesia often causes patients to feel reluctant or afraid to refuse a doctor's advice, so they tend to sign informed consent without really understanding the consequences.

Therefore, there needs to be a joint effort from the government, health workers, and the community to improve understanding of the importance of informed consent. Training for health workers on effective communication with patients needs to be improved, while the community needs to be educated about their rights as patients. In addition, the government must continue to update relevant health regulations to suit the times and the needs of the community.

In conclusion, informed consent is a fundamental concept in health law that aims to protect patient rights and provide legal protection for health workers. Law No. 17 of 2023 concerning Health has provided a clear legal framework regarding the implementation of informed consent, but challenges in the field still require further attention. With a better understanding of the importance of informed consent, it is hoped that medical practice in Indonesia can be more transparent, fair, and in accordance with applicable ethical and legal standards.

High-Risk Medical Procedures and Obligations of Health Workers

High-risk medical procedures include medical interventions or procedures that have a higher level of complexity than regular medical procedures, and usually involve the potential for serious health risks to the patient, including death, long-term complications, or permanent damage to vital organs. Examples of high-risk medical procedures include heart surgery, organ transplantation, neurosurgery, major blood vessel surgery, and medical interventions that use invasive technology. In high-risk medical procedures, informed consent becomes very important because these procedures have consequences that are not only related to the patient's survival, but also their quality of life after the procedure.(Sembiring and Sidi 2024)

In the context of health law in Indonesia, Law No. 17 of 2023 concerning Health emphasizes that health workers have an obligation to provide complete and adequate information to patients or their families before medical procedures are carried out, especially in situations where the procedure involves high risks. This is in line with the principle of informed consent which requires doctors and other medical personnel to ensure that patients fully understand the risks they will face and give their consent consciously and voluntarily.

However, in practice, the implementation of this obligation often does not run smoothly. One of the obstacles often faced by medical personnel is the difference in level of understanding between health workers and patients regarding the risks of medical procedures. Many patients do not have sufficient medical background to understand the complexity and long-term impacts of the procedures to be performed. This imbalance of knowledge can lead to misinterpretation or lack of adequate understanding of the information provided by health workers. On the other hand, medical personnel are also faced with pressure to immediately take action in emergency conditions, where the time available to provide in-depth explanations is very limited.(Meher, Sidi, and Risdawati 2023)

For example, in open-heart surgery, the patient is at risk of death, permanent damage to heart function, stroke, or other complications that can worsen quality of life. The health care provider must explain in detail to the patient or family about all of these risks, including the likelihood of success, complications, and alternative options available. While this is standard practice in many hospitals, there are many factors that can affect the quality of communication between the doctor and the patient. One factor is time constraints, especially in emergency cases where decisions must be made quickly. Another factor is medical language or terminology that is difficult for lay patients to understand, which often leads to confusion or misunderstanding.

In situations where the patient is in critical condition, informed consent is often given by the patient's family or guardian who does not always have an adequate understanding of the medical procedure to be performed. This poses a challenge for health care providers to ensure that the information provided is well understood by the patient's representative. This imbalance in understanding can lead to post-procedure dissatisfaction, especially if the expected outcome is not achieved or unanticipated complications occur.

In addition, in many hospitals in Indonesia, high-risk medical procedures are often performed under conditions where medical facilities and resources are inadequate. For example, limited sophisticated medical equipment or a lack of competent experts in certain areas can increase the risk of complications and worsen the results of medical procedures. In such conditions, even though informed consent has been given, patients may not be fully aware that the risks faced are greater than those explained due to limited medical facilities.(RAMADANI 2016)

One of the main issues in this study is how the implementation of informed consent can be an effective instrument in protecting the rights of patients and health workers, especially in the context of high-risk medical procedures. The implementation of ideal informed consent requires time, clear communication, and a deep understanding from both parties—doctors and patients—regarding the risks and consequences of the actions to be taken. However, in daily medical practice, these conditions are often difficult to achieve for various reasons, including time pressure, emergency conditions, low public health literacy, and communication gaps between doctors and patients.

Another challenge that is a major issue in this study is the legal uncertainty faced by health workers. In emergency situations or high-risk medical procedures, decisions must often be made quickly, while the opportunity to provide complete information to patients is very limited. In situations like this, health workers are often faced with a dilemma: should they wait until the patient

or their family fully understands the risks of the actions to be taken, or should they immediately take action to save the patient's life? If health workers choose the second option and unwanted complications occur, they may face lawsuits for alleged malpractice, even though the actions taken were in accordance with medical standards and were carried out to save the patient's life.

In addition, this study also identified gaps in the regulation and implementation of informed consent in the field. Although Law No. 17 of 2023 has provided a clear legal framework regarding the implementation of informed consent, implementation in the field is often not as expected. Many health workers feel that the informed consent procedure is only an administrative formality, so they do not provide sufficient explanation to patients. This is often caused by a lack of understanding of the importance of informed consent as part of the patient's human rights, as well as limited time and resources available to hospitals or health facilities.

Another issue is the different interpretations of the boundaries between informed consent and therapeutic privilege. In some cases, health workers choose not to provide full information to patients because they are worried that it will increase the patient's anxiety or fear, which can worsen their health condition. However, the boundaries of when and how therapeutic privilege can be applied are often unclear, giving rise to potential legal disputes. Several cases in Indonesia have shown that patients or their families have filed lawsuits after medical procedures have been performed because they felt they were not given sufficient information about the risks of the procedure.(Biondy 2016)

One case that can be an illustration is the case of heart surgery in a large hospital in Indonesia. In this case, a patient who underwent heart surgery experienced post-operative complications that caused permanent damage to one of his vital organs. The patient's family filed a malpractice lawsuit against the doctor who performed the surgery, arguing that they were not informed of the possibility of the complication. Although the doctor had provided informed consent to the patient's family before the surgery was performed, the family felt that the explanation given was not detailed enough and only covered the general risks that usually occur in heart surgery. This case shows that even though informed consent has been obtained, there is disagreement about the level of depth of information that doctors should provide to patients or their families.

To address these issues, this study recommends several steps that can be taken to improve the implementation of informed consent in high-risk medical procedures in Indonesia. First, it is necessary to improve education and training for health workers regarding the importance of informed consent as a legal and ethical instrument, not just an administrative formality. Second, the government needs to encourage increased health literacy in the community so that patients better understand their rights in the medical decision-making process. Third, regulations regarding therapeutic privileges must be clarified so that health workers have better guidance in deciding when and how certain medical information can or cannot be conveyed to patients. With these steps, it is hoped that the implementation of informed consent in Indonesia can be better, so that patient rights are protected and health workers also receive adequate legal protection in carrying out their duties.(Meher, Sidi, and Risdawati 2023)

From this discussion, it can be concluded that informed consent is an important element in the implementation of high-risk medical procedures, both from a legal and ethical perspective. Challenges in its implementation are related to the lack of understanding among the public and health workers, as well as the unclear regulations in emergency situations or the application of therapeutic privilege. The main problem in this study is how to ensure that informed consent is implemented effectively, so that it can protect patient rights without causing legal losses to health workers, especially in medical procedures involving high risks.

CONCLUSION

Based on a legal review of the implementation of informed consent in high-risk medical procedures in Indonesia, Law No. 17 of 2023 concerning Health has provided a strong legal basis to protect patient rights and ensure the responsibility of health workers. Informed consent is an important instrument that guarantees patient autonomy in making medical decisions consciously and voluntarily, while providing legal protection for medical personnel from potential malpractice lawsuits. However, in practice, the implementation of informed consent still faces various challenges, especially in emergency situations, lack of patient understanding, and limited time and resources. Therefore, efforts are needed to increase understanding among health workers and the community, as well as strengthening regulations in its implementation to ensure that informed consent runs effectively and optimally.

BIBLIOGRAPHY

Biondi, Glenn. 2016. "Legal Analysis of the Validity of Electronic Mail (E-Mail) Agreements Based on Indonesian Law." *Premise Law Journal* 19:164959.

Dachban, Yohnly Boelian, Redyanto Sidi, and Yasmirah Mandasari Saragih. 2023. "Legal Review of Hospital Readiness and Hospital Responsibilities Post-Health Ministerial Regulation Number: 24/2022 Concerning Medical Records and Hospital Readiness." *Nursing Journal* 7 (1): 232–39.

Gemilang, Gilang, Ismaidar Ismaidar, and T Riza Zarzani. 2024. "Corporate Criminal Liability in Money Laundering Crimes." *Innovative: Journal Of Social Science Research* 4 (2): 8455–71.

Indra Utama Tanjung. 2024. *BASICS OF LEGAL RESEARCH METHODS*. Karanganyar: CV Pustaka Dikara).
https://scholar.google.com/citations?view_op=view_citation&hl=id&user=rToGqjUAAAAJ&cstart=20&pagesize=80&citation_for_view=rToGqjUAAAAJ:Wp0gIr-vW9MC.

Meher, Cashtry, Redyanto Sidi, and Irsyam Risdawati. 2023. "Use of Personal Health Data in the Big Data Era: Legal and Policy Challenges in Indonesia." *Jurnal Ners* 7 (2): 864–70.

Rahmadsyah, Rudi, and Redyanto Sidi. 2023. "The Position of Informed Consent in Medical Services for Patients in Hospitals Who Have the Status of a Suspect." *Journal of Nursing* 7 (1): 240–44.

RAMADHANI, HANIF ABDURRAHMAN. 2016. "LEGAL PROTECTION OF PATIENTS' RIGHTS AS CONSUMERS OF HEALTH SERVICES IN BUMIAYU REGIONAL HOSPITAL." MUHAMMADIYAH UNIVERSITY OF PURWOKERTO.

Risdawati, Irsyam, and T Riza Zarzani. 2023. "Juridical Review Of Health Service Facilities Based On Law No 17 Of 2023." In *International Conference on Health Science, Green Economics, Educational Review and Technology*, 5:15–20.

Sembiring, Alprindo, and Redyanto Sidi. 2024. "Effectiveness and Legal Protection in Health Services at General Hospitals for BPJS Health Participants: Study of Sembiring Deli Tua General Hospital." *Jurnal Ners* 8 (1): 418–25.

Sidi, Redyanto. 2020. "The Position of Informed Consent in Patient Services at Hospitals." *Iuris Studia: Journal of Legal Studies* 1 (2): 214–19.

Sidi, Redyanto, and Andika Putra. 2022. "Accountability for the Distribution of Hard Drugs Without a Doctor's Prescription and the Role of Islamic Education." *Islamic Education: Journal of Islamic Education* 11 (03).

Situngkir, Andreas Henfri, Fauzan Fauzan, and Redyanto Sidi. 2023. "Legal Protection for Consumers Against the Circulation of Illegal Cosmetics in Online Stores (E-Commerce) Reviewed from RI Law Number 17 of 2023 Concerning Health." *Asian Journal of Healthcare Analytics* 2(2): 383–400.