Legal Analysis of Legal Power and Legal Protection in Informed Consent Practices in High-Risk Surgical Procedures in Hospitals

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Abstract

This research examines the legal force and protective function of informed consent in high-risk surgical procedures, focusing particularly on the latest regulatory framework in Indonesia as stipulated by Law Number 17 of 2023 concerning Health. Currently, there is a notable absence of specific scholarly examination addressing this issue comprehensively. Although the regulation clearly defines patients' rights to comprehensive medical information and mandates healthcare providers to deliver it transparently, practical ambiguities remain regarding the extent of informed consent's binding legal authority and effectiveness in providing legal protection for both patients and medical professionals. Employing a normative juridical approach with descriptive-analytical methods, the study is primarily based on literature review and analysis of relevant Supreme Court decisions. The central objective of this research is to evaluate the legal enforceability and protective role of informed consent within the context of high-risk surgical treatments. The findings reveal that informed consent possesses substantial legal force derived from contractual principles established between patients and healthcare providers, thereby ensuring mutual legal protection during high-risk medical procedures. Informed consent encompasses preventive measures that aimed at averting potential disputes through clear communication, and repressive measures, which offer legal remedies in cases of violation, thus strengthening accountability and legal certainty within healthcare services.

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

A. INTRODUCTION

Several studies have examined the concept of informed consent. Although academic discussions on informed consent have developed significantly, most prior research has tended to focus on theoretical aspects or its general implementation in medical practice (Drabiak, 2022a; Rougereau et al., 2023; Zheng et al., 2023). In clinical reality, high-risk medical interventions frequently give rise to legal disputes between patients and healthcare providers, primarily due to communication barriers or patients' limited understanding of the medical risks involved (Lam et al., 2022; Naik et al., 2022).

The World Health Organization (WHO) recognizes surgical procedures as an essential component of public health services, integral to the implementation of a comprehensive healthcare system. Surgical procedures are inherently associated with various risks that may arise before, during, or after the operation—particularly in high-risk surgeries. High-risk surgeries include operations with a high likelihood of severe complications, elevated mortality rates, and long-term impacts on a patient's quality of life (Long et al., 2021; Mubarak & Zarzani, 2024). Examples include coronary

artery bypass surgery, heart valve replacement, organ transplants, brain surgery, and emergency Cesarean sections with complications such as preeclampsia or placenta praevia, these procedures often carry significant risks, such as severe infections, hemorrhage, or organ failure (Arlette et al., 2022; Tiolince, 2023; Yi et al., 2022).

One of the most crucial components in the execution of surgical procedures is the thorough communication of medical information to the patient, followed by a declaration of consent—legally referred to as informed consent. This procedure represents a direct form of communication between doctor and patient, which is a fundamental element of medical practice (Gabay & Bokek-Cohen, 2019; Sundari et al., 2022; Sutarno & Maryati, 2021). The relationship is founded on the principles of trust, transparency, and the physician's moral responsibility to provide the best possible assistance and alleviate the patient's suffering. The legal relationship between doctor and patient is established through mutual consent, either verbal or written, serving as the legal basis for any medical intervention. The core concept of informed consent is to ensure that the patient has an adequate understanding of the planned medical procedure, including its benefits, potential risks, and alternative treatment options—before voluntarily agreeing to undergo the procedure (Drabiak, 2022b; Van Kolfschooten, 2022).

From a legal standpoint, informed consent carries a juridical dimension that provides legal protection to both patients and medical professionals. Every medical intervention must be based on the patient's consent, granted after receiving clear and comprehensive information about the procedure, this principle is firmly established in national legislation, particularly in Law Number 17 of 2023 on Health, and is further detailed in Government Regulation Number 28 of 2024.

Legal issues concerning the strength of medical consent can be illustrated by Supreme Court Decision Number 3203 K/Pdt/2017, which arose from complications following a dental implant procedure. In this case, the medical practitioner failed to obtain written consent, reasoning that the procedure was not considered high-risk. Although the District Court and High Court dismissed the lawsuit based on Ministry of Health regulations, the Supreme Court reversed the decision at the cassation level, ordering compensation of IDR 100,000,000. This ruling raised concerns about the consistency of legal enforcement regarding the application of the informed consent principle in court.

A contrast can be seen in Supreme Court Decision Number 2811 K/Pdt/2012, which involved a case of severe complications resulting in paralysis after a medical procedure. Although the patient claimed they had not received adequate information regarding the risks involved, the courts at all levels rejected the lawsuit, arguing that consent had been granted. This is problematic, considering existing regulations require comprehensive explanations covering diagnoses, potential complications, and available alternatives before consent is obtained, the comparison between these two rulings highlights inconsistencies between established legal norms and their application in judicial practice.

There has been no study that specifically discusses the application of the principle of informed consent in the context of high-risk surgical procedures based on the latest legal framework, especially those referring to Law Number 17 of 2023 concerning Health and its derivative regulations. It is important to conduct an in-depth legal study on how the principle of informed consent is understood and applied in the Indonesian legal system. Especially in examining in depth the legal force of informed consent in medical practice, especially in high-risk surgical procedures. In addition, it is important to analyze in depth the effectiveness of the role of informed consent as a legitimate legal protection instrument, both in guaranteeing the fulfillment of patient rights and in providing firm legal certainty for medical personnel in carrying out their professional duties(Alderson et al., 2023; Jang et al., 2024; Ursin et al., 2024a).

This study aims to formulate a fair and consistent legal protection model for all parties in a medical relationship, as well as to strengthen the legal position of consent to medical procedures as an instrument of protection in health services. Through an approach to civil law aspects, especially those regulating contracts and unlawful acts, accompanied by an analysis of relevant statutory provisions, this study is directed at strengthening the basis for legal protection for patients. The formulation of the problem that is the focus of this research is to explore the legal force inherent in the process of providing information and medical consent (informed consent) in high-risk surgical procedures and an analysis of the legal protection provided to patients and medical personnel in the practice of implementing informed consent in high-risk surgical procedures in hospitals and the reality of implementation in the field.

B. METHOD

This study is descriptive-analytical in nature, aiming to provide a structured and in-depth presentation of the legal issues under investigation. The analysis is conducted based on empirical data and factual information, which are critically examined to formulate answers to the identified legal problems. The research employs a normative juridical method, which focuses on the study of secondary legal materials. It begins with an examination of legal issues through literature review and an analysis of relevant laws and regulations.

The legal data in this research are derived from secondary sources collected through a document study method. These sources consist of various relevant legal references, categorized as follows:

1. Primary legal materials, which consist of binding legal norms and serve as the main foundation for juridical analysis. These include: 1) Law of the Republic of Indonesia Number 17 of 2023 on Health; 2) Government Regulation of the Republic of Indonesia Number 28 of 2024 as the implementing regulation; 3) Regulation of the Minister of Health of the Republic of Indonesia Number 290/MENKES/PER/III/2008 on Medical Procedures Consent, and 4) Provisions within the Indonesian Civil Code (Kitab Undang-Undang Hukum Perdata).

2. Secondary legal materials, which are closely related to primary legal materials and serve as supporting tools in examining and deepening the understanding of the legal substance being studied. These include legal literature, scientific studies, seminar proceedings, and academic or professional publications relevant to the research topic.
3. Tertiary legal materials, which function as auxiliary sources to clarify or provide guidance in understanding both primary and secondary legal materials.

Data collection in this study is conducted through a literature-based approach, focusing on the acquisition of secondary data from various legal sources. Data are gathered from primary, secondary, and tertiary legal materials. The research instrument used is document study, which involves tracing and compiling statutory regulations, legal documents, and other relevant literature closely related to the legal issues under review. The data collection technique is implemented through document analysis, by examining and reviewing various scholarly sources such as literature, reference books, regulations, and other supporting materials relevant to the research theme.

The data analysis process is a crucial stage in the implementation of this research, as it aims to formulate answers to the legal issues raised. This study employs a qualitative analysis method based on the understanding that social and legal phenomena are complex, structured, yet diverse in practice. Conclusions are drawn using a deductive approach, starting from general legal principles which are then elaborated into more specific and applicable conclusions relevant to the research focus.

C. RESULT AND DISCUSSION

1. Legal Power in Informed Consent Practice in High-Risk Surgery

The informed consent procedure is a critical element in healthcare services, as it guarantees the patient's right to obtain complete and transparent information before any medical intervention is performed. The concept underscores that patient consent must be based on adequate understanding of the proposed procedure, its risks, benefits, and available alternatives, this process is a manifestation of the principle of patient autonomy, granting individuals full authority over decisions concerning their own body and health. Consequently, the patient transitions from a passive object to an active subject in medical decision-making.

In Indonesian law, the provisions governing informed consent are explicitly stipulated in Law No. 17 of 2023 on Health. This regulation mandates that every medical intervention must first obtain the patient's consent, except in emergency situations where prior consent cannot reasonably be secured. The technical guidelines regarding medical consent are detailed in the Regulation of the Minister of Health No. 290/MENKES/PER/III/2008, which provides the implementation framework for informed consent procedures across healthcare facilities.

To be considered legally valid, informed consent must fulfill several essential elements (Everett et al., 2023; Park, 2024):

a. Patient competence, referring to the legal and mental capacity to comprehend the medical information provided and to make rational, conscious decisions.
b. Sufficient information disclosure, which includes comprehensive explanations about the diagnosis, the proposed medical intervention, its potential risks and benefits, and available alternatives.
c. Comprehension, ensuring the patient fully understands the information so that their decision is not the result of confusion or coercion.
d. Voluntariness, meaning the consent must be given freely, without pressure or manipulation.
e. Proper documentation of the entire process and consent itself, serving as legal and administrative evidence.

The significance of informed consent in medical practice is emphasized by J. Guwandi, who argues that medical consent serves two principal purposes: (1) to protect patients from being subjected to medical procedures without adequate understanding and consent, and (2) to provide a strong legal foundation for healthcare providers against negative outcomes, including unavoidable risks, despite adherence to professional and ethical standards. In this sense, informed consent is an essential mechanism for maintaining balance between patient rights and medical professional protection.

One of the key legal foundations for safeguarding patients' rights in healthcare services is found in Articles 293 to 295 of Law No. 17 of 2023. These articles provide a strong legal basis for the implementation of informed consent as a legal instrument of patient protection. In case of any violation, patients are legally entitled to file claims.

Government Regulation No. 28 of 2024 further strengthens the regulation of informed consent. Article 735 paragraph (1)(b) mandates that healthcare professionals must obtain the patient's or their family's consent prior to conducting medical procedures. This obligation affirms that performing medical actions without proper consent constitutes an unlawful act, entailing legal responsibility for both the healthcare provider and the institution.

Technical details on informed consent are elaborated in the Minister of Health Regulation No. 290/MENKES/PER/III/2008, which, under Article 3, requires written consent for high-risk medical interventions. This ensures that surgical or invasive procedures are only carried out with clear patient consent, following full disclosure of associated risks and benefits. Thus, these regulations enhance the legal standing of patients in consenting to medical procedures. Failure to comply with informed consent procedures entitles the patient to claim compensation for damages, and the responsible medical personnel or institution may be held legally accountable.

In medical service agreements, the legal basis is founded on the principle of inspanningsverbintenis (best-effort obligation), not resultaatverbintenis (result-oriented obligation). This means that healthcare providers are required to make their best effort in accordance with professional standards and applicable medical

procedures, without guaranteeing that the outcome will always align with patient expectations (Aaron et al., 2025; Padovano et al., 2022; Ursin et al., 2024b). A legally valid agreement must fulfill four essential elements as stipulated in Article 1320 of the Indonesian Civil Code (KUHPerdata): mutual consent, legal capacity of the parties, clarity of the object of agreement, and a lawful and moral objective. Even if an agreement is acknowledged by the parties, the absence of any one of these elements may render it legally invalid.

In the legal relationship between healthcare professionals and patients, the first element that must be fulfilled is mutual agreement or valid consensus between the doctor and the patient. This principle aligns with the concept of informed consent, in which consent is granted by the patient or their family after receiving adequate and clear information regarding the proposed medical action. In this regard, informed consent is both a key component and a fundamental requirement in the legal therapeutic relationship.

In therapeutic agreements, the consent expressed through informed consent focuses solely on the patient's will, differing from conventional contracts that require mutual negotiation. This is due to the absence of a bargaining process between doctor and patient before the consent is given. The doctor's role is limited to presenting available treatment options suited to the patient's condition. The patient then retains full authority to accept or reject the recommendation after comprehending the information provided. Sociologically, this reflects the knowledge imbalance between the medically trained doctor and the patient, who often lacks technical understanding. The law considers the patient a vulnerable party, at risk of having their rights neglected, the element of consent in therapeutic agreements lies entirely in the hands of the patient, making informed consent a manifestation of the patient's unilateral will.

According to (Habib et al., 2021), informed consent serves as a prerequisite for establishing a therapeutic agreement but is not a formal requirement for its legal validity. In other words, a legal relationship between doctor and patient may be deemed to exist once a therapeutic interaction has occurred, even if not all elements of legal contract validity are met. Nonetheless, for such an agreement to be legally enforceable, the additional three elements outlined in Article 1320 must still be fulfilled. This provision confirms that therapeutic agreements are consensual in nature, originating from mutual understanding between the parties involved.

The legal foundation for therapeutic agreements is enshrined in Article 293, Paragraph Five of Law No. 17 of 2023 on Health, which states that medical practices by doctors and dentists must be based on an agreement with the patient, expressed through informed consent. In therapeutic contracts, this mutual understanding represents the harmonization of intentions between the doctor and the patient, forming the legal basis of the relationship. This harmony indicates a voluntary, mutual agreement that is essential for establishing a legally valid medical commitment.

This harmony is often obstructed by significant challenges. Differing orientations are a primary factor. Doctors, as healthcare providers, tend to emphasize the procedural aspects in accordance with professional standards, focusing on the

medical process itself. In such circumstances, doctors cannot be held liable for imperfect results, particularly in life-saving interventions that involve theological or philosophical values. Patients are more concerned with the final outcome of medical actions and expect results aligned with their personal goals. Thus, while patients are outcome-oriented, doctors prioritize process and professional standards in carrying out medical procedures.

This research analyzes a legal case reflecting the practical application and legal strength of informed consent, offering a broader and more detailed understanding of the legal issues that arise in this context. The Supreme Court Decision No. 3203 K/Pdt/2017 is a landmark ruling concerning the legal protection of patients in healthcare services, particularly regarding the implementation of informed consent.

The case underwent a lengthy legal process. At the first instance, the West Jakarta District Court rejected the plaintiff's claim. This decision was upheld by the Jakarta High Court. However, at the cassation level, the Supreme Court partially granted the plaintiff's claim and overturned the previous rulings, thereby issuing a judgment that differed from the two lower courts. This case underscores the importance of the legal dimension in assessing the liability of healthcare professionals for their obligation to provide adequate information prior to conducting any medical procedure.

Failure to fulfill this obligation can lead to significant legal consequences. Analyzing this ruling is important to evaluate the implementation of the informed consent principle in Indonesian legal practice and to identify the available legal protections for both patients and medical professionals. The ruling emphasized that informed consent cannot be regarded merely as an administrative formality; rather, it constitutes a substantive element in the legal relationship between patients and medical practitioners. Patient consent must be based on information that is clearly, openly, and comprehensively conveyed, ensuring that the decision is truly made with full awareness and personal responsibility (Karampalis et al., 2025; Pham, 2025).

The ruling also outlined the legal responsibility of medical personnel when damages occur due to failure in fulfilling the obligation to provide information. At the same time, it affirmed the legal protection available to practitioners, provided that medical actions are performed in accordance with professional standards, service standards, and applicable legal norms.

2. Legal Protection in Informed Consent Practice in High-Risk Surgery

Legal protection in the context of healthcare services encompasses two main aspects. First is preventive legal protection, which aims to prevent violations by medical and healthcare professionals. This can be achieved through the enforcement of professional standards, the implementation of standardized operational procedures, ongoing training, and systematic internal supervision. These efforts are designed to ensure that healthcare professionals operate in accordance with ethical norms and legal provisions, thereby minimizing the potential risks to patients.

The second aspect is repressive legal protection, which refers to the protection granted to medical and healthcare personnel when they face legal challenges as a consequence of their professional duties. Legal protection serves as an instrument that guarantees healthcare workers the right to a fair and proportional defense when involved in legal disputes, whether criminal charges or civil lawsuits, arising from medical actions they have performed. This protection includes the right to legal counsel, the implementation of objective and accountable legal processes, and treatment that aligns with the principles of justice and non-discrimination.

Implementing these mechanisms is essential to ensure a sense of security and legal certainty for healthcare professionals in the course of medical practice. Without such guarantees, there is a risk of excessive anxiety that may hinder optimal medical decision-making and ultimately compromise the quality of healthcare services. Both dimensions of legal protection must operate in tandem and complement each other: preventive protection reduces the potential for errors or violations, while repressive protection offers certainty and justice when legal issues arise. A comprehensive legal protection system, therefore, forms a critical foundation for achieving quality, safe, and equitable healthcare services for all.

Minister of Health Regulation No. 290 of 2008 Article 6 states that even if a patient has given consent to a medical procedure, this does not exempt medical personnel from legal liability if negligence occurs in the execution of the procedure that results in harm to the patient. In other words, the presence of informed consent does not eliminate the legal obligation of medical professionals if they fail to carry out medical procedures according to professional standards.

Article 10 of the same regulation provides that the explanation of the medical procedure must be given by the attending doctor or medical team. If the primary physician is unable to provide the explanation, the responsibility may be delegated to another doctor with equivalent expertise. Although medical consent may be given verbally, Article 16 emphasizes that rejection of a medical procedure must be made in written form to hold legal weight and be used as a reference in legal proceedings in the event of a dispute. This provision underlines the importance of written documentation in ensuring legal certainty in the relationship between patients and medical professionals.

Legal protection in the healthcare service sector is also explicitly regulated in Government Regulation No. 28 of 2024, particularly Article 723 paragraph (2). This article affirms that one of the key instruments in preventing violations by medical personnel is the mechanism of patient and/or family consent before any medical procedure is performed. This consent reflects the recognition of a patient's right to obtain information and give approval for medical procedures, serving as the basis for legitimizing medical actions by healthcare professionals.

However, this provision also accommodates special circumstances, such as emergency situations, where obtaining verbal or written consent in a timely manner is not feasible. In such cases, healthcare professionals are permitted to take necessary

actions to save lives or prevent worsening conditions, while still adhering to principles of caution and professionalism.

Thus, patient consent should not be seen merely as an administrative procedure, but rather as a substantial element within the legal protection framework guaranteed by the state. This consent affirms that every medical procedure must be carried out based on the patient's awareness and will, thereby preventing unauthorized or excessive medical actions. In practice, the consent mechanism also functions as a preventive tool against potential legal disputes and promotes open and transparent communication between healthcare professionals and patients. The existence of this process also contributes to building trust and enhancing the overall quality of healthcare services.

When legal issues arise in the implementation of informed consent, medical personnel are also entitled to legal protection. The right to legal protection for healthcare workers is explicitly stated in Article 273 paragraph (1) of Law No. 17 of 2023, which guarantees legal protection as long as professional duties are performed in accordance with professional standards, healthcare service standards, standard operating procedures, and codes of ethics, while still considering the interests and needs of the patient. This provision is reinforced by Article 50 letter a of Government Regulation No. 28 of 2024, which emphasizes that doctors and healthcare professionals have the right to legal protection as long as medical practice is conducted in accordance with officially established service standards.

The mechanism for legal protection for medical professionals facing disputes related to informed consent is governed by statutory regulations. One legal defense available to doctors is presenting a signed informed consent document from the patient or their family as evidence that the patient had received adequate information prior to the procedure. In addition, if there are allegations of ethical violations, doctors have the right to defend themselves through dispute resolution mechanisms before the Professional Disciplinary Board (Majelis Disiplin Profesi – MDP). This mechanism allows doctors to uphold their professionalism and explain that procedures were carried out according to established professional standards.

The process of legal protection in the practice of informed consent can be seen in case number 237/PDT.G/2009/PN.JKT.UT., which proceeded to the High Court under decision number 548/PDT/2010/PT.DKI. The case was later submitted to the Supreme Court through a cassation process and decided by the Supreme Court Decision Number 2811 K/Pdt/2012. The basis of the lawsuit in this case was unlawful conduct as regulated in Articles 1365, 1336, and 1367 of the Indonesian Civil Code.

The chronology of the case began when ABS, the plaintiff, experienced back pain starting in October 2005. In March 2009, the plaintiff underwent a medical procedure in the form of spinal cement injection at Siloam Hospital Karawaci. This procedure was initially planned and explained by Dr. EJ (Defendant II), but during its execution, it was performed by Dr. JJ (Defendant III). Prior to the procedure, informed consent was requested by a nurse under Defendant II. However, the plaintiff felt that explanations regarding the procedure, alternative actions, and possible risks were not

thoroughly communicated. Due to their condition and lack of perceived alternatives, the plaintiff signed the consent form. After the procedure, ABS suffered paralysis in the left leg. Subsequently, the plaintiff and their family felt they had not been adequately informed about the change in performing doctors and the complications that occurred during the treatment process.

The Supreme Court concluded that the judgments of the lower courts (Judex Facti) were appropriate, as patient consent was documented through the informed consent form. However, the author observes that the process of providing medical information and obtaining consent lacked comprehensiveness, with the patient and family feeling insufficiently informed about the medical action to be performed (Fraser et al., 2023). The procedure had adverse effects, namely the inability to move the left leg. Although this outcome was a possible medical risk even when the procedure was carried out in accordance with applicable standards, the absence of complete information does not necessarily render the informed consent process invalid. The existence of a signed consent form was deemed evidence that the informed consent process had occurred.

From the patient's perspective, legal protection is often perceived as lacking due to inadequate explanations from the doctor performing the procedure. Legal protection for patients in the information provision process—considered a fundamental right—is sometimes not clearly upheld in the implementation of informed consent. As such, patients frequently feel that they are not receiving equal legal protection within medical practice. Signing a consent form does not automatically mean that the patient fully understands or is aware of potential negative outcomes of a medical procedure. This is often due to communication barriers, such as the use of complex medical terminology or insufficient time allocated for explanation.

Patients have the right to receive clear, complete, and understandable information about surgical procedures, especially when those involve high-risk interventions. Effective and transparent communication is essential so that patients can make decisions based on full understanding and volition, thereby fulfilling the principles of autonomy and legal protection. Patients hold the fundamental right to determine their own choices concerning their body and health—commonly known as the right of self-determination, this includes the authority to accept or refuse medical actions after being provided with adequate information about the procedure, its benefits, risks, and available alternatives, this principle reflects respect for individual autonomy in medical practice and forms the ethical and legal foundation of informed consent.

With the availability of clear information, patients hold an important right to decide whether or not a medical procedure should proceed, as stipulated in Article 737(1)(d) and (5) of Government Regulation No. 28 of 2024. The process of providing information and medical consent must reflect the principle of self-determination—a form of legal protection provided by the state to guarantee every individual's health rights. Legal guarantees for patients when giving medical consent are closely linked

to the fulfillment of human rights, particularly those related to bodily integrity, autonomy, and free decision-making. As emphasized in Article 737(1)(a) and (b) of the same regulation, patients have the right to be informed of their health condition and to freely choose the medical treatment they wish to undergo. This personal right is absolute and must not be violated by any party, including medical professionals. Furthermore, medical personnel are required to ensure that patient consent is given voluntarily and without coercion, pressure, or manipulation.

According to Philipus M. Hadjon, preventive protection is a measure taken by the state to protect individuals before their rights are violated. In medical services, this principle is manifested through the obligation of healthcare providers—including doctors—to provide patients with complete and clear information before any medical action is taken.

Although legislation does not explicitly state who is responsible for delivering such information, Article 737(3) of Government Regulation No. 28/2024 provides that adequate explanations must be given by medical and healthcare professionals in a manner that is comprehensive and understandable for the patient. The information may be delivered by the doctor performing the procedure, another doctor, or other hospital health personnel. If the information is not provided directly by the doctor performing the procedure, it may be seen as insufficient, there are no legal prohibitions against this practice, but the obligation to inform patients thoroughly before a medical procedure is clearly regulated in law. The information must be sufficient—covering key elements to enable conscious decision-making by the patient. Comprehensive information delivery is a critical prerequisite to fulfilling the patient's right to legally valid informed consent.

Despite the existence of guidance on providing explanations and information by medical personnel, the level of detail and depth of information to be conveyed is not strictly regulated. Information provided by nurses, even under a doctor's instructions, may still fall short of meeting a patient's comprehensive understanding needs. Lack of information is difficult to prove in legal contexts, as court rulings often focus on the existence of a signed informed consent document as evidence that the process occurred. Once this is proven, the next step is to assess whether the medical or surgical procedure followed hospital service standards as regulated by prevailing laws.

Minister of Health Regulation No. 3 of 2025 on Professional Discipline Enforcement for Medical and Healthcare Workers, Article 2(1), affirms the fundamental duties of every healthcare professional. These include adherence to three core pillars: professional standards, service standards, and standard operating procedures. These serve as normative guidelines ensuring that all actions meet ethical, technical, and legal principles, thereby safeguarding patient rights. Compliance with these standards constitutes a concrete form of professional and legal responsibility in Indonesian medical practice.

In high-risk medical procedures, especially surgeries, unwanted outcomes remain a possibility that cannot be entirely avoided—even when standards are met.

Such outcomes are inherent to the nature of medical intervention, where certain risks accompany every action, even those performed diligently and ethically. Patient conditions also significantly influence medical risk outcomes, which are not always predictable.

The patient experienced unintended side effects—left leg paralysis—after the spinal cement injection. While such complications may not result in legal liability if the procedure followed established standards, the patient objected to the lack of explanation about potential complications (Raza & Neuberger, 2022; Shenoy et al., 2022). The author notes that the patient might have refused the procedure had they been informed of the risk of paralysis, this risk was not explicitly mentioned in the legal judgment.

Under Articles 1365 and 1366 of the Civil Code, any individual has the right to claim compensation for harm resulting from the fault or negligence of a medical professional or healthcare institution. If a medical procedure is conducted according to standard operating procedures and prevailing health service norms, resulting risks cannot automatically be classified as legal fault or negligence. Further, Article 29(2) of Minister of Health Regulation No. 3 of 2025 states that in civil liability cases against medical personnel, a recommendation from the Professional Disciplinary Council (MDP) is first required. Article 29(6) further explains that the MDP's recommendation must assess whether professional practice aligns with professional, service, and procedural standards.

Within the framework of legal protection for doctors conducting medical procedures, legal certainty is clearly established. Doctors are deemed to have fulfilled their legal obligations if the procedure is carried out according to medical service standards and preceded by valid patient consent. Although courts may not always detail the required depth of risk disclosure, the presence of a written informed consent form is taken as an indication that the patient has understood and accepted the procedure. In this context, the accuracy of the information is not the key legal issue so long as the information delivery followed applicable laws (Cohen & Slottje, 2024; Loeff & Shakhsheer, 2021; Quach et al., 2023). Legal certainty is a core principle protecting medical professionals—without it, doctors would be at risk of disproportionate legal claims for inherent risks in high-stakes medical procedures like surgery.

In providing information to patients, doctors must explain all potential risks and complications that may arise from a medical action, this ensures transparency and enables rational decision-making by the patient. There are acceptable exceptions. First, doctors are not required to explain risks that are already widely known to the public. Second, risks with extremely low probability or minimal impact need not be disclosed. Third, doctors are not responsible for disclosing risks or complications that are medically unforeseeable due to limitations in medical science.

D. CONCLUSION

Informed consent has legal force as the legal basis for medical actions, ensuring that every intervention is carried out legally and responsibly. The validity of consent

is a basic element in ensuring legal protection for patients and medical personnel. Without valid consent, medical actions can be considered as unlawful acts that have legal implications. The implementation of informed consent must meet all legal requirements in order to prevent disputes and strengthen trust between patients and doctors. As a legal instrument, this mechanism plays an important role in legal protection, especially in high-risk procedures such as surgery, through informed consent, patients have the right to detailed and transparent information regarding the diagnosis, action plan, risks, and treatment alternatives. In contrast, medical personnel are obliged to convey information accurately and proportionally. Proper implementation of informed consent strengthens the legitimacy of medical actions and ensures legal certainty for all parties in the health care system. Legal protection for the implementation of informed consent includes two main aspects, namely preventive and repressive.

The preventive aspect aims to prevent violations by providing clear and complete medical information to patients. Meanwhile, the repressive aspect provides a legal path if there is a violation in the consent process, either through complaints, mediation, or the court process. These two aspects are important foundations in ensuring justice and accountability of medical services. Normatively, informed consent is regulated in laws and regulations as a guideline for implementation, including the obligation to provide information, valid forms of consent, and protection of patient rights. This regulation is very important in high-risk medical procedures, such as surgery, which require a strong legal basis. These provisions not only guarantee the patient's right to make choices freely, but also provide legal certainty for medical personnel in carrying out their duties. Compliance with these provisions reflects professional standards and is a form of comprehensive legal protection for all parties in health services.

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