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Informed Consent Reviewed from Indonesian Positive Law: A Legal Analysis of Informed Consent under Indonesian Positive Law

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Abstract:

Informed consent is defined as a statement of approval given consciously by the patient or their family after receiving complete and comprehensible information regarding the medical condition, diagnosis and the risks and benefits of the proposed medical action, serving as a form of legal protection for the patient's rights. The principle of informed consent is grounded in ethical and legal principles that respect individual autonomy in medical decision-making, in line with the patient's right to receive comprehensive information and to give consent voluntarily. The implementation of informed consent is regulated by various laws and regulations in Indonesia, providing a legal basis for respecting patient rights and medical practitioners' obligations in healthcare services. This study aims to analyze the legal position and juridical implications of informed consent under Indonesian positive law, focusing on the protection of patient rights and the legal responsibilities of healthcare providers in medical practice. The research employs a normative legal method with a literature study approach, analyzing primary, secondary, and tertiary legal materials to examine the legal norms governing informed consent within the Indonesian legal system. Based on the findings, informed consent holds a strong legal position within Indonesia's positive legal system. This position is reinforced by several laws and regulations that explicitly govern patient rights and the obligations of medical personnel. Violations of the principle of informed consent may have significant legal implications, including criminal and civil liability, as well as disciplinary and ethical sanctions against the medical practitioners involved.

Keywords: consent to medical procedures; doctor-patient relationship; Indonesian Law; informed consent.

INTRODUCTION

The right to health is the most basic human right, which is the foundation for fulfilling the quality of human life as a whole. Article 25 of the Universal Declaration of Human Rights emphasizes that every individual has the right to a standard of living adequate for health and well-being, which includes access to adequate health services, sufficient food, and a healthy environment (Japar et al., 2024). This statement is fully supported by Article 28H of the 1945 Constitution of the Republic of Indonesia. Health is an inseparable part of the ideals of the founders of the Indonesian nation and must be realized as a constitutional mandate. This reflects the state's responsibility to fulfill the community's right to health, as mandated by the 1945 Constitution of the Republic of Indonesia (Isriawaty, 2015). Fulfilling this right to health is the state's obligation by guaranteeing access to quality, easily accessible health services in every region for all citizens as part of efforts to realize prosperity and social justice.

According to Law Number 17 of 2023 concerning Health, health efforts are a series of integrated and sustainable activities aimed at maintaining and improving the community's health status through promotive, preventive, curative, rehabilitative, and/or palliative measures (Indonesia, 2023). These activities and efforts to improve public health are implemented based on non-discriminatory, participatory, protective, and sustainable principles. This aims to support the development of quality Indonesian human resources, increase national resilience and competitiveness, and foster comprehensive national development (Fitriana, 2023). When a citizen experiences an illness, they will seek medical care at a healthcare facility such as a hospital or clinic. This meeting between the doctor and patient constitutes a legal agreement known as a therapeutic transaction. A therapeutic transaction is an agreement between a doctor and a patient that authorizes the doctor to perform medical procedures based on their expertise and competence. This agreement creates legal rights and obligations for both parties, the doctor and the patient. Therapeutic transactions can be conducted verbally or in writing. The written agreement containing approval for the medical procedure is known as informed consent (Sitepu et al., 2025).

Patient consent can be used as legal evidence for doctors, particularly in situations where surgical procedures involve risks or uncertain outcomes. The practice of therapeutic consent was first recorded during the Ottoman Empire around the seventeenth century. This form of agreement then underwent significant development until the mid-twentieth century, particularly after the publication of the Nuremberg Code, which regulated ethical and legal aspects of medical practice (Julesz, 2023). Furthermore, several sources cite written agreements between physicians and patients refusing certain surgical procedures in the early to mid-nineteenth century in the medical records of surgical patients in several United States hospitals (Osman, 2001). According to D. Veronika Komalawati, S.H., as quoted from Gunawan (2021), informed consent is a patient's agreement to the medical efforts that will be carried out by a doctor on him after receiving information about the medical efforts that can be done to help him along with information about all risks that may occur due to these actions (Widjaja & Firmansyah, 2021). Consent to medical procedures (informed consent) is a legal obligation that must be fulfilled by doctors as part of the implementation of patient rights and professional responsibilities of medical personnel (Filia, 2019).

In Indonesia, the development of the formal legal aspects of informed consent was marked by the issuance of the Indonesian Medical Association (IDI) statement in 1988 regarding informed consent through Decree No. 319/PB/A.4/88 of the Indonesian Medical Association (IDI). This statement was reinforced by the issuance of Regulation of the Minister of Health of the Republic of Indonesia Number 585/Menkes/Per/IX/1989 (Widjaja & Firmansyah, 2021). Subsequently, provisions regarding informed consent were updated through various laws and regulations, including the Law and Regulations of the Minister of Health, which are continuously adjusted to legal developments and health service needs. This update reached its latest form through the ratification of Law Number 17 of 2023 concerning Health, which serves as the primary legal basis for the provision of health services in Indonesia, including regulations regarding consent for medical procedures. Informed consent requires doctors to obtain approval from patients and/or their families after first providing a clear, complete, and understandable explanation. Furthermore, patients also have the right to obtain information regarding their medical condition, the planned medical treatment, answers to questions, and the right to choose alternative treatments (if available), including the right to refuse proposed medical treatment (informed refusal). The information provided by doctors serves as the basis for patients and/or their families to make conscious and responsible medical decisions. In this context, informed consent plays a crucial role as a legal protection mechanism for patients against unauthorized medical procedures that may violate the patient's bodily integrity, as well as a means to encourage rational and informed medical decision-making (Venia et al., 2024).

Issues related to informed consent are crucial and require serious attention from all parties involved, including doctors, healthcare professionals, and patients. This is because informed consent essentially concerns the legal interests of both parties and provides a form of legal protection in medical care (Venia et al., 2024). The lack of informed consent in a medical procedure can lead to allegations of malpractice, particularly for procedures that cause harm or interfere with a patient's bodily integrity without valid consent (Pebrina et al., 2022). In various jurisdictions, the lack of informed consent is even considered a form of medical negligence, which can result in legal consequences, both civil and criminal, as well as ethical and professional (Burso, 2018). However, in practice, doctors are often faced with emergency situations where patients require complex and high-risk medical procedures, such as those to treat life-threatening

conditions, involving significant risks, and potentially causing harm or serious side effects from medication. These situations often present ethical and legal dilemmas for doctors. On the one hand, doctors are scientifically and professionally obligated to immediately perform medical interventions to save the patient's life. However, on the other hand, there is concern about potential lawsuits from the patient or their family if the medical procedure results in death or adverse side effects. This dilemma reflects the tension between the doctor's professional obligation to act quickly and appropriately in emergencies and the principle of legal precaution, which requires patient consent as a form of legal protection (SP & Wisnu, 2023).

Based on the description above, in practice, there are various complexities and dynamics of problems related to the implementation of informed consent. Legal protection in the relationship between doctors and patients requires special attention and careful handling, considering the potential legal risks that can arise from carelessness or negligence in providing consent. Informed consent plays a strategic and important role for doctors as a form of legal prevention (preventive legal measure) against potential future lawsuits. Meanwhile, from the patient's perspective, informed consent serves as an instrument or tool to obtain comprehensive information regarding their health condition and planned medical procedures, allowing them to make informed and independent decisions. This paper aims to reexamine the concept of informed consent and examine its application in healthcare practices in Indonesia. The discussion covers the position of informed consent within the national legal system and the legal implications that may arise if these provisions are not implemented properly, both in emergency and non-emergency situations. Furthermore, this paper is expected to contribute positively to the development of a more comprehensive legal framework that is responsive to the dynamics of medical practice and the growing public expectation of patient rights protection.

METHOD

This research is designed as a normative juridical study by conducting a legal analysis of the concept of informed consent in the context of healthcare (Laurenzi et al., 2023). The research approach focuses on understanding and examining the legal norms governing this aspect. The research began with a review of various laws and regulations, including health laws, government regulations, and other sectoral regulations related to the informed consent process. Next, a literature review was conducted of legal literature, both from doctrine and jurisprudence, at the national and international levels. A critical analysis was applied to the legal provisions governing informed consent, with the aim of identifying potential inconsistencies, normative ambiguities, or legal gaps that could impact the effectiveness of its implementation in medical care practice. This research was also conducted using a comparative law approach, exploring several legal provisions regarding informed consent from various jurisdictions to identify differences and similarities in the applied legal approaches (Brewer-Carias, 2023). Through this approach, this normative legal research aims to contribute to a deeper understanding of the legal framework governing informed consent in Indonesia. The results of this study are expected to highlight the need for updating or harmonizing existing regulations to strengthen the protection of patient rights and interests in healthcare practices.

RESULTS AND DISCUSSION

Definition and Legal Basis of Informed Consent

Etymologically, the term informed consent consists of two words. The word "informed" means having received an explanation or information, and "consent" means giving approval or permission. Thus, informed consent can be interpreted as consent given consciously after the relevant party has obtained sufficient information. In medical services, informed consent is a statement of agreement from the patient and/or their family that is given freely, voluntarily, and rationally, after receiving a clear and complete explanation and information from the doctor regarding the medical condition, the procedure to be performed, along with the possible risks and benefits, and the information has been fully understood by the patient (Rizka et al., 2023). The information that must be conveyed to the patient includes at least the diagnosis of the disease, indications or reasons for the medical procedure, the type of procedure to be performed and its purpose, and the risks and complications that may arise, alternative procedures and their respective risks, risks that may occur if the procedure is not performed, and the prognosis after the procedure is given. After receiving a complete and clear explanation or information, the patient can give consent either in writing or verbally as a form of informed consent (Shaha et al., 2013).

Based on ethical and legal principles that respect individual autonomy, the legal doctrine of informed consent affirms that every adult has the right to determine what will be done to their own body. All medical procedures, including treatment, surgery, and other invasive procedures, for both adult and pediatric patients, require prior consent from the patient or their family. Conducting medical examinations or procedures without valid consent can be categorized as a violation of patient rights and can result in legal consequences, both criminal and civil, for actions that could be considered assault or unauthorized intervention (Damayanti et al., 2024). Legally, informed consent can be defined as the patient and/or their family's agreement to a procedure based on adequate information and explanation regarding the medical procedure to be performed. The primary purpose of informed consent is to protect an individual's right to self-determination. If informed consent is implemented properly and correctly between the doctor and patient, both parties will receive equal legal protection. However, if actions occur outside the provisions stipulated in the legislation, this can be categorized as a violation of the law, which can have legal consequences (Widjaja & Firmansyah, 2021). According to the Medical Action Consent Manual published by the Indonesian Medical Council in 2006, medical action consent is a unilateral statement from the patient or a party who is legally representing him, which contains approval for the medical or dental action plan proposed by the doctor or dentist, after the patient has received sufficient information to make a decision on approval or refusal (I. M. Council, 2006). Because this consent is unilateral, the patient or family has the right to cancel the agreement or withdraw the consent that has been given unilaterally.

In the health law aspect, the relationship between healthcare professionals and patients is a contractual legal bond, known as a therapeutic contract, which is the relationship between healthcare providers (providers) and service recipients (receivers). This relationship creates reciprocal rights and obligations that must be respected by both parties, in order to create a harmonious, professional, and collaborative interaction. However, this relationship has the potential to cause problems when there is a conflict between the principle of beneficence—the healthcare professional's obligation to provide the best treatment for patients based on professional knowledge, skills, and experience—and the principle of autonomy, namely the patient's right to make their own decisions related to their health condition. This dilemma reflects the tension between professional ethics and the patient's legal rights (Octaria & Trisna, 2016). In this context, the principle of protection of patient rights is also in line with the principle of consumer protection as regulated in Law Number 8 of 1999 concerning Consumer Protection, especially the consumer's right to obtain correct, clear and honest information regarding the conditions and guarantees for goods and/or services, including in this case health services (Indonesia, 1999).

A therapeutic agreement, like any agreement in general, must meet the requirements for a valid agreement as stipulated in Article 1320 of the Civil Code (KUHPerdata). These requirements include agreement between the parties, capacity to enter into an agreement, a specific object, and a lawful cause. In the context of informed consent, the element of agreement between the parties is reflected in the consent given by the patient after receiving complete, clear, and understandable information from the healthcare professional (Kurniawan & Chandra, 2024). However, a therapeutic agreement has its own characteristics that distinguish it from other agreements in general. One characteristic is that this agreement is classified as an inspanningverbintenis (effort agreement), not a resultaatsverbintenis (result agreement). This means that the healthcare professional does not promise a specific result from the medical procedure performed, but is obliged to make every effort in accordance with professional standards, codes of ethics, and applicable scientific knowledge in the medical world (Simarmata et al., 2022).

Law Number 17 of 2023 concerning Health explicitly regulates the obligation of medical personnel to obtain informed consent before performing medical procedures. Article 274 letter b emphasizes that doctors are required to obtain informed consent from the patient or their family before performing the procedure. This provision is reinforced in Article 293 paragraph (1), which states that every medical procedure performed by a doctor individually must be preceded by the patient's consent, after the patient has been given adequate explanation or information by the doctor. This provision not only serves to comply with regulations but also has important value in medical practice, including as a form of legal protection for doctors, a means of preventing potential malpractice, evidence of trust in the doctor-patient relationship, and as a manifestation of respect for the patient's right to autonomy in medical decision-making (SP & Wisnu, 2023).

The provisions regarding the obligation to obtain patient consent before undertaking medical procedures have been clearly regulated in various laws and regulations in Indonesia. Article 45 paragraph

(1) of Law Number 29 of 2004 concerning Medical Practice states that every medical or dental procedure performed by a doctor or dentist on a patient must be based on the patient's consent (Indonesia, 2004). This provision is further reaffirmed in Law Number 17 of 2023 concerning Health. Article 276 of the Law states that patients have the right to obtain information regarding their health condition, receive adequate explanations regarding the health services they receive, and have the right to agree to or refuse medical procedures, except in cases where such medical procedures are necessary for the prevention of infectious diseases or the management of outbreaks or epidemics (Indonesia, 2023). In addition, more technical regulations regarding the form and procedure for consent for medical actions are stated in Article 3 paragraph (1) of the Regulation of the Minister of Health of the Republic of Indonesia Number 290 of 2008 concerning Consent for Medical Actions, which states that every medical action that has a high risk must obtain written consent signed by the authorized party (Penyusun, 2008). This provision shows that the Indonesian positive legal system has given serious attention to the aspect of medical consent as part of legal protection for patient rights as well as a form of professional responsibility of medical personnel.

The information that must be provided to patients before providing informed consent should include at least several key points: the diagnosis, medical indications, the type of healthcare procedure to be performed and its purpose, potential risks and complications, alternative procedures and their risks, risks if the procedure is not performed, and the prognosis after the procedure is performed. After receiving adequate explanation or information, patients have the right to provide consent, either in writing or verbally (Syafruddin et al., 2020). From a legal perspective, informed consent is an absolute requirement that must be met by doctors before performing medical procedures, especially in invasive or high-risk procedures. Informed consent serves as a legal protection mechanism for doctors against accusations of legal violations, such as malpractice. For example, if a doctor performs surgery on an unconscious (anesthetized) patient without first obtaining valid consent, the action can legally be classified as a form of physical violence, as it is performed without valid consent and has the potential to deprive the patient of consciousness and control over their own body. This demonstrates that informed consent serves not only an administrative function but also a form of protection for the patient's physical integrity and the legitimacy of medical procedures performed by healthcare professionals (Damayanti et al., 2024).

Informed Consent in Emergency Situations

Under certain conditions, particularly in emergency situations, patients may arrive legally incompetent or lose their competence to make conscious and rational decisions due to a decreased level of consciousness, even to the point of complete unconsciousness. In such circumstances, patients are no longer able to exercise their right to give or refuse consent to medical procedures. This loss of competence makes it impossible to implement conventional informed consent mechanisms (Pemerintah Republik Indonesia, 2023). In such circumstances, doctors have the authority and obligation to make medical decisions based on professional considerations in the best interest of the patient. These decisions are made based on the principle of ethical and legal responsibility, emphasizing that doctors are required to enter into an agreement in the form of an inspanningverbintenis (a contract of effort), namely to provide medical services in accordance with professional standards and to the best of their ability, even without any guarantee of the final outcome of the procedures performed. Therefore, in an emergency, medical procedures may be performed without prior consent, as long as they are carried out proportionally, rationally, and aimed at saving life or preventing a worse condition.

Provisions regarding exceptions to the obligation to obtain informed consent in emergency situations are expressly regulated in Law Number 17 of 2023 concerning Health. Article 4 paragraph (3) states that an individual's right to consent to or refuse part or all of a medical procedure does not apply to people who are unconscious or in an emergency situation. This provision is reaffirmed in Article 80 paragraph (3) and Article 293 paragraph (9), which states that the obligation to obtain informed consent is excluded in certain circumstances, particularly in emergency situations that threaten the patient's life (Kumalasari, 2022). In such circumstances, even if the patient does not have the legal capacity to provide consent, the doctor still has a professional and legal obligation to provide the necessary medical treatment. The applicable legal principle in this context is that protecting the patient's life takes precedence over the administrative obligation to obtain consent. In other words, in an emergency situation, a doctor is permitted to perform

medical interventions without the patient's explicit consent, as long as the action is in the patient's best interest and in accordance with applicable medical professional standards.

The provision regarding the permissibility of medical procedures without patient consent under certain circumstances also has a legal basis in civil law. This is reflected in Article 1354 of the Civil Code (KUH Perdata), which contains the doctrine of zaakwaarneming or voluntary guardianship. The article states that: "If a person voluntarily, without being asked, manages the interests of another person, either with or without the knowledge of the person concerned, then he has tacitly bound himself to continue the management until the person is able to manage it himself." (Wirabrata & Darma, 2018). In the context of medical practice, this provision can be interpreted as a legal basis justifying a doctor's actions to perform medical interventions on patients who are unconscious or legally incompetent, without first obtaining explicit consent. As long as the action is carried out in the best interests of the patient, in good faith, and in accordance with medical professional standards, it cannot be considered an unlawful act.

Any medical procedure that has the potential to pose a significant risk to a patient's safety or health is legally required to be preceded by formal written consent from a party authorized to grant such consent. In this context, this party is usually the patient themselves, or, if the patient is unable to provide consent, the authority may be transferred to a close family member. However, in practice, situations often arise where the person providing consent is not clearly identified or is unavailable at the time the medical procedure is urgently required (SP & Wisnu, 2023). Under normal circumstances, doctors generally have sufficient time to explain the necessary information and obtain informed consent from the patient or their family. However, this situation is very different in emergency situations that require high-risk medical procedures within a very limited timeframe. This time constraint can become a serious obstacle if the doctor must delay the procedure simply because formal approval has not been obtained, even though such a delay could potentially significantly worsen the patient's condition and even threaten their life (Prawira E. P et al., 2024). Therefore, in the context of an emergency, the urgency of the medical procedure must be the primary consideration. Applicable legal provisions, including the doctrine of zaakwaarneming in the Civil Code and various health sector regulations, justify that in an emergency, a doctor can take over medical decision-making for the sake of the patient's safety, even without the written consent required under normal circumstances.

However, in the context of criminal law, the principle of actus non facit reum nisi mens sit rea is recognized, which means that an act cannot be considered a violation of the law unless accompanied by malicious intent (mens rea). This principle is relevant for assessing high-risk medical procedures performed by doctors in emergency situations. In such circumstances, the doctor does not have mens rea, or malicious intent, to harm or cause the patient's death. Instead, the actions taken are based on good faith and aimed at saving the patient's life. Medical procedures performed in emergency situations are based on the principles of medical ethics, specifically the principles of beneficence (the obligation to do good) and non-maleficence (the obligation not to harm). Therefore, even though the procedure carries a high risk that could medically lead to the patient's death, legally it cannot be automatically considered a form of negligence or a criminal offense, as long as it is carried out in accordance with professional standards and within the framework of saving life (SP & Wisnu, 2023). Discussing informed consent in emergency situations is one of the most crucial aspects of the legal relationship between doctors and patients. Under normal circumstances, consent for medical procedures is conscious, voluntary, and based on complete information provided by the doctor. However, emergency scenarios present a different dynamic, as patients often arrive unconscious, with diminished competence, or unable to make rational decisions. In such circumstances, the law does not require conventional informed consent, as delays in treatment can actually jeopardize patient safety (Annas & Miller, 2024). To provide a more systematic understanding of the principles, legal basis, and ethical and criminal implications in the context of informed consent in emergency situations, the following analytical table summarizes all of these important issues.

Table 1 Analytical – Informed Consent in Emergency Situations

No.	Aspect	Analytical Description
1.	Condition of Loss of Patient Competence	In emergencies, patients often arrive unconscious or legally incompetent, preventing them from giving consent. This inability eliminates the possibility of normal informed consent.

2.	Obligations and Authorities of Doctors	Doctors have the authority, as well as the ethical and legal obligation, to make medical decisions based on the patient's best interests. In emergency situations, doctors exercise an obligation to provide the best possible care without guaranteeing results.
3.	Legal Basis for the Health Sector	Law No. 17 of 2023 Article 4(3), Article 80(3), and Article 293(9) states that the obligation to obtain informed consent is excluded in unconscious conditions and emergency situations that threaten the patient's life.
4.	Civil Legal Basis – *Zaakwaarneming* Doctrine	Article 1354 of the Civil Code permits someone to care for another person's needs without being asked, as long as it is done for the benefit of that party. In medical practice, this forms the legal basis for a doctor acting without explicit consent on an unconscious patient.
5.	Written Consent for High-Risk Procedures	Under normal circumstances, high-risk procedures require written consent from the patient or next of kin. However, in emergencies, such procedures may be performed without consent if delay risks worsening the patient's condition.
6.	Obstacles to Obtaining Approval in the Field	The absence of family, unclear consenting parties, or limited time make formal consent difficult. In emergencies, the legal priority is safety, not administrative compliance.
7.	Criminal Law Implications (Mens Rea)	The principle of actus non facit reum nisi mens sit rea asserts that a doctor's actions in an emergency do not involve malicious intent (mens rea). Actions taken in good faith to save the patient cannot be considered a crime if they comply with professional standards.
8.	Principles of Medical Ethics	Emergency measures are based on the principles of beneficence and non-maleficence. As long as the actions are rational, proportionate, and in accordance with professional standards, doctors are ethically and legally protected.
9.	Principle of the Patient's Best Interests	Safety of life and prevention of worsening conditions are the highest priority; therefore, regulations place patient safety above the administrative obligation to obtain approval.

From the analysis in the table above, it is clear that Indonesian health law provides clear scope for medical personnel to act without patient consent in emergency situations. The general principle is that the law should not be a barrier to saving lives. Therefore, administrative obligations such as informed consent cannot be rigidly enforced when the patient is unconscious or legally incompetent, and medical treatment must be performed immediately. Both the Health Law and the Civil Code grant full legitimacy to physicians' actions in emergency situations as long as they are in the patient's best interests and comply with professional standards. Even from a criminal perspective, doctors cannot be held liable unless there is malice and the actions were taken to save the patient. Thus, the Indonesian legal framework is in line with the principles of universal medical ethics and international clinical practice, namely that saving life is the highest priority, and doctors are authorized to act even without explicit consent, as long as the action is rational, proportionate, and carried out in good faith.

Legal Implications of Informed Consent

High-risk medical procedures have the potential to cause death if a breach of duty or malpractice occurs. This situation often triggers medical disputes that have legal implications for doctors and the hospital where they work, especially if there are claims from parties who feel aggrieved by the medical procedure (Widjaja & Firmansyah, 2021). In the context of criminal law, Articles 359 and 360 of the Criminal Code (KUHP) stipulate that anyone who, through negligence, causes death, serious injury, or illness resulting in the inability to perform work, may be subject to criminal sanctions in the form of imprisonment or a fine in accordance with applicable provisions (Sidabutar et al., 2023).

Based on the Decree of the Minister of Health Number 436/MENKES/SK/VI/1993 concerning the Implementation of Service Standards in Hospitals, hospitals are required to meet service standards,

including the fulfillment of requirements related to informed consent. This implication is that hospitals also bear legal responsibility for the actions taken by doctors as health workers practicing in those facilities. This is reaffirmed in Article 46 of Law of the Republic of Indonesia Number 44 of 2009 concerning Hospitals, which states: "Hospitals are legally responsible for all losses arising from the negligence of health workers in the Hospital." In the context of government-owned hospitals, Article 1366 of the Civil Code (KUHPerdata) stipulates that hospitals can be held accountable for paying compensation for the actions of their employees that cause harm to patients (Kurniawati, 2021).

Informed consent serves not only as written proof of agreement but also serves a broader purpose, namely as a form of legal protection for both doctors and patients. Doctors who fail to fulfill their obligation to obtain informed consent can be subject to legal sanctions, including criminal and civil penalties, as well as disciplinary sanctions and violations of professional ethics (Filia, 2019).

In the realm of criminal law, both based on the Criminal Code (KUHP) and the Law on the health sector, the implementation of medical procedures without obtaining informed consent can be categorized as criminal malpractice, especially if it causes harm to the patient. Based on the Criminal Code, actions performed by doctors such as surgery or actions that cause pain, injury, or discomfort to the patient without valid consent and with an element of intent, can be subject to Article 351 of the Criminal Code concerning abuse. In addition, if the action results in death due to negligence, it can be subject to Article 359 of the Criminal Code (Agestya & Hariyanto, 2023).

Furthermore, Article 440 of Law Number 17 of 2023 concerning Health stipulates that medical personnel who negligently cause serious injury to a patient can be punished with a maximum prison sentence of three years and/or a fine of up to IDR 250 million. If the negligence results in the patient's death, the penalty can increase to five years' imprisonment and/or a fine of IDR 500 million (Pemerintah Republik Indonesia, 2023).

From a civil law perspective, the absence of informed consent can result in the non-fulfillment of the elements of a valid agreement as stipulated in Article 1320 of the Civil Code (KUHPerdata), especially in relation to "agreement of the parties." In the legal relationship between a doctor and a patient in the form of a therapeutic agreement, informed consent is a concrete form of agreement. Therefore, medical actions carried out without valid consent can be considered an unlawful act (onrechtmatige daad), as referred to in Article 1365 of the Civil Code, which states that "Every act that violates the law and causes harm to another person, requires the person whose fault causes the loss, to compensate for said loss." (Ramadhan & Nugraha, 2021). Thus, doctors and/or hospitals can be held civilly liable for losses arising from medical actions without informed consent or valid approval from the patient.

Law Number 17 of 2023 concerning Health affirms the principle of legal accountability of hospitals for the actions of medical personnel working within them. This is explicitly stipulated in Article 193, which states that hospitals are legally responsible for losses arising from the negligence of medical personnel working there. This provision emphasizes that patients who suffer losses as a result of the actions of medical personnel have the right to file a lawsuit against the hospital as a healthcare provider, which is legally obligated to ensure the provision of safe, high-quality, and responsible healthcare services. However, Article 308 of the same law imposes limitations by stipulating that before medical personnel can be held civilly liable, a recommendation from the Health Professions Disciplinary Council must first be obtained. This provision emphasizes the importance of an initial assessment of ethical and professional discipline aspects before entering the realm of legal accountability, as a form of legal protection for medical personnel and to ensure that any alleged professional violations have gone through an objective clarification and assessment process in accordance with professional standards (Pemerintah Republik Indonesia, 2023).

In Indonesia, the concept of presumed consent has been introduced in the context of medical services in emergency situations. This concept recognizes that under certain circumstances, where the patient is unable to provide explicit consent and no family members are available to contact, doctors are permitted to perform life-saving medical procedures without first obtaining consent. Although the implementation of high-risk medical procedures in emergency situations is not explicitly regulated in detail, this practice has legal legitimacy as long as the procedures are carried out in accordance with professional standards and the principle of prudence.

The legal basis for the practice of presumed consent can be found in the provisions of Article 80 paragraph (3) and Article 293 paragraph (9) of Law Number 17 of 2023 concerning Health, which states that consent to medical procedures is not required in emergency situations. Furthermore, Article 275 paragraph (1) of the same law emphasizes that in emergency situations, medical personnel are exempt from claims for compensation as long as the actions taken are aimed at saving the patient's life and are carried out in accordance with applicable medical service standards. This provision provides legal certainty and protection for medical personnel in making quick decisions without fear of the risk of lawsuits, as long as the actions are proportionate and based on good faith in the best interests of the patient (SP & Wisnu, 2023).

The International Context of Informed Consent and Its Legal Implications

In global discourse, informed consent has evolved into a key pillar of modern healthcare governance and is considered the most concrete manifestation of respect for patient autonomy, human rights, and ethical clinical practice. Historically, the strengthening of the concept of informed consent is rooted in the tragedy of medical ethical violations around the world, particularly after the revelation of experiments that violated human dignity such as the Nazi Medical Experiments and the Tuskegee Syphilis Study, which then gave birth to international ethical and legal instruments such as the Nuremberg Code (1947) (Weisleder, 2022), the Declaration of Helsinki by the World Medical Association (1964 and revised), and the Universal Declaration on Bioethics and Human Rights by UNESCO (2005) (Kurihara et al., 2025). These documents position free, informed, and uncoerced consent as a universal principle that must be applied in all jurisdictions, while emphasizing that medical procedures without informed consent are not only ethical violations, but can also be violations of law and human rights. The relevance of this framework is crucial, especially for developing countries, including Indonesia, which are still in the process of consolidating patient-centered care-based healthcare governance and facing complex dynamics between professional ethics, the need for rapid service, and legal risks for medical personnel.

In many countries, legal developments related to informed consent indicate that the standard for assessing physicians' responsibilities is increasingly shifting toward an approach that focuses on patients' rights rather than solely on the technical correctness of medical procedures. For example, in the United States, the landmark Canterbury v. Spence (1972) decision affirmed that physicians' obligations extend not only to medical procedures but also to disclosing material information necessary for patients to make rational decisions (Del Villar et al., 2023). The court in this case rejected the "professional standard" (which relies on the judgment of the medical community) in favor of the "reasonable patient standard," which places the patient's perspective as the basis for determining whether consent is valid (Meisel, 1996). This approach has since been widely adopted in various Anglo-Saxon jurisdictions and has influenced global concepts regarding the limits of physicians' authority and the potential for lawsuits if the information provided is deemed inadequate.

Meanwhile, in the UK, the development of jurisprudence through the case of Montgomery v. Lanarkshire Health Board (2015) further emphasized the fundamental transformation from medical paternalism to autonomy-based consent (Lewis, 2021). The Montgomery ruling stated that physicians are obligated to provide information about material risks—those that are objectively significant or subjectively important to the patient. Failure to provide material information is considered a breach of duty, resulting in civil liability. The Montgomery Principles are often cited globally for their influence in modernizing health law, prioritizing patient rights and active participation in clinical decision-making (Hughes et al., 2018). This standard demonstrates that internationally, the legal boundaries for physicians are becoming increasingly strict, and the scope for defenses based on "good faith" or "professionalism" is increasingly limited if consent procedures are not properly implemented.

In Europe, regulations regarding informed consent have been institutionalized in various regional legal instruments, most notably through the 1997 Convention on Human Rights and Biomedicine (Oviedo Convention), which affirms that any medical intervention may only be carried out after the patient has given free and informed consent, except in life-threatening emergencies. The Convention emphasizes that consent is not merely an administrative requirement, but is a fundamental protection of a person's physical and psychological integrity (O. F. E. Council, 1997). Furthermore, the European Court of Human Rights (ECHR), in several decisions, such as Glass v. UK (2004) and V.C. v. Slovakia (2011), emphasized that medical treatment without consent can be considered a violation of the right to personal integrity as

protected by Article 8 of the European Convention on Human Rights (Buelens et al., 2016). This shows that in many regions of the world, violations of informed consent are no longer seen as merely a matter of medical negligence, but can also become a human rights violation.

In Asia, many countries are also following the global trend of tightening the implementation of informed consent. Japan, for example, through its Supreme Court ruling in the Obstetrics Case (2000), affirmed that physicians are obligated to disclose material risks to patients, and failure to do so can result in legal liability (Buchbinder et al., 2024). Japanese courts have recognized that advances in medical technology have made information needs increasingly complex, requiring standards for information delivery to rise in line with evolving patient expectations (Jeganathan et al., 2025). South Korea has also seen a significant increase in medical litigation related to informed consent. A Supreme Court of Korea ruling (2003) emphasized that physicians must provide comprehensive information about risks, alternative treatments, and clinical consequences (Xu et al., 2025). The country even introduced the Medical Dispute Mediation and Arbitration Act (2012), which mandates strict documentation of consent to reduce the high number of medical disputes.

In addition to strengthening legal aspects, global developments also indicate an expansion of the concept of informed consent, particularly in the context of emergencies, health technology, and the use of medical data. The concept of presumed consent in emergency situations has been widely recognized in many jurisdictions, such as the United States, Canada, the United Kingdom, and Australia. This principle is based on the ethical assumption that a patient who is unable to give consent in a life-threatening situation will rationally choose a life-saving action (Beauchamp & Childress, 2019). This model aligns with developments in many countries that provide legal protection for medical personnel who must make rapid decisions in situations without explicit consent, as long as the actions are carried out according to professional standards. This parallels Indonesian regulations, which have begun adopting the concept of presumed consent through the 2023 Health Law. Nevertheless, the practice of presumed consent in many countries is accompanied by strict documentation procedures, ethical audits, and post-procedure medical evaluations to ensure accountability and prevent misuse (Rahman et al., 2025).

From a global ethical perspective, informed consent has also been broadened in its definition as part of the principle of respect for autonomy, one of the four universal principles of bioethics, along with beneficence, non-maleficence, and justice (Beauchamp & Childress, 2019). International organizations such as UNESCO affirm that informed consent is integral to protecting human dignity in medical procedures, health research, and the use of genetic data. Therefore, failure to obtain consent is not only a matter of malpractice but also a violation of globally recognized humanitarian values. The positioning of informed consent as a universal ethical principle requires countries to adjust their domestic legal frameworks to ensure clinical practices align with international standards. This is particularly relevant for Indonesia, particularly in the context of the increasing complexity of healthcare services, the development of biotechnology, and the growing public legal awareness that has led to increasingly numerous and complex medical disputes.

Considering these global developments, Indonesia's position on regulating informed consent through the 2023 Health Law and various previous regulations is part of the process of modernizing the health legal system. However, several challenges require attention to ensure that domestic regulations are not only aligned with national law but also compatible with global standards. First, Indonesia still faces issues of inconsistent operational standards across healthcare facilities, a lack of comprehensive documentation, and often weak communication records between doctors and patients. In many developed countries, standards for doctor-patient communication have been developed through professional guidelines, specialized training modules, and audio-visual recording systems for high-risk procedures. Second, in other countries, independent mediation institutions play a strong role in resolving medical disputes, in contrast to Indonesia, which still relies on an internal ethics process (the Health Professions Disciplinary Council), which is often considered less than fully independent. Third, the implementation of presumed consent in other countries is usually accompanied by detailed clinical guidelines and audits, while in Indonesia, regulations are still general and therefore open to multiple interpretations.

Given these global dynamics, this study provides significant relevance not only for strengthening national health law but also for harmonizing Indonesian medical practice standards with international

frameworks. The insights offered by this global analysis emphasize the importance of: (1) establishing stricter standards for communication and documentation of informed consent; (2) ensuring the implementation of presumed consent based on clear clinical guidelines; (3) strengthening independent health mediation mechanisms in line with international practice; and (4) digitizing the informed consent system to strengthen legal accountability. Thus, this study not only explains Indonesia's domestic context but also places it within the global architecture of modern health governance that demands transparency, accountability, and full respect for patient autonomy as universal ethical and legal principles.

CONCLUSION

Informed consent is a form of agreement given by a patient or their family based on adequate information and a clear explanation regarding the medical procedure to be performed on the patient. In the Indonesian legal system, informed consent has a strong legal standing as a manifestation of respect for the patient's human right to self-determination. The primary objective of this mechanism is to guarantee legal protection for the patient's physical and psychological integrity through conscious and voluntary medical decision-making. Normatively, the existence of informed consent is reinforced by a number of laws and regulations. The implementation of informed consent in accordance with legal provisions not only serves as an instrument of protection for patients but also serves as the basis for legal accountability for medical personnel in carrying out professional and ethical medical practice. Conversely, violations of the principles of informed consent, such as failing to provide sufficient information, failing to obtain patient consent, or performing medical procedures without a valid legal basis, can result in various serious legal consequences. These implications include criminal law, civil law, as well as disciplinary and ethical sanctions for the doctor or medical personnel concerned.

Although the concept of informed consent has a strong legal standing within the Indonesian legal framework, the dynamic development of medical technology and modern medical practices continues to pose new challenges that require adjustments to the existing legal system. Therefore, strengthening and updating more comprehensive and responsive regulations is necessary to accommodate the complexities of contemporary healthcare practices. It is hoped that, along with the development of the national legal system, the existence of informed consent will not only be recognized normatively but also regulated in greater detail and implementation. Thus, the legal relationship between doctors as healthcare providers and patients as service recipients can be realized as an equal relationship, based on respect for human rights and the principle of justice in medical care.

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