

Legal Policy in Improving the Implementation of Informed Consent in Hospitals Based on Health Law No. 17 of 2023

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Abstract

Informed consent is one of the fundamental aspects of medical practice that emphasizes the patient's right to give consent based on a full understanding of the medical procedure to be undertaken. The implementation of good informed consent is essential in safeguarding patients' rights and ensuring that medical procedures are carried out ethically and professionally. Health Law Number 17 of 2023 provides a clear legal basis related to the obligations of hospitals and medical personnel in carrying out informed consent. Article 56 of this Law states that "every medical personnel who performs medical procedures are obliged to provide sufficient information to the patient to obtain written consent before performing medical procedures." This regulation aims to protect patients' rights and improve the quality of health services in hospitals. This study aims to analyze the role of law in improving the quality of the implementation of informed consent in hospitals by referring to Health Law Number 17 of 2023. The method used in this study is normative legal research with an analytical descriptive approach. This approach is used to examine laws and regulations related to informed consent, as well as its application in medical practice in hospitals. The results of the study show that although Health Law Number 17 of 2023 provides a strong legal basis, the implementation of informed consent in hospitals still faces various challenges. The main obstacles found include the lack of understanding of patients and medical personnel regarding the correct procedures, as well as the lack of supervision in the implementation of the policy. This study recommends increased training for medical personnel and stricter supervision of the implementation of informed consent in hospitals.

Keywords: *Legal Role, Informed Consent, Health Law Number 17 of 2023*

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Introduction

Informed consent is a basic concept in medical relationships that requires patients to give consent to medical actions to be performed by health workers. This concept is important because it recognizes the right of patients to make informed decisions regarding their health care. In this case, medical personnel are responsible for providing clear and complete information about the medical procedure, benefits, risks, alternatives, and potential consequences that may occur from the procedure. Through informed consent, patients are given the opportunity to consider all available information before making a decision, which in turn protects the patient's right to autonomy in choosing treatment that suits the patient's wishes and conditions. The importance of informed consent also lies in its function to build a relationship of trust between patients and medical personnel. When patients feel valued and treated with transparency, they will have more trust in the medical personnel and the treatment process undergone. In addition, this process also protects medical personnel from potential claims or lawsuits that may arise as a result of medical actions that are not approved by the patient. Informed consent is not only a formality, but it is also part of the ethics of the medical profession that emphasizes the importance of clear and effective communication between patients and healthcare workers.

In practice, informed consent applies not only to major or high-risk medical procedures, but also to any medical procedure that requires patient intervention. Therefore, medical personnel need to ensure that the patient fully understands the information provided before approving the medical measures to be taken. It includes a sufficient explanation of the patient's medical condition, the procedure to be performed, as well as the available treatment alternatives. The importance of this informed consent is also reflected in health laws that stipulate that any medical procedure must be carried out based on the patient's valid consent, which is obtained after adequate provision of information.

1.1 The Role of Law in Ensuring the Quality of Health Services

The role of law in ensuring the quality of health services is very important because it provides a strong foundation for the protection of patients' rights and ensures that the medical services provided are in accordance with the standards that have been set. One of the basic principles regulated in health law is informed consent, which requires medical personnel to provide clear and complete information about the medical actions to be taken to patients. Through this consent, patients are given the right to make decisions based on sufficient knowledge of medical procedures, risks, and acceptable benefits. With clear regulations, the law serves to maintain the quality of medical services, ensuring that patients are actively involved in their medical decision-making process. In addition, the law also plays a role in ensuring that medical personnel and health facilities meet the standards that have been set. In Indonesia, Health Law Number 17 of 2023 provides a legal basis that regulates the competence of medical personnel and the quality of hospital services. Hospitals are required to meet certain standards which include the quality of medical equipment, trained medical personnel, and an efficient management process of health facilities. The law serves as a regulator to ensure that hospitals not only operate administratively but also conduct medical practices in accordance with applicable ethical principles and professional standards. This aims to minimize medical errors and malpractices that can harm patients.

The law also plays a role in increasing transparency and accountability in health services. One form of transparency regulated by law is the obligation of hospitals and medical personnel to provide sufficient information to patients, not only regarding medical procedures but also about the costs associated with the services provided. With this provision, patients not only get quality services but can also make better decisions about their choices based on complete information. This aspect is important so that there is no discrimination or abuse of power by health care providers, as well as to ensure justice in access to and utilization of health services. Although the role of law in improving the quality of health services is enormous, the

challenges of its implementation remain. One of them is the lack of understanding among patients about their rights in the medical decision-making process. In addition, medical personnel and hospital managers also often face challenges in meeting the standards set due to limited resources, both in terms of experts and medical equipment. Therefore, it is important to continue to increase understanding of health law through education to the public and medical personnel, as well as strengthen the supervision and law enforcement system so that the quality of health services continues to improve.

1.2 The challenges faced by hospitals in implementing informed consent are in accordance with legal principles.

The implementation of informed consent in hospitals faces a number of complex challenges, both from a practical and legal perspective. One of the main challenges is the limited time that medical personnel have in providing thorough explanations to patients. In many cases, medical personnel are hampered by high workloads and time pressures that limit their ability to provide complete and adequate information regarding the medical procedures to be performed. This risks reducing the quality of informed consent given to patients, although legally, the consent process must be obtained in a correct and thorough manner. In addition, another challenge that is often faced is the lack of understanding of patients regarding their rights in a medical context. Many patients do not fully understand the information provided by medical personnel or feel compelled to approve medical procedures due to ignorance or dependence on the hospital. This misunderstanding can lead to consent that is not really grounded in adequate knowledge, which in turn can lead to legal issues in the event of medical complications or inconsistencies with patient expectations. Therefore, it is important for hospitals to take a more educational approach in explaining medical procedures to patients.

The legal aspect is also a big challenge in the implementation of informed consent. Hospitals often face a dilemma regarding how to manage documentation in accordance with legal requirements, especially in cases involving high-risk medical procedures. The lack of clarity regarding the legal standards that must be followed in providing informed consent, as well as the potential for lawsuits in the event of a failure in the consent process, make hospitals very cautious in any medical action. This demands clear internal policies and strict standard operating procedures (SOPs) to ensure that any medical procedure is carried out with lawful consent and in accordance with applicable legal principles.

1.3 The relevance of Health Law Number 17 of 2023 to the practice of informed consent in hospitals.

Law Number 17 of 2023 concerning Health provides a strong legal basis for the practice of informed consent in hospitals in Indonesia. Article 77 paragraph (1) of the Health Law emphasizes that every health service action can only be carried out after obtaining the approval of the patient or his family. This shows that informed consent is not just an administrative formality, but a legal prerequisite that must be met before medical action is taken. Furthermore, Article 77 paragraph (2) of the Health Law details the elements that must be present in the informed consent process, namely an explanation of the medical action to be performed, the purpose and importance of the action, the risks and complications that may occur, other available alternatives and their risks, the prognosis of the action to be taken, and the estimated financing. This emphasis on the quality of information provided to patients is in line with the principle of patient autonomy in medical ethics, which places patients as active subjects in decision-making regarding their health.

In the context of an emergency, the Health Law provides an exception to the obligation to obtain informed consent in advance. Article 77 paragraph (5) states that in an emergency, medical action can be taken without prior approval if it is necessary to save the patient's life. However, after the emergency is resolved, medical personnel are obliged to provide an

explanation to the patient or their family about the actions that have been taken. The implementation of the Health Law in the practice of informed consent in hospitals has the potential to improve the quality of communication between medical personnel and patients. Research shows that more detailed regulation of informed consent can encourage standardization of procedures and improve public health literacy. However, implementation challenges remain, especially in terms of education of medical personnel and the public, as well as the potential for increased medical litigation. Therefore, collaborative efforts from various stakeholders are needed to ensure the effective and ethical implementation of these new informed consent regulations.

Literature Review

2.1 Konsep Informed Consent

Informed consent in the medical context is a process in which a patient or his or her representative is provided with sufficient and relevant information about the diagnosis, the purpose of medical action, benefits, risks, and available alternatives so that he or she can make decisions freely and voluntarily. This process confirms that patient consent is not just about signing a form, but an integral part of the interaction between the medical staff and the patient that respects the patient's autonomy, as well as his or her right to determine what will be done to his or her body. As an ethical and legal norm, informed consent has evolved from traditional paternalistic practices to a more participatory model, where information and shared decision-making take center stage. The implementation of informed consent in hospitals begins with a detailed explanation by medical personnel about the actions to be taken—including the nature of the action, objectives, benefits, risks, consequences of refusal, and available alternatives. Furthermore, patients should be given the opportunity to ask, understand, and consider those options without pressure or coercion. This process is then documented in writing or electronically as evidence that an explanation has been provided and a decision has been made with the patient's consent. In emergency situations or when the patient is unable to make his or her own decisions, special procedures and consent on behalf of the patient should be considered in accordance with applicable regulations.

To ensure the validity of informed consent, there are a number of elements that must be met, namely: (a) the patient has the capacity to understand and make decisions; (b) the information provided must be complete, accurate, and in accordance with the patient's condition; (c) the patient's decision is made voluntarily without pressure; and (d) such consent is specifically related to the action to be taken. Inability to meet these elements can result in informed consent being considered invalid, ultimately with ethical and legal implications for institutions and medical personnel. In hospital practice, in addition to ensuring these elements, institutions also need to establish internal policies and procedures to support the implementation of quality informed consent including training of medical personnel, development of standard forms, and implementation audits. In line with developments in healthcare regulations and standards, the implementation of quality informed consent can increase institutional accountability, strengthen trusting relationships between patients and service providers, and reduce the risk of legal disputes. However, some challenges are still faced in practice: diverse levels of patient health literacy, cultural and cultural differences and values, limited time in treatment, and the complexity of medical procedures that are difficult to understand. Therefore, hospitals need to implement effective communication approaches, carry out transparent documentation, and conduct monitoring to ensure that patients' rights to information and decisions are truly fulfilled in the implementation of informed consent.

2.2 Laws and Regulations Related to Informed Consent

Law Number 17 of 2023 concerning Health provides a firmer legal foothold for the approval of medical measures (informed consent) as an integral part of individual health

services. For example, Article 293 paragraph (1) states that "Every individual health service action carried out by Medical Personnel and Health Workers must be approved." In addition, Article 2 letter g establishes the principles of protection and safety in the implementation of health efforts, which implicitly supports that patients must obtain adequate information before making an apology. This law emphasizes that informed consent is not just an administrative formality, but a patient's right that must be fulfilled as part of the professionalism of health workers and the legal protection of patients.

In addition to the Law, there are supporting regulations that strengthen the implementation of informed consent in health service practices. An example is the Regulation of the Minister of Health Number 290/MENKES/PER/III/2008 concerning the Approval of Medical Measures which specifically regulates the approval of medical measures. Professional codes of ethics such as the Indonesian Code of Medical Ethics affirm that medical personnel are obliged to respect patients' rights to information (Article 10) and obtain approval for medical measures from patients or their guardians. This combination of statutory regulations, ministerial regulations, and codes of conduct creates a more comprehensive normative framework to ensure that patients obtain sufficient information, understand the risks and alternatives, and provide voluntary consent before action is taken.

The relevance of Law Number 17 of 2023 to the practice of informed consent in hospitals can be seen in the increase in documentation obligations and explicit recognition of patient rights. Juridical studies show that the law encourages standardization of informed consent procedures, strengthens doctor-patient communication, and improves public health literacy. However, implementation still faces challenges in the field, such as health workers' understanding of patient rights, paternalistic culture, and availability of time in intensive care. For the record, in emergency situations the Act also provides for exceptions where written consent may not be obtained. Therefore, the implementation of this regulation in hospitals requires collaboration between hospital management, medical personnel, and regulators to ensure that the informed consent process runs effectively, ethically, and in accordance with the applicable legal framework.

2.3 The Role of Law in Informed Consent

The legal role in informed consent is crucial in ensuring that patients provide informed and voluntary consent to the medical procedures to be performed. In this context, the law serves to protect the autonomy of patients, which is the fundamental right of every individual to make decisions regarding his or her health care. This legal aspect also involves the healthcare provider's obligation to provide patients with clear, accurate, and sufficient information about medical procedures, their risks, and benefits, before seeking consent. The law views informed consent as a measure to ensure that patients are not only informed but also fully understand the consequences of the choices they make, which in turn serves as a safeguard against unethical or illegitimate medical practices. In addition, the legal framework that regulates informed consent also includes the enforcement of sanctions in the event of violations. In many jurisdictions, non-compliance with informed consent procedures can lead to claims of medical malpractice or even other legal action. For example, in Indonesia, laws governing medical practice and patient protection require doctors and medical personnel to perform these procedures in accordance with applicable standards. In this case, legal sanctions play a role in enforcing the obligations of health service providers in implementing fair and transparent practices. This sanction serves as a form of accountability for violations of patients' rights, as well as to ensure justice in the implementation of health services.

The importance of evaluation and updating of the existing legal system and sanctions is also a point of concern. The factors that influence legal decisions in informed consent cases are very diverse, ranging from doctors' understanding of their legal obligations, to limited time and resources that can affect the quality of the informed consent process. This evaluation not only

touches on the legality aspect, but also the ethical aspect in the relationship between doctor and patient. Therefore, a fair approach to the implementation of informed consent must involve collaboration between law, medical ethics, and health policy that supports transparency, accountability, and protection of patients' rights.

Research Methodology

This study uses a normative legal method with an analytical descriptive approach to analyze Health Law Number 17 of 2023 and its application in the practice of informed consent in hospitals. This approach focuses on the study of legal norms and their impact on medical procedures that are compliant with regulations. Data sources are in the form of regulations, hospital policy documents, and related literature such as journals, books, and health law articles. The analysis was carried out descriptively to describe the application of the law in hospital practice, especially related to the provision of information to patients and the implementation of informed consent, as well as to identify the conformity between regulations and practices in the field.

Results

4.1 Implementation of Informed Consent in Hospitals

Within the framework of implementation in hospitals, the law strengthens the obligation for health care facilities and medical personnel to obtain consent for individual health measures. As stated in Article 293 paragraph (1) of Law 17/2023 that "Every individual health service action carried out by Medical Personnel and Health Workers must be approved." Implementation in hospitals requires a systematic process: the patient (or his or her representative) must be adequately informed about the benefits, risks, alternatives and consequences if they choose to refuse medical treatment, and then be given the space to make decisions freely. Juridical studies show that the implementation of Law 17/2023 puts pressure on stricter documentation and improved quality of communication between medical personnel and patients. As such, hospitals must develop internal procedures that ensure that consent (written or oral as the condition requires) truly reflects informed consent, not just a formalistic signature.

Although the legal framework is clearer, its implementation in hospitals faces real challenges. First, there is a gap in understanding between medical personnel and patients or families about the meaning and consequences of consent to health measures, many patients simply sign the form without really understanding the content or alternative course of action. Second, the increasing administrative and documentation burden, where hospitals must ensure medical records, written consent (if necessary), and exemption procedures in emergency situations (for example, Article 293 paragraph (9) of Law 17/2023) that allow actions without written consent in certain circumstances. Third, the challenge is a paternalistic culture in medical services there is still a tendency for medical personnel to make decisions on behalf of patients without full patient participation — which is contrary to the spirit of autonomy in *informed consent*. Lastly, the risk of medical litigation increases due to inadequate documentation, which can have an impact on the reputation and legal aspects of the hospital.

To overcome these challenges, hospitals need to strengthen several aspects of implementation. First, the development of internal standard protocols on the informed consent process—including easy-to-understand consent forms, routine training of medical personnel for effective communication, and a system of implementation evaluation and documentation of consent. Second, strengthening the education of patients and families so that they understand their rights, the consequences of actions and alternative options so that consent is truly "informed". Third, systematic internal supervision and audit to ensure that approvals are carried out in accordance with the provisions of Law Number 17 of 2023 concerning Health and other supporting regulations, as well as corrective actions if inappropriate procedures are found. With

these steps, the implementation of *informed consent* In hospitals, it is not only a fulfillment of the law, but also improves the quality of health service ethics, protects patient rights, and minimizes potential legal risks.

4.2 The Role of Law in Improving the Quality of Informed Consent Implementation

The law has a strategic role in improving the quality of the implementation of Informed Consent in health facilities by making the approval of medical procedures not just an administrative procedure, but part of the protection of patients' rights and the accountability of health workers and institutions. For example, the provisions in Law Number 17 of 2023 concerning Health stipulate that every action of individual health services must be approved. With a clear normative framework, medical personnel and hospital management are encouraged to establish documentation systems, ensure that the doctor-patient communication process runs according to standards, and minimize the risk of medical disputes due to inadequate approvals. As evidence, a number of studies show that the implementation of good informed consent is related to a decrease in cases of malpractice claims and an increase in patient trust.

The involvement of health workers and hospital management is crucial for informed consent obligations to be effectively enforced management is responsible for setting internal policies, easy-to-understand consent forms, training for medical staff and periodic audits, while health workers (doctors, nurses) must be active in providing sufficient information, facilitating dialogue with patients or families, and ensuring that consent is given Truly "informed". Research shows that many problems in the field arise due to ineffective communication, substandard forms, or health care workers and management who are not aware of the legal implications that may arise. Proactive hospital management and healthcare workers committed to ethical and legal standards help ensure that informed consent is not just "signed" but a process that is meaningful and meets legal protections. To make informed consent an instrument of sustainable service quality, the law not only establishes obligations but also provides a basis for evaluation and accountability. Through regulations such as Permenkes No. 290/Menkes/Per/III/2008 and provisions in the Health Law, the health system can conduct audits, incident reporting, and handle claims related to violations of medical action approvals. Hospital management that is aware of legal responsibility will integrate informed consent procedures into standard operational protocols, compliance training, and quality of service measurement. Healthcare workers who understand the legal consequences of unauthorized consent will tend to be more cautious and communicative so that the quality of service improves, patients' rights are protected, and the risk of litigation is reduced.

4.3 Barriers to Legal Application and Informed Consent

One of the main obstacles faced by hospitals in implementing informed consent is administrative aspects and documentation that are not optimal so that legal aspects are less guaranteed. For example, studies show that there are still many informed consent forms that are not completed – for example, research at a surgical hospital found that 42.8% of forms are still incomplete, especially in the alternative and risk sections of medical procedures. In addition, hospitals often have limited time in doctor-patient consultations and high workloads, which impacts the quality of the process of providing adequate information and truly "informed" consent. Because consent documents are incomplete or information is lacking, the legal aspects (e.g. patient protection and hospital liability) become vulnerable to claims or disputes.

The analysis shows that there is a real inconsistency between the practice of implementing informed consent in the field and the applicable regulatory provisions. For example, when regulations require that patients must obtain a full explanation of the diagnosis, course options, risks, and consequences of refusing medical procedure, in practice many patients claim to have no understanding of the form they signed or the conditions of the medical

procedure performed. In addition, in regulations such as Law Number 17 of 2023 concerning Health and related regulations, there are exceptions in emergencies, but the practice in some hospitals does not clearly distinguish procedures for emergency and non-emergency conditions so approval may not be obtained formally or informatively. This inconsistency shows that although the legal foundations are already in place, the day-to-day implementation is still not fully aligned with the ideal legal norms. Other barriers are structural and institutional culture: for example, the lack of legal and ethical training for healthcare workers and hospital management, the lack of internal oversight of consent practices, and the lack of reward/punishment that encourages regulatory compliance. The study said that the incompleteness of filling out the informed consent form is often caused by the lack of socialization of hospital procedures, the lack of human resources handling documents, and the absence of a reward or punishment mechanism for violations. To bridge the gap between regulation and practice, hospitals need to strengthen control mechanisms, clarify SOPs for emergency versus non-emergency situations, conduct regular audits, and improve legal literacy for all medical service stakeholders.

4.4 Solutions to Improve the Quality of Informed Consent Implementation

Efforts to improve the quality of informed consent can begin by strengthening patient communication and education as the core of truly informed consent. For example, the consent form should be prepared in simple language that is relevant to the patient's literacy level, and equipped with visual, audio or interactive explanatory media. Studies have found that the use of a "teach-back" approach (patients are asked to repeat the information provided again to ensure understanding) can significantly improve patient understanding. In addition, hospitals need to develop a routine training system for health workers on legal and ethical aspects of informed consent, as well as establish internal protocols that ensure that consent is fully documented and dynamic audits are conducted to evaluate compliance with regulations.

For policymakers and hospital management, the main recommendations include three things: first, formulate clear national or institutional policies regarding minimum informed consent standards (components to be explained, documentation, consultation time, etc.). Second, providing monitoring and accountability mechanisms for example, audits if approvals do not meet standards, collection of quality indicator data, and rewards/penalties for implementers. Third, encourage the integration of technology in the approval process (e.g. electronic forms, educational videos, digital consent track systems) to facilitate transparency and legal track record. Study - Latest shows that the redesigned approval document is concise, with easy language, and enriched with additional media, proven to be better at improving understanding and implementing legally valid consent.

Conclusion

Health Law Number 17 of 2023 provides a clear legal basis for regulating informed consent in hospitals. In this law, it is stipulated that every medical procedure performed by a health worker must be approved by the patient after being given an adequate explanation of the procedure, benefits, risks, and alternative medical measures to be performed. This strengthens the patient's right to bodily autonomy and ensures that medical procedures are carried out on the basis of legitimate consent. The law aims to protect patients' rights, while reducing the potential for legal disputes related to medical malpractice. However, in implementation, many hospitals face various challenges, such as limited time available to explain in detail medical procedures to patients and lack of patient understanding of the information provided. This causes a discrepancy between legal regulations and practices in the field. It is not uncommon for informed consent forms to be considered as an administrative procedure without ensuring that the patient truly understands the information provided. This inconsistency leads to potential legal risks that can be faced by medical personnel and health institutions.

Recommendations

To overcome this obstacle, hospitals must strengthen training for medical personnel on legal obligations in obtaining truly informed consent. The use of technology, such as electronic forms and educational videos, can be a solution to ensure that patients receive clear and easy-to-understand information. Policymakers also need to establish stricter guidelines on the standards for the implementation of informed consent, including procedures for emergency situations and better oversight of implementation on the ground. Thus, the law not only serves as a regulator but also as a driver to improve the quality of medical services that are more transparent and fair.

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