Multidiciplinary Output Research For Actual and International Issue (MORFAI Journal) ISSN (e): 2808-6635
Volumes 6 No. 4 (2026)

THE ROLE OF LAW IN INCREASING THE IMPLEMENTATION OF INFORMED CONSENT IN HOSPITALS BASED ON HEALTH LAW NUMBER 17 OF 2023

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Received : 01 April 2026 Accepted : 05 May 2026
Revised : 10 April 2026 Published : 16 May 2026

Abstract

Informed consent is one of the fundamental aspects in medical practice, emphasizing the patient's right to give consent based on full understanding of the medical procedures they are about to undergo. The proper implementation of informed consent is crucial to safeguard the patient's rights and ensure that medical actions are performed ethically and professionally. The Health Law No. 17 of 2023 provides a clear legal foundation regarding the obligations of hospitals and medical personnel in carrying out informed consent. Article 56 of this Law states that "every medical professional conducting medical procedures must provide sufficient information to the patient to obtain written consent before performing the medical procedure." This regulation aims to protect the patient's rights and improve the quality of healthcare services in hospitals. This research aims to analyze the role of law in enhancing the quality of informed consent implementation in hospitals, referring to Health Law No. 17 of 2023. The research method used in this study is normative legal research with a descriptive-analytical approach. This approach is used to examine the regulations related to informed consent, as well as its implementation in medical practice in hospitals. The research findings indicate that although Health Law No. 17 of 2023 provides a strong legal foundation, the implementation of informed consent in hospitals still faces various challenges. The main obstacles identified include the lack of understanding by both patients and medical professionals regarding the correct procedures, as well as insufficient oversight in the implementation of this policy. This study recommends enhancing training for medical personnel and implementing stricter supervision of informed consent practices in hospitals.
of your findings.

Keywords: *Legal Role, Informed Consent, Health Law No. 17 of 2023,.*

INTRODUCTION

Informed consent is a fundamental concept in the medical relationship that requires patients to provide consent for medical procedures to be performed by healthcare professionals. This concept is important because it recognizes the patient's right to make informed decisions regarding their healthcare. In this regard, medical personnel are responsible for providing clear and complete information regarding medical procedures, benefits, risks, alternatives, and possible consequences of the procedures. Through informed consent, patients are given the opportunity to consider all available information before making a decision, thereby protecting the patient's autonomy in choosing appropriate treatment according to their wishes and condition. The importance of informed consent also lies in its function of building trust between patients and healthcare providers. When patients feel respected and treated transparently, they tend to have greater trust in medical personnel and the treatment process. In addition, this process also protects healthcare providers from potential claims or legal actions arising from medical procedures that were not approved by the patient. Informed consent is not merely a formality but an essential part of medical ethics that emphasizes clear and effective communication between patients and healthcare professionals. In practice, informed consent applies not only to major or high-risk medical procedures but to all medical interventions requiring patient involvement. Therefore, healthcare professionals must ensure that patients fully understand the information provided before agreeing to any medical procedure. This includes adequate explanations regarding the patient's medical condition, the procedure to be performed, as well as available treatment alternatives. The importance of informed consent is also reflected in health laws that stipulate that every medical procedure must be performed based on valid patient consent obtained after adequate information has been provided.

The Role of Law in Ensuring Healthcare Quality

The role of law in ensuring healthcare quality is essential because it provides a strong foundation for protecting patient rights and ensuring that medical services comply with established standards. One of the fundamental principles regulated in health law is informed consent, which obligates healthcare providers to deliver clear and complete information regarding medical procedures to patients. Through this consent, patients are given the right to make decisions based on sufficient knowledge of procedures, risks, and benefits. With clear regulations, law functions to maintain healthcare quality and ensure that patients are actively involved in medical decision-making. In addition, law also ensures that healthcare professionals and facilities meet established standards. In Indonesia, Law Number 17 of 2023 on Health provides the legal basis regulating medical competence and hospital service quality. Hospitals are required to meet specific standards including medical equipment quality, trained medical personnel, and efficient healthcare management systems. Law serves as a regulator ensuring that hospitals not only operate administratively but also conduct medical practice in accordance with ethical principles and professional standards. This aims to minimize medical errors and malpractice that may harm patients.

Law also plays a role in increasing transparency and accountability in healthcare services. One form of transparency required by law is the obligation of hospitals and medical personnel to provide sufficient information to patients, not only about medical procedures but also associated costs. With such provisions, patients can make better-informed decisions based on complete information. This is essential to prevent discrimination or misuse of authority by healthcare providers and to ensure fairness in access to healthcare services. Despite the significant role of law, implementation challenges remain. One of the main issues is the lack of patient awareness regarding their rights in medical decision-making. Additionally, healthcare providers and hospital administrators often face difficulties in meeting regulatory standards due to limited resources, including medical personnel and equipment. Therefore, continuous legal education for both the public and healthcare workers is necessary, along with strengthened supervision and law enforcement systems to improve healthcare quality.

Challenges Faced by Hospitals in Implementing Informed Consent According to Legal Principles

The implementation of informed consent in hospitals faces several complex challenges, both practical and legal. One major challenge is the limited time available for healthcare providers to fully explain medical procedures to patients. High workloads and time constraints often reduce the ability of medical staff to provide complete and comprehensive information, which may compromise the quality of informed consent. Another challenge is the lack of patient understanding regarding their rights in medical contexts. Many patients do not fully comprehend the information provided or feel pressured to agree to procedures due to dependency or lack of knowledge. This may result in consent that is not truly informed, which can lead to legal issues if complications arise. Legal aspects also present significant challenges. Hospitals often face difficulties in managing documentation in accordance with legal requirements, especially for high-risk procedures. Uncertainty regarding legal standards and potential litigation risks make hospitals cautious in every medical action. Therefore, clear internal policies and standard operating procedures (SOPs) are necessary to ensure valid and legally compliant informed consent.

Relevance of Health Law to Informed Consent Practice in Hospitals

Law Number 17 of 2023 on Health provides a strong legal foundation for informed consent practice in hospitals in Indonesia. Article 77 paragraph (1) states that every healthcare service action may only be performed after obtaining patient or family consent. This confirms that informed consent is not merely an administrative formality but a legal requirement. Furthermore, Article 77 paragraph (2) specifies the essential elements of informed consent, including explanation of the procedure, purpose, risks, alternatives, prognosis, and estimated costs. This aligns with the ethical principle of patient autonomy. In emergency situations, Article 77 paragraph (5) provides an exception allowing medical actions without prior consent if necessary to save the patient's life. However, explanation must be provided afterward. The implementation of this law can improve communication quality between patients and healthcare providers, although challenges remain in education and system readiness.

Research Problem

1. How does legal regulation support the effective implementation of informed consent in hospitals?
2. What legal obstacles are faced by hospitals in implementing informed consent under Law Number 17 of 2023 on Health?

Research Objectives
This study aims to analyze the role of law in the implementation of informed consent in hospitals, focusing on legal principles governing patient consent in medical procedures. It also aims to identify legal factors that enhance informed consent implementation and potential challenges affecting its effectiveness. The results are expected to contribute to policy improvement and ethical healthcare practices.

Research Benefits
This research contributes academically to the understanding of the role of Law Number 17 of 2023 in informed consent practices in hospitals. Practically, it provides recommendations for hospitals and healthcare professionals to improve informed consent implementation and ensure patients receive adequate information before medical procedures.

Informed Consent Theory
Informed consent in medical practice is a process where a patient or their representative is provided with sufficient and relevant information regarding diagnosis, procedure objectives, benefits, risks, and alternatives, enabling voluntary and informed decision-making. It emphasizes patient autonomy and shared decision-making.
Implementation involves detailed explanations, opportunity for questions, and documented consent. Valid informed consent requires capacity, adequate information, voluntariness, and specificity. Failure to meet these elements may invalidate consent and create legal consequences.

Legal Framework of Informed Consent
Law Number 17 of 2023 (Article 293 paragraph (1)) states that all healthcare actions require patient consent. Article 2(g) emphasizes protection and safety principles. Ministerial Regulation No. 290/2008 and medical ethics codes further strengthen implementation.
In emergencies, consent may be waived, but explanation must follow afterward. Implementation requires collaboration between hospitals, healthcare workers, and regulators.

The Role of Law in Informed Consent
Law ensures patient autonomy, requires disclosure of information, and enforces accountability. Failure to comply may result in malpractice claims. Legal evaluation is needed to balance ethics, healthcare constraints, and patient rights.

METHOD
This study uses a **normative legal research method** with a **descriptive-analytical approach** to examine Law Number 17 of 2023 on Health and its implementation in informed consent practices in hospitals. This approach focuses on the study of legal norms and their implications for medical procedures in accordance with applicable regulations.
The data sources consist of legal regulations, hospital policy documents, and relevant literature such as journals, books, and health law articles. The analysis is conducted descriptively to illustrate how the law is applied in hospital practice, particularly in relation to the provision of information to patients and the implementation of informed consent, as well as to identify the level of conformity between legal provisions and actual practices in the field.

RESULTS AND DISCUSSION
Implementation of Informed Consent in Hospitals
Within the framework of implementation in hospitals, the law strengthens the obligation for healthcare facilities and medical personnel to obtain consent for individual medical actions. As stated in Article 293 paragraph (1) of Law No. 17/2023, “Every individual healthcare service action carried out by Medical Personnel and Health Workers must obtain consent.” Implementation in hospitals requires a systematic process: patients (or their representatives) must receive sufficient information regarding benefits, risks, alternatives, and consequences of refusing medical treatment, and then be given the opportunity to make decisions freely. Legal studies indicate that the implementation of Law No. 17/2023 places greater emphasis on stricter documentation and improved quality of communication between medical personnel and patients. Accordingly, hospitals must develop internal procedures ensuring that consent (written or verbal depending on the situation) truly reflects informed consent, rather than merely serving as a formal signature.

Although the legal framework is clearer, its implementation in hospitals still faces several practical challenges. First, there is a gap in understanding between medical personnel and patients or their families regarding the meaning and consequences of medical consent; many patients sign forms without fully understanding the content or available alternatives. Second, administrative and documentation burdens are increasing, as hospitals must ensure medical records, written consent (when required), and emergency exception procedures (for example, Article 293 paragraph (9) of Law No. 17/2023) which allows medical action without written consent in certain emergency conditions. Third, there is a persistent paternalistic culture in medical services, where medical personnel tend to make decisions on behalf of patients without full patient participation, which contradicts the principle of autonomy in informed consent. Finally, the risk of medical litigation increases due to inadequate documentation, which may negatively affect hospital reputation and legal standing.

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

Law plays a strategic role in improving the quality of informed consent implementation in healthcare facilities by positioning medical consent not merely as an administrative procedure, but as part of patient rights protection and accountability of healthcare workers and institutions. For example, provisions in Law No. 17 of 2023 on Health stipulate that every individual healthcare service action must obtain consent. With this clear normative framework, medical personnel and hospital management are encouraged to develop documentation systems, ensure effective doctor–patient communication, and minimize the risk of medical disputes arising from inadequate consent. Evidence from various studies shows that proper implementation of informed consent is associated with a reduction in malpractice claims and an increase in patient trust. The involvement of healthcare workers and hospital management is crucial to ensure that legal obligations related to informed consent are effectively enforced—management is responsible for establishing internal policies, creating clear and understandable consent forms, providing staff training, and conducting periodic audits, while healthcare personnel (doctors and nurses) must actively provide adequate information, facilitate dialogue with patients or families, and ensure that consent is truly "informed."

Research indicates that many problems in practice arise from ineffective communication, non-standard forms, or a lack of awareness among healthcare workers and management regarding legal implications. Proactive hospital management and healthcare personnel committed to ethical and legal standards help ensure that informed consent is not merely "signing a form," but a meaningful process that provides legal protection. To make informed consent a sustainable quality instrument, law not only establishes obligations but also provides a basis for evaluation and accountability. Through regulations such as Minister of Health Regulation No. 290/Menkes/Per/III/2008 and provisions in the Health Law, the healthcare system can conduct audits, incident reporting, and claim handling related to violations of medical consent. Hospital management that recognizes legal responsibility will integrate informed consent procedures into standard operating protocols, compliance training, and service quality measurement. Healthcare personnel who understand the legal consequences of invalid consent tend to be more careful and communicative, thereby improving service quality, protecting patient rights, and reducing litigation risks.

Barriers in the Implementation of Law and Informed Consent

One of the main obstacles faced by hospitals in implementing informed consent is suboptimal administrative and documentation practices, which result in insufficient legal protection. For instance, studies show that many informed consent forms are incompletely filled; for example, research in a surgical hospital found that 42.8% of forms were incomplete, particularly in the sections on alternatives and medical risks.

In addition, hospitals often face time constraints in doctor–patient consultations and high workloads, which negatively affect the quality of information delivery and the validity of informed consent. Because consent documents are incomplete or information is insufficient, the legal aspects (such as patient protection and hospital liability) become vulnerable to claims or disputes. Analysis also shows a significant gap between actual informed consent practices and applicable regulations. For example, although regulations require that patients receive full explanations of diagnosis, treatment options, risks, and consequences of refusal, in practice many patients report not fully understanding the forms they sign or the procedures performed.

Furthermore, although regulations such as Law No. 17 of 2023 provide exceptions in emergency situations, in practice some hospitals do not clearly distinguish procedures between emergency and non-emergency cases, resulting in consent not always being properly obtained. These inconsistencies indicate that although the legal framework exists, day-to-day implementation is still not fully aligned with ideal legal norms. Other barriers are structural and institutional, including lack of legal and ethical training for healthcare workers and hospital

management, insufficient internal supervision of consent practices, and weak reward/punishment mechanisms to ensure compliance with regulations.

Solutions to Improve the Quality of Informed Consent Implementation

Efforts to improve the quality of informed consent can begin by strengthening communication and patient education as the core of truly informed decision-making. For example, consent forms should be written in simple language appropriate to patients' literacy levels and supplemented with visual, audio, or interactive explanations. Studies have found that the "teach-back" method—where patients are asked to repeat the information provided to ensure understanding—can significantly improve patient comprehension. In addition, hospitals need to develop regular training systems for healthcare workers on the legal and ethical aspects of informed consent, and establish internal protocols ensuring complete documentation and dynamic audits to evaluate compliance with regulations. For policymakers and hospital management, key recommendations include three main points: first, formulating clear national or institutional policies regarding minimum informed consent standards (including required components, documentation, consultation time, etc.); second, providing monitoring and accountability mechanisms such as audits, quality indicators, and reward/sanction systems; third, promoting technology integration in consent processes (such as electronic forms, educational videos, and digital consent tracking systems) to enhance transparency and legal traceability.

CONCLUSION

Health Law No. 17 of 2023 provides a clear legal basis for regulating informed consent in hospitals. This law stipulates that every medical procedure performed by healthcare professionals must obtain the patient's consent after the patient has been given adequate explanation regarding the procedure, benefits, risks, and available alternatives. This provision strengthens the patient's right to bodily autonomy and ensures that medical actions are carried out based on valid consent. The law aims to protect patients' rights while also reducing the potential for legal disputes related to medical malpractice. However, in practice, many hospitals face various challenges, such as limited time available to provide detailed explanations of medical procedures to patients and patients' insufficient understanding of the information provided. This results in a gap between legal regulations and actual practice in the field. In many cases, informed consent forms are treated merely as administrative procedures without ensuring that patients truly understand the information given. This inconsistency creates potential legal risks for healthcare professionals and healthcare institutions.

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