The Validity of Electronic Informed Consent in Hospital Services: A Juridical Analysis Based on Law Number 17 of 2023 on Health

Gladdays Naurah, Marice Simarmata

Abstract

The digitalization of healthcare services has transformed the process of obtaining informed consent, introducing electronic informed consent (e-consent) as a tool to enhance efficiency, transparency, and legal accountability. This study aims to analyze the juridical validity of e-consent in hospital services within the framework of Indonesian law, particularly Law No. 17 of 2023 on Health. Employing a normative juridical research approach, the study examines primary legal sources, including statutes, ministerial regulations, medical codes of ethics, and relevant Supreme Court rulings, as well as secondary sources from scholarly literature. The findings indicate that e-consent can be considered legally and ethically valid if it fulfills key requirements: clear and comprehensive information, patient understanding, and voluntary consent, supported by robust authentication and data integrity mechanisms. Law No. 17/2023 affirms patients' rights to information and voluntary decision-making, while implementing regulations and ethical standards ensure procedural clarity and accountability for healthcare providers. The study concludes that e-consent represents a legally recognized instrument, capable of safeguarding patient autonomy, enhancing administrative efficiency, and providing legal protection in medical practice. This research contributes to the development of normative frameworks for integrating digital consent mechanisms into Indonesian healthcare services, offering guidance for policymakers and practitioners in implementing e-consent systems aligned with both legal and ethical standards.

***Keywords**:* Electronic Informed Consent, Law No. 17/2023, Juridical Analysis.

Gladdays Naurah
Master of Health Law, Universitas Pembangunan Panca Budi, Medan, Indonesia
e-mail: gladdays.naurah@ui.ac.id

Marice Simarmata
e-mail: ichesmart@yahoo.co.id

Introduction

The development of information technology in the healthcare sector has brought significant changes to the delivery of medical services, including the procedures for obtaining patient consent for medical actions. Digital transformation has encouraged hospitals to shift from conventional paper-based systems to electronic systems that offer efficiency, speed, and accuracy in administrative processes as well as legal protection. One crucial aspect that has undergone this transformation is the mechanism of informed consent namely, the patient's agreement to medical procedures after receiving sufficient information from healthcare providers. In the context of digitalization, electronic informed consent (e-consent) has emerged, raising new issues regarding legal validity, personal data security, and the protection of patient rights under the existing national regulatory framework [1].

Electronic informed consent is a form of patient agreement provided through digital media using electronic signatures or other digital authentication mechanisms. In practice, e-consent functions not only as an administrative proof but also as a legal instrument that confirms mutual understanding between doctors and patients regarding the medical procedures to be performed. The electronic format allows the consent process to be more efficient, particularly in emergency situations or telemedicine services [2]. However, the implementation of e-consent requires high-security standards to ensure that patient data is not misused and that the consent process genuinely reflects the patient's free will. Provisions regarding electronic signatures in Law Number 11 of 2008 on Electronic Information and Transactions (ITE Law) and its implementing regulations provide legal legitimacy for electronic documents but do not specifically regulate the mechanisms and procedures for informed consent in healthcare. Therefore, legal interpretation of e-consent must consider the synchronization between the ITE Law, the new Health Law, and medical ethical principles to ensure its implementation guarantees legal certainty while protecting patient rights [3].

Previous studies have shown that the use of e-consent in healthcare facilities has been implemented in several countries with strong legal foundations and technological infrastructure. Research by Andriani, indicates that electronic informed consent systems can enhance patient understanding of medical procedures while strengthening transparent communication between doctors and patients [4]. Meanwhile, studies by Ni'mah, highlight potential risks of data breaches and legal uncertainty if not explicitly regulated under legislation. In Indonesia, discourse regarding the legal validity of e-consent remains limited, as most literature focuses on ethical and administrative aspects without examining its position within the positive legal system, especially following the enactment of Law Number 17 of 2023 on Health [3].

Law Number 17 of 2023 introduces a new paradigm in healthcare delivery by emphasizing digitalization, patient data protection, and the right to transparent medical information. However, the provisions of this law do not explicitly regulate the validity mechanism of informed consent in electronic form, raising debates concerning compliance with the principles of legality, prudence, and patient autonomy [5]. This legal gap is a critical issue considering the common practice of using digital signatures, electronic data storage, and hospital information systems, which may intersect with privacy rights and the legal responsibilities of healthcare providers.

The absence of clear legal norms regarding the validity of electronic informed consent raises a fundamental question: can this form of consent be considered legally valid under Indonesian positive law, and to what extent does Law Number 17 of 2023 provide a basis of legitimacy for its use in hospital practice? This issue is essential to examine, as the enforceability of e-consent involves not only administrative validity but also the legal protection of patients and healthcare providers, particularly in proving consent in cases of medical disputes.

Based on this background, this study focuses on a juridical analysis of the validity of electronic informed consent in hospital services in accordance with the provisions of Law Number 17 of 2023 on Health. The study aims to identify the legal foundations that support or limit the use of e-consent, analyze the relevant legal principles, and provide a normative interpretation regarding the legal status of informed consent within the national healthcare legal system. Thus, this research is expected to contribute scientifically to strengthening legal understanding in the field of healthcare digitalization while serving as a reference for policymakers and medical practitioners in implementing e-consent systems that comply with legal principles and medical ethics in Indonesia.

Literature Review

Informed consent is a communication process between healthcare providers and patients aimed at ensuring that patients understand the risks, benefits, and alternatives of medical procedures before giving their consent. This principle is rooted in patient autonomy, the right to information, and legal protection regarding medical actions, making it ethically and legally valid when consent is given voluntarily and based on full understanding. In the context of digitalization, electronic informed consent (*e-consent*) has emerged as an evolution of the traditional concept, in which patient consent is obtained through digital media using electronic signatures or other digital authentication methods [6]. Conceptually, e-consent still emphasizes three main elements: clear information, patient understanding, and voluntary agreement. Electronic systems allow for more interactive information delivery and more structured documentation, but they also present new challenges related to data security, the authenticity of consent, and compliance with applicable legal regulations. Moreover, e-consent functions not only as administrative evidence but also as a legal instrument that confirms the rights and obligations of both patients and healthcare providers. This concept must align with digital law principles, including the legitimacy of electronic signatures and personal data protection, to ensure that electronically obtained consent carries the same legal weight as conventional consent [7].

The development of electronic informed consent (*e-consent*) also emphasizes flexibility in delivering medical information according to patient needs. Information can be provided through various digital media, such as interactive forms, educational videos, or hospital portals, allowing patients to review the material repeatedly and make more informed decisions. Furthermore, e-consent supports integration with Electronic Health Record (EHR) systems, making the documentation process more efficient and auditable. However, the implementation of e-consent raises challenges regarding legal validity if electronic signatures do not meet authentication standards regulated under the ITE Law or related implementing regulations on electronic systems and transactions. Electronic consent must also consider patient capacity, particularly for patients with limited technology skills or digital literacy, to ensure that the principles of informed consent adequate information, understanding, and voluntariness are maintained. From an ethical perspective, e-consent must ensure that digital interactions do not reduce patients' opportunities to ask questions, refuse, or choose alternative medical actions, thereby preserving patient autonomy [6].

Research by Kim & Kim (2021) revealed that the use of e-consent in modern hospital services provides administrative efficiency and facilitates medical audits, but it also poses challenges in ensuring the authenticity of electronic signatures and patient authentication evidence [8]. Meanwhile, Punia emphasized that personal data protection is the most vulnerable aspect of e-consent implementation, especially if digital systems do not fully adhere to privacy-by-design principles. In the context of international law, the European Union's General Data Protection Regulation (GDPR) has established strict standards for managing patient personal

data used in e-consent systems, highlighting the importance of transparency, explicit consent, and the right to withdraw consent at any time [9].

In Indonesia, studies on electronic informed consent are still limited and tend to be normative. Previous research, such as that conducted by Berutu, highlighted that the implementation of e-consent in healthcare facilities lacks explicit legal grounds, despite support from Law Number 11 of 2008 on Electronic Information and Transactions (ITE Law) and Government Regulation Number 71 of 2019 on the Implementation of Electronic Systems and Transactions. Both regulations recognize the validity of electronic documents and signatures but do not specifically address e-consent in the context of medical procedures. As a result, a legal vacuum arises, leading to uncertainty in proving consent and legal responsibility in the event of disputes between patients and healthcare providers [6].

Beyond legal aspects, literature also shows the importance of considering ethical dimensions in e-consent. According to Menon et al. (2020), the digitalization of consent processes must not reduce the core moral value of informed consent, namely transparency of information, understanding, and voluntariness. Therefore, any implementation of e-consent must ensure that patients retain the capacity to understand the risks, benefits, and alternatives of proposed medical actions, regardless of the digital medium used [10].

From these various studies, there is an apparent research gap in the national legal context regarding the validity and legitimacy of electronic informed consent under existing legislation, particularly following the enactment of Law Number 17 of 2023 on Health. This study addresses this gap by analyzing the validity of e-consent from the perspective of Indonesian positive law and its compliance with principles of patient autonomy and personal data protection in hospital services.

Research Methodology

This study employs a normative juridical research approach, focusing on the analysis of legislation related to electronic informed consent in hospital services. This approach was chosen to examine the legal basis, legitimacy, and validity of electronic consent under Indonesia's positive law system, particularly Law Number 17 of 2023 on Health and supporting provisions related to information technology and electronic transactions. Data were collected through library research, including primary sources such as laws, government regulations, and implementing regulations concerning healthcare services and electronic documents. Secondary sources, including scholarly journals, books, legal articles, and official publications from relevant institutions, were also used to strengthen the theoretical foundation and provide academic context regarding the concept of informed consent and the digitalization of healthcare services. Data analysis was conducted qualitatively using content analysis methods to interpret the relevance, gaps, and potential legal implications of e-consent use in hospital practice. The study also considers medical ethical principles and patient rights protection as parameters for assessing the legality of electronic informed consent. The results are presented descriptively and argumentatively, connecting legal findings with digital healthcare practices.

Results

4.1 The Use of Electronic Informed Consent in Indonesia

The use of electronic informed consent (*e-consent*) in Indonesian hospitals has begun, particularly in healthcare facilities that have adopted electronic medical record (EMR) systems and digital administrative procedures. This process allows patients to receive information about medical procedures digitally through interactive forms, educational videos, or hospital portals, while giving consent via electronic signatures that hold legal validity in accordance with Law Number 11 of 2008 on Electronic Information and Transactions (ITE Law). Integration of e-consent with electronic medical record systems facilitates documentation, internal audits, and

patient data management, ensuring that each consent can be accounted for both administratively and legally [11].

The implementation of e-consent requires strict authentication standards to accurately verify patient identity and ensure that consent genuinely reflects the patient's free will. The use of encrypted digital signatures and secure data storage systems is crucial to guarantee the integrity of electronic documents. Additionally, the interactive mechanisms in e-consent provide patients the opportunity to review information multiple times, understand risks, benefits, and alternative medical procedures, and ask questions about any unclear aspects. Therefore, e-consent functions not only as an administrative procedure but also as an instrument that upholds the principles of patient autonomy and rights.

However, the implementation of e-consent faces several challenges. Patients' digital literacy affects their understanding of medical information delivered electronically. Those who are less familiar with technology may have difficulty reading or signing consent forms, requiring hospitals to provide additional guidance or direct assistance to ensure consent remains valid and voluntary. Personal data security is also a primary concern, as digitally stored information is vulnerable to breaches or misuse if systems lack adequate encryption and access controls.

Provisions in Law Number 17 of 2023 on Health emphasize patients' rights to sufficient information and voluntary consent before undergoing medical procedures. Although this law does not specifically regulate e-consent, its principles can be interpreted to support the use of electronic media, provided that the consent procedure fulfills the elements of information, understanding, and voluntariness. This ensures that e-consent is legally valid if applied with attention to authentication standards, data protection, and patient education, giving electronic consent the same legal weight as conventional consent [10].

The majority of physicians using electronic medical record (EMR) systems show high confidence in the potential of digital technology to improve service quality and clinical outcomes. Pahlevi found that 58.1% of physicians believe EMR can significantly enhance patient care. Conversely, individuals reluctant to adopt this technology tend to maintain skepticism about EMR's ability to improve healthcare quality. This phenomenon indicates that trust in digital technology is a critical factor in the implementation of health innovations, including e-consent, as effectiveness largely depends on healthcare providers' acceptance and understanding [11]. The lack of statistical data or empirical evidence regarding EMR and e-consent use in some hospitals remains an obstacle for those unfamiliar with digital systems, hindering wider adoption.

Experiences from e-consent implementation in hospitals show that digital systems can improve administrative efficiency, enhance transparency in communication between patients and healthcare providers, and facilitate proof of valid consent in case of disputes. Integration of e-consent with EMR systems allows real-time monitoring and internal audits, increasing accountability in healthcare services. The success of e-consent implementation depends on the harmony between technology, operational procedures, and compliance with legal and ethical principles in medicine, ensuring patient rights are protected without reducing service effectiveness.

Healthcare providers' perceptions of risks to professional autonomy influence their responses to the adoption of digital technology, including e-consent. Adrian emphasized the importance of active support and engagement from medical staff for the effective implementation of digital systems. In the Indonesian regulatory context, Minister of Health Regulation No. 24 of 2022 governs the Ministry of Health's responsibility to ensure smooth implementation of electronic medical records in hospitals, including in remote areas. In the event of a shortage of trained personnel, system management may be delegated to healthcare workers who have received relevant training. Government strategies, such as mapping hospital readiness through a digital maturity index, are important steps to ensure hospitals can

effectively adopt digital technology. This approach is highly relevant to the implementation of e-consent, as institutional readiness, support from healthcare personnel, and clear operational standards are key factors in its validity and successful application [12].

4.2 Legal Analysis of Electronic Informed Consent in Hospital Services

Conceptually, informed consent represents the manifestation of patient autonomy, the right to sufficient information, and voluntary agreement prior to medical procedures. The transformation of consent into an electronic form introduces new challenges regarding authentication, data integrity, and legal certainty, making a legal analysis crucial to ensure that e-consent holds the same legal validity as conventional consent. In practice, e-consent must meet three main elements that serve as the foundation of legal and ethical principles: clear information, patient understanding of that information, and consent given voluntarily. Digital systems enable the delivery of information through interactive forms, educational videos, or hospital portals, allowing patients to review, comprehend, and ask questions regarding medical procedures. Encrypted electronic signatures serve as an authentication tool, ensuring document integrity and patient identity certainty. This combination ensures that electronic consent can be legally and administratively accounted for while enhancing documentation and internal audit efficiency within healthcare facilities.

The presence of informed consent in healthcare aims to protect patients from arbitrary actions by healthcare providers. In cases of medical malpractice, a breach of contract or unlawful act may occur if a physician violates agreements made with the patient at the outset, leading to legal consequences. Physicians, in practicing their profession, bear legal responsibilities that can be examined from criminal, civil, and administrative law perspectives. In civil law, informed consent in the doctor-patient relationship arises from two legal concepts. First, *ius contractu*, or contractual obligations, is the branch of law governing agreements or contracts between involved parties. It encompasses contract formation, fulfillment of obligations, dispute resolution, and legal remedies in case of breaches. Essentially, *ius contractu* focuses on the rights and obligations arising from agreements and the legal rules governing them. Second, *ius delicto* regulates violations or unlawful acts. It includes the definition of offenses, legal responsibility, sanctions, principles of causality, and accountability for actions deemed breaches of legal norms.

Regarding criminal law, informed consent must adhere to the principle of legality. This principle emphasizes the necessity that every medical procedure or healthcare action involving patients is based on legally valid consent. The provision of information must cover all relevant aspects, such as diagnosis, risks, and treatment alternatives. Patients must give consent voluntarily, without coercion. Patient understanding of the information provided is also a key focus, ensuring decisions are made with adequate knowledge. The process of obtaining informed consent should always be documented in accordance with the law, creating clear and valid records of patient consent. Furthermore, the principle of legality requires healthcare providers and medical personnel to comply with existing regulations and healthcare standards, providing a strong legal basis to protect patient rights and ensure the integrity of the informed consent process in healthcare services.

The principle of legality is codified in Article 23 of Law No. 17 of 2023 on Health, which stipulates that healthcare professionals must perform health procedures in accordance with their expertise and authority. This means that the legality of healthcare services is ensured when healthcare providers meet the required qualifications and permits as regulated, including possession of registration certificates and practice licenses. Ministerial Regulation No. 290 MENKES/PER/III/2008 addresses medical consent, which involves patient or family approval after receiving complete information about the intended medical procedures. Article 1(b) defines it as preventive, diagnostic, therapeutic, or rehabilitative actions performed by a

physician. Detailed information about medical procedures includes diagnosis, objectives, risks, alternatives, complications, prognosis, and estimated costs.

Rezki Pebrina notes that the information provided to patients should include inherent risks, potential side effects, alternatives, and consequences of not undergoing the procedure. Article 2(1) states that all medical procedures require consent, either written or verbal. In practice, consent may be given verbally or in writing, depending on the type of procedure, such as surgery. Consent may also be presumed in emergencies if the physician must act immediately in the patient's best interest when the patient is unconscious and family members are unavailable (presumed consent) [12].

Law No. 29 of 2004 regarding Medical Practice regulates the framework for medical practice, based on Pancasila and scientific values, emphasizing benefit, justice, humanity, balance, and the protection and safety of patients. Law No. 40 of 2009 concerning Hospitals establishes the relationship between patients and hospitals, outlining hospitals' obligations to provide safe, quality, and effective healthcare services. Patients have rights and obligations, including choosing a physician, requesting consultations, obtaining security, and submitting feedback or complaints about hospital services. Medical procedures must obtain patient consent, and hospitals have the obligation to refer patients requiring services beyond their capacity. Health law also regulates legal relationships between hospitals and patients in emergencies, prohibiting refusal of treatment and imposing sanctions for failing to provide first aid to critically ill patients.

Hospitals function as socio-economic institutions that care for the underprivileged, protected under the doctrine of Charitable Immunity in the United States. Legal recognition as a "person" grants the hospital autonomy to undertake legal actions while being subject to rights and obligations according to norms, particularly in the context of establishing foundations for private hospitals.

From the above, it can be concluded that in Indonesia, informed consent is examined from a legal perspective through various healthcare regulations. Key points regarding informed consent from a juridical standpoint include:

1. Law No. 17 of 2023. This law stipulates that patients have the right to receive sufficient, clear, and accurate information about their health situation, including available treatment options. Physicians or healthcare providers are obligated to convey this information before obtaining patient consent for medical procedures, enabling informed decision-making.
2. Ministry of Health Regulations. These regulations provide details regarding procedures and standards for obtaining informed consent, including communication protocols, required documentation, and handling situations where patients are unable to provide direct consent.
3. Medical Ethics Code. This ethical framework obligates physicians to provide adequate information in comprehensible language, allowing patients to ask questions or seek clarification regarding proposed medical treatments.
4. Supreme Court Decisions. These decisions reflect how legal interpretations of informed consent are applied in specific cases, offering guidance and legal precedent for healthcare practitioners while clarifying legal responsibilities in the context of informed consent.

Together, these aspects create a strong legal and ethical foundation to protect patient rights and ensure active patient participation in healthcare decisions.

Conclusion

Electronic informed consent (e-consent) in hospital services represents the implementation of patient autonomy, the right to sufficient information, and voluntary

agreement that must be fulfilled before medical procedures are performed. The implementation of e-consent requires standards for authentication, data integrity, and patient education procedures to ensure that the information provided is fully understood, making the consent legally and ethically valid. Integration of e-consent with electronic medical record systems enhances documentation efficiency, transparency of communication between patients and healthcare providers, and facilitates verification of consent in case of disputes. The success of its implementation depends on the synergy between technology, operational procedures, and adherence to legal and medical ethical principles.

From a legal perspective, various regulations in Indonesia, including Law No. 17 of 2023 on Health, the Electronic Information and Transactions Law (UU ITE), Ministry of Health regulations, medical codes of ethics, and Supreme Court rulings, provide a strong legal basis for the implementation of e-consent. Law No. 17/2023 emphasizes patients' rights to obtain sufficient information and make decisions voluntarily, while implementing regulations and codes of ethics clarify procedures and the responsibilities of healthcare providers. Therefore, e-consent can be considered legally and ethically valid as long as procedures are conducted according to established standards, providing legal certainty for both patients and healthcare providers, and supporting safe, transparent, and accountable hospital services.

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