

HEALTH LAW, ETHICS, AND CONSENT: INDONESIAN PERSPECTIVES

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Abstract: Informed consent is an important mechanism for protecting patient autonomy and rights in healthcare services. However, its implementation in Indonesia remains problematic because informed consent may be influenced by clinical paternalism and systemic pressures, causing it to be treated as an administrative requirement rather than a meaningful ethical process. This study examines the polemic of informed consent by analyzing the tension between patient autonomy, clinical paternalism, and administrative practices in the Indonesian health system. This study employs a qualitative medico-legal approach using legislation, professional ethical standards, international ethical instruments, scholarly literature, and relevant legal precedents as secondary data, analyzed conceptually and comparatively. The findings show that the main problem is not the absence of legal requirements for informed consent, but the gap between its formal regulation and implementation in clinical practice. Limited consultation time, high workloads, resource constraints, and unequal doctor-patient relationships may weaken meaningful patient participation in decision-making. This study contributes to strengthening the understanding of informed consent as a substantive ethical-legal process based on patient autonomy and shared decision-making, rather than merely an administrative formality.

Informed consent merupakan mekanisme penting dalam melindungi otonomi dan hak pasien dalam pelayanan kesehatan. Namun, penerapannya di Indonesia masih menghadapi berbagai permasalahan karena informed consent dapat dipengaruhi oleh paternalisme klinis dan tekanan sistemik, sehingga lebih sering diperlakukan sebagai persyaratan administratif daripada sebagai proses etis yang bermakna. Penelitian ini mengkaji polemik informed consent dengan menganalisis ketegangan antara otonomi pasien, paternalisme klinis, dan praktik administratif dalam sistem kesehatan Indonesia. Penelitian ini menggunakan pendekatan medico-legal kualitatif dengan memanfaatkan peraturan perundang-undangan, standar etika profesi, instrumen etika internasional, literatur ilmiah, dan preseden hukum yang relevan sebagai data sekunder, yang dianalisis secara konseptual

dan komparatif. Hasil penelitian menunjukkan bahwa permasalahan utama bukan terletak pada ketiadaan persyaratan hukum mengenai informed consent, melainkan pada kesenjangan antara pengaturan formal dan penerapannya dalam praktik klinis. Keterbatasan waktu konsultasi, beban kerja yang tinggi, keterbatasan sumber daya, serta ketidakseimbangan hubungan antara dokter dan pasien dapat melemahkan partisipasi pasien secara bermakna dalam pengambilan keputusan. Penelitian ini berkontribusi dalam memperkuat pemahaman bahwa informed consent merupakan proses etis-hukum yang substantif, yang berlandaskan pada otonomi pasien dan pengambilan keputusan bersama (shared decision-making), bukan sekadar formalitas administratif.

Keywords: *Informed Consent; Patient Autonomy; Clinical Paternalism; Health Law; Medical Ethics.*

INTRODUCTION

Quality healthcare services not only emphasize advanced technology and the competence of medical personnel, but must also uphold patient rights (Nur Seha, HN, Putri, SI, Andrianty, AA, & Noor, AY 2024). One form of respect for these rights is through the informed consent mechanism: approval for medical treatment given after the patient has received complete information about the medical condition, treatment options, risks, benefits, and treatment alternatives in a clear and easy-to-understand manner. (Susila 2012) From an ethical perspective, patient autonomy is the primary basis for informed consent. International documents such as the Nuremberg Code (1947) and the Belmont Report (1978) emphasize that medical interventions are only legitimate if the patient gives free and informed consent (Ismiyati Jennie and Yuni Lestari 2019). Furthermore, the Declaration of Helsinki (revised 2013) requires that consent be continuously reflected throughout the course of medical care or research (Widjaya 2022). In terms of benefits, informed consent has been proven to improve the quality of communication between doctors and patients, strengthen trust, and serve as a legal protection tool for medical personnel because it proves the patient's understanding and agreement (Yuliana 2024). In Indonesia, the legal obligation to carry out this procedure has been stipulated through Law Number 17 of 2023 concerning Health and Minister of Health Regulation No.290/Menkes/Per/III/2008 concerning Approval of Medical Actions (Priyadarshini 2025).

Its implementation in the field still faces many obstacles. Studies at various hospitals, including Dr. Sardjito General Hospital, have shown that incomplete documentation, ineffective communication, a paternalistic culture, and low patient literacy are significant obstacles (Suhartini 2004). Although the legal framework and ethical standards related to informed consent have been comprehensively regulated, its implementation in the field still faces significant obstacles. Several studies in Indonesia have shown that administrative,

cultural, communication, and patient literacy issues are key barriers to effective informed consent implementation. One study at Dr. Sardjito General Hospital in Yogyakarta revealed that informed consent documentation is often inadequate, both in terms of administration and the substance of the information provided to patients (Rahayu and Sarwinanti 2014). Furthermore, communication between doctors and patients is often one-sided, with minimal explanations and a greater emphasis on formal consent than participatory dialogue. A similar study conducted at Haji Adam Malik General Hospital (RSUP) Medan found that the majority of informed consent forms contained only procedural approval without a comprehensive explanation of risks, alternative procedures, or potential medical consequences (Paramarta, NB, Nyandra, M., and Nurata 2023). These findings indicate that the informed aspect of informed consent is not fully understood and implemented by medical personnel.

Furthermore, several regional hospitals in East Java have revealed that a paternalistic culture still dominates medical practice, with medical decisions largely determined by doctors without the active involvement of patients. This asymmetrical relationship is exacerbated by low public health literacy, leading patients to be passive and leave medical decisions entirely to doctors (Setiawan and Sari 2021). Similar phenomena occur not only in Indonesia, but also in the United States, where ineffective informed consent is common among populations with low levels of education, language barriers, and socioeconomic backgrounds. Even in countries with advanced health systems, communication barriers, knowledge gaps, and unclear information remain critical issues in the informed consent process. An internationally recognized case of failed informed consent occurred in the practice of forced sterilization in the United States in the 1960s and 1970s, where women from ethnic minority groups underwent medical procedures without their knowledge or valid consent (Roberts, 1997) (Shepherd, L.D., and Smith 2023). This case underscores the importance of informed consent as a protective mechanism against human rights violations in healthcare. Furthermore, in Morocco and Senegal, informed consent is often understood in everyday clinical practice as simply signing an administrative form, without adequate explanation of the medical procedure to be performed (Hyder et al. 2014). Cultural factors, power relations, and doctors' limited time are the causes of the weak implementation of the principle of informed consent in these countries.

These findings demonstrate that the problem of informed consent cannot be understood solely as a matter of incomplete documentation or administrative compliance. The central issue lies in the tension between patient autonomy and clinical paternalism, as well as between informed consent as an ethical communication process and consent as an administrative requirement. In addition, clinical informed consent must be distinguished from research informed consent. The Nuremberg Code, Belmont Report, and Declaration of Helsinki primarily provide important ethical foundations in the context of human-subject research, whereas informed consent in clinical practice concerns the patient's decision to accept or refuse medical treatment. Therefore, these instruments are used in this study as

ethical foundations for the principle of autonomy and voluntary consent, rather than as direct regulatory standards for every clinical medical procedure. The existing literature generally discusses informed consent from separate perspectives, including documentation completeness, patient rights, communication, medical ethics, or legal protection. However, these perspectives have not sufficiently explained how the interaction between patient autonomy, clinical paternalism, and systemic pressures can transform informed consent into an administrative formality in actual healthcare practice. This gap is important because the existence of a signed consent form does not necessarily establish that the patient has received, understood, and voluntarily considered adequate information before making a decision.

Therefore, this study aims to examine the position of informed consent as a foundation for respecting patient autonomy and fulfilling the legal responsibilities of medical personnel; identify the main challenges in the implementation of informed consent and its ethical and legal implications; and analyze the tension between ethical requirements and clinical realities in the implementation of informed consent in the Indonesian health system. These findings demonstrate that the obstacles to implementing informed consent are complex and multidimensional. Furthermore, the Supreme Court ruling has clarified that medical procedures without valid informed consent can be categorized as administrative malpractice (Sosiawan et al. 2023). It's not just about technical documentation issues, but also closely related to cultural factors, interpersonal communication, public health literacy, and the unequal relationship between patients and medical personnel. Therefore, improving the implementation of informed consent requires a comprehensive approach that includes patient education, effective communication training for medical personnel, reform of the healthcare culture, and strengthening the monitoring and evaluation system for informed consent procedures in healthcare facilities. Modern therapeutic models demand a shift from a paternalistic approach by physicians to an approach based on patient autonomy (Arimbi, Muflihatin, and Muna 2021). Therefore, an interdisciplinary analysis combining medical ethics and health law perspectives is essential to identify solutions that are not only theoretical but also applicable in daily practice. Therefore, this study aims to examine the position of informed consent as a foundation for respecting patient autonomy and fulfilling the legal responsibilities of medical personnel; identify the main challenges in the implementation of informed consent and its ethical and legal implications; solve the legal ambiguity and inconsistency regarding the obligation of informed consent in the Indonesian Health System and examine the position of informed consent as a foundation for respecting patient autonomy and fulfilling the legal responsibilities of medical personnel.

RESEARCH METHOD

This type of research is medico-legal research. This type of research combines health research with legal research. This medico-legal research analyzes issues related to health law, particularly regarding the status of informed consent in healthcare services in Indonesia. The data used is secondary data processed qualitatively (Soekanto, S dan Mamudji 2021). The data

used in this study were obtained from library research. Library research is a data collection technique that utilizes various literature related to all aspects of law in Indonesia, such as laws and regulations, books, scientific articles, lecture materials, and other secondary data sources relevant to the object of this article. This study employs several approaches, namely the statutory approach, conceptual approach, case approach, and comparative approach. The statutory approach is used to examine the Indonesian legal framework governing informed consent, particularly Law Number 17 of 2023 concerning Health and relevant ministerial regulations. The conceptual approach is used to analyze the concepts of patient autonomy, informed consent, clinical paternalism, beneficence, and shared decision-making. The case approach is used to examine relevant judicial decisions concerning informed consent, while the comparative approach is used to compare the development of informed consent principles in selected international legal and ethical frameworks.

The sources were selected based on their relevance to the research focus, authority, and contribution to the analysis of informed consent. The primary legal materials consist of relevant laws and regulations, professional ethical standards, and relevant judicial decisions. Secondary materials consist of books, scientific articles, and academic literature discussing informed consent, medical ethics, patient autonomy, and health law. International ethical instruments are used as supporting materials to explain the development of the principles underlying informed consent. The collected materials were analyzed qualitatively through identification, classification, interpretation, and comparison. First, the relevant legal and ethical provisions were identified and classified according to the issues of consent, patient autonomy, clinical paternalism, and professional responsibility. Second, these provisions were interpreted in relation to the concepts developed in the scholarly literature. Third, relevant cases and international frameworks were compared to identify similarities, differences, and developments in the understanding of informed consent. The results of the analysis were then synthesized to explain the gap between the normative requirements of informed consent and its implementation as an ethical process in clinical practice.

RESULT AND DISCUSSION

Informed Consent: Upholding Patient Autonomy and Medical Legal Duties

Informed consent in modern medical practice, consent to medical procedures given consciously and voluntarily by the patient plays a very fundamental role, both in ethical and legal dimensions (Lebang and Zukriadi 2023). In simple terms, informed consent can be defined as a communication process between medical personnel and patients, in which patients are given sufficient, clear, accurate, and understandable information regarding the diagnosis, medical treatment options, possible risks and benefits, and other treatment alternatives, before the patient gives consent to the action to be taken (Rizka et al. 2023). In this context, informed consent is not merely an administrative procedure or formality, but rather a manifestation of a key ethical principle in healthcare: respect for individual

autonomy. Patient autonomy refers to the right of every individual to make their own decisions regarding their body and health without coercion from others, including medical personnel. Within the framework of biomedical ethics, respect for autonomy is one of the four fundamental principles, along with beneficence, non-maleficence, and justice. The principle of autonomy requires that all medical interventions be based on the patient's voluntary consent, provided they have received sufficient and adequate information. Therefore, informed consent is a crucial tool in ensuring that a patient's right to self-determination is fully respected. Without informed consent, medical procedures performed on a patient could potentially be considered a violation of human rights and could even be categorized as unlawful acts such as abuse or unauthorized acts that violate the patient's physical integrity.

Patient autonomy, informed consent, and shared decision-making are therefore closely interconnected. Autonomy provides the ethical basis for the patient's right to decide, while informed consent provides the process through which that right can be exercised. Shared decision-making strengthens this process by placing the patient and medical professional in a communicative relationship in which relevant medical information, available alternatives, risks, benefits, and the patient's values and preferences are considered before a decision is made. Thus, informed consent should not be understood merely as the patient's acceptance of a medical procedure, but as a continuing communication process that enables the patient to participate meaningfully in decisions concerning their health. More than simply respecting patient rights, informed consent is also a crucial tool for ensuring that medical personnel fulfill their legal and professional obligations. In practice, medical personnel are required to possess good communication skills so that the information conveyed is not only comprehensive but also understandable to patients, including those with low educational backgrounds or emotionally unstable conditions.

Furthermore, within the broader framework of legal protection, informed consent has implications for fulfilling the right to dignified healthcare, in accordance with the principles of international human rights law. Patients have the right to know and choose the type of medical services they receive, and this cannot be disregarded solely on the pretext of medical professionalism. Therefore, informed consent is not only important in a formal legal context, but also as a key pillar in upholding the principles of justice and protecting human dignity in national and global healthcare systems. Informed consent is the primary foundation for ensuring respect for patient autonomy and is a concrete manifestation of medical personnel's fulfilment of their legal responsibilities. It embodies the values of ethics, professionalism, and legality, integrated into a crucial process in every medical procedure. Raising awareness and understanding of the importance of informed consent is an essential step in realizing equitable, transparent, and human rights-based healthcare.

It is important, however, to distinguish between a consent form and informed consent. A consent form is a document used to record or evidence the patient's decision, whereas informed consent refers to the substantive process through which relevant information is

communicated, understood, considered, and voluntarily accepted by the patient. Therefore, the existence of a signed consent form cannot by itself establish that meaningful informed consent has occurred. The legal and ethical significance of the document depends on whether the underlying communication process was adequate and whether the patient's decision was voluntary and informed. This distinction is particularly important in assessing the legal responsibility of medical personnel. Documentation may provide evidence that a consent process was recorded, but it should not replace the professional obligation to provide appropriate information and facilitate patient participation. Consequently, the responsibility of medical personnel is not exhausted by obtaining a signature but extends to ensuring that the information is sufficiently clear, relevant, and understandable in accordance with the patient's circumstances.

Informed consent may also have evidentiary and legal significance in disputes between patients and medical personnel. Proper documentation can help demonstrate that communication and consent procedures were undertaken. However, informed consent should not be understood as an instrument that automatically protects medical personnel from malpractice claims or establishes the legality of every medical action. Consent does not eliminate professional responsibility for negligence, inappropriate treatment, or failure to meet applicable professional standards. Its legal significance therefore lies in demonstrating that the patient was given an opportunity to make an informed and voluntary decision, while the medical professional remains responsible for providing care in accordance with professional and legal standards.

The position of informed consent therefore reveals the central polemic discussed in this study. On the one hand, the principle of autonomy requires patients to have meaningful control over decisions concerning their bodies and health. On the other hand, medical professionals have duties based on beneficence and non-maleficence to protect patients from harm. The tension becomes more complex when clinical conditions, limited consultation time, unequal knowledge, emergency situations, and institutional pressures affect the communication process. In such circumstances, professional judgment may become dominant and reduce the opportunity for patients to participate actively in decision-making. The problem is therefore not necessarily the existence of medical professional judgment itself, but the possibility that such judgment may displace the patient's opportunity to make an informed decision. The ethical challenge is to maintain an appropriate balance between professional responsibility and respect for patient autonomy. In this context, informed consent functions as a mechanism for maintaining dialogue between the two, rather than merely as evidence of administrative compliance.

Accordingly, informed consent should be positioned as a substantive ethical and legal process. Its effectiveness depends not only on the existence of regulations or written documentation, but also on the quality of communication, patient understanding, voluntariness, and meaningful participation in decision-making. This understanding places informed consent at the intersection of patient autonomy, professional responsibility, and

legal accountability within healthcare services. More than simply respecting patient rights, informed consent is also a crucial tool for ensuring that medical personnel fulfil their legal and professional obligations. In the context of positive law in Indonesia, the obligation to obtain informed consent from patients is expressly stipulated in several regulations, including Law Number 17 of 2023 concerning Health and more technically outlined in Minister of Health Regulation Number 290/Menkes/Per/III/2008 concerning Consent to Medical Procedures. This regulation explains that any medical or dental procedure that is invasive, or that carries a high risk to the patient's life or health, must be preceded by providing complete information and obtaining consent from the patient or their family. Thus, informed consent is not simply an ethical choice, but a legal obligation that cannot be ignored by medical personnel.

Failure to fulfil the obligation to obtain valid informed consent can have serious legal consequences for healthcare workers. In practice, a number of malpractice lawsuits against medical personnel in Indonesia have arisen due to the lack of proper documentation or informed consent processes. Therefore, informed consent must be in writing and, if possible, accompanied by witnesses or digital recordings to provide legal protection for both patients and medical personnel (Rizkika and Sugiarti 2022). In this case, informed consent not only functions as a tool to protect patient rights, but also as a form of legal documentation that can protect medical personnel from accusations of malpractice, if complications occur later or the results do not meet the patient's expectations. Informed consent, in addition to fulfilling legal responsibilities, also reflects a healthy, transparent, and equal relationship between patients and healthcare professionals. In the era of patient-centered healthcare, the presence of informed consent emphasizes that patients are not objects of medical treatment, but rather active subjects in the medical decision-making process concerning their lives and health (Barry and Edgman-Levitan 2012). Therefore, this process must be conducted in a two-way, unhurried atmosphere, and involve empathy and understanding of the patient's psychological state. In practice, medical personnel are required to possess good communication skills so that the information conveyed is not only comprehensive but also understandable to patients, including those with low educational backgrounds or emotionally unstable conditions.

Furthermore, within the broader framework of legal protection, informed consent has implications for fulfilling the right to dignified healthcare, in accordance with the principles of international human rights law. Patients have the right to know and choose the type of medical services they receive, and this cannot be disregarded solely on the pretext of medical professionalism. Therefore, informed consent is not only important in a formal legal context, but also as a key pillar in upholding the principles of justice and protecting human dignity in national and global healthcare systems. Informed consent is the primary foundation for ensuring respect for patient autonomy and is a concrete manifestation of medical personnel's fulfilment of their legal responsibilities. It embodies the values of ethics, professionalism, and legality, integrated into a crucial process in every medical procedure. Raising awareness and

understanding of the importance of informed consent is an essential step in realizing equitable, transparent, and human rights-based healthcare.

Analyzing the national and international regulatory framework (Laws, Ministerial Regulations, Ethical Standards, Court Precedents); Contemporary medical practice prioritizes a professional relationship between doctors and patients based on the principles of trust, ethics, and law. One manifestation of this relationship is the requirement to obtain informed consent before performing medical procedures. Informed consent is not merely an administrative procedure, but rather a form of recognition of the patient's human right to make choices regarding their body and health. This concept is crucial in preventing the application of informed consent in medical practice from being understood solely as an administrative procedure, but rather as a fundamental ethical and legal principle in guaranteeing patient rights and maintaining the professionalism of medical personnel. In Indonesia, the obligation to obtain informed consent has been comprehensively regulated in statutory regulatory instruments. Law Number 17 of 2023 concerning Health through Article 293 requires that every medical action be carried out after the patient or his/her family has given consent, provided that they have received a complete and honest explanation regarding the diagnosis, procedure, alternatives, risks, and possible complications. At the technical regulatory level, Regulation of the Minister of Health of the Republic of Indonesia Number 290/Menkes/Per/III/2008 provides more detailed details regarding the form, procedures, and documentation of consent for medical procedures, including special provisions in emergency situations. Furthermore, Article 1320 of the Civil Code provides the legal basis for viewing informed consent as a form of therapeutic contract subject to the principles of valid agreements.

In addition to the national legal framework, professional ethical standards and international declarations also provide normative guidelines regarding the obligation to obtain informed consent. The Indonesian Code of Medical Ethics (KODEKI) expressly stipulates that every medical procedure must be based on patient consent, as stipulated in Article 11, and requires doctors to provide adequate information to patients before the procedure is carried out, as stated in Article 13. This standard is in line with international provisions contained in the 2013 World Medical Association Declaration of Helsinki, specifically in Paragraphs 25 and 26, which emphasizes that patient participation in research or medical procedures must be based on consent given voluntarily after obtaining sufficient information. A similar principle is also emphasized in the 2005 UNESCO Universal Declaration on Bioethics and Human Rights, specifically Articles 6 and 9, which places informed consent as an integral part of the protection of human rights in the health sector.

The urgency of implementing informed consent is further strengthened by a number of jurisprudential precedents, both nationally and internationally. In Indonesia, various decisions by the Indonesian Medical Disciplinary Council (MKDKI) and courts demonstrate that failure to obtain patient consent can be the basis for ethical and legal sanctions against medical personnel. Meanwhile, internationally, several landmark decisions have shifted the

paradigm of medical practice regarding informed consent. One of the most influential was the *Canterbury v. Spence*, 464 F.2d 772 (1972) decision in the United States, which affirmed that patients have the right to know all material risks before consenting to medical treatment. In the United Kingdom, the *Montgomery v. Lanarkshire Health Board* (2015) UKSC 11 decision was a significant milestone that shifted standards from previously focusing on what doctors considered important to what patients considered relevant and desired to know in the medical decision-making process.

Informed consent this principle is not merely administrative in nature but also has essential ethical and legal dimensions in the provision of healthcare services. The implementation of appropriate, comprehensive, and well-documented informed consent procedures demonstrates respect for patient autonomy, demonstrates the professional responsibility of medical personnel, and is also an instrument of legal protection within the healthcare system. Violations of this principle, whether through failure to provide adequate information or failure to obtain valid consent, have the potential to result in serious legal and ethical consequences. Therefore, systematic efforts are needed to strengthen regulatory implementation, improve education for medical personnel regarding informed consent obligations, and enforce consistent sanctions for any violations to ensure the delivery of ethical, human rights-based healthcare services that align with applicable legal principles.

Informed Consent: Key Challenges and Legal-Ethical Impacts

From a legal perspective, the lack of clarity regarding standards or standard procedures for implementing informed consent remains an important issue in medical practice. Although regulations such as Law Number 17 of 2023 concerning Health and Minister of Health Regulation Number 290/Menkes/Per/III/2008 concerning Approval of Medical Actions regulate the obligation to obtain informed consent, their provisions need to be examined not only from the perspective of whether consent is formally required, but also from the perspective of how consent must be obtained and what information must be provided to the patient. Informed consent is fundamentally related to the patient's right to make an autonomous decision concerning his or her own body and medical treatment (Djusmalinar 2020). Therefore, the legal validity of consent should not be reduced to the existence of a signature on a consent document, but should also be assessed from the process of information disclosure and the patient's opportunity to make a voluntary decision.

This substantive understanding is reflected more explicitly in Law Number 17 of 2023 concerning Health. Article 293 paragraph (1) provides that every individual health service performed by medical personnel or health workers requires the consent of the patient. Article 293 paragraph (2) further provides that consent must be given after the patient has received adequate information. The information referred to in the provision includes the diagnosis, indications, proposed medical action and its objectives, possible risks and complications, alternative actions and their risks, the risks of refusing the proposed action, and the prognosis following the medical action (Law Number 17 of 2023, Article 293 paragraphs (1) – (3)). This

provision demonstrates that Indonesian law establishes a substantive relationship between the provision of information and the validity of the patient's consent. The requirement of adequate information is particularly important because patients generally do not possess the same medical knowledge as physicians or other health professionals. Differences in medical knowledge can create an imbalance in the clinical relationship, making the quality of communication a determining factor in whether consent is genuinely informed. This is consistent with the argument that differences in health literacy may prevent patients from fully understanding medical information even when such information has formally been delivered (Iqbal et al. 2023). Accordingly, the legal obligation to provide information should be understood as an obligation to facilitate meaningful patient decision-making rather than merely an obligation to deliver technical medical information.

Law Number 17 of 2023 also provides a distinction between oral and written consent. Article 293 paragraph (4) provides that consent may be given orally or in writing, while Article 293 paragraph (5) requires written consent for invasive procedures and/or procedures involving a high level of risk (Law Number 17 of 2023, Article 293 paragraphs (4) – (5)). This distinction demonstrates that Indonesian law does not require a written consent document for every medical action. More importantly, the distinction confirms that the form of documentation should not be confused with the substantive concept of informed consent. Oral consent may constitute legally recognized consent in circumstances permitted by law, while written consent provides documentary evidence of the patient's decision in circumstances where written documentation is required. A consent form should not be treated as synonymous with informed consent. A consent form is a documentary instrument, whereas informed consent is a process involving the disclosure of relevant information, communication between the medical professional and patient, understanding, voluntariness, and decision-making. A signed form may demonstrate that a formal consent procedure has taken place, but it does not necessarily prove that the patient actually understood the diagnosis, risks, alternatives, and consequences of refusing treatment. This distinction is particularly important in malpractice disputes because documentation of consent is only one element in assessing whether the patient's decision was properly informed.

Law Number 17 of 2023 also regulates circumstances in which the patient is unable to provide consent personally. Article 293 paragraphs (6) – (8) regulate the provision of consent by a representative when the patient is unable to make the decision personally (Law Number 17 of 2023, Article 293 paragraphs (6) – (8)). The representative-consent mechanism is necessary to ensure that medical treatment can still be legally authorized when the patient lacks decision-making capacity. However, representative consent should not automatically be understood as an unrestricted transfer of the patient's autonomy to family members. The representative mechanism must instead operate within the legal framework governing the protection of the patient's interests and the circumstances that prevent the patient from providing personal consent. A specific exception applies to emergency circumstances. Article 293 paragraphs (9) – (11) regulate situations in which medical action is necessary in an

emergency but consent cannot be obtained because the patient is incompetent and no representative is available. In such circumstances, medical personnel may undertake the necessary medical action in accordance with the patient's best interests, while subsequent communication must be provided when the patient becomes competent or when a representative becomes available (Law Number 17 of 2023, Article 293 paragraphs (9) – (11)). The emergency exception therefore does not eliminate the principle of informed consent. Rather, it constitutes a legally recognized exception to the ordinary requirement of obtaining prior consent where immediate action is necessary and obtaining consent is objectively impossible.

The provisions of Law Number 17 of 2023 should be analyzed in conjunction with Minister of Health Regulation Number 290/Menkes/Per/III/2008 concerning Approval of Medical Actions. Minister of Health Regulation Number 290/2008 provides specific procedural provisions concerning approval of medical actions and requires that the patient or the closest family member receive an explanation concerning the medical action before it is performed (Minister of Health Regulation Number 290/Menkes/Per/III/2008). The regulation also recognizes written and oral consent depending on the circumstances of the medical action. The relationship between Law Number 17 of 2023 and Minister of Health Regulation Number 290/2008 is legally significant because the two instruments operate at different levels and were enacted at different times. Law Number 17 of 2023 is a later statutory regulation, whereas Minister of Health Regulation Number 290/2008 predates the current Health Law. Therefore, the procedural provisions contained in the 2008 regulation must be interpreted consistently with the substantive requirements established by Article 293 of Law Number 17 of 2023. In particular, the newer law expressly specifies the minimum information that must be provided to patients, including risks, alternative actions and their risks, the risks of refusing treatment, and prognosis. The relationship between the two regulations therefore requires harmonization rather than simply treating them as two independent sources of informed-consent regulation.

The enactment of Law Number 17 of 2023 should not automatically be interpreted as meaning that Minister of Health Regulation Number 290/2008 has no further relevance. The regulation may continue to provide procedural guidance to the extent that its provisions remain consistent with the newer statutory framework. The legal issue is therefore whether the existing procedural provisions sufficiently operationalize the substantive requirements of Article 293. Where provisions remain compatible, they may continue to be applied; where they are inconsistent or insufficiently detailed, harmonization or further regulatory development is required. This distinction is important because the problem lies not simply in the absence of legal regulation, but in the relationship between existing procedural rules and the newer substantive requirements. In addition to statutory regulation, informed consent is also connected with professional ethical standards. The Indonesian Code of Medical Ethics (KODEKI) provides ethical guidance concerning the relationship between physicians and patients and the professional responsibilities of physicians. KODEKI should

therefore be distinguished from statutory regulations such as Law Number 17 of 2023. While the law establishes legally binding obligations, KODEKI operates primarily within the ethical and professional sphere. Nevertheless, both dimensions are relevant to informed consent because the obligation to respect the patient is simultaneously a legal and ethical concern. The distinction is necessary to avoid treating every ethical expectation as a statutory requirement while still recognizing the role of professional ethics in shaping appropriate clinical conduct.

From the perspective of legal disputes, documentation remains important because incomplete documentation may create difficulties in demonstrating what information was provided and how the patient's decision was obtained. However, documentation should not be interpreted as a guarantee that the medical professional is legally protected from malpractice claims. The existence of a signed consent document may constitute evidence, but it does not automatically exclude professional liability where other elements of negligence or violation of professional obligations are established. This is consistent with the observation that inadequate documentation of the informed-consent process may become a weakness for medical personnel in legal proceedings (Sinaga 2022). The Indonesian regulatory framework can further be examined through comparative international jurisprudence, particularly *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972). In that case, the United States Court of Appeals for the District of Columbia Circuit considered the physician's duty to disclose information relevant to a patient's decision concerning medical treatment. The case is significant because informed consent was connected with the patient's right of self-determination and the patient's ability to make a meaningful decision concerning medical treatment (*Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972)).

The significance of *Canterbury* for the Indonesian context is comparative rather than binding. The case provides an analytical perspective for assessing whether informed consent should be understood as a substantive process rather than merely a formal authorization. The emphasis on patient self-determination supports an understanding that information disclosure must enable the patient to participate meaningfully in the treatment decision. This comparative perspective corresponds with Article 293 of Law Number 17 of 2023, which requires disclosure of risks, alternatives, consequences of refusing treatment, and prognosis. Thus, both frameworks place the patient's decision at the center of the consent process, although the legal authority of the two systems is different. A similar development can be identified in *Montgomery v. Lanarkshire Health Board* (2015) UKSC 11. In this case, the United Kingdom Supreme Court examined the physician's obligation to inform the patient of material risks associated with the recommended treatment and reasonable alternative or variant treatments (*Montgomery v. Lanarkshire Health Board* (2015) UKSC 11). The case is important because it places greater emphasis on the patient's involvement in medical decision-making and on information that may be material to the patient's decision.

The relevance of *Montgomery* to the Indonesian framework can be seen in the similarity between the information emphasized by the judgment and the information

expressly required by Article 293 of Law Number 17 of 2023. Indonesian law requires information concerning possible risks, alternative actions and their risks, and the risks of refusing the proposed action. The comparative perspective offered by *Montgomery* therefore reinforces the argument that informed consent should concern information that is relevant to the patient's decision rather than information provided merely to complete an administrative procedure (Law Number 17 of 2023, Article 293; *Montgomery v. Lanarkshire Health Board* (2015) UKSC 11). Nevertheless, *Canterbury v. Spence* and *Montgomery v. Lanarkshire Health Board* cannot be treated as directly binding sources of Indonesian law. Their role in this analysis is comparative and conceptual. The applicable legal standards in Indonesia remain primarily determined by the Constitution, Law Number 17 of 2023 concerning Health, relevant implementing regulations, and applicable professional and ethical standards. The international cases are used to illuminate how the principles of disclosure, autonomy, material risk, alternative treatment, and patient participation can be understood in relation to the Indonesian regulatory framework.

Taken together, the national and international frameworks demonstrate that the principal legal issue concerning informed consent is not simply whether consent has been obtained, but whether the consent reflects a meaningful decision based on adequate information. Law Number 17 of 2023 strengthens the Indonesian legal framework by expressly regulating the content of information, oral and written consent, representative consent, and emergency circumstances. Minister of Health Regulation Number 290/2008 provides procedural guidance that must be interpreted consistently with the newer statutory framework. KODEKI complements these legal requirements from the perspective of professional ethics, while *Canterbury* and *Montgomery* provide comparative perspectives emphasizing self-determination, material risks, alternatives, and meaningful patient participation. This regulatory framework also demonstrates why informed consent represents an important point of tension between patient autonomy and clinical paternalism. Physicians possess specialized knowledge and have professional obligations to protect patients from harm.

However, professional responsibility does not automatically justify unilateral decision-making when a patient has the capacity to decide. The regulatory framework instead requires the medical professional to provide adequate information and respect the patient's decision, subject to legally recognized exceptions such as emergency treatment and situations in which the patient lacks decision-making capacity. Accordingly, the existence of a relatively detailed legal framework does not necessarily guarantee that informed consent will be implemented substantively in clinical practice. The critical issue is whether the statutory requirements concerning disclosure and patient participation are actually realized during the clinical encounter. When limited consultation time, institutional workload, communication barriers, or paternalistic clinical practices reduce the process to the signing of a consent form, a gap may arise between the legal concept of informed consent and its implementation in practice.

This gap provides the basis for examining the broader ethical and legal challenges of informed consent and the tension between ethical principles and clinical realities.

Clarifying Informed Consent Laws in Indonesian Healthcare

The problem of legal ambiguity and inconsistency regarding informed consent obligations in the Indonesian health system should not be understood as the absence of legal regulation. Indonesian positive law already provides a normative basis for informed consent, particularly through Law Number 17 of 2023 concerning Health. The main legal issue lies in the extent to which the statutory provisions can be implemented consistently and operationally in clinical practice, particularly where the statutory framework must interact with older technical regulations and institutional procedures. Therefore, the solution should focus on regulatory harmonization, clarification of operational standards, institutional implementation, and effective supervision rather than merely adding general training, guidelines, or health literacy programs. A specific area requiring clarification concerns the relationship between Article 293 of Law Number 17 of 2023 and Minister of Health Regulation Number 290/Menkes/Per/III/2008 concerning Medical Procedure Consent. Article 293 establishes the obligation to obtain consent for individual health services and distinguishes between oral and written consent, including the requirement for written consent for invasive and/or high-risk procedures. The provision also regulates circumstances involving patients who are unable to provide consent and situations in which emergency treatment must be performed without prior consent. Meanwhile, Minister of Health Regulation Number 290/Menkes/Per/III/2008 provides detailed provisions concerning the procedure for obtaining consent. The regulatory issue therefore does not arise because informed consent is unregulated, but because the older technical regulation must be read and implemented consistently with the newer statutory framework.

The potential inconsistency is particularly relevant to the operational distinction between oral and written consent. Article 293 of Law Number 17 of 2023 recognizes both forms of consent but requires written consent for invasive and/or high-risk procedures. In practice, however, the determination of when oral consent is sufficient, when written consent is mandatory, and how oral consent should be recorded may require a uniform technical standard. Without such standardization, different health facilities may adopt different documentation practices, potentially producing different interpretations of whether the consent requirement has been properly fulfilled. The solution should therefore establish a clear national procedure for determining, recording, and verifying the form of consent required for different categories of medical intervention. A second area requiring operational clarification concerns patients who are unable to provide consent themselves. Article 293 recognizes representative consent in circumstances where the patient is not competent to make the relevant decision. However, the practical implementation of this provision requires clear procedures for determining the patient's capacity, identifying the person legally authorized to act as a representative, verifying that person's authority, and documenting the

basis for representative consent. This is important because a signature from a family member should not automatically be equated with legally valid representative consent. The institutional procedure should therefore establish how the representative is identified and how the decision-making process is documented when the patient lacks decision-making capacity.

A third area requiring clarification concerns emergency circumstances. Indonesian law recognizes an exception to the ordinary requirement of obtaining prior consent where an incapacitated patient requires immediate emergency treatment and a person authorized to provide consent is unavailable. The existence of this exception is important for protecting patients from delays in necessary treatment. Nevertheless, its implementation requires documentation of the emergency circumstances, the patient's condition, the reason prior consent could not be obtained, and the medical basis for the action taken. A clear post-emergency procedure should also be established so that the patient or authorized representative can subsequently receive an explanation regarding the treatment that was performed. Accordingly, the emergency exception should be treated as a narrowly defined and documented exception rather than as a general justification for proceeding without patient participation. The first and most important solution is therefore the harmonization and refinement of the existing regulatory framework. The Ministry of Health should conduct a formal review of Minister of Health Regulation Number 290/Menkes/Per/III/2008 in relation to Law Number 17 of 2023 and its implementing regulations. This review should identify which provisions of the 2008 regulation remain consistent with the current statutory framework, which provisions require adjustment, and which provisions require replacement. Such harmonization is preferable to simply stating that the existing regulation is outdated because it directly identifies the specific provisions that require legal clarification.

The regulatory hierarchy should also be maintained. Law Number 17 of 2023 should remain the primary basis for the substantive obligation to obtain informed consent, while Government Regulations and Ministerial Regulations should provide the necessary implementing details. Health facilities should subsequently translate these requirements into institutional procedures without creating standards that contradict or reduce rights guaranteed by higher-level legislation. In this way, the legal framework can provide both patient protection and greater predictability for medical personnel. The second solution is the issuance of a revised or harmonized Minister of Health Regulation concerning informed consent. The regulation should specifically establish minimum national standards regarding the content of information that must be provided, the circumstances requiring oral or written consent, the classification of invasive and high-risk procedures, assessment of patient capacity, representative consent, emergency treatment, refusal of treatment, and documentation of consent. The regulation should also provide a standardized minimum format for informed consent documentation while allowing appropriate adaptation to different clinical circumstances.

This approach would respond directly to the provision of Law Number 17 of 2023 that delegates the further regulation of informed consent procedures to the Minister of Health. More detailed regulation is therefore necessary not because the statutory obligation is absent, but because the practical implementation of the obligation requires a consistent technical framework applicable across different healthcare facilities. The third solution concerns the responsibility of hospitals and other healthcare facilities. Each healthcare facility should develop and implement a specific Standard Operating Procedure (SOP) on informed consent based on the national regulatory framework. The SOP should regulate the entire consent process rather than merely provide a consent form. It should cover the provision of information, communication with patients, assessment of understanding and decision-making capacity, identification of authorized representatives, procedures for emergency situations, documentation, and post-procedure review.

The responsibility for implementing the SOP should be clearly assigned to the healthcare facility leadership, medical committee, and relevant ethics and legal structures within the institution. The treating medical professional remains responsible for providing the information required for the patient's decision and obtaining the appropriate consent, while the institution is responsible for ensuring that the necessary procedures, forms, documentation systems, and monitoring mechanisms are available. Institutional supervision should also be strengthened. Internal review should not be limited to checking whether a consent form contains the patient's or family's signature. Medical audits or institutional ethics and legal reviews should assess whether the information required by law was actually provided, whether the appropriate person gave consent, whether the consent corresponded to the procedure performed, and whether exceptional circumstances such as emergency treatment were properly documented. This approach would transform informed consent from an administrative requirement into an accountable clinical and legal process.

Professional training remains necessary, but it should be made more specific and directly connected to the identified legal requirements. The Ministry of Health, healthcare facilities, and relevant professional institutions should provide continuing professional education on the practical application of informed consent. The training should include communication of material risks, explanation of reasonable alternatives, documentation of oral consent, assessment of patient capacity, representative consent, emergency treatment, and refusal of medical treatment. In this context, training should not be treated as an isolated solution. It should form part of an institutional compliance system in which healthcare professionals understand both the substantive legal obligations and the procedures established by the relevant SOPs. The effectiveness of training can also be evaluated through periodic audits of informed consent practices (Hendrisman 2024). Patient empowerment should likewise be developed as part of the implementation of informed consent. Healthcare facilities should provide information in language that can reasonably be understood by patients and should provide sufficient opportunity for questions and clarification before a decision is made. Where communication barriers exist, appropriate assistance should be

provided. The objective is not simply to obtain a patient's signature but to ensure that the decision reflects adequate information, understanding, and voluntariness.

This approach is particularly important because informed consent is fundamentally connected to patient autonomy. A consent document that is signed without meaningful communication may satisfy a formal administrative requirement but may not adequately reflect the substantive purpose of informed consent. Therefore, patient education and communication should be integrated into the clinical consent procedure rather than treated solely as a general public literacy program. The roles of professional and regulatory institutions should also be clearly differentiated. The Ministry of Health should have the primary role in regulatory harmonization and the development of national technical standards. Healthcare facilities should be responsible for institutional implementation and internal supervision. Professional institutions should contribute to professional standards, ethical guidance, and continuing education, while the competent regulatory and disciplinary institutions should exercise their respective supervisory and enforcement functions in accordance with applicable law.

This division of responsibility is important because informed consent involves overlapping legal, ethical, professional, and institutional dimensions. Effective supervision therefore requires coordination between these actors while maintaining their respective legal mandates. Sanctions, where applicable, should be imposed through the appropriate legal or disciplinary mechanism rather than through informal institutional practices (Hendrisman 2024). The term “*legal ambiguity*” should therefore be used with precision. The Indonesian legal system does not lack a legal basis for informed consent. Rather, the more specific problem concerns the interface between general statutory obligations and their technical implementation, particularly in relation to oral and written consent, patient capacity, representative consent, emergency treatment, and documentation. The coexistence of Law Number 17 of 2023 with the earlier Minister of Health Regulation Number 290/Menkes/Per/III/2008 makes regulatory harmonization necessary so that the technical provisions are consistently interpreted in accordance with the current statutory framework (Sukmaningsih 2024).

Accordingly, the solution should be implemented through a clear sequence. First, the Ministry of Health should review and harmonize the existing regulations. Second, the Ministry should issue or revise the technical regulation governing informed consent. Third, each healthcare facility should adopt an SOP consistent with the national regulation. Fourth, medical personnel and health workers should receive targeted professional education concerning the revised requirements. Fifth, healthcare facilities should conduct periodic audits of informed consent documentation and practice. Finally, the relevant professional, regulatory, and disciplinary institutions should perform supervision within their respective authorities. This sequence provides a more operational response than a general recommendation for “training”, “guidelines”, or “literacy”. It identifies the responsible actor,

the legal or institutional instrument, and the mechanism through which the solution is to be implemented (Rizkika and Sugiarti 2022).

The ultimate objective is not to eliminate professional judgment from medical practice, but to ensure that such judgment operates within a clear and predictable legal framework. A properly harmonized informed consent system should establish minimum standards concerning the provision of information, patient autonomy, capacity, representative decision-making, emergency treatment, documentation, and accountability while allowing medical professionals to exercise appropriate clinical judgment. Through regulatory harmonization, specific technical standards, institutional SOPs, professional education, patient participation, and effective supervision, the Indonesian health system can reduce inconsistencies in the implementation of informed consent. Such an approach provides protection for patients by strengthening their ability to make informed decisions, while simultaneously providing medical personnel with clearer standards for fulfilling their legal and professional obligations. Informed consent can consequently function not merely as an administrative form, but as a substantive legal and ethical process that structures the relationship between patients and healthcare professionals.

CONCLUSION

The findings of this study demonstrate that the central polemic surrounding informed consent in Indonesia lies not in the absence of legal requirements, but in the gap between formal regulation and its implementation in clinical practice. The tension between patient autonomy and clinical paternalism is further reinforced by systemic pressures, including high workloads, limited resources, time constraints, and an uneven referral system. These conditions may cause informed consent to be treated primarily as an administrative requirement rather than as a meaningful process of communication and shared decision-making. Accordingly, strengthening informed consent requires not only compliance with formal legal requirements but also improvements in the clinical conditions that enable patients to exercise their autonomy effectively. Based on this finding, the implementation of informed consent should be strengthened through three complementary measures. First, the government, particularly the Ministry of Health, should develop clear national guidelines for informed consent applicable to healthcare facilities, including standards for communication, consent procedures, and documentation. Second, Minister of Health Regulation No. 290 of 2008 concerning Consent to Medical Procedures should be reviewed and updated to address developments in medical technology and contemporary healthcare practices, including emergency situations, patient incapacity, and telemedicine. Third, healthcare professionals should receive continuous education and training on the ethical, legal, and communicative dimensions of informed consent. These measures constitute the main contribution of this study: positioning informed consent as a substantive medico-legal process that connects patient autonomy, ethical clinical practice, and legal protection, rather than reducing it to an

administrative formality. This study is limited by its reliance on secondary sources and conceptual-comparative analysis and does not incorporate direct empirical data from patients, healthcare professionals, or healthcare institutions. Future research should therefore examine the implementation of informed consent empirically across different healthcare settings in Indonesia to assess how legal requirements, clinical practices, and systemic conditions interact in actual decision-making processes. [W]

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