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# Towards Equitable Healthcare: Redesigning Informed Consent Regulations

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**Abstract**

*Informed consent is a fundamental element of ethical and legal healthcare practices, serving as a cornerstone for patient autonomy and equitable care. In Indonesia, informed consent is regulated under frameworks such as Law No. 17 of 2023 on Health, Government Regulation No. 28 of 2024, and Ministerial Regulation No. 290 of 2008. While these regulations establish foundational guidelines, they are limited in addressing contemporary challenges, particularly in the communication of medical information tailored to diverse patient needs. This article examines the gaps in the current regulatory framework, particularly regarding the inadequacies in ensuring patient understanding and participation in medical decision-making. The analysis highlights key shortcomings, including the lack of detailed technical provisions for adapting information delivery to various patient conditions, such as those with disabilities, language barriers, or limited literacy. It argues that these gaps undermine the principles of equity and justice, potentially resulting in consent that does not reflect informed patient choice. To address these challenges, the article proposes regulatory reconstructions emphasizing justice, transparency, and inclusivity. Suggested reforms include the mandatory use of digital documentation, enhanced communication technologies, and support systems such as translators or visual aids for vulnerable populations. By integrating these reforms into the legal framework, the healthcare system can foster a more inclusive informed consent process, enhancing patient trust, autonomy, and equity in medical decision-making. These changes are crucial for bridging the gap between ethical theory and practical application in Indonesia's evolving healthcare landscape.*

**Keywords:** *Autonomy, Equity, Healthcare, Inclusivity, Consent.*

## Introduction

National development in Indonesia is centred on advancing the welfare of all its citizens, both materially and spiritually, as outlined in the nation's constitution. This comprehensive development spans various sectors, including economy, politics, social welfare, culture, and security, with healthcare being a critical area of focus. As a developing nation, Indonesia faces significant challenges in ensuring equitable access to quality healthcare. This objective aligns with the principles of Pancasila, emphasizing justice and equality across all regions of the Republic of Indonesia.

Healthcare services in Indonesia aim to maintain and improve public health, prevent and treat diseases, and rehabilitate individuals and communities. These services are essential for ensuring equitable health outcomes for a diverse population. The government has undertaken extensive reforms to enhance healthcare services, striving to ensure that all citizens can access quality medical care. This commitment is enshrined in Law No. 17 of 2023 on Health, which guarantees every citizen the right to a healthy and prosperous life. The law defines health as a state of physical, mental, and social well-being, allowing individuals to lead productive lives as mentioned in Article 1 Point 1 of Law No. 17 of 2023 on Health.

In the Indonesian healthcare system, the relationship between healthcare providers and patients is pivotal. Effective communication and trust underpin this relationship, particularly in medical decision-making processes that require informed consent. The concept of informed consent involves obtaining the patient's approval before performing any medical procedure, ensuring they have adequate understanding of the

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diagnosis, treatment options, risks, and expected outcomes. However, challenges arise from disparities in understanding and power dynamics, which can lead to legal disputes and ethical dilemmas.

The significance of informed consent is reflected in Article 293 of Law No. 17 of 2023, which mandates that healthcare providers must obtain patient consent after delivering comprehensive explanations. This regulation ensures that patients have the autonomy to make informed decisions about their treatment while providing legal safeguards for healthcare professionals. However, ambiguities in the law, particularly concerning potential criminalization of medical practitioners under certain conditions, underscore the need for regulatory reform to uphold justice and equity in healthcare.

Justice is central to informed consent regulations, as it ensures that the rights and obligations of both patients and healthcare providers are balanced. Justice-based regulations must address critical aspects, such as clear communication, patient education, and legal protections for all parties involved. Furthermore, they must align with international ethical standards, as highlighted in bioethics and legal studies on healthcare practices in Indonesia.

In this context, redesigning informed consent regulations offers an opportunity to create a more equitable healthcare system. By addressing the gaps in current policies, Indonesia can enhance patient autonomy, improve legal clarity, and protect the rights of healthcare providers. This paper explores the need for justice-oriented reforms in informed consent regulations, emphasizing their role in fostering a balanced and fair healthcare environment.

## Research Methods

The study adopts a post-positivist paradigm, which frames law as an interpretive object influenced by subjective values. This perspective maintains a clear epistemological distinction between the researcher and the subject, treating law as independent of the researcher's cognitive framework. The research methodology employed is sociological juridical, focusing on systematically describing and interpreting the legal framework and its societal implications. The goal is to analyse the phenomena related to the regulation of public health crises and derive comprehensive insights from empirical findings. Data collection integrates primary and secondary sources. Primary data includes field observations in healthcare facilities such as hospitals and community health centres, while secondary data comprises legal documents, academic literature, and research studies. Sources include Indonesia's constitutional and legislative texts, such as the 1945 Constitution, Law No. 17 of 2023 on Health, and regulations addressing informed consent. Supplementary references include Black's Law Dictionary and medical dictionaries to ensure precise interpretation. Data collection methods involve literature reviews, observations, and interviews. Literature reviews focus on existing laws and scholarly works to understand theoretical and practical gaps. Observations allow direct insights into informed consent practices, while interviews with key stakeholders, possibly through Focus Group Discussions (FGDs), enrich primary data. The study employs qualitative analysis to process data systematically, employing coding, classification, and pattern recognition to derive meaningful conclusions and propose new models addressing equitable informed consent regulations. By combining these approaches, the research aims to redefine informed consent practices, aligning them with the principles of justice and inclusivity in healthcare systems. This framework ensures robust and comprehensive findings contributing to the broader discourse on public health law and ethics.

## Results and Discussion

*Global Perspectives on Informed Consent*

Informed consent is a foundational principle in healthcare, ensuring that patients understand the risks, benefits, and alternatives to any proposed medical treatment or procedure. The evolution and application of this doctrine vary globally, particularly between the United States and other nations, with some key similarities and differences in their legal systems. The concept of informed consent has undergone

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significant development, where it is rooted in the common law tradition, and its influence extends to many other jurisdictions.

The United States, with its Anglo-Saxon legal heritage, has integrated informed consent into its healthcare laws, shaped by both judicial precedents and statutory regulations. Initially, the Nuremberg Code of 1947, designed to protect individuals in medical experiments, laid the groundwork for the informed consent doctrine in clinical settings. It was further solidified in 1957 in the case of Salgo v. Leland Stanford Jr. University Board of Trustees, where the court explicitly introduced the term "informed consent," emphasizing the physician's obligation to provide patients with sufficient information to make an educated decision about their medical care.

A key turning point came with the case of Mary E. Schoendorff v. The Society of the New York Hospital in 1914, where the New York Court of Appeals ruled that performing surgery without the patient's consent was a violation of her personal rights, even if the hospital was a charitable institution. This case helped establish the patient's autonomy in medical decision-making as a legal principle in the U.S. Similarly, the Allan v. New Mount Sinai Hospital case in 1980 reinforced the notion that surgery should not be performed without clear, informed consent, establishing that this was not a mere formality but a vital right to personal autonomy.

The landmark case Salgo v. Leland established the requirement for medical professionals to disclose all necessary information, including risks, benefits, and alternatives, so that patients can make informed decisions. This responsibility was further reinforced by the Patients' Bill of Rights introduced by the American Hospital Association in 1972, which stated that patients must be informed of their medical conditions and the treatments available before giving consent.

The ethical concerns surrounding informed consent have also played a significant role in medical research. A notable historical example is the Tuskegee Syphilis Study (1932–1972), where African American men were studied for syphilis progression without being informed or treated. This egregious violation of ethical principles led to widespread reforms, including the publication of the Belmont Report in 1979, which established three core principles for ethical research involving human subjects: respect for persons, beneficence, and justice (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979).

While the U.S. has led the way in formalizing the doctrine of informed consent, the principles have influenced many other countries, particularly in Western legal systems. In countries with common law traditions, informed consent has been integrated into their healthcare systems in similar ways. However, variations exist in how informed consent is practiced, with some nations adopting stricter requirements for patient information disclosure.

In many European countries, the civil law systems typically provide more detailed regulations regarding patient rights and informed consent. Unlike the U.S., where case law plays a central role, many European jurisdictions rely more heavily on statutory law to govern patient consent. This results in a more uniform application of consent requirements across the region, although there are still differences in the extent to which patients must be informed about the risks and alternatives to medical procedures.

The doctrine of informed consent is a crucial element of modern healthcare law, with its roots deeply embedded in the legal systems of the United States. Its application and the ethical guidelines surrounding it have had a significant impact on international legal frameworks, highlighting the importance of patient autonomy and the right to make informed decisions about medical treatment. As healthcare systems continue to evolve, the global recognition of informed consent ensures that patient rights remain a central focus of medical practice, research, and legislation.

*Informed Consent in Indonesia: Current Practices and Challenges*

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In Indonesia, the legal system is based on the Continental European model, inherited from Dutch colonial law. This system incorporates a codified approach, where all laws are compiled into comprehensive regulations. Judicial decisions, though not binding like in the Anglo-Saxon legal system, can be cited as references, and healthcare law in Indonesia integrates both Continental and Anglo-Saxon practices. These practices are adapted to fit the social, cultural, religious, and philosophical aspects of Indonesian society.

A landmark case in the development of informed consent in Indonesia was the 1988 Muhidin case in Sukabumi. In this case, a doctor failed to inform the patient, Muhidin, about the risks of a medical procedure, leading to the patient's lawsuit. The case resulted in the issuance of Fatwa IDI No. 319/P/BA/1988 and was followed by the regulation in Permenkes No. 585/Men.Kes/Per/IX/1989, which mandated informed consent for medical procedures. Despite this development, Indonesia lacks binding jurisprudence on informed consent, hindering its widespread adoption. As a fundamental human right, the regulation of informed consent should ideally be addressed through higher legislation, such as a Law or Government Regulation.

The current legal framework governing informed consent in Indonesia is outlined in Law No. 17 of 2023 on Health. According to Article 293 of this law, every medical procedure performed by healthcare providers must be preceded by patient consent, provided after adequate explanation. This explanation must include information on the diagnosis, the proposed medical action, potential risks, complications, alternative treatments, and the prognosis. Consent can be obtained either verbally or in writing. The law specifies that the patient, or their closest family members in cases of incapacity, are responsible for providing consent. In emergency situations, consent is not required immediately, but once the patient is stable, an explanation and consent must be obtained.

In Indonesia, the influence of individualism in informed consent regulations is evident in the implementation of Permenkes No. 585 of 1990. However, this regulation, which prioritizes individual rights, was not fully compatible with Indonesian cultural values, which emphasize family involvement in healthcare decisions. As a result, in 2008, the Ministry of Health issued new regulations under No. 290/MENKES/PER/III/2008, which also included family consent alongside individual consent but still maintained the importance of patient autonomy. This regulation, however, contained ambiguities, such as the unclear definition of "accompanying persons" in certain contexts, leading to confusion about who could provide consent on behalf of the patient.

In the context of Indonesian civil law, informed consent is viewed as a contractual agreement between healthcare providers and patients, governed by the provisions of the Civil Code. To be valid, this contract must satisfy four elements: mutual consent, competence, a definite subject matter, and a lawful cause (Bambang, 2006). Healthcare providers must ensure that the patient's consent is informed and voluntary. If a medical procedure is performed without consent, it may be considered as battery under the Criminal Code, which highlights the serious legal implications of disregarding patient consent.

Additionally, Indonesia's consumer protection laws, particularly Law No. 8 of 1999 on Consumer Protection, safeguard patients' rights to information and informed consent. While the Indonesian legal framework has evolved to provide clearer regulations on informed consent, challenges remain in aligning these regulations with Indonesia's cultural and social norms, particularly in balancing individual rights with family involvement. Nevertheless, the principle of justice, as enshrined in Article 2 of the Health Law, ensures that healthcare services are accessible, fair, and equitable to all citizens, reinforcing the importance of redesigning informed consent processes in a way that aligns with Indonesia's moral and philosophical values.

*Informed Consent in Islamic Law: Ethical and Legal Considerations*

Health is a holistic state encompassing physical, mental, spiritual, and social well-being. It enables individuals to live productively within social and economic settings, as emphasized by Indonesia's Health Law No. 17 of 2023. In Islam, health is regarded as a vital blessing, with several hadith underscoring its significance. For example, the Prophet Muhammad (PBUH) stated, "Two blessings that many people take

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for granted are good health and free time" (HR. Bukhari). This highlights the Islamic perspective that health is a divine trust and must be preserved responsibly.

Informed consent, a cornerstone of patient rights, is explicitly addressed in Article 4 of the Health Law. It empowers patients to accept or decline medical interventions after receiving complete information. Islam prioritizes fulfilling obligations over claiming rights, and healthcare providers are obligated to convey accurate and honest information to patients. This principle is rooted in Quranic and hadith directives, such as the verse, "And do not mix the truth with falsehood or conceal the truth while you know [it]" (Quran 2:42). The hadith further emphasizes the ethical responsibility to avoid deceit: "It is a grave betrayal if you speak to your brother, and he trusts you, yet you lie to him" (HR. Ahmad and Abu Dawud).

Informed consent, as a mutual agreement between healthcare providers and patients, aligns with Islamic principles of contracts (akad). The Quran commands Muslims to honor agreements: "O you who believe, fulfill [all] contracts" (Quran 5:1). The legitimacy of a contract in Islam requires compliance with Shariah principles, mutual consent, clarity, and fairness. Similarly, informed consent mandates that patients fully understand the proposed medical action and willingly agree without coercion.

Healthcare providers must respect the sanctity of the consent process, as neglecting it violates the trust inherent in the patient-provider relationship. The Quran warns against betraying trust: "O you who have believed, do not betray Allah and the Messenger or betray your trusts while you know [the consequence]" (Quran 8:27).

Islamic teachings stress the importance of delivering truthful information in a compassionate and considerate manner. This is particularly crucial when dealing with patients, whose vulnerability may heighten the psychological impact of medical information. The Prophet Muhammad (PBUH) demonstrated this ethical approach, as illustrated in the hadith about the Bedouin who urinated in a mosque. Instead of reprimanding the man harshly, the Prophet corrected him with wisdom and patience. Healthcare providers should emulate this approach, ensuring that information is communicated in ways that do not exacerbate a patient's condition.

Informed consent in Islamic law is not merely a legal requirement but a moral obligation that embodies honesty, mutual respect, and the fulfilment of trust. It reflects a commitment to uphold the patient's dignity and autonomy while adhering to Shariah principles. By aligning informed consent processes with Islamic ethical values, healthcare systems can ensure equitable and compassionate care that respects both religious principles and patients' rights.

*Redesigning Legal Frameworks: Enhancing Informed Consent for Equity in Healthcare*

Informed consent is a fundamental component of therapeutic agreements, regulated by various Indonesian laws, including the 1945 Constitution, health laws, government regulations, and ministerial decrees. These laws emphasize patient rights and medical practitioners' obligations, providing a legal framework for the administration of healthcare. However, despite the availability of these regulations, challenges persist in ensuring the effective implementation of informed consent practices.

While the legal framework provides guidelines on informed consent, the process often falls short of optimal execution. Patients frequently lack a clear understanding of the medical actions proposed, affecting their ability to make informed decisions. This gap in communication can lead to medical disputes, particularly when the outcomes of medical interventions do not meet patient expectations. Furthermore, many patients tend to rely entirely on the recommendations of their healthcare providers without fully exercising their right to self-determination.

Patients' right to information is critical to their autonomy and decision-making. Article 293 of Indonesia's Health Law No. 17 of 2023 states that consent must be given after patients receive adequate explanations. However, the term "adequate explanations" often lacks clarity in practice, creating ambiguity in legal and ethical accountability. Additionally, healthcare providers must ensure proper documentation of medical

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actions, as mandated by Article 274 of the same law. Yet, the absence of explicit digital documentation requirements poses challenges in maintaining comprehensive records.

Article 274(d) currently mandates that medical practitioner document examinations, care, and actions. This provision could be amended to require documentation to be maintained both manually and digitally, ensuring accessibility and accuracy. Article 293(3), which states that consent must be granted after patients receive adequate explanations, could also be revised to include the use of visual aids, interpreters for vulnerable groups (such as children, the elderly, and individuals with disabilities), and other necessary means to optimize communication. Furthermore, Article 293(4), which allows for oral or written consent, should be updated to accommodate electronic or digital consent methods, aligning with modern communication practices.

The redesigned informed consent framework should be grounded in equity, transparency, participation, and special protections. Equity involves ensuring that all patients, regardless of socioeconomic or health status, have equal access to medical information. Transparency emphasizes the need for clear, comprehensive, and individualized information. Participation entails actively involving patients in medical decision-making processes. Special protections highlight the importance of adapting communication strategies to address the needs of vulnerable groups, such as children, the elderly, and individuals with disabilities.

The proposed revisions aim to enhance the clarity, inclusivity, and effectiveness of informed consent practices. By integrating technological advancements and prioritizing patient-centered communication, these changes can foster greater trust and collaboration between patients and healthcare providers. Such reforms are vital for promoting equitable healthcare and minimizing legal disputes.

## Conclusion

Based on the discussion that has been outlined, it can be concluded that informed consent is a critical component of equitable healthcare, enshrined in several Indonesian regulations, including Law No. 17 of 2023 on Health, Government Regulation No. 28 of 2024, and Ministerial Regulation No. 290 of 2008. While these frameworks provide a comprehensive foundation for healthcare practices, they fall short in addressing certain technical and practical aspects crucial for achieving justice and equity. Specifically, the regulations lack detailed provisions on the effective communication of medical information to patients, which is a fundamental right under the law. The current informed consent process often fails to account for the diverse backgrounds and conditions of patients. Many patients, due to varying levels of education or personal circumstances, struggle to fully comprehend the medical information provided to them. This lack of understanding can undermine their ability to make informed decisions about their care, resulting in consent that may not truly reflect their informed will. Consequently, the existing regulatory framework does not fully ensure fairness in the patient-provider relationship, leaving room for potential inequities and disputes. To address these gaps, key provisions of Law No. 17 of 2023 must be reconstructed to emphasize justice and inclusivity. Proposed amendments include requiring both manual and digital documentation of medical procedures, ensuring the use of supportive technologies and translators for vulnerable populations, and allowing for digital consent alongside traditional oral and written methods. These changes aim to enhance patient autonomy, improve transparency, and foster active participation in decision-making processes. By integrating these reforms, Indonesia's healthcare system can better align with the principles of equity and inclusivity, ensuring that informed consent becomes a meaningful process that empowers patients and strengthens trust between medical practitioners and those they serve.

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