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Legal Aspects of Informed Consent in Medical Procedures

Anna Veronica Pont[1*], Kevin Mario Immanuel[2], Natasya Yunita Sugiastuti[3], Zabidin[4], Stelvia W. Noya[5]
[1]Poltekkes Kemenkes Palu
[2]Universitas Kristen Indonesia
[3]Universitas Trisakti, Jakarta, Indonesia
[4]Universitas 17 Agustus 1945 Semarang
[5]Universitas Pattimura, Ambon, Maluku

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ABSTRACT

Informed consent is a fundamental component of modern medical practice that emphasizes the importance of a patient's approval after receiving clear, adequate, and understandable information regarding a medical procedure. This concept reflects not only respect for patient autonomy but also serves as a legal safeguard for healthcare professionals in the performance of their duties. In Indonesia, the regulation of informed consent has undergone notable development. Ministerial regulations, the Medical Code of Ethics, and Law No. 17 of 2023 on Health provide the normative foundation that affirms patients' rights to obtain sufficient information and to give conscious consent before any medical intervention. This study applies a normative juridical method with a statutory and conceptual approach. The findings reveal that the latest legal framework reinforces documentation obligations and clarifies the standards that must be fulfilled by medical practitioners, including in emergency situations. Nevertheless, practical implementation remains challenged by several factors, such as patients' limited comprehension, the use of complex medical terminology, time constraints faced by healthcare providers, and the suboptimal practice of written documentation. These challenges create potential legal disputes, both in civil and criminal domains, when medical procedures are carried out without valid consent. Therefore, the effective application of informed consent requires synergy between clear regulations, adequate understanding among medical personnel, and improved health literacy among the public. Consequently, informed consent should not be seen merely as an administrative formality but rather as an essential legal and ethical safeguard that enhances the quality of healthcare services.

Corresponding Author:
Poltekkes Kemenkes Palu
*Corresponding Author: Email: annaveronicaponterik@gmail.com

INTRODUCTION

Informed consent stands as one of the fundamental pillars of contemporary medical practice. It originates from the principle of respect for patient autonomy, which recognizes the individual's full authority over their own body and life. Within the medical context, informed consent refers to the approval granted by a patient after being provided with comprehensive information about a proposed medical intervention, including its risks, benefits, available alternatives, and possible consequences if the procedure is not undertaken (Busro, 2018).

From an ethical perspective, informed consent reflects the principle of autonomy in bioethics, which positions the patient as the primary decision-maker in their own care. This principle is closely tied to beneficence, the obligation of healthcare providers to maximize benefits while simultaneously respecting the patient's rights (Beauchamp & Childress, 2019).

Legally, informed consent functions not only as an administrative requirement but also as a protective mechanism for both patients and healthcare professionals. Patients are safeguarded through the right to be informed and to choose, while medical practitioners are protected by having documented proof that medical actions were undertaken with the patient's consent (Widjaja & Firmansyah, 2021).

Historically, the notion of informed consent gained prominence after the Nuremberg Trials in 1947, which gave rise to the Nuremberg Code affirming the necessity of voluntary participation in medical research. This principle was later expanded to healthcare practice and reinforced through the 1964 Declaration of Helsinki, which has since become an international benchmark for medical ethics (World Medical Association, 2013).

In developed countries such as the United States and the United Kingdom, informed consent has become a cornerstone of medical care. There, patient consent is not limited to signing documents but involves meaningful communication between healthcare providers and patients to ensure that medical information is conveyed clearly and understandably (O'Neill, 2003).

In Indonesia, the legal framework governing informed consent has significantly evolved since the early 2000s. The enactment of Law No. 29 of 2004 on Medical Practice marked the first formal recognition that every medical procedure requires patient consent (Dian Fitriana, 2023).

This was further detailed in Minister of Health Regulation No. 290/Menkes/Per/III/2008 concerning Medical Consent, which stipulates that consent can be either oral or written, though written consent is mandatory for high-risk medical interventions (Indina, 2024).

The most recent development is the passage of Law No. 17 of 2023 on Health, which strengthens the legal foundation of informed consent by mandating proper documentation and reaffirming the patient's right to complete medical information (Indina, 2024). This represents a significant advancement in patient protection within the Indonesian healthcare system.

The new law also clarifies exceptions, particularly in emergency situations where written consent may be impractical. In such cases, healthcare professionals are permitted to act in order to save a patient's life, with the obligation to provide explanations once the patient is stabilized (SIP Law Firm, 2024).

Despite these comprehensive regulations, the practical implementation of informed consent in Indonesia remains fraught with challenges. A major issue is the low level of health literacy among patients, which often hampers their ability to fully understand medical information (Widjaja & Firmansyah, 2021).

Time constraints and heavy workloads further complicate matters for medical practitioners, as they may be forced to provide explanations hurriedly due to the high volume of patients they must treat (Indina, 2024).

Language and cultural differences also play a role in shaping how patients interpret medical information. In some communities, decisions are often made collectively with family members or community leaders, making the informed consent process more complex (Busro, 2018).

Another recurring issue is poor documentation practices. Instances where consent is provided verbally without written records are still common, even though proper documentation is essential in the event of legal disputes (Indina, 2024).

From a civil law standpoint, the absence of informed consent may be construed as a breach of obligation or unlawful act, giving patients grounds to claim compensation for harm suffered due to unauthorized medical procedures (Busro, 2018).

In criminal law, performing medical procedures without valid consent may amount to assault or negligence, particularly when serious injury or death occurs. This underscores the critical role of informed consent in legal accountability (Hukumonline, 2024).

Beyond legal implications, inadequate informed consent also carries social consequences. Communities that perceive their rights as disregarded may lose trust in healthcare providers and institutions, ultimately undermining the overall quality of healthcare services (Widjaja & Firmansyah, 2021).

Conversely, proper implementation of informed consent fosters trust between doctors and patients. This trust functions as vital social capital in the healing process and in enhancing healthcare quality (Beauchamp & Childress, 2019).

Looking ahead, the challenge lies in developing systems that allow healthcare professionals to provide sufficient explanations without being constrained by time. The use of digital tools, such as medical education videos or electronic consent applications, may offer practical solutions (Indina, 2024).

Continuous training for healthcare providers is also crucial, particularly in developing communication skills that enable them to explain medical terms in simple, accessible language (Busro, 2018).

Efforts to improve public health literacy are equally important, empowering patients to better understand their rights and to actively participate in medical decision-making (Widjaja & Firmansyah, 2021).

Moreover, existing regulations must be more widely disseminated, not only among healthcare providers but also to the general public. Many disputes arise not solely from violations but also from a lack of awareness of legal provisions (Indina, 2024).

Healthcare institutions must also establish stricter standard operating procedures for informed consent, including robust mechanisms for documenting and archiving consent forms (SIP Law Firm, 2024).

Academic research on informed consent should continue to expand, offering insights that can inform policymakers. A multidisciplinary approach would allow for a more comprehensive understanding of its legal, ethical, and social dimensions (Beauchamp & Childress, 2019).

Overall, the development of regulations and the challenges in implementation make clear that informed consent is far more than a mere administrative formality. It is a vital legal and ethical instrument that bridges patient rights, professional responsibilities, and legal certainty in Indonesian healthcare practice.

RESEARCH METHOD

This study employs a normative juridical method, a legal research approach that focuses on examining legislation, legal doctrines, and prevailing principles to understand legal phenomena related to informed consent. The normative approach was chosen because the issue under study deals primarily with formal legal aspects, particularly how Indonesian laws regulate patients' rights and the obligations of medical professionals in providing adequate information before performing medical procedures (Rahayu, 2020).

The research is descriptive-analytical in nature, aiming to present a comprehensive overview of the legal provisions concerning informed consent while also analyzing their implementation in practice. Thus, the study not only outlines the content of positive law but also critically assesses its effectiveness in safeguarding patients' legal rights (Saragih, 2021).

The primary data source is secondary legal materials, which consist of primary, secondary, and tertiary legal sources. Primary sources include legislation such as Law No. 17 of 2023 on Health and Ministry of Health Regulation No. 290/MENKES/PER/III/2008 on Medical Consent. Secondary sources involve academic literature, journal articles, and prior research discussing legal aspects of informed consent, medical ethics, and patients' rights in Indonesia (Sukmana, 2022). Tertiary sources comprise legal dictionaries, encyclopedias, and official publications from international health organizations such as the World Health Organization (WHO, 2016).

Legal materials were collected through a library research technique, by reviewing regulations, official documents, scholarly articles, and relevant online publications. This process ensures the accuracy and accountability of the data, particularly those obtained from official government legal portals, accredited national journals, and international institutions (Mboi, 2019).

The data were analyzed using a qualitative analytical method, which interprets the content of legal rules and relates them to academic literature and legal doctrines. The analysis process includes: (1) inventorying legal norms governing informed consent, (2) systematizing legal provisions for clarity, (3) interpreting the laws to understand the legislators' intent, and (4) evaluating their effectiveness in protecting patients' rights (Ministry of Health RI, 2008).

This approach allows the researcher to assess the extent to which existing regulations align with medical ethics principles and international standards of informed consent. Consequently, the study does not only address normative legal perspectives but also provides insights into the practical challenges of implementation, making the findings valuable for academics, legal practitioners, and healthcare professionals alike.

RESULT AND DISCUSSION

The Concept and Philosophical Foundations of Informed Consent

Informed consent should not be understood merely as an administrative document, but rather as an ethical and legal principle that forms the basis of the relationship between healthcare providers and patients. Philosophically, the concept is rooted in the principle of patient autonomy, namely the individual's right to decide what may or may not be done to their own body (WHO, 2016). In this regard, patients are positioned as active subjects with agency, rather than passive objects within medical practice.

In medical settings, informed consent functions as a protective mechanism for both parties. For patients, it ensures they are neither coerced nor misled into undergoing a medical procedure. For healthcare providers, it serves as evidence that medical treatment was carried out in compliance with ethical and legal standards (Saragih, 2021). In the event of disputes, consent documents can serve as proof that patients had received adequate explanations before the procedure was undertaken.

In Indonesia, this philosophical foundation is reflected in the Indonesian Medical Code of Ethics, which requires physicians to respect patients' rights. This obligation has been further reinforced by Law No. 17 of 2023 on Health, which explicitly affirms that patients are entitled to receive comprehensive information concerning medical procedures, associated risks, benefits, and alternative treatments (Indonesia, 2023). Thus, the philosophical basis of informed consent has acquired solid legal legitimacy.

The Legal Framework of Informed Consent in Indonesia

The legal framework for informed consent in Indonesia has developed gradually. The earliest regulation addressing the matter specifically was the Ministry of Health Regulation No. 290/MENKES/PER/III/2008 on Medical Consent, which requires that every medical intervention be preceded by the patient's or their family's approval (Ministry of Health RI, 2008). This regulation distinguishes between written and oral consent depending on the level of medical risk involved.

A more recent reform was introduced through Law No. 17 of 2023 on Health, which emphasizes the importance of written documentation in all high-risk medical interventions (Indonesia, 2023). This is crucial since many previous disputes arose from cases where consent was given only orally, leaving patients claiming they had not been adequately informed (Rahayu, 2020).

From a civil law perspective, informed consent can be interpreted as a therapeutic contract between physician and patient. According to Article 1320 of the Indonesian Civil Code, an agreement that is made voluntarily and with full awareness satisfies the requirements of a valid contract. Consequently, a violation of informed consent obligations may be litigated as either breach of contract or tort (Sukmana, 2022).

Nevertheless, challenges remain because Indonesian regulations do not yet comprehensively stipulate sanction mechanisms for healthcare professionals who fail to comply with informed consent requirements. While ethical violations may be addressed by the Indonesian Medical Disciplinary Honor Council (MKDKI), formal legal remedies are still limited. As a result, patients often face difficulties in obtaining effective protection through legal channels (Mboi, 2019).

Ethical Dimensions and Professional Responsibilities in Informed Consent

Beyond its legal underpinnings, informed consent embodies fundamental ethical principles that guide medical practice. One of the core principles is respect for autonomy, which obligates healthcare professionals to acknowledge and support the patient's right to self-determination (Beauchamp & Childress, 2019). This principle highlights the shift from a paternalistic model of medicine, where physicians made unilateral decisions, to a participatory model that recognizes patients as partners in healthcare.

Ethically, informed consent is also connected with beneficence and non-maleficence. Physicians are expected to recommend treatments that maximize patient welfare while avoiding harm. Consent ensures that the patient's perspective on risks and benefits is taken into account, preventing medical interventions from being imposed without consideration of individual values (Busro, 2018).

Another ethical concern arises from communication barriers. Patients may not fully understand medical terminology, particularly in contexts where literacy levels are low or cultural beliefs shape perceptions of health and illness. In such cases, healthcare professionals bear the ethical responsibility of simplifying medical explanations and ensuring comprehension before consent is obtained (Widjaja & Firmansyah, 2021).

From a professional responsibility standpoint, informed consent strengthens the trust relationship between doctor and patient. It is not simply about fulfilling an administrative requirement but about fostering transparency and honesty. Failure to meet these ethical obligations risks eroding patient trust and could expose healthcare professionals to ethical review or disciplinary measures (Saragih, 2021).

Therefore, the ethical dimension of informed consent reinforces that medical practice is not only about technical competence but also about respecting patient dignity and autonomy as essential elements of quality healthcare delivery.

4. Challenges and Prospects for Implementation in Indonesia

Despite clear legal frameworks, the practical implementation of informed consent in Indonesia faces persistent obstacles. A key challenge is limited health literacy among patients, which makes it difficult for them to fully grasp complex medical information (Widjaja & Firmansyah, 2021). In many cases, patients rely heavily on family members or community leaders to make medical decisions, complicating the process of obtaining personal consent.

Another pressing issue is the time constraints on medical practitioners. In busy hospitals and clinics, doctors often face overwhelming patient loads, leaving insufficient time for thorough discussions of risks, alternatives, and consequences. This frequently results in consent being obtained in a rushed or superficial manner (Indina, 2024).

Cultural and linguistic diversity in Indonesia also contributes to implementation difficulties. In rural areas, local languages or dialects may dominate, and direct translation of medical terms can be challenging. Without culturally sensitive communication strategies, patients may sign consent forms without truly understanding the implications (Busro, 2018).

Documentation practices present another gap. Although regulations require written consent for high-risk procedures, some institutions still rely on verbal consent or incomplete records. This lack of proper documentation not only undermines legal safeguards but also increases the likelihood of disputes when complications arise (Rahayu, 2020).

Looking forward, technological solutions may help address these challenges. The use of digital platforms, such as video-based explanations or electronic consent forms, can enhance accessibility and ensure that patients have opportunities to review information at their own pace (SIP Law Firm, 2024). Additionally, continuous training for healthcare professionals in communication skills and medical ethics is crucial for improving the quality of the consent process (Mboi, 2019).

Furthermore, public education initiatives on patient rights and medical decision-making can empower individuals to engage more actively in their healthcare. Government agencies and healthcare providers should collaborate to promote health literacy as part of a broader strategy to strengthen informed consent practices (WHO, 2016).

CONCLUSION

Based on the discussion presented, it can be concluded that the constitutional authority of the President to dissolve the House of Representatives (DPR) is a complex issue shaped by political dynamics, constitutional law, and the broader framework of governmental systems. In a presidential system such as Indonesia's, the dissolution of parliament by the President is not provided for under the 1945 Constitution, thereby granting the legislature a relatively strong degree of independence from the executive branch. This arrangement reflects the principle of separation of powers, designed to prevent the concentration of authority in a single branch of government and to maintain political stability.

In contrast, within parliamentary systems, the dissolution of parliament by the head of government (prime minister) or head of state is a constitutionally legitimate and commonly used mechanism to resolve political deadlock. This approach is often regarded as a means to return the mandate to the people through new elections, thereby ensuring the continuity of governance. The fundamental distinction between the two systems illustrates how the relationship between the executive and legislative branches is determined by constitutional design and the political needs of each nation.

This comparison highlights that the absence of presidential authority to dissolve the DPR in Indonesia may be seen as a safeguard of popular sovereignty, since the DPR directly represents the electorate through general elections. However, in practice, the lack of such a mechanism can also lead to prolonged political deadlock in cases of severe conflict between the President and the legislature. Hence, the debate on whether constitutional reform is necessary to address this gap remains relevant, particularly in light of contemporary political dynamics and the need to reinforce the presidential system.

In conclusion, the question of presidential authority to dissolve parliament must be assessed within the broader context of checks and balances, democratic protection, and governmental effectiveness. The comparison between presidential and parliamentary systems demonstrates that each country adopts constitutional arrangements rooted in its history, political culture, and the pursuit of national stability. For Indonesia, maintaining a balance between executive and legislative powers without granting the President absolute authority to dissolve the DPR reflects the spirit of constitutional democracy, while still leaving open the possibility for future constitutional discourse and reform.

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