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LEGAL ANALYSIS OF THE IMPLEMENTATION OF INFORMED CONSENT IN HEALTHCARE SERVICES IN BAUBAU CITY

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ABSTRACT

Informed consent is a legal instrument designed to protect patients' rights by ensuring they receive adequate information before medical procedures are performed. Although it is regulated by various laws and regulations, its implementation in healthcare practice is still often viewed merely as the fulfillment of an administrative obligation. This situation raises questions about the extent to which informed consent has fulfilled its legal purpose of ensuring the protection of patients' rights. This study aims to analyze the implementation of informed consent in medical procedures at healthcare facilities in Baubau City from the perspective of substantive legal compliance. The study employs a normative-empirical legal method with an evidence-based regulation approach. Data were collected through literature review, interviews with medical staff, healthcare facility management, and patients, and analyzed qualitatively by comparing legal norms with implementation practices. The results indicate that the implementation of informed consent has proceeded according to procedure through the provision of information and the signing of consent forms prior to medical procedures. However, its effectiveness still faces various challenges, including limited service time, the use of medical terminology that is difficult to understand, and suboptimal mechanisms to ensure patients' comprehension of the information provided. This study concludes that the implementation of informed consent in Baubau City has met the procedural compliance dimension but has not fully met the substantive legal compliance dimension. Therefore, strengthening medical communication and evaluating patient understanding are necessary to enhance the effectiveness of protecting patients.

Keywords: Informed Consent; Protection of Patients' Rights; Legal Compliance; Healthcare Services.

1. INTRODUCTION

Informed consent is one of the fundamental instruments in modern healthcare that serves to ensure respect for a patient's right to determine the medical treatment they will receive[1]. From a health law perspective, informed consent is understood not only as an administrative requirement prior to medical treatment but also as a manifestation of the

[1] M. Otero et al., "Informed Consent in Dentistry and Medicine in Spain: Practical Considerations and Legality," *Medicina Oral Patología Oral y Cirugía Bucal*, 2022, e294–300, https://doi.org/10.4317/medoral.25265; Lucia Tattoli and Davide Santovito, "A Medico-Legal Approach to Developing a Structured Decision-Making Process for Patients Refusing Blood Transfusions," *Frontiers in Public Health* 13 (October 2025): 1687101, https://doi.org/10.3389/fpubh.2025.1687101.

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protection of patients' fundamental rights to information, autonomy, and the freedom to make choices regarding the healthcare services they receive[2]. Therefore, informed consent plays a strategic role in establishing a balanced legal relationship between healthcare providers and patients[3].

Normatively, the obligation to obtain informed consent in healthcare services is firmly grounded in Indonesia's health law system. These provisions can be found, among other places, in Law No. 17 of 2023 on Health, which affirms patients' right to receive accurate, clear, and honest information regarding their health condition and the medical procedures they will undergo. Furthermore, provisions regarding consent for medical procedures are more specifically regulated in Minister of Health Regulation No. 290/Menkes/Per/III/2008 on Consent for Medical Procedures, which requires physicians or dentists to provide an explanation that includes, at a minimum, the diagnosis, the procedure's methodology, the purpose of the procedure, alternative procedures, risks and complications, and the prognosis regarding the procedure to be performed[4]. These regulations demonstrate that the regulators do not view informed consent merely as an administrative obligation involving the signing of a consent form, but rather as a legal mechanism aimed at ensuring the patient's right to adequately understand medical information before making a decision regarding the medical procedure they will undergo.

At the institutional level, Baubau Mayor's Regulation No. 31 of 2018 on Internal Regulations (Hospital Bylaws) of the Baubau City General Hospital also reaffirms patients' rights to receive information regarding diagnosis, treatment alternatives, risks and complications, as well as the right to grant or withhold consent for medical procedures[5]. Furthermore, these regulations require doctors to provide complete and honest information to patients and mandate that hospitals respect and protect patients' rights[6]. Thus, the entire regulatory framework demonstrates that the essence of informed consent goes beyond the

[2] Živa Kovic et al., "Valid Consent in the Acute Hospital Setting: Perspectives of Patients and Members of the Public," *Irish Journal of Medical Science (1971 -)* 193, no. 4 (August 2024): 1703–14, https://doi.org/10.1007/s11845-024-03658-w.

[3] Francesco Orsini et al., "Towards a European End-of-Life Regulation: A Necessary Analysis," *Healthcare* 13, no. 2 (January 2025): 130, https://doi.org/10.3390/healthcare13020130; Maria Cristina Plaiasu, Dragos Ovidiu Alexandru, and Codrut Andrei Nanu, "Physicians' Legal Knowledge of Informed Consent and Confidentiality. A Cross-Sectional Study," *BMC Medical Ethics* 23, no. 1 (September 2022): 93, https://doi.org/10.1186/s12910-022-00835-3; Corinna Porteri et al., "Towards the Implementation of Law n. 219/2017 on Informed Consent and Advance Directives for Patients with Psychiatric Disorders and Dementia. Physicians' Knowledge, Attitudes and Practices in Four Northern Italian Health Care Facilities," *BMC Medical Ethics* 25, no. 1 (January 2024): 7, https://doi.org/10.1186/s12910-023-00997-8.

[4] Karine Giudici-Wach et al., "Learning from Informed Consent Litigation to Improve Practices: A Systematic Review," *Patient Education and Counseling* 105, no. 7 (July 2022): 1714–21, https://doi.org/10.1016/j.pec.2021.10.009.

[5] Orsini et al., "Towards a European End-of-Life Regulation."

[6] Firman Firman et al., "Enhancing Citizen Participation: The Key To Public Service Transparency," *Journal of Law and Sustainable Development* 12, no. 1 (January 2024): e2937, https://doi.org/https://10.55908/sdgs.v12i1.2937.

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mere formal granting of consent; rather, it demands a communication process that enables patients to adequately understand medical information before making a decision[7].

Consequently, the level of a patient's understanding serves as a key indicator for assessing whether the legal objectives of implementing informed consent have been met. Regulations regarding informed consent in Indonesia have a relatively adequate legal foundation through various provisions in health and medical practice legislation[8]. These regulations require medical personnel to provide complete information regarding the diagnosis, the purpose of the procedure, risks, benefits, and alternative medical treatments before obtaining the patient's consent[9]. These regulations demonstrate that the law recognizes patients as individuals who have the right to understand and make medical decisions consciously and freely[10].

Nevertheless, various studies indicate that the implementation of informed consent in healthcare practice still faces a number of practical challenges. Informed consent is often treated as an administrative formality characterized by the signing of a consent form, while the substantive aspect the patient's understanding of the medical information provided has not yet fully become a primary concern. This situation means that the goal of protecting patients' rights, which forms the basis for the establishment of informed consent norms, has not yet been fully achieved[11].

Previous studies have generally focused on procedural compliance with regulations, the validity of consent for medical procedures, or the level of patients' understanding of medical information. However, studies that specifically analyze the implementation of informed consent from the perspective of substantive legal compliance remain relatively limited. Consequently, there remains an academic gap that needs to be addressed to

[7] Kovic et al., "Valid Consent in the Acute Hospital Setting"; Porteri et al., "Towards the Implementation of Law n. 219/2017 on Informed Consent and Advance Directives for Patients with Psychiatric Disorders and Dementia. Physicians' Knowledge, Attitudes and Practices in Four Northern Italian Health Care Facilities."

[8] Paa-Kwesi Blankson et al., "The Informed Consent Process: An Evaluation of the Challenges and Adherence of Ghanaian Researchers," *Developing World Bioethics* 25, no. 1 (March 2025): 55–61, https://doi.org/10.1111/dewb.12447; Svenja Wiertz and Joachim Boldt, "Ethical, Legal, and Practical Concerns Surrounding the Implemention of New Forms of Consent for Health Data Research: Qualitative Interview Study (Preprint)," preprint, Journal of Medical Internet Research, August 29, 2023, https://doi.org/10.2196/preprints.52180.

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[10] Ida Ayu Sadnyini et al., "Legal Approaches for Clinical Audits and Sanctions in Indonesian Health Service Facilities," *Jurnal Hukum Prasada* 11, no. 1 (March 2024): 16–24, https://doi.org/10.22225/jhp.11.1.2024.16-24; Antonio Sandu, "Ethical and Legal Perspectives on Informed Consent in the Context of International Human Rights Law," *Logos Universality Mentality Education Novelty: Law* 13, no. 1 (June 2025): 21–29, https://doi.org/10.18662/lumenlaw/13.1/95.

[11] Madhan Jeyaraman et al., "Informed Consent Form for Platelet Rich Plasma Injections: Evidence-Based and Legally Guide for Orthopaedic Surgeons," *European Journal of Medical Research* 29, no. 1 (August 2024): 422, https://doi.org/10.1186/s40001-024-02019-8; Antonio Oliva et al., "Management of Medico-Legal Risks in Digital Health Era: A Scoping Review," *Frontiers in Medicine* 8 (January 2022): 821756, https://doi.org/10.3389/fmed.2021.821756.

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understand the extent to which the implementation of informed consent truly functions as an instrument for protecting patients' rights rather than merely an administrative mechanism within healthcare services.

This issue is also evident in healthcare practices in Baubau City. Based on preliminary observations of medical staff, healthcare facility management, and patients, it was found that informed consent procedures are generally carried out in accordance with applicable operational standards[12]. However, this implementation still faces various obstacles, including time constraints during patient care, high patient volumes, the use of difficult-to-understand medical terminology, and the lack of adequate mechanisms to ensure patients' level of understanding of the information provided. On the other hand, some patients admitted to having signed consent forms without fully understanding the information regarding the medical procedures they were about to undergo.

These findings indicate a gap between the normative purpose of informed consent as an instrument for protecting patients' rights and the reality of its implementation in healthcare services. This gap is not merely related to the existence of regulations but also concerns the effectiveness of implementing legal norms in ensuring patients' understanding and freedom in giving consent to medical procedures. Thus, studies on the implementation of informed consent should focus on an analysis of substantive legal compliance to assess the extent to which patients' rights are truly protected in healthcare practice.

Based on this background, the central research question of this study is: How is informed consent implemented in medical procedures at healthcare facilities in Baubau City, viewed from the perspective of substantive legal compliance in ensuring the protection of patients' rights? The study focuses on identifying the alignment between the legal norms governing informed consent and their practical implementation, while also analyzing the factors that influence the effectiveness of patient rights protection in the process of obtaining consent for medical procedures. Additionally, this study aims to identify gaps between the normative provisions and the implementation practices of informed consent and to analyze their implications for the protection of patients' rights in healthcare services

2. RESEARCH METHODS

The research used is normative-empirical legal research with an evidence-based regulation-based problem-solving approach[13]. This approach integrates normative analysis of laws and regulations in the field of health and medical practice with empirical findings

[12] Nofil Gusfira, "Tinjauan Yuridis Terhadap Kesalahan Profesi Oleh Tenaga Kesehatan," *Jurnal Hukum Samudra Keadilan* 17, no. 2 (December 2022): 262–74, https://doi.org/10.33059/jhsk.v17i2.6199.

[13] Hari Sutra Disemadi, "Lenses of Legal Research: A Descriptive Essay on Legal Research Methodologies," *Journal of Judicial Review* 24, no. 2 (November 2022): 289, https://doi.org/10.37253/jjr.v24i2.7280; Achmad Irwan Hamzani et al., "Implementation Approach in Legal Research," *International Journal of Advances in Applied Sciences* 13, no. 2 (June 2024): 380, https://doi.org/10.11591/ijaas.v13.i2.pp380-388; Achmad Irwan Hamzani et al., "Legal Research Method: Theoretical and Implementative Review," *International Journal of Membrane Science and Technology* 10, no. 2 (August 2023): 3610–19, https://doi.org/https://10.15379/ijmst.v10i2.3191; Isnaeni Yuliani et al., "Evidence-Based Policy: Data's Use In Supporting Public Policy Process," *Interdisciplinary Social Studies* 2, no. 3 (December 2022): 1699–705, https://doi.org/10.55324/iss.v2i3.341.

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obtained through in-depth interviews and direct studies at health care facilities in Baubau City, especially at the Baubau City Regional General Hospital (RSUD). The analysis was conducted qualitatively by mapping the gap between legal norms and implementation practices, resulting in policy recommendations and a model for strengthening informed consent that is applicable, contextual, and adaptive to the characteristics of regional health services.

3. RESEARCH RESULT AND DISCUSSION

The Implementation of Informed Consent in Healthcare Services in Baubau: Between Procedural Compliance and Practical Realities

The implementation of informed consent basically cannot be assessed solely based on the existence of formal procedures regulated in statutory regulations. In the perspective of protecting patient rights, it is important to assess how these legal norms are implemented in daily health care practice. Therefore, the discussion regarding the implementation of informed consent in this research is not only directed at identifying the conformity of procedures with applicable legal provisions, but also to understand how the process of providing information and consenting to medical procedures takes place in the relationship between health workers and patients.

This approach is important because the effectiveness of informed consent is essentially determined by the quality of interactions that occur before consent is given. Thus, analysis of the implementation of informed consent needs to start from the understanding of health service implementers regarding the concept of informed consent, its implementation mechanisms, as well as the patient's experience as the party receiving information and giving consent.

Based on the results of interviews, medical personnel and health facility management understand informed consent as the patient's consent given after receiving an explanation regarding medical procedures, benefits, risks and alternative actions available. In practice, the implementation of informed consent refers to regulations and standard operating procedures that apply in health service facilities. This procedure is generally carried out by providing an explanation by the doctor to the patient or the patient's family which is then followed by signing a consent form before the medical action is carried out.

These findings show that institutionally informed consent has become part of the health service mechanism that must be implemented before medical action is carried out. However, the existence of consent procedures and documents does not necessarily reflect the quality of the implementation of informed consent as a whole. To understand the effectiveness of its implementation, it is necessary to further explore the various obstacles faced in the process of conveying information to patients.

In this context, the interview results show that the implementation of informed consent still faces a number of obstacles. Medical personnel informants revealed that limited service time, the high number of patients, the low level of patient education, and the use of medical terms that are difficult to understand are factors that influence the effectiveness of communication between medical personnel and patients. In addition, there are not always mechanisms available to ensure that patients fully understand the information they have been given before signing a consent form.

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These various obstacles show that the implementation of informed consent is not only influenced by regulatory aspects, but also by practical factors that arise in the provision of health services. Therefore, to obtain a more comprehensive picture regarding the implementation of informed consent, it is important to look at how the process is perceived by the patient as the party receiving information and providing approval for medical treatment.

From the patient's perspective, most respondents admitted that they had received an explanation before the medical procedure was carried out. However, the information received is often considered too short and difficult to understand because it uses unfamiliar medical terms. Some patients also stated that they still signed the consent form even though they did not fully understand the information provided. Even under certain conditions, patients feel they have little choice but to follow the recommendations of the medical personnel treating them.

If examined as a whole, these empirical findings show that the implementation of informed consent in the Baubau City health service facilities has been procedurally carried out in accordance with applicable regulations. However, the same findings also show an indication that the success of implementing informed consent is still more measured based on the fulfillment of administrative procedures rather than the patient's level of understanding of the medical information they receive. This condition then raises further questions regarding whether the implementation of informed consent has fulfilled the dimensions of substantive legal compliance as the main objective of its regulation in health law.

Assessing Substantive Legal Compliance in Informed Consent: A Patients' Rights Perspective

The empirical findings in the previous section indicate that informed consent has become a routine procedure in healthcare services in Baubau City. Every medical procedure requiring patient consent is generally preceded by the provision of information by medical personnel and the signing of a consent form by the patient or family. From an administrative perspective, this demonstrates that healthcare facilities have endeavored to fulfill their legal obligations as stipulated in applicable laws and regulations and standard operating procedures.

However, the existence of consent procedures and documents alone is not sufficient to determine whether the legal objectives underlying informed consent have been truly achieved. Therefore, analysis cannot stop at the question of whether informed consent is implemented but must address a more fundamental question: the extent to which such implementation ensures the protection of patient rights as mandated by health law.

In this context, the concept of substantive legal compliance becomes relevant as an analytical framework. Substantive legal compliance not only assesses whether legally mandated procedures are met but also assesses whether the objectives intended by these legal norms are actually achieved in practice. Thus, the success of informed consent cannot be solely measured by the existence of a signed consent form. It must be measured by

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whether or not the patient's right to obtain adequate information, understand the consequences of the proposed medical procedure, and give free and informed consent is fulfilled.

This normative framework aligns with the provisions for informed consent in Indonesian health law. Law Number 17 of 2023 concerning Health positions patients as legal subjects entitled to receive accurate, clear, and understandable information regarding their health condition and the medical procedure they will receive. More specific provisions are contained in Minister of Health Regulation Number 290/Menkes/Per/III/2008 concerning Consent to Medical Procedures, which requires doctors to provide an explanation of the diagnosis, purpose of the procedure, procedure, alternative procedures, risks and complications, and the patient's prognosis. These provisions demonstrate that informed consent does not stop at formal approval but rather requires a communication process that allows patients to adequately understand medical information before making a decision. Therefore, patient understanding is a crucial indicator that directly reflects whether or not the legal objectives of informed consent have been achieved.

When these standards are used to assess research findings, a discrepancy is evident between fulfilling procedural aspects and achieving the substantive objectives of informed consent. Interviews indicate that medical personnel provided explanations to patients before medical procedures were performed. However, medical personnel also acknowledged that mechanisms were not always in place to ensure patients fully understood the information provided. Furthermore, limited service time, high patient volumes, and the use of complex medical terminology hindered medical communication.

These findings were confirmed from the patient perspective. Some patients reported receiving an explanation before the procedure, but found the information provided brief and difficult to understand due to the use of unfamiliar medical terminology. Some patients even admitted to signing consent forms despite not fully understanding the information about the procedure. In certain circumstances, patients also felt they had little choice but to follow the recommendations of their medical personnel.

If these findings are placed within the framework of protecting patient rights, then the problem that arises is no longer related to the completeness of administrative procedures, but rather concerns the effectiveness of implementing legal norms themselves. At this point there is an important distinction between procedural success and substantive success. The procedure can be considered to have been carried out because the consent form has been signed, but the legal objectives are not necessarily achieved if the patient still experiences limitations in understanding the information on which the consent was given.

This condition shows that there is a gap between the normative construction of informed consent and its implementation in health service practice. Normatively, informed consent is built on the assumption that the patient is a legal subject who has the capacity to

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make rational decisions after obtaining sufficient information regarding the medical action to be carried out. However, in practice, the consent process often takes place in a situation of information inequality between medical personnel and patients. The medical knowledge possessed by health personnel cannot always be translated into language that is easily understood by patients, so that consent given is potentially based more on trust in the authority of medical personnel than on a complete understanding of the information received.

In this perspective, the existence of a consent form cannot always be used as an indicator that the patient's rights have been optimally protected. On the other hand, the form has the potential to simply serve as administrative evidence that a procedure has been carried out without guaranteeing that the communication process behind it actually produces adequate understanding on the part of the patient. The findings of this research show that the orientation towards implementing informed consent still tends to place consent documents as the main indicator of compliance, while the aspect of patient understanding as the core of informed consent has not received equal attention.

Analysis of the Baubau Mayor's Regulation Number 31 of 2018 concerning Internal Regulations (Hospital By Laws) of the Baubau City Regional Hospital shows that the substance of the hospital's internal regulations has placed informed consent as an instrument for protecting patient rights that is integrated with clinical governance, service quality and patient safety. However, the research results show that the implementation of these norms is still more dominant in fulfilling administrative aspects through signing consent forms. This condition shows that there is a gap between the normative objectives of Hospital By Laws and the practice of health services, so that the compliance that is realized still tends to be procedural in nature and has not fully achieved substantive legal compliance which is oriented towards patient understanding and autonomy in making medical decisions.

Based on the overall findings and analysis, it can be understood that the main problem with implementing informed consent in Baubau City does not lie in the absence of regulations or standard operating procedures. A more fundamental problem lies in the effectiveness of implementing legal norms in realizing the goal of protecting patient rights. Therefore, the measure of the success of informed consent needs to be shifted from simply fulfilling procedures to achieving patient understanding as the essence of consent to medical treatment.

Thus, the implementation of informed consent at health service facilities in Baubau City can be considered to have fulfilled the procedural compliance dimension, but has not fully fulfilled the substantive legal compliance dimension. Even though the procedures for providing information and signing consent have been carried out in accordance with applicable regulations, the research results show that patients' understanding of the medical information provided is still not optimal. This condition means that the function of informed consent as an instrument for protecting patient rights has not been implemented optimally

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and still requires strengthening through improving medical communication, simplifying health information, and developing mechanisms for evaluating patient understanding before consent is given.

4. CONCLUSION

The implementation of informed consent in medical procedures at health service facilities in Baubau City has generally been carried out in accordance with applicable procedural provisions through providing information by medical personnel and signing a consent form before medical procedures are carried out. Research findings show that medical personnel and health facility management understand informed consent as part of health service obligations that must be implemented based on applicable regulations and standard operating procedures.

However, from the perspective of substantive legal compliance, the implementation of informed consent is not yet fully capable of guaranteeing optimal protection of patient rights. Even though formal procedures have been carried out, the research results show that there are still obstacles in the medical communication process that affect the patient's level of understanding of the information provided. Limited service time, the use of medical terms that are difficult to understand, and the absence of adequate mechanisms to ensure patient understanding mean that the consent given does not fully reflect a decision based on complete understanding and adequate awareness.

This research found that the main problem with implementing informed consent in Baubau City does not lie in the absence of regulations or standard operational procedures, but in the effectiveness of implementing legal norms in realizing the goal of protecting patient rights. Thus, the implementation of informed consent in Baubau City can be considered to have fulfilled the dimensions of procedural compliance, but has not fully fulfilled the dimensions of substantive legal compliance. This condition shows that the orientation of the implementation of informed consent still tends to focus on fulfilling administrative aspects rather than achieving legal objectives in the form of patient understanding as a basis for granting approval for medical treatment. Therefore, strengthening the quality of medical communication, simplifying health information, and developing mechanisms for evaluating patient understanding are important steps to realize informed consent as an effective instrument for protecting patient rights in health services.

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