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NORMATIVE ANALYSIS OF PROFESSIONAL ETHICS AND LEGAL ACCOUNTABILITY OF HEALTH WORKERS IN THE IMPLEMENTATION OF INFORMED CONSENT

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Abstract

The practice of informed consent in health services in Indonesia is still often understood administratively, without a comprehensive understanding of the underlying ethical and legal foundations. This condition creates a gap between the moral obligations and legal responsibilities of health workers in providing services that are oriented towards patient rights. This study aims to analyze the legal responsibilities of healthcare professionals in implementing informed consent based on Law Number 17 of 2023 concerning Health, as well as to assess the alignment between legal norms and the ethical principles of the healthcare profession. The type of research used is a literature study with a legal-normative approach. Data were collected through a review of legislation, scientific literature, and professional codes of ethics, then analyzed using qualitative descriptive methods through normative analysis. The results of the study show that there is a stronger integration between the principles of patient autonomy, professional responsibility, and positive legal norms in the practice of informed consent. However, it is still necessary to strengthen ethical education, health law training, and the development of comprehensive national standard operating procedures (SOPs). The conclusion of the study emphasizes the importance of implementing informed consent that is not only formally legal but also ethically and humanistically dignified.

Keywords: Informed Consent, Professional Ethics, Legal Responsibility, Health Workers, Legal-Normative Approach

INTRODUCTION

In modern healthcare practice, the relationship between healthcare providers and patients has undergone a fundamental transformation from a paternalistic relationship to a partnership that upholds patient rights and autonomy (Mediatrix et al., 2024). This paradigm requires that every medical action no longer be carried out unilaterally in the name of professional expertise, but rather through a mechanism of consent after adequate explanation or informed consent (Venia et al., 2023). Informed consent is the embodiment of the ethical principle of patient autonomy, which requires that every individual be given the freedom to accept or refuse medical intervention after obtaining sufficient, clear, and honest information from healthcare professionals (Beauchamp & Childress, 2023). Therefore, the application of informed consent is not only related to administrative procedures, but also concerns the moral values and professional integrity of medical personnel.

As public legal awareness continues to rise, society's expectations for ethical, accountable, and transparent medical practices have become increasingly urgent. In Indonesia, the issue of *informed consent* frequently lies at the heart of legal disputes between patients and healthcare providers, reflecting growing public sensitivity toward patients' rights and professional accountability (Junaidi, 2021; Wahyuni et al., 2021). Numerous malpractice cases reveal that deficiencies, whether the absence, incompleteness, or weakness, of the *informed consent* process remain a recurring problem, highlighting a persistent gap between regulatory provisions and actual clinical implementation (Supardi et al., 2021). This discrepancy not only undermines patient trust but also exposes healthcare institutions to legal and ethical vulnerabilities. Therefore, strengthening the understanding and application of professional ethics, alongside reinforcing the legal responsibilities of healthcare practitioners, is imperative. A comprehensive and dignified implementation of *informed consent* must move beyond mere administrative formality, evolving instead into a moral and legal commitment that safeguards patient autonomy, upholds justice, and elevates the credibility of the healthcare profession.

From a professional ethical perspective, informed consent is part of the principles of beneficence (doing good), non-maleficence (not causing harm), and justice, as formulated in bioethics theory by Beauchamp and Childress (2013). Healthcare professionals have a moral obligation to protect the interests of patients, provide honest information, and uphold human dignity (Kristiawan, 2021). However, in practice, challenges often arise due to time constraints, work pressure, and differences in patients' health literacy levels. This situation can lead to distortions in the delivery of information and affect the quality of patients' decisions. Therefore, professional ethics must be the foundation of every medical consent process.

In the realm of Indonesian positive law, regulations regarding informed consent have been strengthened through the enactment of Law Number 17 of 2023 concerning Health, which explicitly regulates the obligation of health workers to obtain medical consent from patients, especially for invasive or high-risk procedures (Article 293) (Arini et al., 2021; Kristiawan, 2021). This law not only affirms the right of patients to be given comprehensive explanations, but also provides legal protection for health workers, especially in emergency conditions that require immediate action without written consent. This regulation is an important normative basis for ensuring that healthcare practices are carried out within the corridor of ethics and law (Rahmadiliyani & Wati, 2021).

Previous studies have revealed that the implementation of informed consent in Indonesia still faces various challenges (Dzulhizza et al., 2024; Junaidi, 2021; Kurniawati, 2021; Mediatrix et al., 2024). Research by Dzulhizza et al., (2024) shows that many hospitals do not yet have adequate standard operating procedures (SOPs) for implementing informed consent, while medical personnel often find it difficult to convey information effectively to patients with low levels of education. Meanwhile, a study by Mediatrix et al., (2024) indicates that medical personnel's legal understanding of informed consent is still low, which risks lawsuits in the event of medical complications. This fact highlights the importance of a multidisciplinary approach that integrates professional ethics, health law, and therapeutic communication in the implementation of informed consent.

Based on this description, a study of the implementation of informed consent by health workers is highly relevant, particularly from the perspective of professional ethics and legal responsibility based on the latest normative foundations. This study aims to critically explore how healthcare professionals implement informed consent in their daily medical practice, the extent to which they understand their legal responsibilities as stipulated in Law No. 17 of 2023, and how professional ethical values are applied in the clinical decision-making process. This study is expected to contribute to the strengthening of institutional policies, the renewal of health professional curricula, and the protection of patient rights in the future.

LITERATURE REVIEW

Bioethics Theory

Bioethics theory was developed by Beauchamp and Childress (2013), who formulated four basic moral principles in medical practice, namely autonomy, beneficence, non-maleficence, and justice. The principle of autonomy emphasizes respect for the patient's right to make their own decisions based on clear and honest information. Beneficence directs healthcare professionals to act for the good of the patient, while non-maleficence requires that every medical action does not cause physical or psychological harm. The principle of justice emphasizes the importance of fair treatment for every patient without discrimination. In the context of informed consent, bioethical theory provides a moral foundation that connects the ethical and practical dimensions of the medical consent process. This ethic ensures that every medical decision is not only legally valid but also morally dignified because it respects the human value of the patient (Arini et al., 2021; Kristiawan, 2021).

Legal Liability Theory

Legal liability theory emphasizes that every healthcare professional has a legal obligation for the medical actions they perform, whether civil, criminal, or administrative. According to Dzulhizza et al., (2024), legal responsibility arises when there is a violation of patient rights due to negligence in the implementation of informed consent. Legally, healthcare professionals must ensure that every medical action has been consciously and voluntarily approved by the patient based on complete information (Partama et al., 2025). Failure to fulfill this obligation can result in legal claims, both in the form of compensation and ethical and administrative sanctions. Mediatrix et al., (2024) add that the aspect of legal responsibility also includes protection for medical personnel who have acted in accordance with procedures and professional standards. Thus, this theory emphasizes the importance of a balance between legal protection for patients and legal certainty for healthcare professionals in the application of informed consent.

The Theory of Patient Rights

The theory of patient rights is rooted in human rights principles that place patients as active subjects in medical decision-making. According to Kristiawan (2021), patient rights include the right to obtain accurate information, the right to consent to or refuse medical treatment, and the right to privacy and confidentiality of medical data. Informed consent is a concrete manifestation of respect for these rights because it guarantees patients' freedom to make choices about the medical procedures they will undergo (Pramesuari, 2024). Within the framework of

Indonesian health law, patients' rights are also recognized in Law Number 17 of 2023 concerning Health, which emphasizes the importance of the principles of justice and respect for human dignity. Therefore, the theory of patient rights serves as a philosophical basis that connects ethical and legal aspects in the application of informed consent to create an equal medical relationship between health workers and patients (Venia et al., 2023; Wahyuni et al., 2021).

Professional Ethics Theory

Professional ethics theory emphasizes that healthcare workers have a moral and social responsibility to carry out their duties based on the values of honesty, integrity, and responsibility. According to Arini et al., (2021), the implementation of good informed consent reflects the moral integrity of medical personnel in respecting the patient's right to know the risks and benefits of the actions to be taken. Professional ethics also serve as guidelines in building trust between healthcare professionals and patients through open, empathetic, and transparent communication. Rahmadiliyani & Wati (2021), add that a weak understanding of professional ethics often results in informed consent being practiced only administratively without deep moral reflection. Thus, professional ethics theory plays an important role in shaping the professional character of healthcare workers so that the implementation of informed consent does not merely fulfill legal obligations but also reflects moral responsibility towards the humanity of patients.

RESEARCH METHOD

This research employs a juridical-normative design, focusing on the analysis of laws and legal documents governing the practice of *informed consent* in healthcare services. The juridical-normative approach aims to examine legal principles, statutory regulations, and doctrinal interpretations related to professional ethics and the legal responsibility of healthcare workers. The study centers on the provisions of Law No. 17 of 2023 on Health, particularly Article 293, and related regulations such as Minister of Health Regulation No. 290/Menkes/Per/III/2008 concerning medical consent procedures. This design was chosen to obtain a doctrinal understanding of the legal norms that regulate the implementation of *informed consent* without involving empirical field data. The research targets the body of legal and ethical regulations governing *informed consent* in Indonesia. The population includes all national legal instruments and academic literature related to healthcare law and medical ethics. The sample consists of selected documents, laws, ministerial regulations, journal articles, and previous studies, that are directly relevant to the topic of *informed consent* and professional responsibility.

The research uses secondary data collected through a comprehensive literature study. The data sources include statutory regulations, official government documents, accredited national journals, international journal publications, academic articles, and textbooks published within the last ten years. The main research instrument is a document review checklist, designed to identify and categorize information based on ethical and legal dimensions. Data were analyzed using a qualitative descriptive method combined with content analysis. This technique was applied to interpret the meaning, coherence, and relevance of legal norms concerning *informed consent* in relation to professional ethics in healthcare. The analysis

process involves data reduction, categorization of legal and ethical themes, and synthesis of findings to identify patterns of consistency between legal standards and ethical principles. To ensure the validity of the findings, a source triangulation technique was applied by comparing legal norms from multiple sources, such as laws, ministerial regulations, and institutional ethical codes, with scholarly literature and academic interpretations. The triangulation process ensures that the conclusions are consistent, comprehensive, and aligned with current legal and ethical frameworks.

RESULT AND DISCUSSION

The Basic Concept of Informed Consent in Health Ethics

The concept of informed consent represents one of the main pillars of modern health ethics, grounded in the respect for patient autonomy as the right of individuals to make medical decisions concerning themselves. Within the framework of bioethical theory developed by Beauchamp and Childress (2013), informed consent is understood not merely as an administrative procedure but as a moral interaction between healthcare professionals and patients. This theory emphasizes four fundamental principles of bioethics, autonomy, beneficence, non-maleficence, and justice, with autonomy serving as the most prominent philosophical foundation in the practice of informed consent. In essence, patients have the right to receive complete, accurate, and honest information regarding their diagnosis, available medical alternatives, associated risks, and possible outcomes before giving their conscious and voluntary consent.

This principle aims not only to fulfill legal requirements but also to foster trust and establish an ethical therapeutic relationship between patients and healthcare providers. In this context, communication becomes an essential ethical element, not merely a one-way transmission of information, but an open dialogue grounded in honesty and respect for the patient's values and intellectual capacity (Wahyuni et al., 2021). Honesty here entails the healthcare provider's openness in delivering information without manipulation or coercion, while justice is manifested through equal treatment of all patients regardless of their social, economic, or cultural background. Thus, informed consent functions not only as a legalistic instrument but also as a concrete expression of moral values in humane and equitable healthcare practice.

The Ethical Dimensions of Professionalism in the Implementation of Informed Consent

The implementation of *informed consent* is inseparable from the professional ethical responsibilities inherent in healthcare practitioners. As individuals who possess scientific authority and clinical competence, healthcare professionals carry a moral obligation to ensure that every patient attains sufficient understanding before making decisions about the medical procedures they will undergo (Venia et al., 2023). This positions medical personnel not merely as technical executors but as ethical communicators who uphold human dignity throughout the healing process. According to Gillon (2023), the principle of *respect for autonomy* is not fulfilled merely by presenting a consent form; it must be accompanied by comprehensive explanation, patience in responding to patients' inquiries, and empathy toward their psychological conditions. Therefore, the ability to communicate risks, benefits, and alternative

treatments honestly and comprehensibly constitutes an integral aspect of ethical medical professionalism.

In the Indonesian normative context, these ethical obligations are reinforced by the Indonesian Medical Code of Ethics (KODEKI) and the Nursing Code of Ethics, both of which emphasize honesty, clarity, and respect for patient choice (Arini et al., 2021). Article 11 of KODEKI, for instance, stipulates that every physician is obliged to provide medical information accurately and comprehensibly before obtaining patient consent for a planned procedure. Likewise, the Indonesian Nursing Code of Ethics mandates that nurses provide education and information consistent with the patient's condition while upholding decisions made consciously by the patient. The application of these ethical codes serves as a moral foundation for ethical and humanistic medical practice, an increasingly vital principle amid the growing challenges of clinical settings that often prioritize time and administrative efficiency over ethical engagement with patients.

From the perspective of normative ethical theory, the principles underlying *informed consent* can be analyzed through two major approaches: deontology and utilitarianism (Junaidi, 2021). Deontological ethics, as articulated by Dzulhizza et al., (2024), centers on moral duty regardless of consequences. In this view, healthcare professionals must respect patient decisions because doing so is intrinsically the morally right action, irrespective of the medical outcomes. Conversely, the utilitarian approach developed by Jeremy Bentham and John Stuart Mill evaluates ethical decisions based on the greatest good for the greatest number. Thus, *informed consent* can also be seen as a means to minimize potential conflicts, legal disputes, or patient dissatisfaction, thereby generating broader collective benefits. Although distinct, these two ethical frameworks complement one another in explaining why the ethical implementation of *informed consent* is crucial not only for individual patients but also for maintaining the integrity and legitimacy of the healthcare profession as a whole.

Legal Responsibilities of Healthcare Professionals Under Indonesian Law

The legal responsibilities of healthcare professionals in implementing *informed consent* in Indonesia have been significantly reinforced through the enactment of Law No. 17 of 2023 on Health. Article 293 paragraph (1) stipulates that every medical procedure or health intervention must be preceded by the patient's consent after receiving sufficient, accurate, and comprehensible information. This provision affirms the *legal principle* of a patient's right to informed and conscious consent while obliging healthcare workers not only to deliver technical information but also to take into account the patient's psychological, social, and cognitive conditions. Furthermore, Articles 56(3) and 61 of Law No. 17 of 2023 emphasize that patients have the right to refuse medical treatment after proper explanation, thereby strengthening the principle of autonomy in the legal relationship between doctor and patient. These provisions indicate that the responsibilities of healthcare workers are no longer limited to moral or administrative duties but have evolved into *legal obligations* with potential criminal, civil, and administrative consequences if violated (Sinaga, 2021)

Compared to previous regulations, such as Law No. 36 of 2009 on Health and the Minister of Health Regulation No. 290/Menkes/Per/III/2008 on Medical Consent, Law No. 17 of 2023 represents both continuity and normative strengthening (Arini et al., 2021). The 2008 Ministerial Regulation provided detailed provisions regarding the components of *informed*

consent, including the obligation to provide information, the requirement for written or verbal consent, and the condition that the patient must be conscious and competent. However, as a ministerial regulation, it did not possess the same legal authority as an act of law, making its enforcement largely administrative and with limited direct implications for legal accountability. Similarly, Law No. 36 of 2009 recognized the patient's right to information and consent, yet it was not as comprehensive or assertive as the provisions within Law No. 17 of 2023, which adopts a more progressive stance in protecting patient rights and clarifying the legal accountability of healthcare professionals (Adhari, 2023). This reflects a paradigmatic shift from a physician-centered approach toward a *patient rights–based and ethically legal accountability* framework.

Within the framework of positive law, the failure of healthcare professionals to fulfill their obligations regarding *informed consent* can lead to serious legal consequences. Violations such as the failure to provide adequate information or performing medical procedures without the patient's consent may subject healthcare practitioners to criminal sanctions, as stipulated in Articles 404 and 456 of Law No. 17 of 2023. In addition to criminal liability, patients or their families may file civil lawsuits based on *unlawful acts (onrechtmatige daad)* or *breach of professional duty*. Moreover, administrative sanctions, including the revocation of professional licenses, may be imposed by the Indonesian Medical Disciplinary Honor Council (MKDKI) or other professional bodies in cases of ethical violations. Therefore, a comprehensive understanding of the legal aspects of *informed consent* is essential not only to safeguard patient rights but also to function as a *preventive legal instrument* that upholds the integrity and accountability of the healthcare profession in the eyes of the law and society (Kristiawan, 2021; Widiastuti & Ropii, 2024).

Normative Analysis: The Alignment Between Professional Ethics and Law No. 17 of 2023

The harmonization between the principles of professional ethics and legal norms in healthcare practice is a crucial aspect in ensuring the realization of fair, humane, and accountable health services. The ethics of healthcare professions, fundamentally rooted in universal moral values such as autonomy, justice, and non-maleficence, now gain stronger legitimacy through Law No. 17 of 2023 on Health. This legislation not only regulates the administrative and technical aspects of healthcare services but also affirms the integration of ethical principles with positive legal norms. For instance, the principle of patient autonomy, explicitly reflected in the provisions on *informed consent* (Article 293), demonstrates that the law is no longer merely instructive or one-directional; instead, it recognizes the moral agency of patients as sovereign individuals with authority over their own bodies and health (Arini et al., 2021; Rahmadiliyani & Wati, 2021; Sinaga, 2021).

The provisions of Law No. 17 of 2023 reveal that ethical values such as justice and patient rights protection serve as the normative foundation in legal formulation. This is reflected in Articles 56 to 61, which guarantee patients' rights to obtain information, to consent to or refuse medical treatment, and to receive fair and equitable care (Venia et al., 2023). Justice in this context extends beyond equal treatment, it encompasses sensitivity to each patient's specific physical, psychological, and social needs. The principles of *non-maleficence* and *beneficence*, which form integral parts of bioethical theory, are also consistent with the spirit of health law that emphasizes the avoidance of unnecessary risks and the prioritization of

medical benefit. Thus, the new health regulation does not merely control healthcare practitioners' conduct in a formal-legal sense but also functions as a normative framework that upholds human dignity and fundamental human rights in medical practice.

The role of *informed consent* within this context is particularly strategic, as it represents the intersection between ethical and legal dimensions. Ethically, *informed consent* embodies respect for the patient's autonomy and decision-making based on complete and comprehensible information. Legally, it constitutes both the recognition of patient rights and a legal safeguard for healthcare professionals against potential litigation. In practice, *informed consent* serves as a preventive and promotive instrument, fostering transparent, responsible, and just healthcare delivery. Therefore, *informed consent* transcends its normative-administrative nature and stands as a symbol of the integration of ethical values into Indonesia's health law system. Research by Sudiro (2022) further indicates that effective implementation of *informed consent* correlates positively with higher levels of patient trust and satisfaction within healthcare systems.

In conclusion, the normative analysis of Law No. 17 of 2023 demonstrates a progressive alignment between professional ethical principles and existing legal norms. This marks a significant advancement in national health system reform, one that not only emphasizes efficiency and legality but also reinforces the moral dimension of medical service delivery. The harmonization between ethics and law forms a strong foundation for building a holistic health system that prioritizes patient rights protection and preserves the dignity of the healthcare profession itself. Within this framework, *informed consent* serves as tangible evidence that healthcare practice must be grounded in free will, ethical communication, and social justice, anchored in the complementary relationship between ethical principles and legal norms.

Recommendations for Strengthening Informed Consent Practices in Indonesia

Strengthening the practice of *informed consent* in Indonesia requires a comprehensive approach that extends beyond normative legal aspects, encompassing policy reforms and ethics-based education. According to the bioethical framework proposed by Beauchamp and Childress (2013), *informed consent* is not merely an administrative document, but rather a moral communication process between healthcare professionals and patients that embodies the principles of autonomy, beneficence, and justice. Unfortunately, in practical settings, the implementation of *informed consent* often remains formalistic, conducted without a full understanding of the underlying moral values (Sudiro, 2022). Therefore, policy reformulation is necessary, not only to reinforce legal obligations but also to internalize ethical values in every medical intervention.

One strategic step is to strengthen education in health ethics and health law across all levels of medical training, from diploma and undergraduate to professional programs. Medical and nursing education often focuses primarily on clinical competence and disease-centered curricula, while essential *soft skills*—such as patient communication, medical ethics, and legal literacy—are treated as secondary. This poses a major challenge, considering that *informed consent* requires a high level of communication competence and comprehensive juridical understanding. Hence, integrating an interdisciplinary curriculum of ethics and health law will equip future healthcare professionals with reflective capacity and ethical responsibility to

navigate medical dilemmas in an increasingly complex healthcare environment (Harris, 2020; Adhari, 2023).

Furthermore, to ensure uniformity and accountability in practice, the government, through the Ministry of Health, should develop a National Standard Operating Procedure (SOP) on *Informed Consent* that directly aligns with the mandate of Law No. 17 of 2023. This SOP must be practical and context-sensitive, tailored to various service types (inpatient, outpatient, invasive procedures, etc.), levels of medical risk, and patient cultural characteristics. Such a technical guideline will not only serve as a legal safeguard for healthcare providers but also enhance patient trust in the healthcare system. Research by Sulistyowati (2023) shows that procedural clarity and transparency of information within *informed consent* significantly improve ethical compliance and reduce the likelihood of medical disputes. Thus, a standardized national SOP constitutes an integral part of ethical and human-rights-based healthcare governance. By combining normative, ethical, and technical policy approaches, these recommendations provide both conceptual direction and practical solutions applicable across various levels of healthcare service delivery. A robust and high-quality *informed consent* practice not only signifies legal compliance but also represents a key indicator of healthcare that is humane, dignified, and socially just. Therefore, the synergy among health professional education, national legislation, and field-level implementation is essential to achieving a more ethical and patient-centered transformation of Indonesia's healthcare system.

CONCLUSION

Based on the normative and ethical analysis of *informed consent* practices in Indonesia's healthcare system, this study concludes that *informed consent* serves not only as a legal requirement but also as an ethical manifestation of respect for patient autonomy and human dignity. Law No. 17 of 2023 on Health strengthens the legal foundation for informed consent, emphasizing the moral and legal obligation of healthcare professionals to provide complete, accurate, and comprehensible information before performing any medical action. The harmonization between ethical principles—autonomy, beneficence, non-maleficence, and justice—and statutory law represents a progressive step toward an accountable and human-centered healthcare system. The practical implication of this study is the need for the integration of ethics and health law education into medical and nursing curricula, as well as the establishment of a standardized national *Standard Operating Procedure* (SOP) for informed consent. This approach can improve communication quality, strengthen professional accountability, and enhance patient trust in healthcare services. However, this study is limited by its normative focus, which relies on legal and ethical literature without empirical validation from field data. Future research should involve empirical or mixed-method approaches to examine the actual implementation of informed consent in various healthcare settings, including hospitals, clinics, and community health centers. Such studies would provide a more comprehensive understanding of the gaps between regulation and practice, allowing policymakers to design more effective ethical and legal frameworks for patient protection in Indonesia.

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