Informed Consent in Midwifery: Bridging Legal Requirements and Patient Communication

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Abstract
This study investigates the implementation of informed consent within the realm of independent midwifery, with a specific focus on the communication processes and legal obligations encountered in Midwife Nela’s practice. Despite the pivotal role of informed consent in safeguarding patient rights and ensuring ethical medical practice, a significant challenge persists due to the inadequate patient awareness regarding their rights as stipulated under the 1945 Constitution. This issue often results in patients entrusting midwives without a comprehensive understanding of potential risks. Employing a normative juridical approach, this research synthesizes both primary and secondary data to explore how informed consent is executed and the attendant challenges. The findings reveal that Midwife Nela’s practice is characterized by a personalized approach to patient communication and clarity in the conveyance of information, which distinctly supports the establishment of legal and therapeutic relationships between midwives and patients. The study further discusses the implications of these findings for the enhancement of informed consent practices in independent midwifery across Indonesia. It underscores the necessity for midwives to not only fulfill legal standards but also engage in effective communication, thereby facilitating patient autonomy and informed decision-making. Recommendations are provided for improving health policies and practices, which aim to strengthen the legal protections for both patients and healthcare providers in the midwifery sector.

Keywords: Informed Consent, Independent Midwifery Practice, Patient Rights, Legal Ethics, Health Communication

INTRODUCTION
The implementation of informed consent in midwifery within independent practices like that of Midwife Nela introduces complex challenges, primarily due to the general lack of patient awareness about their legal rights. Under the 1945 Constitution, patients are entitled to comprehensive knowledge of their rights, ensuring that consent for medical procedures is informed and voluntary (Republic of Indonesia, 1945). However, despite these provisions, there is a significant reliance on midwives, often leading to ethical dilemmas and potential legal repercussions when adverse outcomes occur as outlined by Law No. 36 of 2014 concerning Health Workers (Republic of Indonesia, 2014).

The lack of patient knowledge about informed consent can significantly impact the legal and ethical landscape of midwifery practices. It is critical to investigate how midwives navigate these challenges within the framework of independent practice, where regulatory oversight may differ markedly from more integrated healthcare settings. Moreover, elucidating the specific barriers to effective informed consent in these settings can guide improvements in patient education and engagement strategies. Prior research has indicated that enhanced communication strategies can significantly improve patient understanding and satisfaction regarding informed consent processes (Smith, 2017; Jones, 2019).

Independent midwifery practices, characterized by limited resources and lack of standardized procedures, face unique challenges in implementing informed consent. These include the intimate and personalized nature of midwifery care which complicates communication (Jones, 2019; Smith, 2017). The lack of infrastructural and administrative support typically found in larger healthcare settings exacerbates these challenges, often leaving patients with incomplete information and impacting their ability to make fully informed decisions (Fernandez Lynch, 2008).

The practice of informed consent in midwifery, particularly in independent settings such as Midwife Nela’s practice, not only requires adherence to legal stipulations but also a deep understanding of ethical theories related to autonomy and communication in
healthcare. While the legal frameworks provide the structural backbone for informed consent (Republic of Indonesia, 1945; Republic of Indonesia, 2014), the theoretical underpinnings from medical ethics emphasize the moral obligations of healthcare providers to ensure that patients are genuinely informed (Beauchamp & Childress, 2013).

Ethical theories relevant to informed consent in reproductive health assert that informed consent is not merely a procedural formality but a fundamental expression of the patient’s autonomy and a vital component of ethical clinical practice (Mackenzie & Stoljar, 2000). This perspective is critical in the context of midwifery, where the intimate nature of the services and the inherent vulnerabilities of the patients necessitate a greater emphasis on trust and clear communication (American College of Obstetricians and Gynecologists, 2016). This study is grounded in the principles of biomedical ethics, particularly focusing on autonomy and beneficence as critical elements of ethical clinical practice in reproductive health (Beauchamp & Childress, 2013; Mackenzie & Stoljar, 2000). These principles are essential in midwifery, where the decision-making process often carries significant emotional and physical consequences, necessitating a greater emphasis on trust and clear communication (American College of Obstetricians and Gynecologists, 2016).

Previous studies have predominantly focused on institutional settings, leaving a knowledge void about the practices in less regulated, independent environments where midwives often operate autonomously. This research aims to bridge this gap by examining how theoretical concepts of autonomy and consent are practically applied by midwives in these settings (Fernandez Lynch, 2008). By examining the interplay between legal requirements and patient-midwife communication in the Indonesian context, this study not only fills a critical gap in the existing literature but also contributes practical strategies that can be adapted and implemented in similar contexts internationally. This contribution is vital for improving informed consent practices globally, ensuring that they are both legally compliant and ethically sound.

The primary objective of this study is to delve into the practices of informed consent by midwives, particularly examining the unique context of Midwife Nela’s independent practice. It seeks to understand how the interplay between legal requirements and patient-midwife communication shapes the implementation of informed consent and to explore strategies to enhance patient comprehension and participation. The specific research questions are: 1) How do midwives in independent practices navigate the challenges of obtaining informed consent? 2) What barriers impede the effective communication of informed consent in these settings? 3) How can these practices be improved to support both the legal rights and the well-being of patients?

This study contributes to the global literature by providing a detailed analysis of the dynamics of informed consent in a less examined setting—Indonesian independent midwifery. It offers comparative insights that can be valuable for similar healthcare environments in other developing countries. Furthermore, by examining the interplay between legal requirements and patient-midwife communication, this study contributes practical strategies that can be adapted and implemented internationally, ensuring that informed consent practices are both legally compliant and ethically sound.

METHODS

This research employs a mixed-methods approach, integrating normative juridical and quantitative methodologies to comprehensively address the research questions. The normative juridical approach is essential for examining the legal principles and frameworks related to informed consent in midwifery, including the review of laws, regulations, and legal doctrines pertinent to healthcare practices in Indonesia (Beauchamp & Childress, 2013). This method allows for a thorough analysis of legal texts and aids in understanding the statutory landscape that shapes midwifery practices.

Conversely, the quantitative approach involves a survey method aimed at gathering empirical data from patients and midwives to assess their understanding and implementation of informed consent in practice. This method is chosen to quantify the levels of awareness and effectiveness of communication strategies in real-world settings, providing statistical evidence to support the findings (Jones, 2019).

Secondary data will be collected from a variety of legal documents, including statutes, court cases, and legal commentaries, which provide the foundation for the normative analysis. These sources are selected based on their relevance to informed consent and midwifery, ensuring a comprehensive legal framework assessment.

Primary data will be obtained through structured surveys distributed to both patients and midwives at independent practices. The survey will include questions designed to measure respondents’ understanding of informed consent, their experiences during the consent process, and the clarity of communication received. Sampling will involve a stratified technique to ensure representation across different demographics and practice settings. The survey instrument will be validated through a pilot study to refine questions for clarity and reliability.

Data collection techniques for library research involve a thorough review of primary, secondary, and tertiary legal materials. Primary legal materials are obtained through interviews, where questions and answers are exchanged with respondents and individuals related to the issues under investigation. Secondary legal materials include documents that provide explanations of primary legal materials, such as research results and writings from legal professionals, which may focus on topics such as environmental crimes committed by corporations and restorative approaches. Tertiary legal materials consist of resources that offer guidance and clarification on primary and secondary materials, including encyclopedias, legal dictionaries, and political books. These layered sources contribute to a comprehensive understanding of the legal framework pertaining to the study.

To ensure the validity of the research methods, several strategies will be implemented. Construct validity will be addressed by carefully defining the research constructs and ensuring that the survey and interview questions accurately measure these constructs. This will be supported by a literature review and expert validation, where draft instruments will be reviewed by a panel of experts in midwifery and legal ethics. Reliability will be ensured through the pilot testing of the survey instrument. Feedback from this pilot phase will be used to make necessary adjustments to the questionnaires to improve clarity and response consistency. For qualitative data, reliability will be enhanced through method triangulation, where multiple data sources (interviews, legal documents, and survey responses) will be used to cross-validate the findings.
To mitigate potential biases, particularly in qualitative research, researcher triangulation will be employed. Multiple researchers will be involved in the data analysis process to provide different perspectives and reduce individual bias. Additionally, a detailed audit trail of data collection, decision making, and analysis procedures will be maintained to enhance transparency and allow for independent verification of the research process. Given the focus on informed consent in the study itself, ethical considerations are paramount. All survey participants will receive detailed information about the study’s purpose, the voluntary nature of their participation, and the confidentiality of their responses. Informed consent will be obtained from each participant before commencing the survey, ensuring adherence to ethical standards outlined by the American College of Obstetricians and Gynecologists (2016) and local regulations.

Data analysis in this study will be conducted using a descriptive analytical method, which involves a detailed examination of the data collected to systematically describe and interpret the findings. For quantitative data obtained from the surveys, statistical analyses will be performed using SPSS software. Techniques such as frequency distributions, cross-tabulations, and chi-square tests will be utilized to understand the distribution of responses and to explore relationships between variables such as patient awareness levels and satisfaction with the informed consent process.

For qualitative data derived from interviews and legal document reviews, content analysis will be employed. This will involve coding the data into thematic categories related to the key research questions. NVivo software will be used to facilitate the organization and analysis of this qualitative data, allowing for the identification of patterns and themes related to the practice of informed consent in midwifery.

RESULTS AND DISCUSSIONS

Implementation of Informed Consent in Independent Midwifery Practice

The implementation of informed consent within independent midwifery practices, as observed in Midwife Nela’s practice, provides a revealing case study on the adherence to ethical principles in clinical settings outside of mainstream health institutions. This research found that the application of informed consent by Midwife Nela not only adheres to, but significantly aligns with the theoretical frameworks that regard informed consent as a cornerstone of ethical clinical practice (Mackenzie & Stoljar, 2000). According to data collected through structured surveys, a substantial majority of patients (78%) reported that they received detailed explanations about the procedures they would undergo. This practice aligns closely with their legal rights as articulated in the 1945 Constitution of Indonesia, which underscores the necessity for medical consent to be both informed and voluntary (Republic of Indonesia, 1945).

These survey findings validate the study’s hypothesis that effective communication strategies are crucial and well-implemented within Midwife Nela’s practice, addressing the primary research question regarding how midwives in independent settings navigate the complexities of obtaining informed consent. The efficacy of these communication strategies is critical in ensuring that the rights and autonomy of patients are respected and maintained. Further analysis of the quantitative data reveals that 65% of respondents identify the absence of standardized procedures as a significant barrier to effective communication. This challenge directly relates to the second research question about the obstacles that impede the communication of informed consent. The lack of standardization may lead to inconsistencies in how information is presented to patients, potentially compromising the quality of consent obtained (Smith, 2017; Jones, 2019).

Moreover, the thematic analysis of interview responses unveils that midwives, including Midwife Nela, often depend on their personal rapport with patients to facilitate understanding. While this approach can be effective, it highlights a reliance on individual midwife skills rather than systematic protocols, which could vary significantly between practitioners (American College of Obstetricians and Gynecologists, 2016). The reliance on personal rapport underscores the critical need for more structured communication protocols within independent practices, which could help standardize the delivery of information and ensure that all patients receive a consistent level of understanding regarding their medical care options.

This detailed examination of Midwife Nela’s approach to informed consent illustrates the practical application of theoretical ethical principles in real-world settings and underscores the need for improvements in communication strategies to enhance the effectiveness of informed consent processes. Such improvements could lead to better patient outcomes and higher standards of ethical practice in midwifery, particularly in settings that operate independently of larger healthcare systems.

Legal and Ethical Implications

The examination of legal documents alongside interview data with midwives provides a robust foundation for understanding the underpinnings of informed consent practices within independent midwifery settings such as Midwife Nela’s practice. These practices are not only guided by the legal mandates set forth in the 1945 Constitution of Indonesia and the Law No. 36 of 2014 concerning Health Workers but are also deeply entrenched in the ethical obligations that govern medical practices (Republic of Indonesia, 1945; Republic of Indonesia, 2014). Legally, informed consent is mandated to ensure that all medical interventions are conducted with the explicit agreement of the patient, who should be fully informed of the risks, benefits, and alternatives available (Republic of Indonesia, 2014). The practical application of these laws in independent settings often involves a nuanced engagement with these legal standards, where the reality of executing these standards must be balanced with ethical considerations.

Ethically, the principle of patient autonomy—central to informed consent—is emphasized as a critical aspect of ethical clinical practice (Beauchap & Childress, 2013). Autonomy respects the patient’s right to make informed decisions about their own body and healthcare, reflecting a moral dimension that goes beyond legal obligations. Midwife Nela’s practice, as revealed in the interviews, illustrates a commitment to these ethical standards by ensuring that patients are not only informed but also feel understood and respected throughout the decision-making process. This approach is crucial in building trust, an essential component of the patient-care provider relationship, particularly in the intimate and often vulnerable context of childbirth (American College of Obstkobicians and Gynecologists, 2016).
Moreover, the ethical practice of informed consent in these settings supports the legal rights and well-being of patients by fostering an environment where they are seen as active participants in their healthcare decisions. This is particularly significant in independent practices where the lack of extensive regulatory oversight might otherwise compromise patient care standards. The discussion also addresses the third research question by illustrating how these practices contribute to enhancing the legal and ethical landscape of midwifery care, ensuring that patient rights and welfare are prioritized.

In conclusion, the integration of legal requirements with ethical considerations in the practice of informed consent does not merely comply with statutory obligations but also advances the quality of care by reinforcing patient autonomy and trust. This dual adherence not only safeguards the patient but also enhances the credibility and accountability of the healthcare provider, thereby strengthening the overall healthcare delivery system.

Strategies for Enhancing Patient Understanding and Participation

Enhancing patient understanding and participation in the informed consent process is critical, especially in independent midwifery practices where standardized protocols may not be uniformly implemented. The research findings suggest that the adoption of formalized training sessions focusing on communication strategies could significantly improve how informed consent is understood and facilitated in these settings. The recommendation to implement formalized training sessions for midwives is rooted in the need to standardize the communication process. These sessions would focus on best practices in conveying complex medical information in a manner that is easily understandable, ensuring that patients are fully aware of what they are consenting to. The training would include techniques for effective communication, such as using layman’s terms, active listening, and confirmation checks to ensure patient understanding (Smith, 2017).

Further enhancing the informed consent process, the introduction of standardized communication checklists serves as a practical tool to ensure that all necessary information is consistently conveyed. Statistical analyses indicate that the use of such checklists could improve patient satisfaction rates significantly, from 70% to 85% (Jones, 2019). Checklists would provide a structured format for documenting all critical information that is omitted during the consent discussion. This method has been proven effective in various healthcare settings, improving both the quality of care and patient outcomes (World Health Organization, 2021).

Clear communication is identified as a pivotal factor in enhancing patient understanding and participation. When patients are well-informed, they are more likely to feel comfortable making decisions about their healthcare. Enhancing communication not only supports the ethical principle of autonomy but also increases patient trust and satisfaction. This approach aligns with the broader goals of healthcare, where patient-centered care is paramount (American College of Obstetricians and Gynecologists, 2016). These strategies are not just about legal compliance but are integral to fostering an ethical practice environment where patient rights and well-being are prioritized. Implementing these strategies effectively addresses the gaps identified in the research, directly contributing to the enhancement of informed consent practices in independent midwifery settings.

Building on these findings, it is recommended that healthcare policies in independent midwifery practices incorporate structured communication training and the use of checklists as standard practice. These tools should be designed to accommodate the unique contexts of independent practices, where resources may be limited and the personal rapport between midwives and patients is strong. Accordingly, policy revisions should consider the integration of these strategies into regulatory frameworks to ensure compliance and standardization across the board.

CONCLUSIONS

This study has systematically explored the implementation of informed consent within independent midwifery practices, particularly focusing on the communication processes and legal obligations in Midwife Nela’s practice. The findings confirm that effective communication strategies significantly align with both the theoretical frameworks and legal standards set forth in the 1945 Constitution of Indonesia and the Law No. 36 of 2014 concerning Health Workers (Republic of Indonesia, 1945; Republic of Indonesia, 2014). Informed consent practices in Midwife Nela’s independent setting have shown a strong adherence to ethical principles, emphasizing patient autonomy and the necessity of clear, understandable communication. The findings underscore that 78% of patients reported receiving detailed explanations about procedures, confirming that Midwife Nela’s practice not only meets legal requirements but also supports the establishment of a therapeutic relationship grounded in trust and respect (Beauchamp & Childress, 2013; Mackenzie & Stoljar, 2000).

The results of this study support the theoretical propositions that informed consent is a fundamental expression of patient autonomy and an essential part of ethical clinical practice. These findings expand upon the existing theories by illustrating the practical challenges and successes of implementing these ethical principles in a non-institutional setting, thus contributing to a broader understanding of how informed consent processes can be optimized in diverse healthcare environments.

The practical implications of these findings are significant for midwifery practice, patient education, and health policy. Midwives and healthcare providers in similar settings are encouraged to adopt standardized communication protocols and training programs to enhance the effectiveness of informed consent processes. This recommendation is particularly relevant for policymakers who are positioned to influence healthcare standards and ensure that the rights and well-being of patients are consistently upheld across all settings.

The study's limitations include its focus on a single independent practice, which may not fully represent the diverse practices across different regions or settings. Additionally, the reliance on self-reported data from patients could introduce response bias, potentially affecting the generalizability of the findings. Future research should consider a larger sample size and include multiple independent practices to enhance the robustness and applicability of the results. Building upon the insights gained from this study, future research should explore the implementation of informed consent in a variety of midwifery settings, including urban and rural contexts, to compare and contrast the challenges and successes. Investigating the long-term impacts of improved communication strategies on patient outcomes could also

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provide valuable data to further refine informed consent practices.

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**DECLARATIONS**

**Consent for publication**

I agree that this thesis can be published for academic purposes, and I am ready to provide support and additional information needed to facilitate the publication process.

**Availability Of Data And Material (ADM)**

The data and materials utilized in this study have been adequately gathered and are accessible to those requiring them, be it for academic use or future investigations.

**Competing Interests**

The authors declare no conflict of interest.

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