JLPH: Journal of Law, Politic and Humanities
E-ISSN: 2962-2816
P-ISSN: 2747-1985
https://dinastires.org/JLPH dinasti.info@gmail.com +62 811 7404 455
DOI: https://doi.org/10.38035/jlph.v6i1

Legal Accountability and Innovative Strategies in Enhancing Healthcare Workers' Compliance with the Implementation of Informed Consent and Refusal in Midwifery Services in Medan City

Edo Maranata Tambunan[1*], Sridama Yanti Harahap[2], Khansa Khalishah[3], Atika Rahmadhani Lubis[4], Briyan Valentino Sitompul[5]
[1]Universitas Murni Teguh, Indonesia, edomaranata8@gmail.com
[2]Universitas Murni Teguh, Indonesia, damaharahap@gmail.com
[3]Universitas Murni Teguh, Indonesia, khansa.ayokerja@gmail.com
[4]Universitas Murni Teguh, Indonesia, atikadhani06@gmail.com
[5]Universitas Murni Teguh, Indonesia, briyanvalentino71@gmail.com

[*]Corresponding Author: edomaranata8@gmail.com

Abstract: The implementation of *informed consent* and *refusal* is a legal, ethical, and professional obligation in midwifery services, aimed at protecting patients' rights and mitigating the risks of disputes and legal liabilities for healthcare providers. However, its implementation still faces serious challenges. The objective of this study is to assess the level of compliance among healthcare workers in implementing informed consent and refusal, and examine aspects of legal accountability and innovative strategies supporting midwifery services in Medan City. The research method used in this study employed normative juridical and empirical methods with a descriptive-analytical approach. Data were collected through purposive sampling using the Slovin formula and analyzed both quantitatively and qualitatively. Based on the survey results, the majority of respondents were categorized as compliant (66.7%), although one-third were non-compliant (33.3%). Institutional support through Standard Operating Procedures (SOPs) was relatively strong; however, legal training and the adoption of digital documentation remained limited, resulting in weak legal awareness and substantive compliance. These findings underscore the importance of strengthening legal capacity through the dissemination and enhancement of health law literacy. Furthermore, standardization of implementation and the acceleration of digital transformation are required to minimize legal risks and improve the quality of services.

Keyword: Informed Consent, Refusal, Healthcare Workers' Compliance, Legal Accountability, Midwifery Services

INTRODUCTION

The compliance instrument for healthcare workers represents adherence to regulations, standards, and ethics established to protect patients' rights and prevent legal risks

(Kurmeningsih, 2024). In practice, non-compliance is still found, mainly due to limited legal understanding among healthcare workers and the lack of regulatory dissemination, such as Law Number 17 of 2023 concerning Health and Minister of Health of the Republic of Indonesia Regulations Number 290/MENKES/PER/III/2008 concerning Approval of Medical Procedures (Kombih et al., 2020).

Informed consent is a fundamental ethical and legal process in healthcare, requiring practitioners to secure a patient's voluntary agreement before any medical procedure, following a clear and comprehensive explanation of the procedure, its potential benefits, associated risks, and available alternatives. Conversely, refusal is the patient's right to decline medical treatment even after sufficient information has been provided. Both principles function to safeguard patients' rights and prevent medical actions without valid consent.

The implementation of informed consent and refusal constitutes a legal, ethical, and professional obligation in the healthcare field, particularly in midwifery practice (Adnan et al., 2022). Adherence to these procedures protects patients' rights and mitigates the risk of disputes and legal accountability for both healthcare facilities and practitioners. In the local context, mapping the level of compliance and its supporting or inhibiting factors is crucial for designing targeted improvement strategies. This study analyzes survey data summarizing healthcare workers' perceptions and practices concerning regulatory, procedural, institutional support, and technological developments.

The instrument for implementing informed consent and refusal remains a serious issue, particularly in Medan City. Various challenges persist, including limited regulatory understanding among healthcare workers, operational time constraints, and the low adoption of digital transformation in documentation and procedures (Tambunan et al., 2024). Moreover, this study finds that in midwifery services in the Netherlands, medical procedures during childbirth are often performed without adequate patient consent, and in some cases, carried out even when patients had explicitly refused (Van Der Pijl et al., 2023).

Non-compliance with informed consent and refusal procedures can result in serious legal implications for healthcare workers (Laura, 2023). Violations of these principles may lead to legal accountability in three domains: civil, criminal, and administrative. In the civil aspect, patients have the right to file claims if they suffer harm due to medical actions performed without valid consent. In the criminal aspect, healthcare workers may be sanctioned if negligence or coercion is proven in the execution of medical procedures. In the administrative aspect, violations of legal procedures may result in sanctions such as reprimands, revocation of practice licenses, or other disciplinary measures (Manullang, 2020).

Therefore, it is necessary to establish consistent legal accountability mechanisms for healthcare workers, accompanied by the formulation of relevant innovative strategies to enhance compliance with regulations concerning the implementation of informed consent and refusal (Fadlian, 2020). Such measures are expected to strengthen the midwifery service system, safeguard patients' rights, and provide legal certainty for healthcare workers. Furthermore, they could contribute to the development of policies that promote greater transparency, accountability, and effectiveness in midwifery services.

METHOD

This research employs both Normative Juridical and Empirical Juridical (socio-legal) methods with a descriptive-analytical approach to obtain a comprehensive data analysis, covering both normative aspects (written law) and empirical practices in the field (Dr. Takdir, S.H., 2018). The Normative Juridical method is used to examine regulations governing informed consent and refusal in midwifery services, while the Empirical Juridical method is applied to evaluate the level of healthcare workers' compliance as well as legal accountability

mechanisms based on field findings (Arif Rachman, (Cand)E. Yochanan, Andi Ilham Samalangi, 2013).

The study was conducted in three Primary Midwifery Clinics located in Medan Tenggara, Medan Denai District, Medan City, North Sumatra Province. The research population consisted of healthcare workers (midwives) directly involved in implementing informed consent/refusal procedures. Purposive sampling was employed to select respondents, involving 45 individuals from a total population of 50 midwives, determined using Slovin's formula with a 5% margin of error.

Data collection was carried out through questionnaires, interviews, focus group discussions (FGDs), and field observations. Data analysis applied a quantitative approach through questionnaires with descriptive-inferential statistical analysis, as well as a qualitative approach through interviews, FGDs, and observations, using thematic analysis to identify issues of compliance and legal accountability in greater depth (Sigit Sapto Nugroho, Anik Tri Haryani, 2020). The questionnaire instrument was developed using a five-point likert scale (Strongly Agree (SA) = 5; Agree (A) = 4; Doubtful (D) = 3; Disagree (DA) = 2; Strongly Disagree (SDA) = 1)x`, with items covering compliance with informed consent/refusal, legal accountability, and innovative strategies. Furthermore, compliance levels and categories of accountability/strategies were classified to provide a more structured overview of the studied phenomenon.

RESULTS AND DISCUSSION

Legal Accountability of Healthcare Workers in Implementing Informed Consent and Refusal

Legal accountability of healthcare workers refers to the legal obligations inherent in every healthcare professional for all medical and non-medical actions carried out in providing healthcare services, whether directly or indirectly, to patients (Ayu et al., 2025). Such accountability arises when healthcare workers fail to perform their professional duties in accordance with professional standards, standard operating procedures, and applicable laws and regulations (Fakultas Hukum Universitas Surabaya, 2022). Forms of legal accountability may include civil, criminal, or administrative liability, depending on the nature of the violation committed (Mahendra et al., 2025).

1. Civil Liability

Civil liability refers to a legal obligation that arises as a consequence of harm suffered by another party, either due to breach of contract when the patient-healthcare worker relationship is construed as a service agreement or due to unlawful acts (onrechtmatige daad), such as when medical actions without consent cause negative physical or psychological impacts. In the medical context, civil liability may be imposed on healthcare workers if medical procedures are performed without valid patient consent, resulting in physical or psychological harm.

Article 1365 of the Indonesian Civil Code (Onrechtmatige Daad/Unlawful Act) "Every unlawful act which causes harm to another obliges the person whose fault caused the loss to compensate for such harm." Accordingly, if a healthcare worker carries out a medical procedure without valid patient consent (without informed consent), the patient may file a claim for damages because the act was unlawful and caused harm (Subekti & Tjitrosudibio, 2019).

Article 1243 of the Indonesian Civil Code (Compensation for Default or Negligence) "Compensation for costs, losses, and interest due to non-performance of an obligation shall be required if the debtor, despite being declared in default, continues to neglect the obligation, or if the matter to be delivered or performed can only be done after the specified period has elapsed." Thus, in the context of medical services, the relationship between patient

and healthcare worker may be regarded as a contract. Failure to explain procedures or obtain consent constitutes a breach of contract (Subekti & Tjitrosudibio, 2019).

2. Criminal Liability

Criminal liability arises when a person commits an act prohibited and punishable by law, whether intentionally or through negligence (Purawijaya et al., 2025). In medical practice, healthcare workers may be subject to criminal liability if medical procedures are carried out without informed consent and cause injury, suffering, or death, particularly where elements of negligence or coercion are proven (Manse et al., 2025). For example, invasive medical procedures without consent that result in serious injury may be prosecuted as a criminal offense if severe negligence is established (Rakha et al., 2025).

Article 351 of the Indonesian Penal Code (Assault) (Kementerian Hukum dan HAM, 2018)

a. Assault is punishable by imprisonment of up to two years and eight months, or a fine of up to four thousand five hundred rupiah.
b. If the act results in serious injury, the offender shall be liable to imprisonment for up to five years.
c. If the act results in death, the offender shall be liable to imprisonment for up to seven years.
d. Assault includes deliberately impairing another's health.

Article 359 of the Indonesian Penal Code (Negligence Causing Injury or Death) "Any person who, through negligence, causes another's death shall be liable to imprisonment for up to five years or confinement for up to one year." (Kementerian Hukum dan HAM, 2018)

Article 440 of Law No. 17 of 2023 on Health (UU No 17 Tahun 2023 Tentang Kesehatan, 2013)

a. Any medical or healthcare worker whose negligence results in serious injury to a patient shall be liable to imprisonment for up to three years or a fine of up to IDR 250,000,000 (two hundred and fifty million rupiah).
b. If such negligence results in death, the offender shall be liable to imprisonment for up to five years or a fine of up to IDR 500,000,000 (five hundred million rupiah).

3. Administrative Liability

Administrative liability arises from violations of administrative provisions or internal institutional regulations. In the healthcare sector, this applies to healthcare workers who fail to comply with established procedures or Standard Operating Procedures (SOPs) set by healthcare facilities, health authorities, or professional organizations. Administrative sanctions may include written or verbal warnings, suspension or revocation of practice licenses, or recommendations for retraining and disciplinary measures.

Article 459(1) of Law No. 17 of 2023 on Health

Administrative sanctions may include written warnings, administrative fines, suspension of practice licenses, or revocation of practice licenses.(UU No 17 Tahun 2023 Tentang Kesehatan, 2013)

Article 49 of Law No. 29 of 2004 on Medical Practice

Doctors or dentists who violate provisions as referred to in Article 51 may be subject to administrative sanctions in the form of written warnings, recommendations for revocation of registration certificates, or recommendations for revocation of practice licenses.(UU No 17 Tahun 2023 Tentang Kesehatan, 2013)

4. Relevance and Research Findings

Research findings at three Midwifery Primary Clinics located in Medan Tenggara, Medan Denai District, Medan City, North Sumatra Province, indicate that the level of legal

liability and healthcare workers' compliance with informed consent procedures remains low, thus requiring improvement and reinforcement. In addition, this study also identifies several strengths as well as certain aspects that remain relevant to be maintained and further developed.

Table 1. Distribution of Healthcare Workers' Compliance with Informed Consent and Refusal

No	Question	SA (5)		A (4)		D (3)		DA (3)		SDA (1)		Total Score
		f	%	f	%	f	%	f	%	f	%	
1	I am aware of the contents of Law No. 17 of 2023 on Health regarding informed consent. **(Q1)**	2	4,4	6	13,3	12	26,7	19	42,2	6	13,3	114
2	I understand the patient's right to give or refuse medical treatment. **(Q2)**	3	6,7	21	46,7	19	42,2	2	4,4	0	0,0	160
3	I always provide a comprehensive explanation to the patient before medical procedures are performed. **(Q3)**	5	11,1	9	20,0	17	37,8	14	31,1	0	0,0	140
4	I allocate specific time to explain the procedures and risks of medical interventions. **(Q4)**	5	11,1	6	13,3	22	48,9	12	26,7	0	0,0	139
5	I accurately document the patient's consent or refusal. **(Q5)**	3	6,7	6	13,3	17	37,8	16	35,6	3	6,7	125
6	I feel time-constrained when explaining informed consent (reverse-scored). **(Q6)**	3	6,7	12	26,7	18	40,0	9	20,0	3	6,7	138
7	I am aware of the legal consequences if informed consent is not properly obtained (reverse-scored). **(Q7)**	1	2,2	6	13,3	22	48,9	14	31,1	2	4,4	125
8	I consider informed consent merely as an obligation. **(Q8)**	12	26,7	19	42,2	14	31,1	0	0,0	0	0,0	178

The analysis of Table 1 indicates that the lowest score was found in the aspect of regulatory knowledge (Q1 with a total score of 114), reflecting a limited understanding of the provisions in Law No. 17 of 2023 concerning informed consent. Procedural practices such as providing comprehensive explanations (Q3 with a total score of 140), allocating sufficient time (Q4 with a total score of 139), and documentation (Q5 with a total score of 125) remain at a moderate level. Two reverse items on time constraints (Q6 with a total score of 138) and legal consequences (Q7 with a total score of 125) highlight operational challenges and weak comprehension of legal implications. Interestingly, the perception that informed consent is "merely an obligation" (Q8) received the highest score of 178, suggesting that compliance is predominantly normative-administrative rather than substantively grounded in ethical-legal meaning.

A closer examination of indicator Q1 reveals a regulatory knowledge gap compared to procedural practices. This finding highlights the need for strengthening regulatory literacy, particularly regarding the implementation of Law No. 17 of 2023 on Health in midwifery practice. Although certain operational aspects (Q3–Q5), such as the depth of explanation, adequacy of time, and accuracy of documentation, have been implemented, their application remains inconsistent. This indicates that the compliance observed tends to be administrative in nature and has not fully developed into substantive compliance.

Furthermore, the aspect of legal consequences (Q7) reflects the persistence of operational barriers rooted in healthcare workers' limited understanding of the juridical implications of their actions. This condition underscores that compliance has not yet been

fully based on substantive awareness, but rather leans toward administrative compliance. Therefore, strengthening legal literacy and enhancing practical capacity are essential to enable healthcare workers to internalize legal consequences comprehensively, ensuring that midwifery services are carried out not only in accordance with procedures but also grounded in prudential legal awareness.

Table 2. Distribution of Compliance Level Categories

Compliance Level	Frequency (f)	Percentage (%)
Compliance	30	66.7
Non-Compliance	15	33.3
Total	**45**	**100**

The analysis results of Table 2 regarding the categorization of healthcare workers' compliance levels show that 66.7% of respondents were "Compliance" (n=30) and 33.3% were "Non-Compliance" (n=15) out of a total of 45 respondents. This indicates that the majority were compliant, yet the proportion of non-compliance remains significant from the perspective of service quality and legal risks. The availability of Standard Operating Procedures (SOPs) and dissemination support from leadership are essential driving factors in ensuring healthcare workers' compliance. However, without adequate training on health law aspects, the implementation of SOPs risks being limited to administrative formality or merely a checklist-based approach, lacking a substantial understanding.

The findings further reveal that although the majority of healthcare workers demonstrated compliance, approximately one-third of respondents had not adhered optimally. This condition indicates a significant risk of potential legal violations in healthcare practices. On the other hand, the high interest of healthcare workers in attending training (Q14) presents a strategic opportunity for change. This can serve as a bridge to close the gap between normative provisions in regulations and the practical skills that healthcare workers must master.

Table 3. Distribution of Legal Accountability and Innovative Strategies

No	Question	SA (5)		A (4)		D (3)		DA (2)		SDA (1)		Total Score
		f	%	f	%	f	%	f	%	f	%	
1	I understand the types of legal accountability in case of negligence in informed consent. **(Q9)**	3	6,7	11	24,4	20	44,4	8	17,8	3	6,7	138
2	There is a specific SOP on informed consent and refusal at my workplace. **(Q10)**	8	17,8	37	82,2	0	0,0	0	0,0	0	0,0	188
3	Leaders always disseminate the importance of informed consent. **(Q11)**	6	13,3	15	33,3	19	42,2	5	11,1	0	0,0	157
4	I have received health law training to improve healthcare workers' compliance. **(Q12)**	0	0,0	0	0,0	21	46,7	19	42,2	5	11,1	106
5	I use digital-based informed consent forms. **(Q13)**	6	13,3	10	22,2	7	15,6	13	28,9	9	20,0	126
6	I am willing to participate in training that enhances my understanding of	10	22,2	21	46,7	14	31,1	0	0,0	0	0,0	176

	health law in midwifery practice. **(Q14)**

The analysis results of Table 3 reveal the presence of strategic institutional support, as reflected in the availability of SOPs for informed consent/refusal (Q10 with a total score of 188) and leadership-led dissemination (Q11 with a total score of 157). However, experience with health law training is low (Q12 with a total score of 106), while commitment to attending training is high (Q14 with a total score of 176). The adoption of digital forms remains moderate to low (Q13 with a total score of 126), indicating that the acceleration of digital transformation has not yet been optimal. Understanding of the types of legal accountability (Q9 with a total score of 138) is at a moderate level. The limited experience in health law training (Q12) highlights a significant gap in knowledge of regulations and legal standards, which should serve as the foundation of healthcare practice. This limitation affects healthcare workers' ability to identify, analyze, and anticipate juridical risks in medical services.

From an academic perspective, this phenomenon reflects weaknesses in capacity building and the lack of continuity in health law education programs. Therefore, systematic interventions are required through the integration of health law training for medical personnel to support continuing professional development (CPD). This step aims to create a balance between clinical competence and legal compliance.

Furthermore, digital transformation serves as a strategic instrument to improve the quality of services. The finding (Q13) indicates that the adoption of digital forms in informed consent/refusal procedures remains suboptimal. Digitalization has the potential to strengthen documentation systems by improving traceability, information completeness, signature validity, and audit trails. Proper implementation of digitalization will reinforce the legal standing of healthcare institutions and professionals, particularly in the event of potential medical disputes.

Table 4. Distribution of Categories for Interpretation of Legal Accountability and Innovative Strategies

Interpretation Category	Frequency (f)	Percentage (%)
Good	27	60.0
Fair	18	40.0
Poor	0	0.0
Total	**45**	**100**

Analysis Results of Table 4. Most respondents fell into the "Good" category (60%; n=27), followed by the "Fair" category (40%; n=18), with no respondents in the "Poor" category. This aligns with the support of SOPs and leadership socialization, although there remains a need for capacity strengthening and the use of technology. This means that, in general, healthcare workers have awareness, but require enhancement in legal literacy/capacity and the implementation of innovative strategies. Noncompliance among one-third of respondents has both clinical and juridical impacts on Service Quality and Patient Safety. Clinically, inadequate informed consent may reduce patients' understanding of risks/benefits, thereby affecting informed decision-making. Juridically, noncompliance increases exposure to civil lawsuits, administrative sanctions, and ethical implications, particularly when documentation is weak.

Innovative Strategies to Enhance Healthcare Workers' Compliance in Implementing Informed Consent and Refusal

Efforts to improve healthcare workers' compliance in implementing informed consent and refusal require a strategic approach that is not only creative but also systematic and regulation-based (Sitepu et al., 2025). The innovative strategies referred to here are a series of

measures designed to ensure that healthcare workers not only understand the legal and ethical aspects of medical consent procedures but also possess the capacity to respect and apply them in midwifery services practice consistently (Mubarak et al., 2024).

All of these approaches are directed at building a healthcare system that upholds patients' rights while ensuring professional standards among healthcare workers (Purbobinuko et al., 2021). The strategies proposed in this study are comprehensively designed to enhance compliance with the implementation of informed consent and refusal. These strategies include: Strengthening healthcare workers' legal and ethical capacity through structured, practice-based training programs. Digitalizing the informed consent documentation system to ensure validity, security, and ease of data access. Reformulating Standard Operating Procedures (SOPs) in line with the latest regulations and professional codes of ethics. Implementing technology-based supervision to enable real-time monitoring and continuous evaluation. Formulating healthcare workers' legal compliance policy models with adaptive approaches to regulatory dynamics and healthcare service needs.

Through this strategic approach, it is expected to make a tangible contribution to strengthening the health law system at the level of primary care services, while also improving the quality of the patient–healthcare worker relationship through the application of comprehensive ethical and legal principles.

Innovative Strategy Through Strengthening the Legal and Ethical Capacity of Healthcare Professionals

The strategy of strengthening legal and ethical capacity is designed as an innovative and comprehensive approach aimed at fostering normative awareness and ethical responsibility among healthcare professionals. This strategy is not only intended to enhance legal literacy but also to internalize ethical principles into daily work behaviour through structured education, tiered training, and systematic supervision. The objectives are to improve healthcare professionals' legal understanding of informed consent procedures and patients' rights to refuse medical treatment, to promote the development of professional and ethical attitudes in clinical decision-making, to reduce potential legal violations stemming from ignorance or procedural negligence, and to ensure the delivery of accountable, transparent, and patient rights–oriented midwifery services (Ediyanto et al., 2025).

The stages of implementing this strategic instrument for strengthening the legal and ethical capacity of healthcare professionals are as follows:

a) Competency Mapping and Training Needs Assessment. The initial step involves surveys and assessments to determine the level of legal and ethical understanding among healthcare professionals and to identify barriers in implementing informed consent procedures.
b) Development of Contextual Training Guidelines. Training manuals are developed based on national regulations and local case studies, covering topics such as: legal aspects (Law No. 17/2023, MoH Regulation No. 290/2008, the Criminal Code, and the Civil Code), professional ethical principles, case studies of ethical violations and their resolutions, and simulations of effective communication with patients. The development of these guidelines is carried out through collaboration between health law academics, clinical practitioners, and professional organizations.
c) Tiered and Continuous Training. Training is conducted through multiple mechanisms: Basic Training: In-depth study of health law regulations and fundamental principles of professional ethics. Advanced Training: Case simulations of ethical/legal violations and practice-based learning (role play). On-the-Job Training: Direct mentoring in clinical implementation of procedures. Refresher Training: Periodic retraining every 6–12 months.

d) Competency Certification. Participants who meet the required standards will be awarded certificates integrated into performance appraisal and human resource development systems. Evaluation is conducted through pre-tests and post-tests to measure improvement in understanding.
e) Internal Monitoring and Evaluation. Regular audits of informed consent documentation are conducted, supported by supervision from management and feedback-based evaluations involving both patients and healthcare professionals.
f) Digitalization of Modules and Achievement Tracking. The development of e-learning platforms facilitates self-directed learning, while reporting systems and training achievement tracking are managed digitally.

Table 5. Indicators of Success for Legal Capacity-Building Strategies

No	Indicator	Target Achievement
1	Percentage of healthcare workers attending training	≥ 90% of total healthcare workers
2	Improvement in legal understanding (pre-test vs. post-test)	≥ 70% increase in average score
3	Completeness of informed consent documentation	≥ 95% in accordance with regulatory standards
4	Patient satisfaction with procedural information and communication	≥ 85% of patients report satisfaction
5	Reduction in the number of complaints/legal disputes related to procedures	≥ 50% reduction within one year

Innovative Strategy Through Digitalization of Informed Consent Documentation Systems

The modernization of healthcare systems, particularly in the aspect of legal documentation, has become an essential need in line with increasing demands for accountability and transparency in medical services. The digitalization of informed consent documentation represents an innovative solution that not only adapts to developments in information technology but also strengthens legal protection for both patients and healthcare professionals. Research conducted in Medan City suggests that digital implementation can enhance data traceability, reduce procedural errors, and facilitate compliance with quality standards of care. This aligns with findings affirming that the use of digital documentation enhances the reliability of medical consent systems (Van Der Pijl et al., 2023).

The strengthening of digitalization aims to ensure the integrity and security of medical consent data, reinforce healthcare professionals' procedural compliance, simplify internal and external audit processes, and provide legally valid electronic documents. The implementation strategy is carried out in stages, beginning with the development of an integrated digital consent application linked to electronic medical records (EMRs). This system is designed to include consent forms compliant with regulations, covering explanations of risks, benefits, and treatment alternatives, as well as being equipped with features such as electronic signatures with time stamps, encrypted cloud storage, and audit trail logs.

To ensure effective system adoption, healthcare professionals may be provided with technical training, including system operation, digital communication with patients, and an understanding of data privacy standards and legally recognized electronic signatures as stipulated under Law No. 1 of 2024 concerning the Second Amendment to Law No. 11 of 2008 on Electronic Information and Transactions. Pilot trials are conducted within midwifery service units through direct simulations and user experience evaluations. Following the initial evaluation, the system will be fully implemented in daily operations with ongoing monitoring and digital audits.

Further strategic reinforcement is undertaken through updates to internal policies and clinical SOPs, mandating the digitalization of all consent procedures and ensuring their legal

validity. The digitalization workflow is designed to be simple and efficient, beginning with the input of medical procedure data, patient digital consent, automatic storage, and access by verifiers when required. The success of this strategy will be measured through key performance indicators.

Table 6. Success Indicators of Document Digitalization

No	Indikator	Target
1	Number of digitalized consent forms	≥ 90% of all procedures
2	Time for completion and filing	≤ 5 minutes per document
3	Availability of forms during audits	100% accessible and complete
4	User satisfaction (staff & patients)	≥ 85% satisfied

With the implementation of comprehensive and sustainable digitalization, this strategy is expected to enhance the efficiency of midwifery services, strengthen the legal position of healthcare institutions, and build public or patient trust in a transparent, accountable, and technology-based service system.

Innovative Strategy Through Reformulation of Service SOPs

Reformulasi The reformulation of Standard Operating Procedures (SOPs) is an innovative strategy aimed at improving, adjusting, and aligning healthcare operational procedures with regulatory developments, professional best practices, and dynamic field needs. In the context of midwifery services, particularly regarding the implementation of informed consent and refusal, this strategy is intended to establish procedural workflows that are legally sound, clear, patient-centered, and provide legal certainty for healthcare professionals.

The urgency of SOP reformulation is further reinforced by recent regulations, such as Law No. 17 of 2023 on Health and Ministry of Health Regulation No. 290 of 2008 on Consent for Medical Actions, which mandate that medical service procedures be conducted lawfully, voluntarily, and with proper documentation. Misalignment of SOPs with these regulations can weaken service accountability and reduce public trust.

Therefore, the SOP reformulation strategy has several key objectives, including: increasing legal compliance through alignment of SOPs with applicable laws and regulations; ensuring consistency of midwifery service procedures with standardized guidelines; supporting the digitalization of informed consent and refusal documentation; strengthening legal protection for patients and healthcare professionals; minimizing potential legal claims through valid and proper documentation; and promoting service quality improvement through transparent and participatory procedures. The implementation steps of this strategy include:

a. Audit and Benchmarking of Existing SOPs**.** Inventory current SOPs, review their compliance with the latest regulations, and identify weaknesses and implementation barriers.
b. Drafting New SOPs. The SOP reformulation draft is prepared by a multidisciplinary team (health, legal, and quality). First, procedural steps are outlined from explaining medical actions to documenting patient consent/refusal. Second, complete procedures are included in case a patient refuses treatment, including risk mitigation. Third, guidance is provided for communicating risks in easily understandable language. Fourth, integration with digital consent systems, including data input, validation, and backup.
c. SOP Trial and Simulation. SOPs are internally tested through procedural simulations with midwifery staff. Focus group discussions (FGDs) are conducted to gather practical feedback and identify potential implementation challenges.
d. Approval and Distribution of SOPs. The finalized SOPs are approved by healthcare facility leadership (clinics/hospitals) and distributed to all relevant service units.

e. Socialization and Training. Through workshops, e-learning, and procedure simulations, healthcare professionals are given a practical understanding of the new SOPs, ensuring their implementation is internalized into daily work culture, not just administrative compliance.
f. Periodic Monitoring and Evaluation. An SOP audit team is established to assess compliance and effectiveness. Evaluations are conducted annually or whenever regulations change, incorporating feedback from patients and healthcare professionals. Violations of SOPs may result in administrative or ethical sanctions according to professional organization regulations.

Table 7. Indicators of Success for SOP Reformulation

No	Indicator	Target Achievement
1	Percentage of healthcare workers trained on the new SOP	≥ 95%
2	Compliance with the new SOP	≥ 90% of actions in accordance with the procedure
3	Completeness of consent documentation	≥ 95% of documents fully recorded
4	Reduction in audit findings of SOP violations	≥ 50% reduction within 1 year
5	Patient satisfaction level	≥ 85% of patients report satisfaction with services

Innovative Strategy Through Technology-Based Supervision

The Technology-based supervision is a strategy that utilizes digital systems and information applications to monitor, evaluate, and follow up on healthcare workers' compliance in carrying out service procedures, particularly in documenting informed consent and refusal. This strategy is designed to replace conventional manual and sporadic supervision systems with a real-time, integrated, transparent, and data-driven approach. Technology-based supervision serves as an innovative solution, ensuring traceability of every action, enhancing transparency, facilitating internal and external audits, and improving supervision efficiency.

The strategy can be implemented directly, systematically, and consistently as follows:

a. Development of a Digital Monitoring System. Healthcare institutions need to build or integrate a supervision module into the electronic medical record (EMR) system, including: A dashboard monitoring healthcare workers' compliance in completing informed consent and refusal forms; A summary of medical procedures requiring patient consent; Automatic notifications for incomplete documents; and an audit trail feature recording who inputs, verifies, and stores documents.
b. Establishment of Digital Key Performance Indicators (KPIs). KPIs are developed and integrated automatically into the system, such as: Percentage of completed consent documents; Average time to complete forms; Number of medical procedures performed without documented consent.
c. Real-Time Monitoring. Supervisory teams can access daily, weekly, or monthly reports from the system dashboard; analyze violations or declines in compliance; and issue written notifications through the system when violations are detected.
d. Automatic Notification System (Alert System). The system automatically sends alerts to healthcare workers if: Informed consent forms are incomplete or unsigned; Time gaps exceed the standard between procedure execution and documentation; Discrepancies exist between the type of procedure and information recorded in the form.
e. Periodic Evaluation. Periodic evaluations are conducted to assess compliance based on system indicators; identify units or individuals at highest risk of violations; and formulate corrective actions or empowerment through advanced training.
f. Reporting and Follow-Up. Supervision results are compiled into digital reports and periodically submitted to: Heads of service units (e.g., Head of Midwifery Unit); Internal

quality teams and ethics committees if required; Management for decision-making, recognition, or administrative sanctions.

Table 8. Success Indicators for Technology-Based Supervision

No	Indicator	Target Achievement
1	Complete documentation of consent forms	≥ 98%
2	Non-compliance notifications addressed	100% within 3 working days
3	Routine electronic audits are conducted	100% according to schedule
4	Compliance with using the monitoring system	≥ 95% of healthcare workers are using the system

With this strategy, the supervision of informed consent and refusal implementation is no longer incidental but becomes an integral part of the quality management system. It is expected to foster a work culture that is accountable, transparent, and oriented toward the protection of patient rights as well as the professionalism of healthcare providers.

Innovative Strategy Through the Formulation of a Health Worker Legal Compliance Policy Model Based on Regulatory Adaptation

The formulation of this Policy Model is a policy approach designed to establish a specific, implementable, and sustainable internal regulatory framework at the healthcare facility level, aimed at enhancing health workers' compliance with the implementation of informed consent and refusal. This policy will not only serve as a procedural guide but also function as a managerial control tool, a legal compliance assurance, and a means of fostering an organizational culture oriented toward ethics and professionalism. The urgency of this strategy lies in its ability to bridge the gap between macro-level regulations and micro-level operational needs within healthcare facilities, create an internal system that ensures consistent implementation of informed consent and refusal procedures, and provide proportional legal protection for health workers through documented and structured operational standards. Strategic implementation steps include:

a. Regulatory Analysis: The drafting team thoroughly reviews relevant legislation, including Law No. 17 of 2023, Minister of Health Regulation No. 290/MENKES/PER/III/2008, and professional codes of ethics. Provisions requiring local adaptation are identified as the basis for policy substance development.
b. Formation of the Drafting Team: A cross-functional working team is established, comprising clinic management, health worker representatives, legal units, and quality departments. Focus Group Discussions (FGDs) are conducted to gather implementation challenges and technical input from direct users.
c. Drafting the Policy: The policy draft includes: objectives, scope, mandatory procedures, reporting and evaluation mechanisms, and internal sanctions for non-compliance. The document format is structured for immediate implementation as internal organizational regulations.
d. Pilot Testing and Validation: Implementation simulations are conducted in one or two service units to test the policy. Results are evaluated with input from health workers and management to revise the policy content before formal approval.
e. Approval and Dissemination: Once validated, the policy is approved by the highest authority of the healthcare facility (clinic head or director). Training and dissemination are then conducted for all health workers to ensure uniform understanding.

By implementing this strategy, healthcare facilities will not only possess a robust internal legal instrument but also enhance the professionalism and accountability of health workers toward patient rights. A standardized, practical, and periodically evaluated policy

serves as the primary foundation for building a transparent, ethical, and sustainable midwifery service system (Mubarak et al., 2024).

CONCLUSION

Research conducted at three primary obstetric clinics in Medan City indicates that the implementation of informed consent and refusal procedures still faces several substantive and operational challenges. Healthcare workers' regulatory knowledge of legal provisions, particularly Law Number 17 of 2023, remains low, resulting in weak legal awareness and substantive compliance. Compliance analysis shows that although the majority of healthcare workers are categorized as "compliant" (66.7%), a third of respondents are still non-compliant (33.3%), indicating significant risks to service quality and potential legal disputes.

Obstacles were also identified in understanding legal consequences, further emphasizing the need to strengthen legal literacy. From an institutional perspective, the availability of standard operating procedures (SOPs) and support from leaders in disseminating information are important supporting factors, but these are not yet supported by adequate health law training experience. The high level of interest in training provides a strategic opportunity to bridge the gap between normative provisions and practical skills. Meanwhile, the use of digital forms remains limited, despite the significant potential of digital transformation to improve traceability, validity, and the strength of legal evidence.

Overall, this study confirms that improving healthcare workers' compliance and legal accountability requires comprehensive and innovative interventions. By implementing these innovative strategies, it is hoped that the midwifery care system will not only operate in accordance with formal regulations but also be grounded in a deep ethical and legal awareness. This effort will not only strengthen the protection of patient rights but also enhance the overall quality of healthcare services. Furthermore, it ensures legal certainty for both patients and healthcare providers while simultaneously offering professional protection for healthcare workers in carrying out their duties responsibly and ethically.

REFERENCE

Adnan, C., Saraswati, R., & Retnaningsih, C. (2022). Application of Aspects of Consent in Medical Procedures (Informed Consent) As a Form of Consensualism Principle. *Soepra*, *8*(2), 234–250. https://doi.org/10.24167/shk.v8i2.5164

Arif Rachman, (Cand)E. Yochanan, Andi Ilham Samalangi, H. P. (2013). *Metode Penelitian Kuantitatif, Kualitatif, dan R&D* (Issue January).

Ayu, P., Supraba, A., Parsa, I. W., Bagus, I., & Fajar, G. (2025). *94332-2-Pb*. *11*(1), 126–131.

Dr. Takdir, S.H., M. . (2018). Hukum Kesehatan. In *Lembaga Penerbit Kampus IAIN Palopo* (Vol. 20, Issue 4).

Ediyanto, Markoni, Kanthika, I. M., & Asri, D. P. B. (2025). Legal Analysis of Legal Power and Legal Protection in Informed Consent Practices in High-Risk Surgical Procedures in Hospitals. *International Journal of Science and Society*, *7*(2), 465–479. https://doi.org/10.54783/ijsoc.v7i2.1443

Fadlian, A. (2020). Pertanggungjawaban Pidana Dalam Suatu Kerangka Teoritis. In *Jurnal Hukum Positum* (Vol. 5, Issue 2).

Fakultas Hukum Universitas Surabaya. (2022). Urgensi Informed Consent Sebagai Pencegahan Tindak Pidana Oleh Dokter. *Hukum, Jurnal Volume, Kenotariatan Sinta, Terakreditasi*, *6*(2), 1201–1215.

Kementerian Hukum dan HAM. (2018). Pasal 188 KUHP. In *Hukum Pidana* (Vol. 5, Issue 2).

Kombih, S. U., Fitriani, A. D., & Simanjorang, A. (2020). Analisis Kepatuhan Perawat

Terhadap Penggunaan Standar Prosedur Operasional (Spo). *Media Publikasi Promosi Kesehatan Indonesia*, *3*(1), 136–142.

Kurmeningsih, E. F. (2024). Kepatuhan Penerapan Informed Consent Pemeriksaan Human Immunodeficiency Virus Di Poli Voluntary Counselling And Testing Rsud Dr. Abdoer Rahem. *Plenary Health : Jurnal Kesehatan Paripurna*, *1*(3), 172–176.

Laura, Z. G. (2023). Penerapan Hukum Kesehatan Dalam Hak Dan Kewajiban. *Adagium: Jurnal Ilmiah Hukum*, *1*, 82–92. https://ejournal.mejailmiah.com/index.php/adagium/article/view/16/16

Mahendra, M., Afrita, I., & Triana, Y. (2025). Tanggung Jawab Hukum Tenaga Medis Terhadap Standar Kompetensi Atas Tindakan Medis. *Jurnal Kesehatan Tambusai*, *6*(1), 246–271. https://doi.org/10.31004/jkt.v6i1.41831

Manse, Y. R., Siregar, R. A., & Panggabean, M. L. (2025). Pertanggungjawaban Pidana Tenaga Medis dalam Malpraktik. *Jurnal Ilmu Hukum, Humaniora Dan Politik*, *5*(5), 4682–4688. https://doi.org/10.38035/jihhp.v5i5.5771

Manullang, H. (2020). Pengantar Tata Hukum Indonesia Herlina Manulang. In *Lex Crimen: Vol. IX*.

Mubarak, M. H., Djalaluddin, N. A., Panggeleng, A. M. F., Heriyati, H., Page, M. T., Shabir, A. M., & Hidayat, L. (2024). Menata Ulang Norma: Praktik Informed Consent Yang Inovatif Oleh Dokter Penanggung Jawab (Studi Kasus Rumah Sakit Pemerintah Di Sulawesi Barat). *Journal of Governance and Public Administration*, *1*(3), 494–501. https://doi.org/10.59407/jogapa.v1i3.966

Purawijaya, H. R., Jollis, J., & Aswan, A. (2025). Informed Refusal as an Application for The Protection of Patients' Human Rights and Legal Protection for Doctors and Health Workers in Health Services From A Criminal Law Perspective. *Jurnal Impresi Indonesia*, *4*(6), 2007–2016. https://doi.org/10.58344/jii.v4i6.6648

Purbobinuko, Z. K., Prahesti, R., & Puspita Ningsih, K. (2021). Upaya Meningkatkan Kepatuhan Profesional Pemberi Asuhan Pasien Dalam Dokumentasi Rekam Medis. *Jurnal Ilmiah Perekam Dan Informasi Kesehatan Imelda (JIPIKI)*, *6*(2), 205–212. https://doi.org/10.52943/jipiki.v6i2.607

Rakha, M., Fadillah, H., & Sewu, L. S. (2025). *Perlindungan Hukum Bagi Pasien yang diberi Tindakan Medis Tanpa Informed consent dihubungkan dengan Asas Perlindungan dan Keselamatan Pasca Lahirnya Undang-Undang Nomor 17 Tahun 2023 tentang Kesehatan Jo*. *5*(3), 2049–2062.

Sigit Sapto Nugroho, Anik Tri Haryani, F. (2020). Metodologi Riset Hukum. In Sarjiyati (Ed.), *Oase Pustaka* (Pertama). Oase Pustaka.

Sitepu, F., Isnaini, I., & Akmal, M. R. H. (2025). Implementation of Informed Consent at Bandung Hospital, Medan City. *Journal of Public Representative and Society Provision*, *5*(2), 259–270. https://doi.org/10.55885/jprsp.v5i2.526

Subekti, R., & Tjitrosudibio, R. (2019). Kitab Undang-undang Hukum Perdata (KUH Perdata). In *Angewandte Chemie International Edition, 6(11), 951–952.*

Tambunan, E. M., Harahap, S. Y., Valentine, R., Mei, D., Sianturi, R., & Afandi, M. (2024). *Analisis Yuridis Terhadap Penerapan Informed Consent dan Refusal Pada Seluruh Aspek Tindakan Pelayanan Kebidanan di Kota Medan*. *5*(1), 59–68.

UU No 17 Tahun 2023 Tentang Kesehatan. (2013). Kesehatan. In *UU No 17 Tahun 2023 Tentang Kesehatan* (Issue 187315). http://www.amifrance.org/IMG/pdf_HM9_Mental_Health.pdf

Van Der Pijl, M. S. G., Klein Essink, M., Van Der Linden, T., Verweij, R., Kingma, E., Hollander, M. H., De Jonge, A., & Verhoeven, C. J. (2023). Consent and refusal of procedures during labour and birth: a survey among 11 418 women in the Netherlands. *BMJ Quality and Safety*, 511–522. https://doi.org/10.1136/bmjqs-2022-015538