KEMAS 21 (4) (2026) 813-826

Jurnal Kesehatan Masyarakat

http://journal.unnes.ac.id/nju/index.php/kemas

Legal Protection in Providing Informed Consent for Obstetric Procedures

Anggrainy Dwifitriana Kouwagam[1]✉, Hamzah Halim[1]

[1]Faculty of Law, Hasanuddin University, Makassar, Indonesia.

Article Info

Article History:
Submitted August 2025
Accepted March 2026
Published April 2026

Keywords:
Legal Barriers; Informed Consent; Legal Implementation; Obstetric Procedures

DOI
https://doi.org/10.15294/kemas.v21i4.33148

Abstract

The purpose of this study is to inform that consent is a crucial part of medical procedures, particularly in obstetrics, serving as legal protection for both patients and medical personnel. International studies show that 44.7% of women in France did not provide consent before administering oxytocin in 2021, and in Indonesia, only 55% of patients fully understood their rights and informed consent procedures by 2024. This study aims to analyze the implementation of the law regarding informed consent in obstetric procedures and identify the legal barriers encountered. The method used was normative legal research with a legislative approach and qualitative data analysis using NVivo. The results showed that although written consent procedures are widely implemented, the substance of the information provided is often not well understood by patients. The primary legal barriers identified were incomplete documentation, lack of patient understanding, and time constraints in medical emergencies. The study concluded that despite clear regulations, their implementation still faces significant obstacles. Recommendations include improving medical personnel's understanding of the importance of clear communication, improving documentation, and providing legal training for patients. The recommendation of this study is the need to improve regulations and procedures to ensure more effective and comprehensive implementation of informed consent.

Introduction

Informed consent is an essential part of every medical procedure, including obstetrics, serving as legal protection for medical personnel as well as the fundamental rights of patients. Through informed consent, patients are given a comprehensive explanation of the risks, benefits, and alternatives of the medical procedures before giving consent (Abiola *et al*., 2025). This ensures that the medical procedure is not performed arbitrarily, but rather based on conscious consent given by the patient willingly after understanding the consequences of the action (LaFata, 2019). Especially in obstetric procedures related to the delivery process or reproductive procedures, informed consent is crucial considering the high risks and health implications for both mother and fetus (Hollinghurst & McConnell, 2022). The proper implementation of informed consent not only protects the rights of patients but also maintains the professionalism and legal responsibility of doctors (Kurniasi & Sakharina, 2022).

The basis of international law related to informed consent is clearly regulated in a series of instruments, including the Helsinki Declaration (1964, last updated 2013), which affirms the right of patients to adequate information and to provide voluntary consent before medical or research procedures (Kaye *et al*., 2019). Article 7 of the Universal Declaration of Human Rights (1948) also emphasizes the right to freedom and protection of medical treatment without consent (Spiridonov *et al*., 2024). In addition, the International Covenant on Civil and Political Rights (ICCPR), Articles 7 and 10 affirm that no one should be forced to undergo medical procedures without explicit

✉ Correspondence Address:
Faculty of Law, Hasanuddin University, Makassar, Indonesia
Email: anggrainydk@gmail.com

pISSN 1858-1196
eISSN 2355-3596

permission (Henderson & Griffiths, 2019). At the regional level, the UN Convention on the Rights of the Child (1989), Article 24 underlines the right of children to health protection, which implicitly includes the consent of medical measures by parents or guardians in the best interests of the child (Campbell, 2021). All of these instruments underscore the principle of informed consent as a crucial element of human rights protection in the context of global health services.

Legal protection of informed consent in Indonesia is mentioned in detail in various laws and regulations. The main legal basis governing this includes Law Number 17 of 2023 concerning Health, which, in Article 293 paragraph 3, emphasizes the obligation of medical personnel to provide explanations about diagnosis, risks, and alternative medical measures to patients (Karwur, 2024). Law Number 29 of 2004 concerning Medical Practice also provides an important legal basis, especially in Article 45 paragraphs 1-3, which regulates the approval of medical measures, as well as Article 50 letters a and d related to professional standards and protection of doctors. Furthermore, Article 52 gives patients the right to a complete explanation regarding the medical procedure to be carried out. Law Number 44 of 2009 concerning Hospitals, Article 37, paragraph 1 emphasizes the importance of approving medical measures before they are implemented. Law Number 36 of 2014 concerning Health Workers also regulates in Article 57 letter a jo 75 and Articles 77-78 concerning the obligations of health workers and patient rights, including related to compensation and dispute mediation. Regulation of the Minister of Health Number 290 of 2008 concerning Approval of Medical Measures, especially Articles 2 and 11-12, further regulates informed consent in emergency conditions. The Decree of the Minister of Health Number 129 of 2008 concerning Minimum Service Standards for Hospitals also adds clarity on the procedure for approving medical procedures in hospitals (Syamsiah, 2021).

The theory of therapeutic contracts is closely related to the legal protection of informed consent introduced by Leonard Riskin, a medical-legal expert from the United States, in 1985, which is very relevant (Mena-Tudela *et al*., 2020). This theory explains the legal relationship between doctor and patient as a binding contract, in which the doctor is obliged to provide medical care according to professional standards and the patient is entitled to complete information as the basis for legal consent (Baranowska *et al*., 2019). This therapeutic contract emphasizes the aspects of mutual agreement and transparency in medical practice, so that the actions taken are legal and ethical. The risk is that, without proper informed consent, this contract may be null and void or cause legal disputes due to violations of patient rights (Zaami *et al*., 2019). The application of this theory, especially in risk-prone obstetrics, can strengthen the legal and ethical basis for the protection of patients' rights as well as the obligations of doctors.

Based on the latest international research data for the 2021-2024 period, the practice of providing informed consent in obstetrics still faces significant challenges. A population study in France in 2021 showed that 44.7% of women reported not being given consent before the administration of oxytocin, 60.2% not being given consent before an episiotomy, and 36.6% of emergency caesarean sections performed without adequate patient consent (Jacques *et al*., 2025). Observational research in Ethiopia also reported that compliance with obtaining informed consent before obstetric surgery was only about 55% in 2023 (Pittalis & Sackey, 2024). On the other hand, a study at Ain Shams Hospital, Egypt, in 2023/2024 found that the quality of the informed consent process in gynaecological and obstetric elective surgeries tended to be low, especially in patients with low levels of education and a lack of understanding of the right to give voluntary consent (Ferede & Fetene, 2025). This phenomenon indicates that although the instruments and legal principles of patient rights are clear, implementation in the field is still hampered by the factors of communication, patient education, and training of health workers related to approval procedures (Biyazin & Yetwale, 2022).

Nationally, empirical facts show that the application of informed consent in obstetrics, particularly in surgical procedures such as sectio caesarea, still faces significant challenges

and has continued to be in the spotlight in recent years. In 2021, research at Patria Hospital IKKT West Jakarta recorded an average completeness of informed consent for sectio caesarea procedures of 91.73% (Purwanto & Romlah, 2022). However, this figure is still below the minimum standard required by the Ministry of Health, which must reach 100% completeness in all form components. In 2022, research at Setia Mitra Hospital in South Jakarta found that some important aspects, such as explanations of risks and complications, are often not fully listed in 100% of the files, even though basic identification is complete. Data for 2023 in Yogyakarta states that the level of completeness in filling out informed consent forms still ranges from 74% to 97%, with the percentage of incompleteness reaching 26%, which is mostly due to a lack of understanding of patients or families regarding the importance of informed consent (Mursyid & Dewanto, 2023). Meanwhile, in 2024, national primary data indicate that out of 200 respondents, only 55% fully understand informed consent rights and procedures, while the remaining 45% do not understand, especially in the aspect of explaining the risks and complications of obstetrics procedures (Stuart & Stuart, 2024).

One of the most recent international legal cases related to informed consent in obstetrics is the decision of the European Court of Human Rights (ECHR) in the case of Y.P. v. Russia, Application No. 43399/13, decided on January 19, 2021. In this case, Y.P., a Russian woman undergoing a caesarean section, underwent a permanent sterilization without her consent. The hospital argued that the measure was necessary to prevent future medical risks, but never obtained explicit consent from the patient, either verbally or in writing. The European Court of Justice affirms that no emergency situation or direct threat to life can justify such actions without informed consent. The ECHR ruled that such medical measures violate the patient's right to privacy and bodily integrity under Article 8 of the European Convention on Human Rights and affirmed the importance of legal protection of informed consent in obstetric services, especially in irreversible measures such as sterilization. The ruling emphasizes international standards that any medical procedure, especially those that are high-risk in obstetrics, must obtain free, conscious, and explicit consent from patients (Den Exter, 2023).

The second very relevant case is the decision of Montgomery v. Lanarkshire Health Board [2015] UKSC 11, decided by the Supreme Court of the United Kingdom on 11 March 2015. This case began with Nadine Montgomery, a pregnant woman with a history of diabetes, who did not get complete information about the risk of shoulder dystocia if she gave birth vaginally. As a result of the doctor's failure to provide material information about the risk, Montgomery's son suffered a severe brain injury. The U.K. Supreme Court ruled that medical personnel are obliged to convey all "material" risks, i.e., risks that would be considered important by the patient in their position, not just based on one-sided medical considerations. This ruling makes the legal standards of informed consent stricter, requiring doctors and health care workers to truly involve patients in conscious medical decision-making, and an integral part of the patient's right to autonomy. Any failure to provide sufficient information can be legally sued as a violation of the patient's human rights (Devaney & Black, 2025).

This research is highly necessary because, although there are clear regulations, practice in the field shows a gap between legal theory and actual implementation, particularly regarding patient understanding and procedural inconsistencies that occur. In the context of normative law, this study is important to evaluate the suitability of existing laws and the practice of providing informed consent in obstetrics in Indonesia and to identify factors influencing the implementation in accordance with applicable regulations. The formulation of the problem in this study is: 1) How is the implementation of the law regarding informed consent in obstetrics? 2) What are the legal obstacles faced in the application of informed consent in obstetrics?

Method

This research method uses a normative legal approach to analyze and evaluate the legal provisions that govern informed consent in

obstetrics in Indonesia. The legislative approach is used to examine various related regulations, such as Law Number 36 of 2009 concerning Health, as well as other regulations that regulate the procedures and implementation of informed consent in medical practice (Bachril & Maskun, 2022). This study aims to identify the differences between written legal norms and their implementation, focusing on the obstacles and challenges faced by medical personnel and patients in implementing informed consent in obstetric procedures. The research design is descriptive and analytical, with a qualitative approach that prioritizes the analysis of legal documents, court decisions, and relevant scientific literature (Suyanto, 2023).

The subject of this study is Indonesian laws and regulations that regulate informed consent, as well as literature that explores the application of this law in obstetric medical practice. The object of this research is the legal norms contained in these regulations, both in the form of national (for example, Law Number 36 of 2009) and international laws related to informed consent, such as the Helsinki Declaration. This study aims to describe the application of the law regarding informed consent in obstetrics, as well as identify the challenges that exist in the conformity between regulations and practices in the field. The focus of this research is on the proper implementation of the law, as well as how existing regulations can be optimized to address problems that arise in medical practice (Suyanto, 2023).

The data analysis technique in this study combines the normative descriptive analysis method with the application of NVivo, a software for qualitative data analysis. NVivo will be used to encode and analyze secondary data collected, such as legal documents, regulations, scientific articles, and court rulings related to informed consent in obstetric actions (Wahid & Kususiyanah, 2023). The analysis process will be carried out systematically to identify key themes, legal gaps, and obstacles in the implementation of existing regulations (Syahrum, 2022). The data collection technique is carried out through literature studies, by tracing relevant references in libraries, journals, law books, and related official documents. The collected data will then be analyzed by relating legal theory to the facts of its application in the field, as well as using NVivo to provide a more structured and in-depth analysis of the implementation of the law (Sukmawan & Damayanti, 2025).

Result and Discussion

The results of this study focused on the implementation *of informed consent* law in obstetric procedures, analyzed using NVivo software. Qualitative data analysis was carried out on observations, as well as supporting documents, with open, axial, and selective coding techniques to identify the main themes that emerged. Through *node mapping* and *queries* on NVivo, patterns were found that showed the level of health workers' understanding, the mechanism of providing information to patients, and the conformity of *informed consent* practices with applicable legal provisions.

The bar chart visualization of the law implementation shows that written consent is the most dominant aspect in the implementation of informed consent in obstetrics. This dominance indicates that medical practice emphasizes the fulfillment of administrative elements as a matter of legal compliance. Medical personnel tend to prioritize the presence of signatures or consent forms as legal evidence, although the substance of providing information to patients is not necessarily fully understood. This condition reflects the tendency to formalize the law in the practice of informed consent. The aspect of compliance with the Law and Regulation of the Minister of Health and the fulfillment of patient rights also showed a relatively high frequency. This indicates that normatively, medical personnel and health institutions have referred to the applicable legal framework in implementing informed consent. However, the frequency that is not as high as written consent indicates that the understanding and implementation of patient rights is often still procedural, not substantive, so that the fulfillment of patient rights has not been fully realized in the form of participatory and transparent medical communication.

The aspect of legal protection for doctors has the lowest frequency. These findings indicate that informed consent has not been

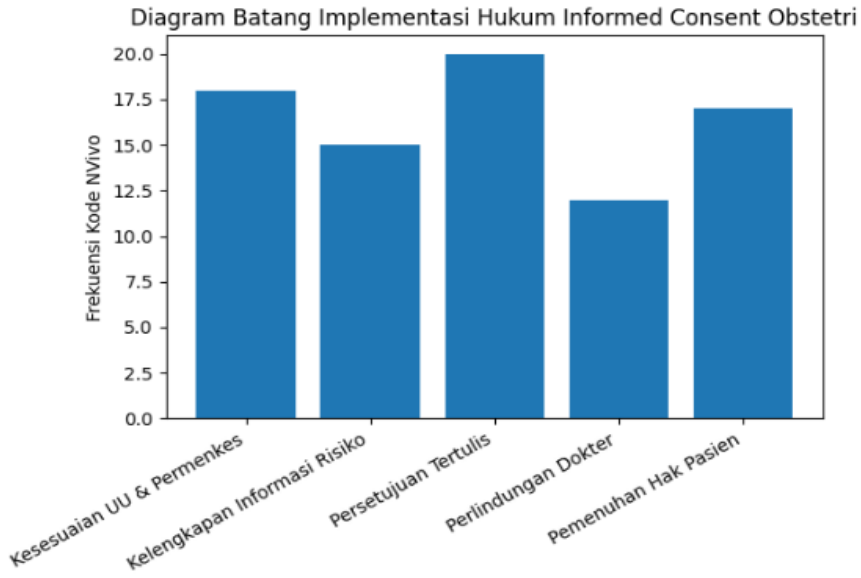

Figure 1. Results of NVivo Visualization Bar Diagram of the Implementation of the Informed Consent Law in Obstetrics

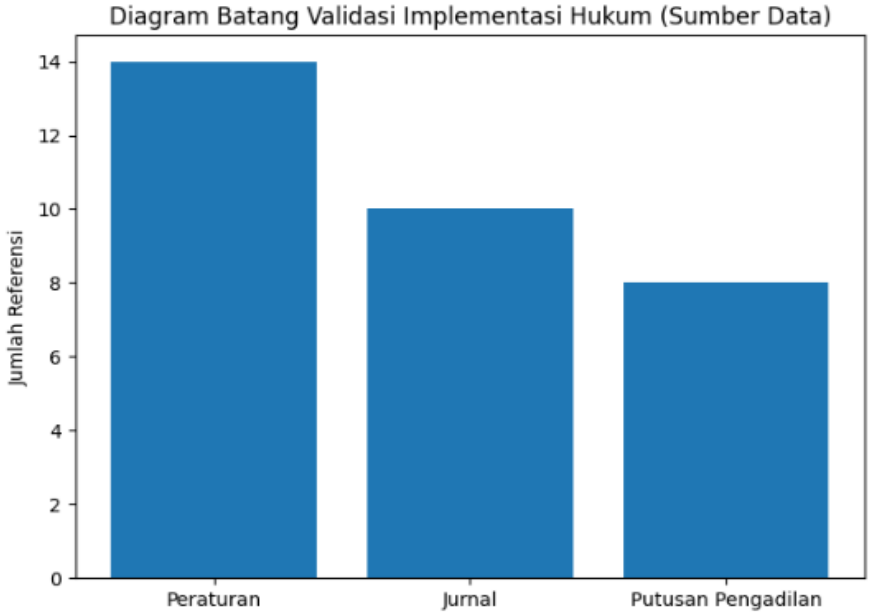

Figure 2. Results of NVivo Visualization Bar Diagram Validation of the Implementation of the Informed Consent Law in Obstetrics

fully understood as a two-way protection instrument, for both patients and medical personnel. The lack of attention to this aspect has the potential to pose legal risks for doctors in the event of a medical dispute. Therefore, the implementation of informed consent laws in obstetrics still requires strengthening the understanding that informed consent is part of a therapeutic contract that protects both parties in a balanced manner. The bar chart of legal implementation shows that laws and regulations are the most dominant source of reference in the discussion of informed consent. This shows that the study and practice of informed consent in Indonesia relies heavily on binding written norms. The dominance of regulatory sources indicates a strong normative approach in the application of health law, especially in

obstetrics.

Scientific journal sources occupy the second position as a reinforcement of the analysis of the implementation of informed consent laws. The existence of scientific journals plays a crucial role in criticizing and evaluating the gap between legal norms and practice in the field. Findings from the academic literature show that although the regulation has been sufficiently comprehensive, its implementation still faces various structural and cultural barriers. Especially, related to communication between doctors and patients. Court decisions have the lowest frequency as a source of validation. This shows that legal disputes related to informed consent obstetrics are relatively rare to reach the realm of litigation, or the resolution is more often done non-judicially. The low number of references to court decisions also indicates the lack of jurisprudence precedents that can be used as a practical reference, so that the implementation of informed consent is still more dependent on written norms than on the development of judicial practice.

The implementation of laws related to informed consent in obstetrics procedures is clearly regulated both at the international and national levels. At the international level, the Helsinki Declaration of 1964 was last updated in 2013, emphasizing that medical measures or research should be carried out only with the voluntary consent of the patient, after obtaining sufficient and clear information. This legal basis creates a global standard that underlies the protection of patients' rights in the healthcare sector. Meanwhile, Article 7 of the Universal Declaration of Human Rights (DUHAM, 1948) affirms that every individual has the right to freedom and protection of medical treatment without explicit consent, which in this context applies to obstetric medical procedures that can be high-risk.

The legal regulations regarding informed consent in obstetrics in Indonesia are regulated in Law Number 36 of 2009 concerning Health, especially Articles 45 and 46, which state the obligation of health workers to provide adequate explanations about diagnosis, procedures, and risks that may arise. These articles emphasize the patient's right to refuse medical treatment after being provided with sufficient information. Furthermore, the Regulation of the Minister of Health Number 290/MENKES/PER/III/2008 regulates procedural standards for obtaining informed consent, including explanations of diagnosis, medical procedures, and existing alternatives. The application of this law, which aligns with international principles, aims to ensure that any medical procedure, particularly in high-risk obstetric procedures, is carried out based on the conscious consent of the patient or the patient's family.

National legal arrangements also accommodate international principles related to children's rights, as in the 1989 UN Convention on the Rights of the Child, which requires parents or guardians to provide medical consent for children based on the child's best interests. At the national level, Indonesian law is in line with this principle, where medical procedures on children must be preceded by the consent of a parent or legal guardian. Thus, both internationally and nationally, the law prioritizes the protection of patients' right to privacy and autonomy through the principle of informed consent. The basis of international and national law related to informed consent in obstetrics provides strong protection for the patient's right to know and consent to the medical procedure to be performed, while providing clear limits on the violation of patients' rights in the medical context. The implementation of this law in medical practice still faces challenges, especially in ensuring that informed consent procedures are carried out effectively and thoroughly, especially in the context of obstetric procedures that require high awareness of medical and ethical risks.

This is in line with research conducted by (Glaser *et al*., 2020) which found that although the Clinic has carried out the obligation to ask for approval of the action in accordance with the Regulation of the Minister of Health Number 28 of 2017, the completeness of the contents of the medical action approval form is still lacking, so there is a need for improvements in regulations and procedures so that the implementation of informed consent can be optimal and provide better legal protection for both patients and medical personnel. Research (Chervenak *et al*., 2024) emphasizes that the legal obligation of health workers, especially midwives, is

to provide adequate information to patients and respect the patient's decision, as part of the enforcement of human rights in health services. Research (Yildirim & Mert-Karadas, 2025) found that the mechanism of informed consent must be carried out consciously and thoroughly, which also accommodates the principle of surrogate consent in obstetric emergencies according to the proper medical decision-making flow.

The theory of therapeutic contract in the context of medical law explains that the relationship between doctor and patient is a binding legal relationship, where the medical action given by the doctor must be based on the patient's consent after receiving sufficient explanation (Fitriahadi *et al*., 2024). In obstetrics, this theory is relevant because many medical procedures involve significant risks, such as caesarean sections or other obstetric procedures. According to this theory, a medical procedure without the explicit consent of the patient or their family would cause the act to be null and void, as there is no valid basis for consent. The consent given by the patient should be based on accurate, clear, and understandable information.

This therapeutic contract theory also emphasizes the importance of transparency in the process of providing medical information. In an obstetric procedure, for example, the doctor must explain in detail about the procedure to be performed, the possible risks, and the available alternatives. This ensures that the consent given by the patient really comes from a comprehensive understanding of the medical measures to be performed. Failure to provide adequate information to patients may be considered a violation of the patient's rights, which may result in lawsuits against the medical personnel concerned (Suhardono *et al*., 2024). This is especially important in high-risk situations, where failure to explain risk can lead to irreparable loss.

The case of Y.P. v. Russia, which was ruled by the European Court of Human Rights (ECHR) on January 19, 2021, illustrates the importance of implementing the principle of informed consent in medical procedures involving irreversible procedures. In this case, Y.P., a woman who underwent a caesarean section, underwent permanent sterilization without explicit consent. Although the hospital reasoned that such measures were necessary to prevent future medical risks, the ECHR ruled that there was no emergency justifying such measures without the patient's consent. The Court affirmed that medical measures must be based on free and informed consent, as stipulated in Article 8 of the European Convention on Human Rights, which protects the right to privacy and bodily integrity. This case is a crucial example that violations of the principle of informed consent in the context of medical procedures, especially those that are permanent, can lead to serious human rights violations.

This ECHR decision provides a clear standard for the requirement of explicit and informed consent. Especially in irrevocable medical procedures. In these cases, the hospital and medical personnel are responsible for the violation of the patient's rights for not providing sufficient information and not obtaining explicit consent from the patient. The case also reinforces the understanding that a patient's right to control their body, including the right to consent to medical procedures, should be upheld in global medical practice, particularly in high-risk obstetric procedures. The case of Montgomery v. Lanarkshire Health Board, decided by the UK Supreme Court on 11 March 2015, also has great relevance to the implementation of informed consent laws in obstetrics. This case involved a pregnant woman with a history of diabetes who was not given complete information about the risk of shoulder dystocia if she gave birth vaginally. The UK Supreme Court ruled that medical personnel have an obligation to convey all risks of a material nature, i.e., risks that are considered important by the patient in his position, not solely based on medical considerations. This decision directly reinforces the understanding of the importance of patient involvement in medical decision-making, with an emphasis on patient autonomy.

This decision sets a crucial precedent for the Indonesian legal system in the context of informed consent application in obstetrics. Although Indonesia is not directly bound by British law, the principles contained in this

decision are relevant in assessing the obligation of medical personnel to provide adequate information to patients. The application of legal standards that demand information disclosure and patient involvement in medical decision-making is key in protecting patients' rights (Muflih *et al*., 2024). If a physician fails to provide sufficient information, as happened in Montgomery's case, the patient has the right to sue for violation of their rights, which can also have implications for a breach of therapeutic contract law.

This is in line with research conducted by (Propst *et al*., 2019), which highlights the obligation of health workers, especially midwives, to provide adequate information and respect for patients' decisions as part of the enforcement of Human Rights (HAM) in health services. Legal awareness and the quality of informed consent implementation are expected to increase through better legal recommendations. Research (Irvine *et al*., 2025), He added that in obstetric emergencies, the presumed consent mechanism can be used as a first step, but the implementation of informed consent remains the primary choice when the patient is in a stable condition. Research (Grünebaum *et al*., 2025) said that

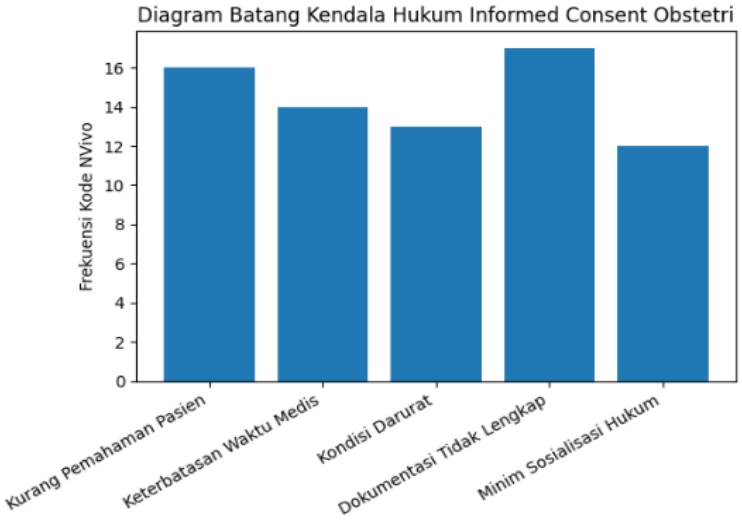

Figure 3. Results of NVivo Visualization of Legal Barriers in the Implementation of Informed Consent

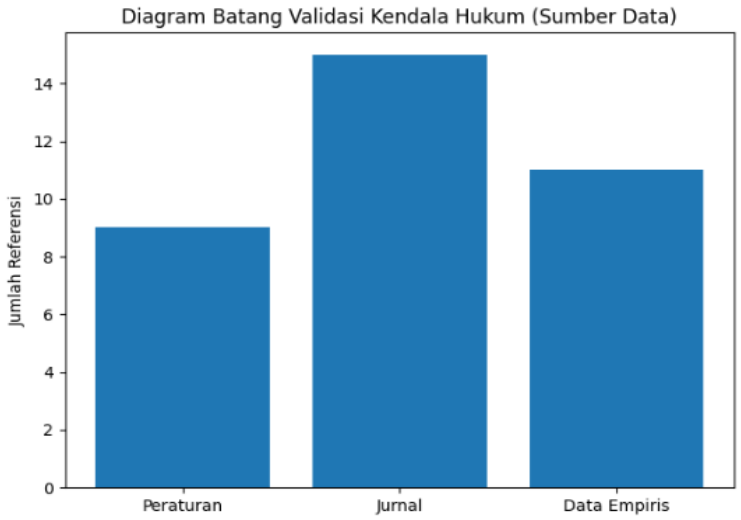

Figure 4. NVivo Visualization Results of the Validation Bar Diagram of Legal Barriers in the Implementation of Informed Consent

the application of these principles is in line with international and national standards, such as Law No. 36 of 2009 concerning Health and Regulation of the Minister of Health No. 290/MENKES/PER/III/2008, which requires that informed consent procedures be carried out thoroughly, clearly, and based on patient awareness in giving consent to medical procedures, especially obstetric procedures that have high risk. The results of this study are directed at the legal obstacles in the application *of informed consent* in obstetrics procedures identified through qualitative data analysis using NVivo software. Data derived from interviews, observations, and document analysis are analyzed through the *process of coding* and node *grouping* to produce main themes related to normative, structural, and cultural constraints in the implementation of *informed consent*.

The bar chart visualization of legal constraints shows that incompleteness of documentation is the major obstacle in the implementation of informed consent for obstetric procedures. These findings confirm that even if medical procedures have been performed with the patient's consent, the accompanying legal documentation is often incomplete or non-standard. This condition has the potential to weaken the legal position of medical personnel and health institutions in the event of a legal dispute in the future. Poor understanding of patients is also a significant obstacle in the practice of informed consent. Patients or their families often sign consent forms without an adequate understanding of the risks, benefits, and alternatives of medical procedures. This indicates a gap in medical communication that has a direct impact on the quality of consent given. Informed consent in this context tends to be an administrative formality, rather than a conscious consent based on a comprehensive understanding.

Another concern is the limitation of medical time and obstetric emergencies. Emergency situations often place medical personnel in a dilemma between the duty to save lives and the legal obligation to obtain complete informed consent. So, legal aspects are often compromised for medical considerations, which can ultimately lead to legal problems if not supported by adequate documentation and a clear legal basis. The bar chart of legal constraints shows that scientific journals are the main source in identifying obstacles to the implementation of informed consent. The dominance of this source confirms that the problem of informed consent is revealed more through empirical studies and academic analysis than through written legal norms alone. Scientific journals provide a real picture of practice in the field that often differs from normative provisions (Kusumadewi *et al*., 2024).

Empirical data sources also have a significant contribution in validating the legal constraints of informed consent. This data reflects the first-hand experience of patients and medical personnel in obstetric practice, including communication limitations, time pressures, and differences in levels of legal understanding. The existence of empirical data strengthens the finding that the main obstacle to informed consent is not caused by a legal vacuum, but by implementation factors. Laws and regulations have the lowest frequency in validating legal constraints. This shows that existing regulations have basically adequately regulated informed consent, but are not fully responsive to the reality of obstetric practice. The primary problem lies in the effectiveness of implementation and supervision, not in the substance of the legal norms themselves (Astuti *et al*., 2024).

The basis of international law on informed consent expressly governs the protection of patients' rights to consent to medical procedures, as stated in the 1964 Helsinki Declaration, updated in 2013, which emphasizes the right of patients to obtain adequate information before being granted medical treatment or research. Although this declaration guarantees the patient's right to give voluntary consent, the obstacle that arises is the fact that, in certain conditions, such as a medical emergency, this principle cannot always be met. Articles 7 and 10 of the ICCPR also stipulate that no one should be forced to undergo a medical procedure without explicit consent, but a legal obstacle that arises in practice is the difficulty in determining whether a medical condition is really a legitimate emergency according to

international standards to override explicit consent. Sometimes these assessments become ambiguous and vulnerable to misuse by medical parties.

The law in Indonesia provides a clear legal basis related to informed consent, through Articles 45 and 46 of Law Number 36 of 2009 concerning Health; there are obstacles in its implementation. The provision requires medical personnel to provide a complete explanation of medical procedures and risks to patients and obtain written consent. The main obstacle lies in the interpretation and application of Article 1320 of the Civil Code, which regulates the validity of agreements. Consent given without coercion or fraud must meet the full awareness element of the patient. The legal obstacle that arises is the possibility of subjective assessment of whether consent given by the patient is really without pressure, or whether the patient truly understands the risks of the medical procedure. Regulation of the Minister of Health Number 290/MENKES/PER/III/2008, which regulates the standards for approval of medical procedures, there are potential obstacles in the interpretation related to the obligation of medical personnel to provide a clear explanation of medical procedures, complications, and alternative medical procedures.

The UN Convention on the Rights of the Child Article 24 is also an important legal basis that affirms the protection of children through informed consent, which requires parental or guardian consent to medical procedures. Legal obstacles arise regarding the assessment of whether a person representing children or individuals who is unable to give consent directly meets the specified legal requirements, both morally and legally. The primary problem lies in the uncertainty about who is entitled to consent in certain circumstances, as well as the difficulty in determining whether the medical measures taken are really in the best interests of the child. This adds complexity in the application of the legal basis that is supposed to protect children, but in reality, these legal barriers can limit their right to appropriate medical protection.

This is in line with research conducted by (Sturgeon *et al.*, 2021), which found that the implementation of informed consent in childbirth by midwives still faces obstacles, especially in the completeness of the contents of the medical action consent form. This obstacle shows the need to improve regulations. So, the implementation of informed consent can provide effective legal protection for patients and medical personnel. Research (Garcia, 2020) highlighted the obstacles in the implementation of informed consent in all aspects of midwifery services, especially related to the obligation of medical personnel to provide adequate information and respect the patient's decision. Research (Kingma, 2021) found the main obstacle in the implementation of informed consent is the patient's lack of understanding of the content and risks of medical procedures, as well as the existence of a subjective assessment of whether the patient's consent is truly free from pressure, in accordance with the conditions for the validity of the agreement in Article 1320 of the Civil Code.

The therapeutic contract theory introduced by Leonard Riskin describes the relationship between doctor and patient as a binding contract, which requires the conscious consent of the patient before medical action is performed. This theory normatively requires a clear agreement between the patient and the doctor based on complete and transparent information. The primary legal obstacle that arises in the context of the application of this theory lies in the interpretation of what is meant by "conscious consent" and "complete information." Valid consent can only be granted if the patient receives sufficient information about the medical procedure, the risks that exist, and the alternatives available. The law does not always provide sufficient tools to ensure that the information provided by medical personnel actually meets the standards in question. Legal obstacles also arise in terms of interpretation of whether the patient really understands the information provided, or whether the presence of certain situations, such as their unconsciousness due to a medical condition or emotional distress, could invalidate the validity of the consent given (Skarayadi *et al.*, 2024).

The theory of therapeutic contract demands transparency between the medical staff and the patient. So, any medical action must

be based on information conveyed in a way that the patient can understand. The legal obstacle that arises in the application of this theory is when there is an imbalance in the provision of information, for example, in obstetric cases involving high-risk medical procedures. Legal obstacles arise due to the lack of clarity in determining the boundary between sufficient information and excessive information. Although the therapeutic contract theory puts forward a clear principle of agreement, the law often faces difficulties in guaranteeing that all relevant information has been conveyed and fully understood by the patient.

The case *of Y.P. v. Russia* (ECHR, 2021) illustrates the legal obstacles that arise in the application of the principle of informed consent, despite a clear legal basis in international conventions. Y.P. undergoes permanent sterilization without explicit consent, which indicates that there are obstacles in the interpretation of medical emergencies that justify medical actions without the patient's consent. Although hospitals reasoned that such measures were necessary to prevent future medical risks, the European court affirmed that there were no conditions that justified medical decision-making without the explicit consent of the patient. The legal obstacle that arises is how international law responds to emergency medical situations that require quick action, while on the other hand, the law does not allow medical procedures to be performed without the patient's consent under any circumstances. These legal barriers demonstrate the tension between the legal obligation to respect the right to privacy and the integrity of the patient's body, as well as the medical obligation to provide care in emergency situations.

The case *of Montgomery v. Lanarkshire Health Board* (2015) also illustrates the legal barriers related to informed consent in obstetrics. The UK Supreme Court's ruling requires doctors to provide sufficient information about the material risks associated with the medical procedure to be performed. The main legal obstacle seen in this case is the inconsistency between the information considered "material" to the patient and the medical personnel's decisions regarding the information that needs to be conveyed. This obstacle arises from the lack of clarity regarding objective and subjective standards in providing information to patients. Although the court underscored the importance of providing adequate information, significant legal obstacles remain in terms of how to determine the type of information that must be disclosed to patients, as well as how to determine whether failure to disclose such information can be considered a lawful violation.

This is in line with research conducted by (Lin *et al*., 2019), which shows that the biggest obstacle in the implementation of informed consent is the limitation of patients in understanding their legal rights, especially in independent midwifery practices. A patient's lack of knowledge of consent leads to ineffective communication and poses legal risks. Research (Häggsgård & Rubertsson, 2024) showed that less than one in five women who give birth actually get full informed consent to all the obstetric interventions they undergo. The main obstacles are incomplete information about actions, a lack of alternative discussions, and limited consultation time. Research (Elf & Nicholls, 2024) It also found a gap in legal knowledge among midwives in the wake of the Montgomery ruling, signaling the need for ongoing training on the latest legal standards for informed consent to run as expected and court-decided.

Conclusion

The implementation of the law on informed consent in obstetrics in Indonesia shows that, despite the awareness of the importance of written consent as legal evidence, substantive understanding and implementation are still often overlooked. The communication process between medical personnel and patients is often hampered by time constraints and an incomplete understanding of the patient, leading to administrative formalities without adequate understanding. Other legal obstacles arise when the approval documents are incomplete or not in accordance with the set standards, thus potentially posing legal risks for medical personnel. In addition, although Indonesian law has established clear regulations on informed consent, its implementation still faces major challenges, especially in medical

emergencies where decisions must be made quickly, even if consent procedures have not been fully implemented.

Increasing understanding of informed consent laws is essential to improve their implementation in obstetric practice. More intensive training is needed for medical personnel on the importance of clear and transparent communication to patients regarding procedures, risks, and alternative medical measures. This must be supported by improvements in the adequate documentation system, as well as strengthening the monitoring mechanism for the implementation of the law. In emergency situations, there needs to be clearer guidelines on how informed consent can still be properly implemented, without neglecting patient safety. In addition, legal education for patients needs to be expanded so that they better understand their right to consent, which in turn will strengthen legal protections for both parties in obstetric procedures.

References

Abiola, L., Legendre, G., Koechlin, A., & Coutellec, L., 2025. Barriers to Informed Consent in Obstetric Care During Childbirth from Practitioner's Perspective: A Qualitative Study. *BMJ Open*, 15(6), pp.,e101591–e101599.

Astuti, F.A., Syafrudin, S., & Susilowati, I., 2024. Socioeconomic and Public Health Impacts of Waste Management in Piyungan Landfill, Bantul-Indonesia. *Jurnal Kesehatan Masyarakat*, 19(4), pp.637–644.

Bachril., & Maskun., 2022. Tinjauan Normatif Penerapan Prinsip Tanggung Jawab Produsen dalam Pengaturan Tata Kelola Sampah Plastik di Indonesia. *Bina Hukum Lingkungan*, 6(2), pp.184–200.

Baranowska, B., Doroszewska, A., Kubicka-Kraszyńska, U., Pietrusiewicz, J., Adamska-Sala, I., Kajdy, A., Sys, D., Tataj-Puzyna, U., Bączek, G., & Crowther, S., 2019. Is There Respectful Maternity Care in Poland? Women's Views About Care During Labor and Birth. *BMC Pregnancy and Childbirth*, 19(1), pp.520–535.

Biyazin, T., & Yetwale, A., 2022. The Practice of Surgical Informed Consent in Obstetric and Gynecologic Surgery. *Perioperative Care and Operating Room Management*, 26(8), pp.100229.

Campbell, C., 2021. Medical Violence, Obstetric Racism, and the Limits of Informed Consent for Black Women. *J. Race & L*, 25(5), pp.47–60.

Chervenak, F.A., McLeod-Sordjan, R., Pollet, S.L., Jones, M.D.F., Gordon, M.R., Combs, A., Bornstein, E., Lewis,D., Katz, A., & Warman, A., 2024. Obstetric Violence is a Misnomer. *American Journal of Obstetrics and Gynecology*, 230(3), pp.S1138–S1145.

Den Exter, A., 2023. Obstetric Violence: Sterilisation Without Consent the Case of YP v. Russian Federation. *European Journal of Health Law*, 30(5), pp.551–560.

Devaney, S., & Black, I., 2025. Ten Years on from Montgomery: Equity in Healthcare Still on the Horizon. *Medical Law International*, 25(1), pp.3–11.

Elf, R., & Nicholls, J., 2024. Consent Practices in Midwifery: A Survey of UK Midwives. *Midwifery*, 129(2), pp.103893.

Ferede, A.A., & Fetene, M.G., 2025. Knowledge and Associated Factors of Patients Toward Informed Consent in Obstetric and Gynecologic Surgical Procedures at Debre Markos Comprehensive Specialized Hospital, Ethiopia. *Frontiers in Surgery*, 12(4), pp.1472033.

Fitriahadi, E., Rosida, L., Syagata, A.S., & Binti Makbul, I.A.A., 2024. Giving Baby Porridge Made From Moringa Leaves and Snakehead Fish to Toddlers in Yogyakarta Indonesia. *Jurnal Kesehatan Masyarakat*, 20(2), pp.1–11.

Garcia, L.M., 2020. A Concept Analysis of Obstetric Violence in the United States of America. *Nursing Forum*, 55(4), pp.654–663.

Glaser, J., Nouri, S., Fernandez, A., Sudore, R.L., Schillinger, D., Klein-Fedyshin, M., & Schenker, Y., 2020. Interventions to Improve Patient Comprehension in Informed Consent for Medical and Surgical Procedures: An Updated Systematic Review. *Medical Decision Making*, 40(2), pp.119–143.

Grünebaum, A., Dudenhausen, J., & Chervenak, F.A., 2025. Enhancing Patient Understanding in Obstetrics: The Role of Generative AI in Simplifying Informed Consent for Labor Induction with Oxytocin. *Journal of Perinatal Medicine*, 53(6), pp.688–695.

Häggsgård, C., & Rubertsson, C., 2024. Informed Consent to Midwifery Practices and Interventions During the Second Stage of Labor—An Observational Study Within the Oneplus Trial. *PLoS One*, 19(6), pp.e0304418.

Henderson, K., & Griffiths, S., 2019. Obtaining Consent for Obstetric Procedures.

Anaesthesia & Intensive Care Medicine, 20(9), pp.515–517.

Hollinghurst, J., & McConnell, P., 2022. Consent in Obstetrics. *Anaesthesia & Intensive Care Medicine*, 23(8), pp.477–480.

Irvine, K., Brown, R.C.H., & Savulescu, J., 2025. Disclosure and Consent: Ensuring the Ethical Provision of Information Regarding Childbirth. *Journal of Medical Ethics*, 51(8), pp.550–557.

Isnoviana, M., & Lestari, R.D., 2024. Analisis Fenomena Informed Consent: Tantangan dan Anomali bagi Dokter Muda di Jawa Timur. *Mahesa: Malahayati Health Student Journal*, 4(10), pp.4499–4517.

Jacques, M., Chantry, A.A., Evrard, A., Lelong, N., Le Ray, C., Group, E.S., Le Ray, C., Lelong, N., Cinelli, H., & Blondel, B., 2025. Consent for Interventions During Childbirth: A National Population-Based Study. *International Journal of Gynecology & Obstetrics*, 168(1), pp.333–342.

Karwur, C.E.T., 2024. Pemenuhan Hak Memperoleh Kesehatan Ditinjau dari Pasal 28 h Ayat 1 Undang–Undang Dasar Negara Republik Indonesia Tahun 1945. *Lex Privatum*, 13(2), pp.1–11.

Kaye, D.K., Chongwe, G., & Sewankambo, N.K., 2019. Ethical Tensions in the Informed Consent Process for Randomized Clinical Trials in Emergency Obstetric and Newborn Care in Low and Middle-Income Countries. *BMC Medical Ethics*, 20(1), pp.27–40.

Kingma, E., 2021. Harming One to Benefit Another: The Paradox of Autonomy and Consent in Maternity Care. *Bioethics*, 35(5), pp.456–464.

Kurniasi, N.F., & Sakharina, I.K., 2022. Elimination of Violence Against Children During the Covid-19 Pandemic based on the United Nations Convention on the Rights of the Child (UNCRC 1989). *Khazanah Hukum*, 4(2), pp.154–169.

Kusumadewi, A.F., Marchira, C.R., Widyandana, D., Wirasto, R.T., Dwidjoyono, B.D.L., & Phillabertha, P.S., 2024. Medical Students Vulnerability on Anxiety: Its Frequency and Associated Factors. *Jurnal Kesehatan Masyarakat*, 19(4), pp.541–549.

LaFata, M., 2019. Informed Consent in Maternity Care: A Global Perspective. *Ariz. J. Int'l & Comp. L.*, 36(2), pp.225–238.

Lin, Y.-K., Liu, K.-T., Chen, C.-W., Lee, W.-C., Lin, C.-J., Shi, L., & Tien, Y.-C., 2019. How to Effectively Obtain Informed Consent in Trauma Patients: A Systematic Review. *BMC Medical Ethics*, 20(1), pp.8–20.

Mena-Tudela, D., Iglesias-Casás, S., González-Chordá, V.M., Cervera-Gasch, Á., Andreu-Pejó, L., & Valero-Chilleron, M.J., 2020. Obstetric violence in Spain (Part I): Women's perception and interterritorial differences. *International Journal of Environmental Research and Public Health*, 17(21), pp.7726.

Muflih, M., Widaryanti, R., & Erwanto, R., 2024. Identifying Malnutrition Risk Factors In Vulnerable Groups: A Fundamental Approach To Implementing Complementary Therapy In Health Crisis Mitigation. *Jurnal Kesehatan Masyarakat*, 20(2), pp.1–11.

Mursyid, M., & Dewanto, A., 2023. Analisis Presumed Consent pada Penanganan Kasus Kegawatdaruratan Obstetri dari Persepsi Dokter dan Pasien. *Jurnal Kesehatan Reproduksi*, 10(2), pp.1–11.

Pittalis, C., & Sackey, C., 2024. Surgical Informed Consent Practices and Influencing Factors in Sub-Saharan Africa: A Scoping Review of the Literature. *BMJ Quality & Safety*, 33(10), pp.653–662.

Propst, K., O'Sullivan, D.M., Ulrich, A., & Tunitsky-Bitton, E., 2019. Informed Consent Education in Obstetrics and Gynecology: A Survey Study. *Journal of Surgical Education*, 76(4), pp.1146–1152.

Purwanto, A., & Romlah, S.N., 2022. Tinjauan Kelengkapan Pengisian Formulir Informed Consent Pada Pasien Yang Melakukan Tindakan Section Caesaria Sebagai Aspek Legal Rekam Medis Di Rumah Sakit Setia Mitra Jakarta Selatan. *EDU RMIK Jurnal Edukasi Rekam Medis Informasi Kesehatan*, 1(1), pp.1–11.

Skarayadi, O., Untari, E.K., Octaviani, P., & Larasati, N., 2024. The Economic Evaluation of Rare Disease Medicines. *Jurnal Kesehatan Masyarakat*, 19(3), pp.350–360.

Spiridonov, V.A., Kan, N.E., Latfullina, R.R., & Tyutyunnik, V.L., 2024. The Role of Informed Consent for Medical Intervention in the Investigation of Legal Cases Against Obstetrician-Gynecologists. *Obstetrics and Gynecology*, 12, pp.157–165.

Sturgeon, T.E., Ayaz, H., McCrorie, K., & Stewart, K., 2021. Informed Consent in Obstetrics–A Survey of Pregnant Women to Set a New Standard for Consent in Emergency Obstetric Interventions. *Journal of Obstetrics and Gynaecology*, 41(4), pp.541–545.

Suhardono, S., Yenis Septiariva, I., Mulyana, R., Koko Suryawan, I.W., Ulhasanah, N., Prayogo, W., & Mutiara, S.M., 2024. Perspectives and Socioeconomic Influences of Personal

Protective Equipment Waste Management on Post-COVID-19. *Jurnal Kesehatan Masyarakat*, 20(2), pp.1–11.

Sukmawan, Y.A., & Damayanti, D., 2025. Metode Penelitian Hukum Normatif dan Empiris sebagai Strategi Penguatan Perspektif Kajian Ilmu Hukum. *Notary Law Journal*, 4(3), pp.114–128.

Suyanto., 2023. *Metode Penelitian Hukum Pengantar Penelitian Normatif, Empiris Dan Gabungan*. Jakarta: Unigres Press.

Syahrum, M., 2022. *Pengantar Metodologi Penelitian Hukum: Kajian Penelitian Normatif, Empiris, Penulisan Proposal, Laporan Skripsi dan Tesis*. Jakarta: CV. Dotplus Publisher.

Syamsiah, D., 2021. Kajian Terkait Keabsahan Perjanjian E-Commerce Bila Ditinjau Dari Pasal 1320 Kuhperdata Tentang Syarat Sah Perjanjian. *Jurnal Inovasi Penelitian*, 2(1), pp.327–332.

Wahid, S.H., & Kususiyanah, A., 2023. *Analisis Data Kualitatif Menggunakan Nvivo*. Publica Indonesia Utama.

Yildirim, S., & Mert-Karadas, M., 2025. The Invisible Wounds of Women: Ethical Aspects of Obstetric Violence. *Nursing Ethics*, 32(5), pp.1493–1509.

Zaami, S., Stark, M., Beck, R., Malvasi, A., & Marinelli, E., 2019. Does Episiotomy Always Equate Violence in Obstetrics? Routine and Selective Episiotomy in Obstetric Practice and Legal Questions. *European Review for Medical and Pharmacological Sciences*, 23(5), pp.1847–1854.