

The Legal Certainty of Informed Consent in High-Risk Tooth Extraction: An Indonesian Health Law Perspective

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ABSTRACT

This research investigates the legal certainty of informed consent for high-risk tooth extraction within the framework of Indonesian health law. Informed consent is a vital component of medical practice, safeguarding patients' right to clear and adequate information before procedures and protecting practitioners from malpractice allegations. Particularly in emergency extractions, the legal certainty of informed consent is critical for patient rights and legal protection for dentists. A study at a private dental practice in North Sumatra observed patients often underestimate informed consent's significance. Findings indicate dentists can mitigate malpractice claims if they provide explanations consistent with Ministerial Regulation No. 290/20kes/Per/III/2008 Article 7 and obtain signed consent. Nevertheless, the regulation lacks detailed provisions on timing, potentially weakening legal evidence during disputes. The study recommends updating this regulation to bolster legal certainty in medical practice, especially for high-risk dental procedures in private settings

INTRODUCTION

Healthcare services have long existed in society, but as advancements in medical science and technology continue, the ethical and legal dimensions of these services also evolve. A key issue that frequently comes into focus is informed consent (Sidi, 2020). Introduced in the 20th century, informed consent has since become a fundamental element in contemporary medical practice. Its development is grounded in the recognition of human rights – especially the right of individuals to make decisions about their own bodies and lives.

In the healthcare setting, this principle ensures that patients are entitled to receive thorough and transparent information about any medical procedure they are to undergo, including the associated risks and benefits. This aligns closely with the principle of individual autonomy, which emphasizes that every person has the authority to make decisions about their own body (Rahmadsyah and Sidi, 2023).

According to Article 1 of the Indonesian Minister of Health Regulation No. 290/Menkes/Per/III/2008 on Medical Action Consent, the regulation defines the following:

1. Medical action consent is the agreement given by the patient or their closest family member after a full explanation of the proposed medical or dental procedure.
2. Closest relative refers to a spouse, biological parents, children, siblings, or a legal guardian.
3. Medical action encompasses preventive, diagnostic, therapeutic, or rehabilitative procedures carried out by a doctor or dentist.
4. Invasive procedures are those that directly affect the integrity of a patient's body tissue.
5. High-risk medical procedures are those that carry a significant probability of causing death or disability.

Informed consent, or The consent provided by a patient after receiving sufficient information about a planned medical procedure is a core principle in modern healthcare (Risdawati and Zarzani, 2023). This concept not only ensures the protection of patients' rights but also offers legal safeguards for healthcare professionals as they carry out their responsibilities. This principle becomes especially crucial in high-risk procedures, such as tooth extraction when the patient is experiencing acute pain.

Article 7 of the Indonesian Minister of Health Regulation No. 290/Menkes/Per/III/2008 on Medical Action Consent outlines the following:

1. Patients and/or their closest relatives must be given a clear explanation of the medical procedure, regardless of whether they request it.
2. If the patient is a child or unconscious, the explanation must be provided to a family member or accompanying individual.
3. This explanation must include at least:
 - a. The diagnosis and details of the medical procedure;
 - b. The purpose of the procedure;
 - c. Alternative options and their associated risks;

- d. Potential risks and complications of the procedure;
- e. The expected outcome (prognosis);
- f. The estimated cost of the procedure.

Tooth extraction is a common medical action in dental practice. However, tooth extraction in a state of acute pain, where the patient experiences severe pain, presents its own challenges. In such conditions, the risk of post-extraction complications increases, and the decision to perform or postpone tooth extraction must be based on a careful medical evaluation. Patients often urge for their tooth to be extracted immediately to relieve pain, even though the action may not be recommended in medical Standard Operational Procedures (SOPs). (Anwar, Zarzani, and Chermanto 2023)

In such circumstances, the importance of informed consent becomes even more critical when performing high-risk procedures. Before proceeding with a tooth extraction – particularly in cases involving acute pain – a dentist must clearly explain the associated risks, benefits, and available alternatives. This includes informing the patient about potential complications such as infection or inflammation that may follow the procedure. It is essential that the patient fully understands this information so that the consent given is truly informed and not the result of confusion or pressure (Hakim, 2023).

In Indonesia, the concept of informed consent is strongly reinforced by legal frameworks. For instance, Law No. 17 of 2023 on Health – which replaces Law No. 36 of 2009 along with ten other health-related laws – clearly states that all medical procedures require patient consent, which must be obtained after providing sufficient information (Daulay, Rafianti, and Fitrianto, 2024). Similarly, Ministerial Regulation No. 290/Menkes/Per/III/2008 obliges healthcare professionals to give comprehensive explanations before carrying out medical procedures, particularly those that involve significant risks.

Furthermore, Article 274 of Law No. 17 of 2023 outlines the responsibilities of medical and health professionals, which include:

1. Delivering healthcare services according to professional standards, service guidelines, operating procedures, ethical norms, and patient needs;
2. Securing informed consent from the patient or their family before administering treatment;
3. Preserving the confidentiality of patient health information;
4. Documenting and maintaining records related to examinations, treatments, and procedures carried out; and
5. Referring patients to other qualified and authorized healthcare professionals when necessary.

However, in practice in the field, a frequent situation is patients experiencing acute toothache forcing the doctor to immediately perform tooth extraction, even though this condition contradicts the SOP. Patients are often in a semi-conscious state or severely stressed by pain, making them unable to fully understand the information provided by the doctor. In some cases, after the action is performed and complications arise, the patient or their family may claim that the informed consent given was invalid because it was given under improper

circumstances or without adequate understanding (Darwaman, Sidi, and Saragih 2023).

High-risk tooth extraction in the context of health law is defined as a dental medical action that has the probability or possibility of causing serious complications, either directly or indirectly, to the patient's health. This action does not only include the physical tooth extraction procedure but also includes the series of preparations, execution, and post-action care performed under certain medical conditions where the patient's health risk increases. Such medical conditions include, among others, acute pain, active infection, or when the patient has a history of comorbidities that can affect the recovery process or increase the risk of post-extraction complications (Njoto 2011). In dental practice, high-risk tooth extraction requires a comprehensive evaluation of the patient's medical condition and the application of strict standard operational procedures. Therefore, before performing this action, medical personnel are obligated to provide detailed explanations regarding the inherent risks, benefits, and possible complications that may arise. This information must be conveyed completely and clearly as part of the informed consent process so that the patient has adequate understanding and can make a conscious decision

Juridically, high-risk tooth extraction is regulated in Law No. 17 of 2023 on Health, along with Ministerial Regulation No. 290/Menkes/Per/III/2008, mandates that any medical procedure with the potential to cause disability or death must first be carried out with the patient's informed consent, provided after they receive adequate and clear information. patient is given clear and comprehensive information. The enforcement of this standard is intended to protect patient rights in receiving safe healthcare services and to maintain legal accountability for medical personnel in carrying out their duties. Furthermore, high-risk tooth extraction emphasizes the importance of professional responsibility and medical ethics, especially in ensuring that the decision to perform or postpone medical action is based on objective medical considerations and not solely on patient pressure.

LITERATURE REVIEW

Legal Certainty

Legal certainty (*Rechtssicherheit*) fundamentally Legal certainty carries two key meanings: first, it involves the presence of general rules that clearly define which actions are allowed and which are prohibited for all individuals. Second, it provides a legal safeguard against arbitrary actions by the government, since these rules set boundaries on the state's authority over its citizens (Syahrani, 1999, p. 23). This concept is encapsulated in the saying *lex dura, sed tamen scripta*—the law may be harsh, but it is written and must be followed. Without certainty, the law loses its purpose as a standard for behavior, as reflected in the principle *ubi jus incertum, ibi jus nullum*—where there is no legal certainty, there is no law.

Informed Consent

Informed consent refers to the permission granted by a patient or their family after receiving comprehensive information about a proposed medical procedure, including its risks and benefits (Kusnadi, 2023). It is fundamentally a

communicative process between the doctor and the patient, aimed at reaching mutual understanding and agreement on the treatment to be carried out (Busro, 2018). This process involves a two-way exchange of information and culminates in the formal documentation of consent.

METHODOLOGY

This research employs a normative juridical method (Indra utama Tanjung 2024), focusing on a doctrinal study of the applicable laws and regulations related to informed consent in high-risk medical actions, such as tooth extraction. This normative juridical method will be conducted through a juridical analysis of Law Number 17 of 2023 concerning Health, the Ministerial Regulation of Health Number 290/Menkes/Per/III/2008 concerning Approval for Medical Actions, and relevant legal literature to understand the legal basis governing the validity of informed consent and the legal protection for medical personnel.

This analysis aims to explore the legal principles underlying the application of informed consent, particularly in the context of high-risk dental procedures. With this normative approach, the research will examine the legal certainty in the implementation of informed consent and identify the legal protection available to medical personnel in Indonesia when performing tooth extractions on patients in conditions requiring high-risk evaluation.

RESULTS AND DISCUSSION

The Urgency of Informed Consent in Healthcare Services

Legal certainty encompasses two fundamental aspects. First, it requires the existence of general legal norms that clearly delineate which actions are permitted and which are prohibited for all individuals. Second, it ensures protection against government arbitrariness by establishing legal boundaries that restrict state actions toward individuals (Syahrani, 1999, p. 23). This principle is embodied in the Latin maxim *lex dura, sed tamen scripta*—the law may be harsh, but it is written and must be upheld. Without such clarity, law loses its role as a guide for human conduct, as expressed in *ubi jus incertum, ibi jus nullum*—where there is no legal certainty, there is no law.

Informed Consent

Informed consent is defined as the approval given by a patient or their family after receiving detailed and adequate information about a proposed medical procedure, including potential risks and benefits (Kusnadi, 2023). It is not merely a formality but a vital communication process between physician and patient, aimed at achieving mutual understanding and agreement regarding the medical action to be undertaken (Busro, 2018). This process involves an open exchange of information and is formalized through a documented consent build a relationship of trust between doctor and patient, respects patient autonomy, and supports informed decision-making. Furthermore, given the complexity of medical actions and the potential risks involved, informed consent helps ensure that patients fully understand what they are agreeing to, including possible outcomes and consequences (Pradana 2024). Therefore, comprehensive The systematic and consistent implementation of informed consent is crucial for

enhancing healthcare quality and minimizing conflicts or misunderstandings that could lead to malpractice claims. This highlights the urgent need to continuously improve education and training for healthcare professionals, particularly in the legal and communication aspects of medical practice.

Informed consent is a fundamental principle in healthcare that upholds the patient's right to make well-informed decisions about their treatment. It emphasizes patient autonomy and the necessity for transparency in the doctor-patient relationship. When properly implemented, informed consent enables patients to fully understand their medical condition, treatment options, associated risks and benefits, and possible outcomes. Therefore, informed consent acts as a vital communication link between doctors and patients, bridging knowledge gaps and ensuring decisions are made with full understanding.

In Indonesia, the Ministerial Regulation Number 290/Menkes/Per/III/2008 on Approval for Medical Actions defines informed consent as "Persetujuan Tindakan Kedokteran" (Approval for Medical Actions) in Chapter I, Article 1. It describes this as the approval given by the patient or their closest relative after receiving a complete explanation about the medical or dental procedure to be performed. Based on this definition, informed consent reflects two key patient rights in their relationship with healthcare providers: the right to receive information and the right to give approval or consent (Dachban, Sidi, and Saragih, 2023). Importantly, the explanation regarding the medical action must be delivered clearly and directly to the patient, not solely to the patient's family. Article 7, paragraph (1) of the same regulation states that explanations must be given directly to the patient and/or their closest relative, whether requested or not. Furthermore, Article 2 requires that consent must be obtained for all medical procedures performed on a patient.

It is essential to understand that informed consent forms part of the medical record. The medical record must include detailed documentation of the consent process. The legal significance of medical records and informed consent lies in their role in providing legal certainty, ensuring justice in law enforcement, and serving as evidence in legal matters. Medical records are primary written evidence that can assist in resolving legal, disciplinary, and ethical issues. Informed consent documents also provide accountability and can be used by medical personnel to respond to legal claims from patients or their families.

The information provided to patients or their families must be explained in clear, simple language they can easily understand. According to J. Guwandi, this includes: a. Risks inherent in the action; b. Possibility of side effects; c. Other alternatives (if any) besides the proposed action; d. Possible consequences if the action is not performed.

Article 7 (3) of the Ministerial Regulation No. 290/Menkes/Per/III/2008 on Approval for Medical Actions specifies that explanations about medical procedures must include at least the following: a) the diagnosis and details of the procedure; b) the purpose of the medical action; c) alternative treatments and their associated risks; d) possible risks and complications; e) the expected prognosis; and f) estimated costs. According to Guwandi, informed consent can take several forms:

1. Expressed consent, which can be:
 - a. Oral
 - b. Written
2. Implied or tacit consent, which occurs:
 - a. Under normal circumstances (also called constructive consent)
 - b. In emergency situations.

For serious medical procedures, obtaining written consent is crucial for both the patient and the physician. In cases where medical complications arise and legal disputes occur, doctors can refer to the informed consent form as proof. However, if the form does not meet the standards of informed consent – meaning it fails to provide clear, adequate information – it cannot serve as strong evidence to justify the medical action taken.

According to the 1999 Decree from the Directorate General of Medical Services (No. HK.00.06.3.5.1866) on Guidelines for Medical Action Approval, hospitals must follow these rules when developing and implementing informed consent policies and procedures:

1. Medical action approval must be formalized in policies and standard operating procedures (SOPs).
2. Patients have the right to receive information and explanations, and doctors have the duty to provide them.
3. Informed consent applies to specific medical procedures.
4. Consent must be given voluntarily, without coercion.
5. Only mentally competent patients legally authorized to give consent can provide it.
6. Consent should only be given after patients have received sufficient information and necessary explanations.

Informed consent carries both ethical and legal significance. It recognizes an individual's legal right to control what happens to their body and protects patients from unwanted or inappropriate medical interventions. Properly implemented informed consent helps prevent malpractice claims, reduces legal conflicts, and strengthens trust between doctors and patients. Additionally, it contributes to higher-quality healthcare, better patient compliance with treatment, and improved health outcomes.

Given the complexity of medical procedures and their possible consequences, there is a clear need to enhance informed consent practices within the healthcare system (Astuti and Sh, 2009). Achieving this requires healthcare professionals to continuously develop their communication skills to ensure patients receive adequate information for informed decision-making. Moreover, healthcare institutions and policymakers must foster environments that support effective informed consent through policy formulation, professional training, and patient education. In this context, informed consent is not just seen as an administrative formality, but as a vital component of high-quality patient care. Achieving this demands a comprehensive and coordinated effort involving all stakeholders within the healthcare system to prioritize patient rights and well-being consistently. By raising awareness, enhancing education and training, and enforcing supportive

policies, informed consent can remain a foundational element in delivering ethical and patient-centered healthcare services.

The Legal Certainty of Informed Consent in High-Risk Tooth Extraction

High-risk tooth extraction refers to a medical procedure of tooth extraction that carries a significant probability of causing serious complications for the patient's health. In the context of health law, this procedure involves more significant risks compared to regular tooth extraction, particularly when performed under certain medical conditions such as active infection, tissue swelling, or when the patient has comorbidities like diabetes, blood clotting disorders, or hypertension. These risks include the potential for severe infection, heavy bleeding, and even systemic complications that can affect other body organs (Ramadhani 2016).

According to health regulations in Indonesia, as stipulated in Law Number 17 of 2023 concerning Health and the Ministerial Regulation of Health Number 290/Menkes/Per/III/2008 concerning Approval for Medical Actions, high-risk tooth extraction requires specific informed consent ensuring the patient has received complete information about the risks, benefits, and alternative actions. This aims to guarantee that the patient is fully aware of the potential dangers associated with the procedure and provides valid consent based on a comprehensive understanding. From a legal perspective, high-risk tooth extraction necessitates dentists to exercise greater caution in performing the procedure and to provide more detailed information. Patient consent becomes an essential element to avoid potential legal claims should post-procedure complications occur. In this condition, medical records that clearly document the consent given and include a complete explanation of the risks are important instruments that can provide legal protection for the doctor if legal issues arise in the future.

Informed consent is a principal pillar in medical practice that guarantees the patient's right to obtain clear and adequate information before undergoing a medical action. Legal certainty in the implementation of informed consent is highly important, especially in high-risk medical actions such as tooth extraction in a state of acute pain (Lestari 2023). In Indonesia, the legal basis regarding informed consent is regulated in various regulations, including Law Number 17 of 2023 concerning Health and the Ministerial Regulation of Health Number 290/Menkes/Per/III/2008 concerning Approval for Medical Actions. Both regulations affirm that every medical action must obtain consent from the patient after they receive adequate explanation regarding the risks, benefits, and alternative actions to be performed.

In dental practice, tooth extraction is a common medical action. However, when this procedure is performed under less than ideal conditions, such as when the patient is experiencing acute tooth pain, the risk of complications increases significantly. In this condition, patients often urge for their tooth to be extracted immediately to relieve pain, even though the action may not be recommended in medical Standard Operational Procedures (SOPs). Dentists are faced with a dilemma between fulfilling the patient's wishes and adhering to applicable medical standards. The importance of informed consent becomes more crucial in

this context, as patients must fully understand the risks, benefits, and alternatives of the action before deciding to proceed with tooth extraction.

This research was conducted at drg. Evi Imelda Pelawi - Dental Care, an independent dental practice located at Jl. Rajamin Purba (Samping Indomaret, Perdagangan) Kec. Bandar, Kabupaten Simalungun, North Sumatra. This practice has been operating since 2013 and is still actively serving the community. During the period 2013-2018, this practice collaborated with BPJS, PTPN 3, and PT Lonsum. However, since 2018 until now, the practice has operated as an independent non-BPJS practice. Monthly, the practice receives an average of 100 patients, with most cases involving patients who do not prioritize the importance of informed consent, especially in high-risk tooth extraction procedures.

The importance of legal certainty in the implementation of informed consent cannot be underestimated, especially in high-risk medical procedures such as tooth extraction. Informed consent not only protects patient rights but also provides legal protection for medical personnel, particularly dentists, in carrying out their duties (Christy, Wilsen, and Rumaisa 2020). As medical practice evolves, Indonesian health law has adapted to ensure that patient rights are respected and well-protected.

Law Number 17 of 2023 concerning Health replaces Law Number 36 of 2009 and strengthens legal protection for patients by affirming that every medical action must obtain consent from the patient after they receive adequate explanation regarding the action. Furthermore, the Ministerial Regulation of Health Number 290/Menkes/Per/III/2008 concerning Approval for Medical Actions further stipulates that doctors are obligated to provide complete explanations before performing medical actions, especially in cases of high-risk actions.

Article 1 of the Ministerial Regulation of Health Number 290/Menkes/Per/III/2008 states: "Medical action approval is approval given by the patient or closest relative after receiving a complete explanation regarding the medical or dental action that will be performed on the patient." This article emphasizes the importance of transparency in communication between doctor and patient, especially in explaining the risks associated with the medical action to be performed. In the context of high-risk tooth extraction, this explanation includes the diagnosis, the procedure, potential risks and complications, and alternative actions that may be taken. This is in accordance with Article 7 of the same regulation, which states: "The explanation regarding medical action must be given directly to the patient and/or closest relative, whether requested or not requested." From a legal perspective, the responsibility of dentists in cases of high-risk tooth extraction is significant. In accordance with Article 7 of the Ministerial Regulation of Health Number 290/Menkes/Per/III/2008, the explanation about medical action must include the diagnosis, the procedure, potential risks and complications, and alternative actions that may be taken (Risawati et al. 2023). In cases of tooth extraction performed in emergency situations or under pressure, the dentist must ensure that the patient has received this information completely and that consent is given consciously and without coercion. This is very important given that consent given under less than ideal circumstances can lead to legal problems if the patient or their family claims that informed consent was given

without adequate understanding or in a semi-conscious state. If post-procedure complications occur, medical records, including the signed informed consent form, become primary evidence in the legal defense process. However, this also demands the doctor to provide information in a manner understandable to the patient and to ensure that the consent given is the result of an effective communication process between the doctor and the patient (Sidi 2020).

Furthermore, it is important for dentists to follow applicable standard operational procedures (SOPs), as well as take preventive actions that can minimize the risk of complications. In cases where a patient files a claim after the procedure, the dentist can argue that they acted in accordance with the procedures regulated by law.

The legal implications of violating informed consent in cases of high-risk tooth extraction can be very serious. If it is proven that informed consent was given under invalid conditions – for instance, if the patient was in a semi-conscious state or if the information provided was inadequate – the dentist could be sued for malpractice. Malpractice in this context is not only related to technical failures in the medical procedure but also involves the failure to fulfill the legal obligation to provide adequate information to the patient. According to Law Number 17 of 2023 concerning Health, medical personnel who violate provisions regarding informed consent can be subject to sanctions, both in the form of administrative sanctions and criminal sanctions if negligence is proven to have caused harm to the patient. To mitigate this legal risk, it is important for dentists to understand and comply with all regulations related to informed consent. This includes ensuring that all communication with the patient is well-documented, that consent is given in writing for high-risk procedures, and that patients are given the opportunity to ask questions and understand all information conveyed before signing the informed consent. Additionally, medical records must be well-maintained as primary evidence in facing potential legal claims.

The practice at drg. Evi Imelda Pelawi - Dental Care has been operating since 2013, serving an average of 100 patients per month. Based on years of experience, it has been observed that almost every month there are patients who do not prioritize the importance of informed consent, especially in cases of high-risk tooth extraction. Patients often urge for their tooth to be extracted immediately even though they do not fully understand the risks involved, or they are in a state of pain that prevents them from fully focusing on the information provided (Risdawati et al. 2023). In these cases, the biggest challenge for the dentist is ensuring that the patient still receives adequate information and that the consent given is legally valid. This experience highlights the importance of having a good documentation system and effective communication between the doctor and patient. Although the practice previously collaborated with BPJS and large companies like PTPN 3 and PT Lonsum, the challenge in maintaining legal certainty related to informed consent remains a major concern, especially since the practice shifted to being an independent non-BPJS practice in 2018. (Siregar et al. 2024)

After a thorough analysis of the implementation of informed consent in dental practice, particularly at drg. Evi Imelda Pelawi - Dental Care, it can be concluded that as long as the doctor has provided adequate explanation regarding the risks, benefits, and alternatives of the medical action to the patient or their family – as regulated in Article 7 of the Ministerial Regulation of Health Number 290/Menkes/Per/III/2008 – and the patient or family agrees to these risks by signing the informed consent, the doctor is free from malpractice claims. This provision explicitly affirms that explanations about medical actions must be given directly to the patient and/or closest relative, whether requested or not requested. The signing of informed consent after the patient receives a complete explanation serves as strong legal evidence that the patient's right to make informed decisions regarding medical actions has been fulfilled. The existence of this evidence not only demonstrates that the doctor has fulfilled their obligation to provide information comprehensively and transparently but also provides significant legal protection for the doctor against allegations of malpractice. In this context, the theory of legal certainty put forward by Gustav Radbruch, a prominent legal scholar, provides a deep perspective on the importance of law that is not only stable and predictable but also fulfills the principles of justice, utility, and certainty. According to Radbruch, law must fulfill three basic values: *Rechtssicherheit* (legal certainty), *Gerechtigkeit* (justice), and *Zweckmäßigkeit* (utility). In the implementation of informed consent, legal certainty is reflected through clear and documented procedures, where the doctor is obligated to provide comprehensive information related to the risks, benefits, and alternatives of the action. This procedure ensures that the patient has the opportunity to understand the action to be performed, so that the consent given is based on adequate information. Legal certainty according to Radbruch demands that legal procedures and practices leave no room for doubt or uncertainty, as this can disrupt the legal protection for the parties involved.

However, this research found that the Ministerial Regulation of Health Number 290/Menkes/Per/III/2008 concerning Approval for Medical Actions does not specifically regulate the recording of time (hour, date, month, and year) on informed consent. The accurate timing in informed consent is very important to ensure the validity and legal certainty of medical actions that have been performed. Without clear time recording, the strength of evidence that informed consent was given before the medical action was performed becomes weak. This has the potential to raise doubts regarding the doctor's compliance in fulfilling the information obligation required by law. Therefore, to support the principle of *Rechtssicherheit* or legal certainty emphasized by Radbruch, an amendment to the Ministerial Regulation of Health Number 290/Menkes/Per/III/2008 needs to be made by adding detailed provisions regarding the time of signing the informed consent. The addition of this provision will strengthen legal protection for doctors, particularly in high-risk independent practices, and ensure justice and utility of the law for all parties involved.

CONCLUSIONS AND RECOMMENDATIONS

The conclusion of this research underscores the importance of informed consent as a legal and ethical foundation in high-risk medical actions, particularly in tooth extraction procedures. As a component of patient rights, informed consent not only grants patients control over medical decisions but also protects medical personnel by ensuring that every action is performed based on valid consent and adequate understanding. In the context of high-risk tooth extraction, such as in conditions of acute pain or the presence of comorbidities, dentists are obligated to convey comprehensive information regarding the risks, benefits, and alternatives of the action. This aligns with the mandate in Law Number 17 of 2023 concerning Health and the Ministerial Regulation of Health Number 290/Menkes/Per/III/2008, which ensure transparency and patient rights in healthcare services.

However, this research also identifies a shortcoming in the informed consent regulation, which has not stipulated detailed time recording in the medical action consent document. This provision is essential for strengthening *Rechtssicherheit* or legal certainty, as suggested by Gustav Radbruch's theory, to ensure that procedures and documentation in healthcare fulfill the aspects of legal clarity, justice, and utility. This regulatory update will provide greater protection for doctors when facing malpractice claims and ensure that the consent given by the patient is truly legally valid, thereby supporting an ethical professional relationship between doctor and patient in high-risk dental practice.

FURTHER STUDY

This further study underscores the importance of informed consent as a legal and ethical foundation in high-risk medical actions, particularly in tooth extraction procedures. As a component of patient rights, informed consent not only grants patients control over medical decisions but also protects medical personnel by ensuring that every action is performed based on valid consent and adequate understanding. In the context of high-risk tooth extraction, such as in conditions of acute pain or the presence of comorbidities, dentists are obligated to convey comprehensive information regarding the risks, benefits, and alternatives of the action, in line with the mandate in Law Number 17 of 2023 concerning Health and the Ministerial Regulation of Health Number 290/Menkes/Per/III/2008, which ensure transparency and patient rights in healthcare services. However, this research also identifies a shortcoming in the informed consent regulation, which has not stipulated detailed time recording in the medical action consent document; this provision is essential for strengthening *Rechtssicherheit* or legal certainty, as suggested by Gustav Radbruch's theory, to ensure that procedures and documentation in healthcare fulfill the aspects of legal clarity, justice, and utility. This regulatory update is expected to provide greater protection for doctors when facing malpractice claims and ensure that the consent given by the patient is truly legally valid, thereby supporting an ethical professional relationship between doctor and patient in high-risk dental practice.

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