LEGAL CERTAINTY OF INFORMED CONSENT IN HIGH-RISK TOOTH EXTRACTION: AN INDONESIAN HEALTH LAW PERSPECTIVE

Evi Imelda Pelawi [*1] **Irsyam Risdawati** [*2] **Redyanto Sidi** [*3]
[123] Universitas Pembangunan Panca Budi
*Email :*eviimeldapelawi76@gmail.com* *irsyamrisdawati@dosen.pancabudi.ac.id*

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Abstract
This study discusses the legal certainty of informed consent in high-risk tooth extraction from the perspective of health law in Indonesia. Informed consent is a key element in medical practice that guarantees the patient's right to obtain clear and adequate information before undergoing medical treatment and protects doctors from allegations of malpractice. In the context of tooth extraction performed in an emergency, the legal certainty of informed consent is very important to protect patient rights and provide legal protection for dentists. This study was conducted at the independent practice of drg. Evi Imelda Pelawi - Dental Care located in Simalungun, North Sumatra, where it was found that many patients still do not prioritize the importance of informed consent.
The results of the study indicate that dentists can be free from malpractice claims as long as they have provided adequate explanations in accordance with Article 7 of the Regulation of the Minister of Health Number 290/Menkes/Per/III/2008 and the patient or family has signed an informed consent as proof of agreement. However, this study also found weaknesses in the regulation related to the provisions on time recording which are not regulated in detail, thus potentially weakening legal evidence in the event of a dispute. Therefore, this study recommends that the regulation be updated to strengthen legal certainty in medical practice, especially in high-risk tooth extraction procedures in independent practices.

I. INTRODUCTION

Health services are not new in society, but along with the development of medical science and technology, ethical and legal aspects have also changed and improved. One important aspect of health services that is often in the spotlight is informed consent.(Sidi 2020)The term informed consent was first introduced in the 20th century and has become an integral part of modern medical practice. In its development, the concept of informed consent is based on human rights, especially the right to regulate and determine everything about oneself. In the medical context, this means that patients have the right to receive complete and clear information about the medical actions that will be performed on them, including the potential risks and benefits. This concept is deeply rooted in the principle of individual autonomy, where each individual has sovereignty over their body and themselves.(Rahmadsyah and Sidi 2023)

Article 1 of the Minister of Health Regulation Number 290/Menkes/Per/III/2008 concerning Approval of Medical Actions

In this Ministerial Regulation, the following terms are defined as:

1. *Consent for medical procedures is consent given by the patient or closest family member after receiving a complete explanation regarding the medical or dental procedures that will be carried out on the patient.*
2. *The closest family is the husband or wife, biological father or mother, biological children, biological siblings or their guardians.*
3. *Medical or dental procedures, hereinafter referred to as medical procedures, are preventive, diagnostic, therapeutic or rehabilitative medical procedures carried out by a doctor or dentist on a patient.*

4. *Invasive procedures are medical procedures that can directly affect the integrity of the patient's body tissue.*
5. *High-risk medical procedures are medical procedures that, based on a certain level of probability, can result in death or disability.*

Informed consent, or consent given by the patient after receiving adequate information about the medical procedure to be performed, is one of the fundamental principles in modern medical practice.(Risdawati and Zarzani 2023)This concept not only serves to protect the rights of patients, but also provides legal protection for medical personnel in carrying out their duties. This principle is very important, especially in high-risk medical procedures such as tooth extraction in acute pain.

Article 7 of the Minister of Health Regulation Number 290/Menkes/Per/III/2008 concerning Approval of Medical Actions

1. *Explanations regarding medical procedures must be given directly to the patient and/or closest family, whether requested or not.*
2. *In the case of a child or an unconscious person, an explanation is given to the family or person accompanying them.*
3. *Explanation of medical actions as referred to in paragraph (1) at least includes:*

a. Diagnosis and procedures for medical action;

b. The purpose of the medical action taken;

c. Alternative courses of action, and their risks;

d. Possible risks and complications; and

e. Prognosis of the actions taken;

f. Financing estimates.

Tooth extraction is a common medical procedure in dental practice. However, tooth extraction in acute pain, where the patient is in severe pain, poses a challenge. In such conditions, the risk of post-extraction complications increases, and the decision to perform or delay tooth extraction must be based on careful medical evaluation. Patients often insist on immediate tooth extraction to relieve pain, even though such an action may not be recommended in the medical Standard Operating Procedure (SOP).(Anwar, Zarzani, and Chermanto 2023)

In such conditions, the importance of informed consent becomes even more crucial. Before performing an extraction, the dentist must provide complete information about the risks, benefits, and alternatives of the procedure to the patient. This information includes possible complications, such as infection or inflammation that may occur after tooth extraction is performed in a state of acute pain. The information provided must be understood by the patient to ensure that the consent given is truly based on clear understanding and not under duress or misunderstanding.(Judge 2023)

The principle of informed consent has been explicitly regulated in several regulations in Indonesia. For example, Law Number 17 of 2023 concerning Health replaces Law Number 36 of 2009 and 10 Other Health-related laws and regulations, emphasizing that every medical action must obtain the consent of the patient after the patient has been given adequate information.(Daulay, Rafianti, and Fitrianto 2024)Minister of Health Regulation Number 290/Menkes/Per/III/2008 concerning Consent for Medical Procedures also stipulates that doctors are required to provide a complete explanation before carrying out medical procedures, especially in cases of high-risk procedures.

Article 274 of Law Number 17 of 2023 concerning Health

Medical personnel and health workers in carrying out mandatory practices must:

1. *give Service Health in accordance with professional standards, professional service standards, operational procedure standards, and professional ethics as well as patient health needs.*
2. *obtain consent from the patient or his/her family for the action to be taken;*
3. *maintaining patient health confidentiality;*
4. *create and store records and/or documents regarding examinations, care, and actions taken; and*
5. *refer patients to medical personnel or other health workers who have the appropriate competence and authority.*

However, in practice in the field, a situation that often occurs is that patients who experience acute toothache force doctors to immediately perform tooth extraction, even though this condition is contrary to the SOP. Patients are often in a semi-conscious state or are so depressed by the pain that they cannot fully understand the information given by the doctor. In some cases, after the procedure is performed and complications arise, the patient or his family may claim that the informed consent given is invalid because it was given in an improper state or without adequate understanding.(Darwaman, Sidi, and Saragih 2023)

High-risk tooth extraction in the context of health law is defined as a dental procedure that has the probability or possibility of causing serious complications, either directly or indirectly, to the patient's health. This procedure does not only include the physical tooth extraction procedure, but also includes a series of preparations, implementation, and post-treatment care carried out in certain medical conditions where the patient's health risk is increased. These medical conditions include, among others, acute illness, 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 thorough evaluation of the patient's medical condition and the implementation of strict standard operating procedures. Therefore, before carrying out this action, medical personnel must provide a detailed explanation of 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.

Legally, high-risk tooth extraction is regulated in Law Number 17 of 2023 concerning Health and Regulation of the Minister of Health Number 290/Menkes/Per/III/2008, which states that any medical action that has the potential to cause disability or death must obtain consent after the patient is given clear and comprehensive information. Enforcement of this standard is intended to protect the patient's rights to receive safe health services and maintain legal accountability for medical personnel in carrying out their duties. In addition, 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 made based on objective medical considerations and not solely at the patient's insistence.

II. RESEARCH METHODS

This research uses a normative legal method(Indra Utama Tanjung 2024)which focuses on doctrinal studies of applicable laws and regulations related to informed consent in high-risk medical procedures such as tooth extraction. This normative legal method will be carried out through a legal analysis of Law Number 17 of 2023 concerning Health, Regulation of the Minister of Health Number 290/Menkes/Per/III/2008 concerning Approval of Medical Procedures, and relevant legal literature to understand the legal basis governing the validity of informed consent and legal protection for medical personnel.

This analysis aims to explore the legal principles underlying the application of informed consent, especially in the context of high-risk dental procedures. With this normative approach, the study will examine the legal certainty in the implementation of informed consent and identify the legal protection available to medical personnel in Indonesia in carrying out tooth extraction procedures in patient conditions that require high-risk evaluation.

III. RESULTS AND DISCUSSION

A. The Urgency of Informed Concent in Health Services

*Informed consent*consists of two words, namely "informed" which means information or information and "consent" which means agreement or giving permission. So the definition of Informed consent is an agreement given after receiving information. Thus Informed consent can be defined as a statement from the patient or his legal representative, the contents of which are in the form of an agreement to the medical action plan submitted by the doctor after receiving sufficient information to be able to make an agreement or refusal. Approval of the action to be carried out by the Doctor must be done without any element of coercion.(Wibowo, Putera, and Pramono 2023)

For patients, informed consent is the realization of their right to receive complete information about their medical condition, the actions to be taken, the risks, alternative therapies, and the prognosis. This study emphasizes the importance of doctors implementing informed consent effectively to reduce the knowledge gap between patients and doctors, thereby preventing malpractice. The recommendation of this study is to improve the practice of informed consent among medical professionals to ensure transparency and patient participation in medical decisions that affect them.

With the growing awareness of patients and demands for patient rights, informed consent has become not only an ethical but also a legal obligation for health practitioners. Effective

implementation of informed consent helps build a trusting relationship between physician and patient, respects patient autonomy, and supports informed decision-making. Furthermore, given the complexity of medical procedures and the potential risks involved, informed consent helps ensure that patients fully understand what they are agreeing to, including the potential outcomes and consequences.(Prince 2024)Therefore, the implementation of comprehensive and systematic informed consent is key to improving the quality of health services and reducing conflicts and misunderstandings that can lead to malpractice claims. This shows the urgency to continue improving education and training for health professionals regarding the legal and communication aspects of their medical practice.

*Informed consent*in health care is a fundamental principle that supports the patient's right to make informed decisions about their medical care. It recognizes patient autonomy and the importance of transparency in the doctor-patient relationship. Effective informed consent enables patients to fully understand their medical condition, available treatment options, the risks and benefits of each medical procedure, and the potential outcomes. Informed consent thus acts as a bridge of communication between doctors and patients, reducing knowledge gaps, and ensuring that medical decisions are made based on good understanding.

In the Regulation of the Minister of Health of the Republic of Indonesia number 290/Menkes/Per/III/2008 concerning Consent to Medical Actions, it is determined that informed consent is translated into Consent to Medical Actions, which is regulated in Chapter I Article 1 which determines that consent is given by the patient or closest family after receiving a complete explanation regarding the medical or dental actions to be performed on the patient. Based on the above understanding, informed consent contains two essential patient rights in their relationship with doctors, namely the right to information and the right to approval or consent.(Dachban, Sidi, and Saragih 2023)Explanation of information regarding the actions to be taken on the patient must be given clearly and given directly to the patient, not to the patient's family. This is regulated in Article 7 paragraph (1) of the Minister of Health Regulation No. 290/Menkes/Per/III/2008 which stipulates that explanations regarding medical actions must be given directly to the patient and/or the patient's closest family, whether requested or not. Regarding the right to consent, Article 2 of the Minister of Health Regulation in the same regulation stipulates that all medical actions to be taken on a patient must receive consent.

One thing that must be understood is that informed consent is part of the medical record. The medical record must contain a complete record of consent to medical action. The legal aspect of medical records and informed consent has legal value because its contents concern the issue of guaranteeing legal certainty on the basis of justice in an effort to enforce the law and provide evidence to uphold justice. Medical records are the main evidence in written form, so they are useful in resolving legal, disciplinary, and medical ethics issues. Informed consent is used as a material for accountability and reporting by medical personnel if there is a lawsuit from the patient or the patient's family.

The information that needs to be given and explained in simple words that are understood by the patient or his/her family. According to J. Guwandi, the information that needs to be conveyed to the patient or patient's family includes:

a. The risks inherent in the action;
b. Possible side effects;
c. Other alternatives (if any) other than the proposed action;
d. What might happen if the action is not taken.

Article 7 (3) of the Regulation of the Minister of Health of the Republic of Indonesia No. 290/Menkes/Per/III/2008 concerning Consent to Medical Actions stipulates that an explanation of medical actions must at least include:

a. Diagnosis and procedures for medical procedures;
b. The purpose of the medical action taken;
c. Alternative actions and their risks;
d. Possible risks and complications;
e. Prognosis of the actions taken;
f. Cost estimation.

According to Guwandi, informed consent can take the form of:

1. Expressed
   a. Orally
   b. In writing (written)
2. Implied or tacit consent
   a. Under normal circumstances (normal or constructive consent)
   b. In case of emergency.

In carrying out serious medical procedures, written consent for medical procedures is very

important for both patients and doctors. If there is a medical risk, legal problems arise, doctors can say that this has been stated in the informed consent, but it turns out that the informed consent form that was made does not comply with the doctrine of informed consent itself so that the informed consent form does not provide clear information so that it cannot be used as strong evidence to prove that the medical procedures carried out on the patient are correct. According to the Decree of the Directorate General of Medical Services No. HK.00.06.3.5. 1866 of 1999 concerning Guidelines for Medical Procedure Consent in determining and implementing policies and procedures on informed consent, every hospital must pay attention to the following provisions:

(1) Regulation of consent for medical actions must be in the form of policies and procedures (Standard Operating Procedure/SOP);
(2) Obtaining information and explanation is a patient's right and conversely providing information and explanation is a doctor's obligation;
(3) *Informed consent*given for specific medical actions;
(4) *Informed consent*given without coercion;
(5) *Informed consent*given by a person to a patient who is mentally healthy and who is legally entitled to give it;
(6) *Informed consent*given after sufficient (adequate) information and explanation are required.

Furthermore, informed consent has not only an ethical dimension, but also a legal one. It reflects the legal recognition of the right of individuals to determine what happens to their own bodies, and the importance of protecting patients from unwanted or inappropriate medical treatments. Proper implementation of informed consent helps prevent medical malpractice, reduces the potential for legal conflicts, and builds trust in the doctor-patient relationship. The practice is also essential for improving the quality of health care, ensuring patient compliance with treatment plans, and improving overall health outcomes.

Given the complexity of medical procedures and the possible consequences, the urgency to strengthen informed consent practices in health systems is clear.(Astuti and Sh 2009)This requires a commitment from health professionals to continually improve their communication skills and ensure that patients are provided with sufficient information to make informed decisions. In addition, health institutions and policy makers need to support an environment that promotes effective informed consent practices, including through policy development, professional training, and patient education. In this context, informed consent is not simply seen as an administrative formality, but as a critical element of quality patient care. This requires a holistic and integrated approach, involving all stakeholders in the health system, to ensure that the rights and well-being of patients are always a priority. Through increased awareness, education and training, and the implementation of supportive policies, informed consent can continue to be an important pillar of ethical, patient-centered health care.

B. Legal Certainty of Informed Consent in High-Risk Tooth Extraction

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

According to health regulations in Indonesia, as stipulated in Law Number 17 of 2023 concerning Health and Regulation of the Minister of Health Number 290/Menkes/Per/III/2008 concerning Consent for Medical Actions, high-risk tooth extraction requires special informed consent that ensures that the patient has received complete information about the risks, benefits, and alternatives to the procedure. This aims to ensure that the patient is fully aware of the potential dangers associated with the procedure and provides valid consent based on a thorough understanding. From a legal perspective, high-risk tooth extraction requires dentists to be more careful in carrying out the procedure and provide more detailed information. Patient consent is an important element to avoid potential lawsuits if post-procedure complications occur. In this condition, medical records that clearly record the

consent given and include a complete explanation of the risks are important instruments that can provide legal protection for doctors if legal problems arise in the future.

*Informed consent*is a main pillar in medical practice that guarantees the patient's right to obtain clear and adequate information before undergoing medical procedures. Legal certainty in the application of informed consent is very important, especially in high-risk medical procedures such as tooth extraction in acute illness.(Sustainable 2023)In Indonesia, the legal basis for informed consent is regulated in various regulations, including Law Number 17 of 2023 concerning Health and Regulation of the Minister of Health Number 290/Menkes/Per/III/2008 concerning Consent to Medical Actions. Both of these regulations emphasize that every medical action must obtain consent from the patient after they have received adequate explanation regarding the risks, benefits, and alternatives to the action to be taken.

In dental practice, tooth extraction is a common medical procedure. However, when this procedure is performed under non-ideal conditions, such as when the patient is experiencing acute toothache, the risk of complications increases significantly. In these conditions, patients often insist that their teeth be extracted immediately to relieve pain, even though this may not be recommended in the medical Standard Operating Procedure (SOP). Dentists are faced with a dilemma between fulfilling the patient's wishes and complying with applicable medical standards. The importance of informed consent becomes even more crucial in this context, because patients must fully understand the risks, benefits, and alternatives of the procedure before deciding to proceed with tooth extraction. This study was conducted at drg. Evi Imelda Pelawi - Dental Care, an independent medical practice located on Jl. Rajamin Purba (Next to Indomaret, Perdagangan) Kec. Bandar, Simalungun Regency, North Sumatra. This practice has been operating since 2013 and is still actively serving the community. In the 2013-2018 period, this practice collaborated with BPJS, PTPN 3, and PT Lonsum. However, since 2018 until now, this practice has been operating as an independent non-BPJS practice. Every month, this 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 application of informed consent cannot be underestimated, especially in high-risk medical procedures such as tooth extraction. Informed consent not only protects the rights of patients, but also provides legal protection for medical personnel, especially dentists, in carrying out their duties.(Christy, Wilsen, and Rumaisa 2020)As medical practice has evolved, health law in Indonesia has adapted to ensure that patient rights are respected and safeguarded. Law Number 17 of 2023 concerning Health replaces Law Number 36 of 2009 and strengthens legal protection for patients by affirming that every medical procedure must obtain consent from the patient after they have received adequate explanation regarding the procedure. In addition, Regulation of the Minister of Health Number 290/Menkes/Per/III/2008 concerning Consent for Medical Procedures further stipulates that doctors are required to provide a complete explanation before performing a medical procedure, especially in cases of high-risk procedures.

Article 1 of the Minister of Health Regulation Number 290/Menkes/Per/III/2008 states:

"Consent for medical procedures is consent given by the patient or the closest family member after receiving a complete explanation regarding the medical or dental procedures that will be performed on the patient."

This article emphasizes the importance of transparency in communication between doctors and patients, especially in explaining the risks associated with the medical procedure to be performed. In the context of high-risk tooth extraction, this explanation includes the diagnosis, the procedure, the risks and complications that may occur, and other alternative actions that may be taken. This is in accordance with Article 7 of the same regulation, which states that:

"Explanations about medical procedures must be given directly to the patient and/or immediate family, whether requested or not."

From a legal perspective, the dentist's responsibility in high-risk tooth extraction cases is very large. In accordance with Article 7 of the Minister of Health Regulation Number 290/Menkes/Per/III/2008, an explanation of medical procedures must include the diagnosis, procedures, risks and complications that may occur, and alternative actions that may be taken.(Risdawati et al. 2023)In cases of tooth extraction performed in an emergency or under

duress, the dentist must ensure that the patient has received this information in full and that consent is given consciously and without coercion. This is especially important considering that consent given under less than ideal circumstances can raise legal issues if the patient or his/her family alleges that informed consent was given without adequate understanding or in a semi-conscious state. If post-procedure complications occur, medical records including the patient's signed informed consent form are the main evidence in the legal defense process. However, this also requires the doctor to provide information in a way that can be understood by 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)In addition, it is important for dentists to follow applicable standard operating procedures (SOPs), as well as take preventive measures that can minimize the risk of complications. In cases where patients sue after the action, dentists can maintain that they have acted in accordance with the procedures stipulated by law.

The legal implications of violating informed consent in high-risk tooth extraction cases can be very serious. If it is proven that informed consent was given under unlawful conditions—for example, if the patient was in a semi-conscious state or if the information provided was inadequate—the dentist can be sued for malpractice. Malpractice in this context is not only related to technical failures in medical procedures, but also involves 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 the provisions regarding informed consent can be subject to sanctions, both in the form of administrative sanctions and criminal sanctions if it is proven that there was negligence that 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 communications with patients are properly documented, that consent is given in writing for high-risk procedures, and that patients are given the opportunity to ask questions and understand all the information provided before signing the informed consent. In addition, medical records must be properly maintained as the main evidence in facing potential lawsuits.

Practice at drg. Evi Imelda Pelawi - Dental Care has been operating since 2013, with an average of 100 patients served per month. Based on years of experience, it has been found that there are almost always patients every month who do not prioritize the importance of informed consent, especially in cases of high-risk tooth extraction. Patients often insist on having their teeth removed immediately even though they do not fully understand the risks involved, or they are in a state of illness that prevents them from fully focusing on the information provided.(Risdawati et al. 2023)In these cases, the biggest challenge for dentists is to ensure that patients remain adequately informed and that the consent given is legally valid. This experience shows the importance of having a good documentation system and effective communication between doctors and patients. Although the practice previously collaborated with BPJS and large companies such as PTPN 3 and PT Lonsum, the challenge of maintaining legal certainty regarding informed consent remains a major concern, especially since the practice switched to an independent non-BPJS practice in 2018.(Siregar et al. 2024)

After an in-depth analysis of the application of informed consent in dental practice, especially 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 medical procedures to the patient or his/her family—as regulated in Article 7 of the Regulation of the Minister of Health Number 290/Menkes/Per/III/2008—and the patient or family agrees to the risks by signing the informed consent, then the doctor is free from malpractice claims. This provision explicitly states that an explanation of medical procedures must be given directly to the patient and/or immediate family, whether requested or not. Signing an informed consent after the patient has received a complete explanation is strong legal evidence that the patient's right to make a conscious decision regarding medical procedures has been fulfilled. The existence of this evidence not only shows that the doctor has fulfilled his/her obligation to provide comprehensive and transparent information, 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 leading legal expert, provides an in-depth perspective on the importance of laws that are not only stable and predictable, but also fulfill the principles of justice, usefulness, and certainty.

According to Radbruch, the law must fulfill three basic values: Rechtssicherheit (legal certainty), Gerechtigkeit (justice), and Zweckmäßigkeit (benefit). In the application of informed consent, legal certainty is reflected through clear and documented procedures, in which doctors are required to provide comprehensive information regarding the risks, benefits, and alternative actions. This procedure ensures that patients have the opportunity to understand the actions to be taken, 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, because this can interfere with legal protection for the parties involved.

However, this study found that the Regulation of the Minister of Health Number 290/Menkes/Per/III/2008 concerning Approval of Medical Actions has not specifically regulated the recording of time (hour, date, month, and year) in informed consent. The provision of the right time in informed consent is very important to ensure the validity and legal certainty of the medical action that has been carried out. Without a clear recording of the time, the strength of the evidence that informed consent was given before the medical action was carried out becomes weak. This has the potential to raise doubts about the doctor's compliance in fulfilling the information obligations required by law. Therefore, in order to support the principle of Rechtssicherheit or legal certainty emphasized by Radbruch, an update to the Regulation of the Minister of Health Number 290/Menkes/Per/III/2008 needs to be carried out by adding detailed provisions regarding the time of signing the informed consent. The addition of these provisions will strengthen legal protection for doctors, especially in high-risk independent practices, and guarantee justice and legal benefits for all parties involved.

IV. CONCLUSIONS AND RECOMMENDATIONS

The conclusion of this study emphasizes the importance of informed consent as a legal and ethical basis for high-risk medical procedures, especially in tooth extraction procedures. As part of patient rights, informed consent not only gives patients control over medical decisions, but also protects medical personnel by ensuring that every action is carried out on the basis of valid consent and based on adequate understanding. In the context of high-risk tooth extraction, such as in acute illness or comorbidities, dentists are required to provide comprehensive information regarding the risks, benefits, and alternatives to the action. This is in accordance with the mandate of Law Number 17 of 2023 concerning Health and Regulation of the Minister of Health Number 290/Menkes/Per/III/2008, which ensures transparency and patient rights in health services.

However, this study also identified shortcomings in the informed consent regulation that has not yet stipulated detailed time recording in the medical action consent document. This provision is essential to strengthen Rechtssicherheit or legal certainty, as suggested by Gustav Radbruch's theory, to ensure that procedures and documentation in health services meet the aspects of clarity, fairness, and legal benefits. This regulatory update will provide more protection for doctors in facing malpractice lawsuits and ensure that the consent given by patients is truly legally valid, as well as support an ethical professional relationship between doctors and patients in high-risk dental practices.

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