



LEGAL PROTECTION FOR DENTISTS IN HANDLING PATIENTS IN CASES OF TOOTH EXTRACTION WITHOUT INFORMED CONSENT (STUDY AT VARIOUS INDEPENDENT PRACTICE PLACES FOR DENTISTS IN PEMATANGSIANTAR)

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Abstract

This study aims to determine and analyze legal regulations regarding the obligation of informed consent in tooth extraction services, the responsibility of dentists towards patients in providing informed consent in cases of tooth extraction and legal protection for dentists in handling patients in cases of tooth extraction without informed consent in various places. Independent practice of dentist in Pematangsiantar. The method in this research uses descriptive analytical empirical juridical research. The data sources obtained used primary data and secondary data. The data collection technique used is library research. The results of this research reveal that legal regulations regarding the obligation of informed consent in tooth extraction services by dentists in Indonesia have been regulated in various laws, including Law no. 36 of 2009 concerning Health, Law no. 44 of 2009 concerning Hospitals and now Law no. 17 of 2023 concerning Health. The dentist's responsibilities include providing sterile tools and materials, examining the patient's medical history, and carrying out extractions according to SOP and competency. Legal protection for dentists in cases of extractions without informed consent in Pematangsiantar reflects awareness of the importance of informed consent. UU no. 17 of 2023 emphasizes two principles of legal protection: preventive and repressive. If the dentist does not carry out the obligation to carry out informed consent, there could be civil and criminal consequences. This study recommends that every dentist provide informed consent in treating patients.

Keywords: Health Services, Informed Consent, Dentist, Legal Protection

INTRODUCTION

Health is a healthy condition both physically, mentally and spiritually which enables everyone to live a productive life socially and economically. A supporting factor that is very influential in the success of implementing health efforts is the availability of adequate and quality health service facilities. The availability of adequate and quality health service facilities is the duty and responsibility of the state. The state is responsible for providing adequate health service facilities and public services as stated in Article 34 Paragraph 3 of the 1945 Constitution. Health services are defined as the implementation of health efforts in the series of maintaining and improving the level of personal health, all health service activities are carried out based on legal rules contained in binding regulations. Dentists are one of the main components in providing health services to the community, especially dental and oral health. The medical profession as a profession in health services, dentists have an obligation to carry out their service duties professionally. The main basis for dentists to carry out

medical procedures on other people is science, technology, and the competencies they possess and obtain through education and training.¹

The rapid development of dental science and technology has had an impact on the existence of health workers at various levels who have not been able to fully support the ideals of health services. In order to overcome these problems and ensure the quality of health services, Indonesian Medical Council Regulation Number 48/KKI/PER/XII/2010 concerning Additional Authorities of Doctors and Dentists (hereinafter referred to as PKKI Number 48 of 2010) has been issued. The additional authority as intended is the authority given to doctors or dentists to carry out certain medical practices independently after attending education and/or training.

The obligation to provide explanations or information to patients is among the responsibilities of a doctor towards patients. As stated in Article 10 Paragraph (1) of the Regulation of the Minister of Health of the Republic of Indonesia No. 290/MENKES/PER/III/2008 concerning Approval of Medical Procedures, namely "The explanation as intended in Article 9 is given by the doctor or dentist treating the patient or one of the doctors or dentists from the team of doctors treating him." However, if you are unable to do so, then another doctor or other health worker can provide explanation or information to the patient with the knowledge and responsibility of the doctor concerned. There is a distinction between surgical and non-surgical procedures. For surgical procedures, the doctor must provide the information for non-operative procedures. The operation should be carried out by the doctor concerned, but it can also be done by a nurse².

The implementation of the right to consent to medical treatment for information is also included in Article 7 of Law Number 36 of 2009 concerning Health, which states that everyone has the right to receive balanced and responsible information and education about health. Meanwhile, the provisions regarding implied consent for emergencies are contained in Article 4 paragraph (1) of the Minister of Health Regulation Number 290/Menkes/Per/III/2008 concerning Approval of Medical Procedures which states that in an emergency situation, to save the patient's life and/or prevent disability, no consent to medical procedures. "No medical action approval is required" means that doctors can take their own medical action to save a patient's life without asking for prior approval from the patient's family or guardian.³

Issues related to informed consent are something that must be considered by both doctors and health workers and patients for the interests and legal protection of all parties in medical service activities. However, there are no regulations that explain how dentists who treat patients without informed consent are protected, so that mistakes often occur regarding the function and role of informed consent. Therefore, it is necessary to study the legal protection for dentists in cases of tooth extraction without the patient's informed consent. Because there are still patients who do not understand the medical measures that will be carried out due to gaps in the patient's knowledge regarding the medical world, where this therapeutic agreement is not an engagement with a clear object (*resultaatverbintenis*), but rather an engagement whose object is maximum effort/result (*inspanningverbintenis*), where the level of healing Patients are not only influenced by the doctor's abilities but also other

¹Mela Karina Maya Riza and Ninis Nugraheni, "Legal Responsibility of Dentists for the Risks of Placing Dental Implants in Patients," *Ners Journal*, Vol. 7, no. 2 (2023), Pg.. 1040–1054

²Cecep Triwibowo, *Ethics and Health Law*, Nuha Medisa, Yogyakarta, 2014, Page.. 76

³Kusnadi, "Informed Consent from a Legal Perspective," *Iuris Scientia Journal*, Vol. 2, no. 1 (2023), Pg..



factors⁴. Based on the problems that occur, it is important to conduct research regarding legal protection for dentists in cases of tooth extraction for patients without informed consent. This research aims to explore various legal aspects related to tooth extraction services by dentists in Indonesia. The main aim of this research includes three things: first, to examine and analyze the legal arrangements governing the obligation of informed consent in tooth extraction procedures. Second, this study aims to understand and analyze the dentist's responsibilities towards patients regarding the delivery of informed consent in the context of tooth extraction. Lastly, this research seeks to examine and analyze the legal protection provided to dentists in treating patients who undergo tooth extraction procedures without informed consent, especially in various independent dentist practice locations in Pematangsiantar.

METHOD

This research uses empirical juridical methods with analytical descriptive specifications. The data used consists of primary data, obtained through interviews with 10 dentists who practice independently in Pematangsiantar, selected based on certain criteria such as the number of patient visits and willingness to be respondents. The names of respondents include Drg. Budi Gautama, drg. Diana Prima Nainggolan, and drg. Theresia Maridjan. Secondary data was collected from official documents, books, research reports, theses, dissertations, statutory regulations, and related literature. Data collection was carried out through interviews and literature study. Data analysis was carried out using a qualitative approach, using inductive and deductive logic to connect the data with relevant legal provisions.

RESULTS AND DISCUSSION

Legal Regulations Regarding the Obligation of Informed Consent

The implementation of dental and oral health services includes dentists, dental nurses and dental technicians who are health workers where they are required to carry out work in accordance with the professional ethics of health workers. There is a process of relationship between the doctor or dentist and the patient, where in this case the dentist has the authority and permission to provide health services by treating and examining, so the professional interaction that occurs between the doctor and the patient is the anamnesis process. Anamnesis is an examination activity through medical interviews and has the aim of gathering as much information as possible from the patient regarding the patient's disease state. Apart from that, anamnesis is part of the process for making a diagnosis and continues at the therapy planning stage. Documents in health services consist of approval for medical action or informed consent and there are medical records as archives of patient treatment activities within a certain period of time.⁵

According to Muhammad in Dwi Shandry et al.,⁶The process of consenting and signing the informed consent form can be divided into three phases. The first phase begins when the

⁴Anggun Rezki Pebrina, Johni Najwan, and Evalina Alissa, "The Function of Applying Informed Consent as Agreement in Therapeutic Agreements," *Journal of Civil and Business Law*, Vol. 3, no. 3 (2022), pp. 468–486

⁵Nabila Nurfauziah and Utari Dewi Fatimah, "Legal Protection of Patients for Medical Record Errors Due to Lack of Informed Consent in Health Services Reviewed Based on Health Law and Medical Practice (Decision Analysis Study No. 3203/K/Pdt/2017)," *Mahupas Journal*, Vol. 1, No. 2, 2022, Pg. 153–162

⁶Dwi Sandry Resky Dzulhizza, Darwis Anatami, and Ramon Nofrial, "Judicial Aspects in the Legal Responsibility of the Medical Profession from the Perspective of Informed Consent Services to Realize Legal Protection," *Journal of Scientific Studies*, Vol. 23, no. 1, 2023, Pg. 43–50

patient comes to the doctor's office, which indicates that the patient has implicitly given consent for the examination. The second phase occurs when the patient sits with the doctor and the doctor begins to take an anamnesis and record it in the patient's medical record, indicating the existence of a doctor-patient relationship. The third phase is when the doctor carries out a physical examination and possibly other additional examinations, and provides conclusions about the patient's illness, treatment, advice and medical procedures accompanied by sufficient explanations. According to Article 274 of Law Number 17 of 2023 concerning Health, medical and health personnel are obliged to: first, provide health services in accordance with professional standards, service standards, SOPs, professional ethics and patient needs; second, obtain consent from the patient or family for the action to be carried out; third, maintaining patient health confidentiality; fourth, create and store records and documents regarding examinations, care and actions; and fifth, refer the patient to medical or other health personnel who are competent and authorized.⁷

Based on the results of the interview, there are several important steps that must be followed by dentists in providing informed consent to patients before carrying out tooth extraction. First, the dentist must provide a clear explanation regarding the diagnosis of the patient's disease and the recommended action, including the reasons for the need for tooth extraction, the procedure to be carried out, as well as the risks and complications that may occur after extraction. Second, a detailed explanation of the tooth extraction procedure must be given, including stages such as the use of local anesthesia, special tools used, and the recovery process, as well as potential risks such as bleeding, infection, or nerve damage. Third, dentists need to ensure that patients have received and understood the information, as well as discussing alternative courses of action. Patients should be given the opportunity to ask questions and seek clarification before signing the informed consent form, indicating their voluntary and conscious consent. Fourth, the dentist must provide complete documents regarding approval or refusal of medical treatment, as well as explain the importance of informed consent in medical treatment. Finally, signing informed consent by the patient is the final step in this process, which ensures that the patient has given voluntary consent and understands the consequences of the action to be performed, thereby minimizing legal risks and providing protection for both dentist and patient.

The results show that the information and consent process is very important in medical practice, especially for tooth extraction. The dentist must provide a thorough explanation of the diagnosis, procedure, risks and alternative actions to the patient before carrying out an extraction. This is in line with Article 293 paragraph 3 of Law Number 17 of 2023 concerning Health, which regulates that every medical procedure must be accompanied by a complete explanation and free, conscious and uncoerced consent from the patient. By adhering to established procedural standards, the practice of tooth extraction can provide protection for both patients and dentists. Tooth extraction cases that require informed consent are teeth damaged due to caries, periodontal disease, supernumerary teeth, impacted teeth, teeth that are no longer amenable to endodontic treatment, and teeth involved in cysts and tumors and teeth involved in jaw fractures.⁸ A therapeutic agreement is an agreement made in order to provide therapy that concerns all aspects of health, starting from promotive,

⁷Article 274 of Law Number 17 of 2023 concerning Health

⁸Erdianto Setya Wardhana, Increasing Public Understanding of Tooth Extraction and Informed Consent in Health Services in Tegal Regency, <http://jurnal.unissula.ac.id/index.php/dentmas>, Accessed on Saturday 16 December 2023 at 12:54 WIB



preventive, curative and rehabilitative. The legal regulation of therapeutic agreements between doctors and patients is based on the provisions in Law Number 17 of 2023 concerning Health, the relationship between doctors and patients in therapeutic agreements can occur because of an agreement that refers to the provisions of Article 1320 of the Civil Code, namely regarding the conditions for the validity of the agreement. In this case, informed consent plays a very important role as the basis for a therapeutic agreement because informed consent explains information about the disease suffered by the patient⁹. Implementation of informed consent in health services. Approval of Medical Procedures is regulated in various statutory regulations, namely Law no. 36 of 2009 concerning Health, Law no. 44 of 2009 concerning Hospitals, the Civil Code (Civil Code) and Law Number 17 of 2023 concerning Health. Every action that will be carried out in implementing the Medical Action Approval is guided by existing laws and regulations, based on the consent form.

Legal regulations regarding informed consent policies in tooth extraction services by dentists in Indonesia can be linked to the theory of legal agreements. An informed consent policy can be thought of as a form of agreement between the dentist and the patient. The patient agrees to undergo tooth extraction based on the information provided by the dentist regarding the diagnosis of the disease, the procedure to be carried out, risks and complications, as well as the prognosis of the procedure. By giving consent, the patient is deemed to have agreed to the terms of the agreement that have been explained by the dentist. Dentists are responsible for providing complete and clear information to patients and carrying out procedures in accordance with applicable medical standards. Thus, the principles of legal agreements, such as agreement between the parties involved, the provision of honest and complete information, and consent given voluntarily by both parties are the basis for legal regulations regarding informed consent policies in tooth extraction services by dentist in Indonesia.

Based on the description above, it can be concluded that the steps that dentists must pay attention to in providing informed consent before carrying out a tooth extraction include explaining the diagnosis of the disease, recommended actions, risks of the action, and signing the agreement. Consent to medical treatment must be given by a competent patient, which includes an adult or non-child, whose consciousness is not disturbed, able to communicate reasonably, and not experiencing mental disorders. Implementation of approval for medical procedures in dental and oral health services refers to various laws and regulations that regulate approval for medical procedures, including Law no. 36 of 2009 concerning Health, Law no. 44 of 2009 concerning Hospitals, the Civil Code (KUHPerdata) and Law Number 17 of 2023 concerning Health.

Dentist's Responsibilities towards Patients in Providing Informed Consent in Cases of Tooth Extraction

Cases of tooth extraction that require informed consent are teeth damaged due to caries, periodontal disease, supernumerary teeth, impacted teeth, teeth that are no longer amenable to endodontic treatment, and teeth involved in cysts and tumors and teeth involved in jaw fractures. Compensation for unlawful acts not regulated by law is analogous to compensation for losses due to default. In relation to compensation and unlawful acts, losses that will arise from unlawful acts can be in the form of material property losses but can also be immaterial. Property losses include losses and unearned profits. To determine the amount of the loss, it

⁹Christiana Jullia Makasenggehe, Theodorus HW Lumunon, and Cobi EM Mamahit, "Legal Aspects of Therapeutic Transactions Between Medical Personnel and Patients," *Lex Privatiun Journal*, Vol. 12, no. 1, 2023, Pg. 1–10

must be returned in its original condition, but it must be taken into account that the person who suffered the loss did not gain any benefit as a result of the unlawful act. Compensation for losses arising from unlawful acts intentionally or negligently causing injury or disability to body parts, which can be claimed in this case concerns the costs of healing the patient, compensation resulting from injury or disability. This is regulated in Article 1371 of the Civil Code¹⁰. Implementing the responsibilities of doctors or hospitals in providing clear and accurate medical information to patients is an obligation as regulated in Article 29 paragraph (1) point a of Law Number 44 of 2009 concerning Hospitals which reads "Every hospital has an obligation provide correct information about hospital services to the public." Article 45 paragraph (3) of Law Number 29 of 2004 concerning Medical Practice explains that every doctor in carrying out his medical practice is obliged to provide an explanation of the diagnosis and procedures for medical procedures; the purpose of the medical action performed; alternative actions, risks and complications that may occur and the prognosis for the actions taken.

Furthermore, the doctor's obligation to provide good and correct information is also regulated in the implementation of the 2012 Indonesian Medical Code of Ethics, regarding the obligation of doctors to respect the rights of patients that "A doctor is obliged to provide clear and adequate information and respect the patient's opinion or response to the doctor's explanation." . Apart from that, it is also stipulated that "a doctor should not hide information that the patient needs, unless the doctor believes it is in the patient's interests, in which case the doctor can convey this information to the patient's family or guardian." The Hospital Code of Ethics (Kodersi) regulates the hospital's obligation to provide information to patients regarding their illness as stated in Article 10 of the Hospital Code of Ethics which reads: "Hospitals must provide an explanation of what the patient is suffering from, and what actions they intend to take.

Indonesian laws and regulations do not yet clearly regulate criminal liability for malpractice. Law no. 17 of 2023 concerning Health includes provisions related to this in Article 447 paragraph (1), which states that if a criminal act of malpractice is committed by a corporation, criminal liability is imposed on the corporation, management with a functional position, giver of orders, control holder, and/or owner corporate benefits. In addition, Article 440 of the same law regulates sanctions for medical or health personnel who commit negligence: if they cause serious injury, they can be sentenced to prison for a maximum of 3 years or a fine of up to IDR 250,000,000.00. If the negligence results in death, the sanction is a maximum prison sentence of 5 years or a fine of up to IDR 500,000,000.00.¹¹

The results of the interviews show that dentists who open independent practices in Pematangsiantar have a big responsibility in providing informed consent for tooth extraction cases. They must follow Standard Operating Procedures (SOP) and ensure optimal skills and knowledge. The dentist must provide a clear explanation of the procedure to be performed, including the risks and side effects, as well as ensure that the tools and materials are sterile and check the patient's medical history before the procedure. Apart from that, the dentist must carry out the extraction according to the SOP and provide post-procedure education. Complying with SOPs and providing adequate information helps reduce legal risks and improve the quality of dental health services. Providing health information is carried out by the doctor in charge of the patient, with nurses playing an important role in providing

¹⁰Vicky Novriansyah and Syamsuddin Pasamai & Anza, Op Cit, p. 960

¹¹Article 440 of Law Number 17 of 2023 concerning Health



additional education and support to patients and families in accordance with SOPs. Doctors have civil liability for losses arising from several legal grounds, namely: first, unlawful acts in accordance with Article 1365 of the Civil Code; second, negligence or lack of caution as regulated in Article 1366 of the Civil Code; and third, the responsibility of superiors towards subordinates in accordance with Article 1367 of the Civil Code.¹² Hans Kelsen divides responsibility into several categories, namely: first, individual responsibility, where a person is responsible for the violation he himself committed; second, collective responsibility, where someone is responsible for violations committed by others; third, responsibility based on fault, where a person is responsible for violations committed intentionally and with the aim of causing harm; and fourth, absolute liability, where someone is responsible for violations that occur accidentally and are not expected.¹³

The dentist's responsibility towards the patient in providing informed consent in cases of tooth extraction, the theory of responsibility plays an important role. This theory emphasizes that dentists have an ethical and legal obligation to provide clear, complete and easy to understand information to patients about tooth extraction procedures, including risks, benefits, alternative actions and possible consequences. The dentist must also ensure that the patient understands the information before giving consent. If dentists fail to fulfill these obligations, they may be held liable for the legal and moral consequences arising from such actions. Thus, understanding and applying this theory of responsibility is very important for dentists in ensuring that the services provided are in accordance with high ethical and professional standards.

Based on the explanation above, it can be concluded that a medical action is not unlawful, so the action must meet the requirements in the form of the action being carried out in accordance with medical professional standards or carried out legally, which is reflected in the presence of medical indications in accordance with concrete treatment objectives and carried out in accordance with with standard medical procedures, as well as fulfilling the patient's rights regarding informed consent. Because almost all medical procedures are essentially abuse that is justified by law, the potential risk of injury or even death is very difficult to avoid, especially those related to anesthesia and surgery. Criminal law adheres to the principle of "no crime without error". Furthermore, Article 2 of the Criminal Code states that "criminal provisions in Indonesian law apply to every person who commits an offense in Indonesia. The formulation of this article determines that every person within the jurisdiction of Indonesia can be held criminally responsible for the mistakes they make.

Legal Protection for Dentists in Handling Patients in Cases of Tooth Extraction Without Informed Consent

The legal relationship between a doctor or dentist and their patient is based on mutual trust. The doctor's main obligation is to make hard and serious efforts (inspanning) to cure the patient. Therapeutic contracts between doctors and patients create rights and obligations for both parties and are subject to the general provisions of contract law, as regulated in Article 1320 of the Civil Code. This article stipulates four conditions for the validity of an agreement, namely: (1) agreement of the parties involved; (2) the ability to create agreements; (3) the specific object of the agreement; and (4) valid reasons for the

¹²Christiana Jullia Makasenggehe, Theodorus HW Lumunon, and Cobi EM Mamahit, "Legal Aspects of Therapeutic Transactions Between Medical Personnel and Patients," *Lex Privatiun Journal*, Vol. 12, no. 1, 2023, p. 1–10

¹³Dian Kristanti Budiastuti, Ardiansah, and Yeni Triana, "Responsibility of Dentists for Negligence to Patients," *Law, Development & Justice Review Journal*, Vol. 5, no. 1, 2022, p. 115–127

agreement.¹⁴ Article 293 of Law Number 17 of 2023 concerning Health stipulates several important provisions regarding approval for medical procedures. First, every health service action by medical personnel and health workers must obtain consent from the patient. If the patient is not capable of giving consent, then consent can be given by the party representing the patient. Second, written consent for health service procedures must be signed by the patient or his representative and witnessed by one of the medical personnel or health workers. Third, in emergency situations where the patient is incompetent and no party can give consent, medical procedures can be carried out without consent. These provisions are designed to ensure that medical procedures are carried out with valid consent and are appropriate to the patient's situation.

The relationship between a doctor and a patient is known as a therapeutic relationship, which in a legal context is considered an agreement to provide medical services with the aim of achieving the results expected by the patient. In medical law, this relationship is categorized as a contract, which indicates an agreement between two parties regarding something called a consensual agreement. The first party, namely the doctor, commits himself to providing medical services, while the second party, namely the patient, is the recipient of the service. This contract has two main elements: first, consent, which refers to the agreement between the doctor and the patient regarding the treatment services to be provided; second, trust, which reflects a contractual relationship based on a fiduciary relationship, namely mutual trust between the doctor and the patient.¹⁵

The results of the interviews show that there is a diverse understanding among dentists in Pematangsiantar regarding the importance of informed consent in every case experienced by a patient. Dentists are aware of the importance of this procedure and routinely apply it, while others may not be fully aware of it or apply it consistently. Dentists emphasize that every tooth extraction procedure must begin with filling out informed consent, which includes an explanation of the procedure, risks and available treatment alternatives. Dentists who understand the importance of informed consent consider it as a form of protection for themselves and the patient, as well as a form of the patient's approval or understanding of the action to be carried out. However, dentists need to further improve their understanding of the principles of informed consent in ensuring that each patient receives an adequate explanation before undergoing dental procedures.

It is important for patients to know the benefits and risks of the medical procedures they will undergo. Before the procedure is carried out, the doctor must explain the steps, benefits and risks of the medical procedure. After receiving an explanation and understanding the information, the patient can decide to agree or reject the recommended medical treatment. Clear and complete informed consent ensures that the patient understands all aspects of the therapy, including the benefits, risks, and goals of treatment. This also prevents misunderstandings that can arise if the results of medical procedures do not meet expectations and are considered malpractice. The informed consent form must include the identity of the patient and medical personnel, information about the diagnosis, type of procedure, risks and benefits of medical procedures, alternative procedures, and estimated costs.¹⁶

After the patient reads and agrees to the informed consent, the patient is considered to have received all information regarding procedure and treatment options from the doctor.

¹⁴ (Nurhayati & Purwanto, 2022)

¹⁵ Tjokorda Istri et al., "Implementation of Informed Consent at the Tiara Husada Pratama Clinic," *Journal of Legal Interpretation*, Vol. 3, no. 2, 2022, p. 339–345

¹⁶ (Flora, 2024)



Patients also understand the information provided, have the opportunity to ask questions, and decide whether to undergo or reject recommended treatment steps.¹⁷ Delivery of information is usually done orally to ensure there is two-way communication that allows questions and answers, so that information can be conveyed more broadly and in depth. While the informed consent form only presents brief and concise information, more detailed explanations are made verbally to allow direct interaction between the patient or family and the doctor. If the patient refuses to receive information, the doctor can provide the information to the family in the presence of another health worker.¹⁸

Articles 274 and 275 Health Law no. 17 of 2023 essentially means that if a doctor treats a disease outside his or her area of competence, then both the doctor and dentist are obliged to offer the patient the option of being referred or consulted to another competent doctor or dentist in accordance with the patient's medical needs.¹⁹ Filling out the Informed Consent form is carried out at least 24 hours in cases of dental surgery before surgery, after surgery and if the patient is allowed to go home. So that the Informed Consent form contained in the medical record file will be returned to the medical record storage unit and the returned file should have been filled in completely. Before being stored on the storage shelf, the medical record file will be analyzed by the medical records officer. If parts are found that are incomplete, the file will be returned to the inpatient unit to be completed by the nurse/doctor who is responsible for patients whose medical record files have not been filled in completely. The medical records officer will mark files that are not completely filled in by folding the file. The minimum time to complete the file is 2x24 hours until it returns to the medical record file storage unit²⁰.

Based on this explanation, the researcher can conclude that the implementation of informed consent is very important in medical practice, because every patient has the right to know the benefits and risks of the medical treatment they will undergo. Doctors are obliged to provide adequate explanations to patients, and ensure that each patient gives clear consent before undergoing medical treatment. This information is usually conveyed verbally, so that there is two-way communication between the doctor and the patient. In practice, several dentists in Pematangsiantar have understood and implemented informed consent procedures well, but there are still other dentists who need to improve their understanding of the principles of informed consent. This is important to ensure that each patient receives an adequate explanation before undergoing dental procedures.

The relationship between a doctor and a patient is an agreement whose object is medical services or healing efforts, known as a therapeutic transaction. The therapeutic transaction is an agreement to determine and find the right therapy for the patient. As a result, the patient's position, which was originally only as a party who depends on the doctor in determining the method of healing, has now changed to being equal to the doctor, namely as a subject in medical services, so that between the two, reciprocal rights and obligations arise.²¹ The relationship between a doctor and a patient, known as a therapeutic transaction, is an agreement where the object is medical services or healing efforts. In this context, the main goal is to determine and find the right therapy for the patient. With this relationship, the position of patients who were previously completely dependent on doctors in choosing healing methods has now changed to become equal, making them active subjects in the medical service process. This leads to reciprocal rights and obligations between doctors and

¹⁷ (Buruhi et al., 2023)

¹⁸ (Buruhi et al., 2023)

¹⁹ (Damanik et al., 2024)

²⁰ (Mufidah & Syntia, 2021)

²¹ (Budiastuti et al., 2022)

patients. According to Syahrul Machmud, the relationship between doctors and patients can be grouped into three stages. The first stage is an active-passive relationship, where the patient does not provide feedback on the services received and completely submits the decision to the doctor. This can happen because the patient fully trusts the doctor's abilities, the patient is unaware, or is unable to determine the choice of medical treatment. The second stage is a guided collaborative relationship, where the patient is aware and willing to cooperate with the doctor, but decisions regarding medical procedures are still dominated by the doctor. The third stage is a joint participation relationship, where the patient positions himself as an equal to the doctor and decisions on medical treatment are taken based on mutual agreement after intensive communication.²²

The dentist's actions in providing services to patients without conveying information to the patient and without asking for consent is a violation of the principle in Health Law, namely informed consent which connects information and consent. Informed consent is approval given by a patient to a health worker or doctor to carry out a medical action aimed at curing the disease he is suffering from. In essence, informed consent is an agreement based on information that is a tool to enable self-determination that functions in health services²³. This explanation was also confirmed in the results of interviews conducted with several dentists at various independent practice places in Pematangsiantar. In this case, it refers to the importance of informed consent as legal protection in cases of tooth extraction carried out by dentists in various independent practice places in Pematangsiantar. If there is a dispute or lawsuit related to tooth extraction, the dentist can use informed consent as proof that the patient knows and agrees to the procedure being carried out. Thus, informed consent has an important position as legal protection for dentists in their practice.

Based on the results of the interview above, it can be seen that the informed consent that has been carried out by dentists at various independent practice places in Pematangsiantar has an important role as legal protection in cases of tooth extraction. This is proven by ensuring that the patient has given conscious and voluntary consent to the procedure which strengthens the dentist's legal position in the face of disputes. In addition, by providing clear and complete information to patients before tooth extraction, dentists can prove that they have carried out their professional responsibilities well. The position of informed consent in the tooth extraction process is very crucial, because without informed consent, medical procedures carried out by the dentist can be considered invalid. The informed consent document also functions as written proof that the dentist has fulfilled his obligation to provide complete information to the patient, thus providing protection against legal claims. With informed consent, patients can also obtain adequate information about the tooth extraction procedure, including the risks and benefits, as well as protecting the dentist from malpractice claims. Thus, informed consent is a very important element in protecting the rights of patients and dentists in tooth extraction cases.

The concept of informed consent refers to the process by which a patient gives formal consent to undergo a medical procedure that is carried out in a professional manner. Consent is often misunderstood and equated with the patient's signature on the form. A signature on the form is proof that the patient has given his consent but is not proof that the consent is valid. If someone is handed a form in a hurry (with little information) then the consent will be

²² (Pratama & Ngadino, 2022)

²³ (Hendrik, 2011)



invalid, even though there is the patient's signature.²⁴ Medical procedures that are not included in the provisions can be given with verbal consent. Consent is made in the form of a statement contained in a special form created for that purpose. Consent can be given in the form of a statement of agreement or a nodding movement of the head which can be interpreted as an agreement. If the verbal approval given is considered doubtful, written approval can be requested. In an emergency situation, to save the patient's life and/or prevent disability, approval for medical action is not required. The decision to carry out medical procedures is made by the doctor or dentist and recorded in the medical record. In the case of a medical procedure, the doctor or dentist is obliged to provide an explanation as soon as possible to the patient after the patient is conscious or to the closest family²⁵.

This statement illustrates that informed consent has a very important position as legal protection in cases of tooth extraction carried out by dentists in various independent practice places in Pematangsiantar. Informed consent ensures that the patient has given conscious and voluntary consent to the procedure, strengthening the dentist's legal position in the face of disputes. By providing clear and complete information to patients before tooth extraction, dentists can prove that they have carried out their professional responsibilities well. Without informed consent, medical procedures performed by a dentist may be considered invalid. The informed consent document serves as written proof that the dentist has fulfilled his obligation to fully inform the patient, provide protection against lawsuits, and protect the dentist from malpractice claims. Therefore, informed consent is a very important element in protecting the rights of patients and dentists in the tooth extraction process.

According to Law Number 29 of 2004 concerning Medical Practice, Article 53 regulates the rights and obligations of patients in relation to therapeutic contracts, where patients have certain rights and obligations, namely as follows:

- a. Provide complete and honest information about health problems to the doctor who is treating him.
- b. Comply with the doctor's advice and instructions.
- c. Comply with the provisions that apply at health service locations, whether hospitals or health centers or other health service locations.
- d. Providing service compensation for services received, obliged to fulfill things that have been agreed upon or agreements that have been made.²⁶

The existence of a therapeutic transaction is an agreement between the doctor and the patient which is the basis of the legal relationship between the two which gives rise to rights and obligations for both the patient and the doctor. This is of course different from transactions in general that may be carried out by society, therapeutic transactions have special characteristics that are different from agreements in general. This special characteristic lies in the object agreed upon in the transaction. When examined, what is actually the object of a therapeutic transaction is the healing effort that will be given to the patient. So according to law, the object of the agreement in a therapeutic transaction is not the patient's recovery but rather seeking appropriate efforts for the patient's recovery²⁷.

Form caution regarding the actions of the doctor's profession as a guideline for carrying out them with full responsibility. Responsibility for a doctor's actions as a form of legal protection in carrying out his profession and dealing with the law. However, in Article 310 concerning Settlement of Disputes, Health Law Number 17 of 2023 concerning Health, it is

²⁴ (Sutamaya et al., 2022)

²⁵ (Solihan, 2022)

²⁶ (Wahyudi & Annisa, 2020)

²⁷ (Sulistyaningrum, 2022)

clear that when medical personnel make mistakes in carrying out their profession, causing harm to patients which results in a dispute, therefore the first step that can be taken is to complain to Professional Disciplinary Council (to enforce professional discipline/assembly formed by the Minister of Health)²⁸. *Informed Consent* must be attached to the medical record. The contents of the medical record at a minimum include the patient's identity, examination results, diagnosis, treatment and follow-up plan, signed by the dentist and responsible health worker. In a legal context, medical records function as legal written evidence in trials to prove medical errors by health workers. Even though it has an important role, its position in terms of proving medical errors is considered below that of expert testimony presented directly at the trial. Medical records are used to substantiate legal, ethical, and disciplinary issues related to medical practice.²⁹

The results of the interview show awareness of the importance of providing informed consent in every tooth extraction procedure for dentists in Pematangsiantar. Without informed consent, it is feared that dentists will not receive applicable legal protection. This is because tooth extraction without informed consent can have an impact on the weak legal basis that protects dentists. They also emphasized that no legal protection can be provided if the dentist does not provide informed consent for tooth extraction, so legal protection for dentists who do not provide informed consent should still be provided. Apart from that, tooth extraction treatment carried out without informed consent is also considered not protected by law because there is no written proof of the patient's consent to the action. Therefore, the results of this interview emphasize that informed consent is part of the standard operating procedures (SOP) that must be adhered to by dentists so that the tooth extraction procedure can be carried out correctly and obtain maximum legal protection.

From a doctor's point of view, approval for medical treatment is closely related to the doctor's obligation to provide information to the patient and this action is also an obligation to carry out medical procedures in accordance with medical professional standards. An informed consent can be said to be valid if it fulfills the following 3 elements:

- a. Sufficient disclosure of information provided by the doctor;
- b. Patient competency in giving consent;
- c. Patient voluntariness in giving consent;³⁰

In the context of medical law, Law Number 17 of 2023 provides legal protection for doctors through several important provisions. Doctors are obliged to comply with the principle of informed consent, namely the obligation to provide a complete explanation of the medical action to be carried out and its risks to the patient, and obtain clear consent from the patient or his family. In addition, doctors must create and keep medical records that record all data related to examinations, treatment and medical procedures given to patients, as regulated in Article 296 of the Law. Doctors also cannot be held responsible if patients are dishonest about their medical history or refuse medical instructions, in this case it is known as contributory negligence or the patient's own fault. In the complex field of medicine, doctors can maintain their practice if they follow generally accepted medical opinion even though it is not always agreed with by all parties, in accordance with respectable minority rules. Finally, the doctrine of *res ipsa loquitur* shifts the burden of proof to doctors to show that

²⁸ (Kesuma, 2023)

²⁹ (Nur, Fitrianto & Sembiring, 2024)

³⁰ (Mariyani, 2020)



their actions do not fall into the category of negligence, if there is an obvious disability or injury resulting from their medical actions.³¹

Violations of the principle of informed consent are regulated in Article 306 of Law Number 17 of 2023 concerning Health, which stipulates that doctors who carry out medical procedures without obtaining appropriate consent from the patient can be subject to sanctions ranging from verbal warnings, written warnings, to revocation of their Practice License. . In addition, Article 189 of the same Law also regulates administrative sanctions for violations of this obligation in accordance with statutory regulations. Although general law still applies to the medical profession, there are several specific factors that influence a doctor's responsibilities in a medical context. One of these factors is the risk of treatment, namely the inherent risk of allergic reactions or complications that may occur even though the doctor has met practice standards and provided adequate information to the patient. Another factor is medical accident or misadventure, which includes unexpected medical accidents and is not the aim of medical treatment. Non-negligent error of judgment refers to an error of clinical judgment in which the doctor is not considered negligent if he chooses a medically approved treatment method. The principle of *volenti non fit inura* states that someone who knows and voluntarily accepts the risk cannot make a claim. Finally, contributory negligence refers to the patient's unreasonable actions that result in loss or injury to himself, which can eliminate the doctor's responsibility, regardless of whether there was negligence on the doctor's part.³²

The rule of law provides protection to dentists through two main principles. First, preventive legal protection, which is regulated in Article 50 of Law of the Republic of Indonesia Number 17 of 2023 concerning Health, offers protection for dentists with certain conditions. Doctors must have a Registration Certificate (STR) and Practice License (SIP), as well as carry out medical procedures according to applicable standards and document informed consent in the medical record. These protections are proactive, contingent on physicians' compliance with these requirements to ensure the safety and quality of medical practice. Second, repressive legal protection, as regulated in Article 193 of Law no. 17 of 2023, focuses on handling disputes that have arisen, such as allegations of malpractice or negligence. If the patient files a civil lawsuit, the dispute resolution must be through mediation first. This principle aims to resolve civil issues peacefully before proceeding to formal legal proceedings, providing an opportunity for a more harmonious and fair resolution.³³

The theory of legal protection is very relevant in the context of handling patients with tooth extraction cases without informed consent by dentists in Pematangsiantar. Dentists who perform procedures without informed consent risk serious legal problems, as the law requires clear informed consent from the patient. Without informed consent, doctors are considered to be violating the patient's right to know information regarding procedures, risks and treatment alternatives. Legal protection theory encourages dentists to adhere to the principle of informed consent to protect themselves from potential lawsuits. Awareness of the importance of informed consent in the practice of tooth extraction shows that dentists in Pematangsiantar must always comply with standard operational procedures and fulfill legal requirements to obtain maximum legal protection. Informed consent and complete medical records are part of the professional standards that must be met, although doctors also need to consider the risks of treatment, medical accidents, and the contribution of patient negligence. By complying

³¹ (Estrada, 2024)

³² (Flora, 2024)

³³ (Sartika et al., 2024)

with legal principles and professional standards, doctors can practice medicine with optimal legal protection.

CONCLUSION

Based on the research, the main conclusions are as follows:

1. Legal Protection: Dentists require informed consent to obtain adequate legal protection. Without informed consent, dentists are not legally protected, and treatment without consent is considered invalid. Legal protection is regulated in Law no. 17 of 2023 concerning Health, includes preventive protection (Article 50) and repressive protection through mediation for cases of negligence (Article 193).
2. Legal Regulation of Informed Consent: In Indonesia, the obligation of informed consent in tooth extraction is regulated by various laws such as Law no. 36 of 2009 concerning Health, Law no. 44 of 2009 concerning Hospitals, and now Law no. 17 of 2023 concerning Health. Important steps in informed consent include diagnosis, procedures and risks, consent, providing documents, and signing.
3. Dentist Liability: Dentists are civilly and criminally responsible for errors or omissions in the informed consent process and tooth extraction. Civil liability is regulated in Articles 1365-1367 of the Civil Code, while criminal liability is regulated in Law no. 17 of 2023, especially Article 447 paragraph (1), which covers the responsibilities of related corporations and individuals.

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