
The Role of Informed Consent as Legal Protection for Doctors in Conducting Medical Procedures

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ABSTRACT: The field of Health Law recognizes Therapeutic Transactions as an agreement between a doctor and a patient, granting authority to the doctor to provide healthcare services to the patient based on their expertise and skills. Therapeutic transactions take the form of informed consent or approval of medical procedures before they are carried out. Informed consent involves the doctor explaining to the patient the condition of their illness and the medical procedures intended to address it, in the doctor's efforts to achieve recovery. Research findings indicate that informed consent plays a crucial role in the relationship between doctors and patients, serving as written evidence of the agreement between the doctor and the patient before medical procedures are undertaken. Informed consent can serve as the basis for proving whether a patient accepts or refuses a medical procedure, providing protection to the doctor. Legal protection for doctors is obtained as long as they carry out procedures in accordance with professional standards and operational procedures. For doctors, informed consent provides a sense of security when performing medical procedures on patients and can be used as a means of self-defense against potential claims or lawsuits from patients or their families if the medical procedure results in unintended consequences. Legal measures that doctors can take in the event of an undesired outcome related to medical procedures include attempting mediation with the patient first. If mediation fails or lacks good faith, the resolution may proceed through the legal system.

Keywords: Informed Consent, Legal Protection, Medical Procedures



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INTRODUCTION

Medical services are of utmost importance in everyday human life. This is because health is something that must be carefully maintained. Without good health, every individual will find it difficult to carry out their daily activities. When someone falls ill, they seek medical services, which can be provided in hospitals or clinics. They receive healthcare services from attending doctors. The meeting between a doctor and a patient constitutes an agreement or transaction known as Therapeutic Transaction. Therapeutic Transaction is defined as an agreement between a doctor and a patient that authorizes the doctor to provide healthcare services to the patient based on the

doctor's expertise and skills. Therapeutic Transactions generate rights and responsibilities for both parties, including the doctor and the patient.

In contrast to agreements made by the general public, therapeutic agreements have specific objects and characteristics (Nasution, n.d.). The object of therapeutic transactions is healthcare services provided by a doctor, where the doctor endeavors to heal the patient using their knowledge, expertise, and skills. The relationship between the doctor and the patient is equal, placing both parties with legal responsibilities based on the therapeutic transaction.

The relationship between a doctor and a patient is founded on trust, as expressed in the therapeutic agreement, resulting in rights and obligations for both parties. One of the patient's rights is to receive information about their illness and the medical procedures that the doctor will perform on them, serving as the basis or foundation for taking medical action (informed consent).

Law No. 17 of 2023 Regarding Health, in Article 293, states that: Every individual Health Service procedure carried out by Medical Personnel and Health Personnel must receive consent. This consent is given orally or in writing after the patient has received adequate explanation.

According to Article 293 of the Health Law, an informed consent must include: (a). Diagnosis; (b). Indications; (c). Healthcare service procedures performed and their purposes; (d). Risks and complications that may occur; €. Alternative procedures and their risks; (f). Risks if the procedure is not performed; (g). Prognosis after receiving the procedure (Director, 2023).

By encompassing these elements, the patient is provided with a comprehensive and adequate understanding of the medical procedure to be undertaken and its implications.

Furthermore, Article 45 paragraph (1) of Law Number 29 of 2004 Regarding Medical Practice states that: "Every medical or dental procedure to be performed by a doctor or dentist on a patient must obtain consent." In addition, the provisions regarding informed consent are regulated in Minister of Health Regulation No. 290/Menkes/Per/III/2008 Concerning Approval of Medical Procedures, which states that: "Approval of Medical Procedures is the consent given by the patient or closest family after receiving a comprehensive explanation of the medical or dental procedure to be performed on the patient." (Nainggolan et al., 2023).

Medical services are inherently prone to risks due to the possibility of accidents. However, as long as the doctor has provided thorough and accurate information to the patient, obtained consent, and performed the medical procedure according to established procedures, the doctor cannot be held accountable if unforeseen risks still arise. On the other hand, if a doctor makes a mistake or acts negligently, deviating from established procedures, the patient may file a lawsuit against the doctor for malpractice.

A doctor, in carrying out their profession, must adhere to professional standards as outlined in Article 51, paragraph 1 of Law Number 29 of 2004 regarding Medical Practice. Professional standards are guidelines that must be followed to conduct the profession properly. Regarding medical services, the guideline used is the medical service standard, with a focus on medical procedure protocols (Komalawati, n.d.).

There are two forms of informed consent:

a). Implied Consent (deemed given): Implied consent is given under normal circumstances, meaning the doctor can infer consent for the medical procedure from signals given or actions taken by the patient. This is also applicable in emergency cases when the doctor requires immediate

action, and the patient is unable to give consent, and there are no family members present. In such situations, the doctor can proceed with the best medical intervention according to their judgment.

b). Expressed Consent (stated): Expressed consent can be given orally or in writing. For medical procedures that are invasive and carry risks, it is advisable for the doctor to obtain written consent, for example, through an operation consent form.

In essence, informed consent is the agreement or permission from the patient or family, granting the doctor the right to perform medical procedures on the patient, such as physical examinations and other diagnostic measures, administering medication, assisting in childbirth, and even carrying out follow-up procedures in case of complications, and so forth. In addition to consenting to medical procedures, informed consent also involves a comprehensive explanation of the actions undertaken by the respective doctor. Receiving a thorough explanation is one of the patient's rights recognized by the law; hence, in other words, informed consent is an agreement following an explanation (Kituuka et al., 2023; Tanaka et al., 2023).

The Indonesian Medical Association's (IDI) statement on informed consent is as follows:

- 1) Healthy adult individuals, both physically and mentally, have the full right to determine what should be done to their bodies. Doctors are not entitled to perform medical procedures contrary to the patient's will, even for the patient's own benefit.
- 2) All medical procedures (diagnostic, therapeutic, and palliative) require informed consent, whether oral or written.
- 3) Any medical procedure with significant risks necessitates written consent signed by the patient after receiving strong information about the necessity of the procedure and its risks.
- 4) For procedures not covered in point 3, only verbal consent or silent agreement is required.
- 5) Information about medical procedures must be provided to the patient, whether requested or not. Withholding information is not allowed, except when the doctor assesses that the information may harm the patient's health interests. In such cases, the doctor can provide information to the patient's closest family, with the presence of a nurse or other paramedic as a crucial witness.

Some elements of medical procedure consent (informed consent) frequently cited by patients as reasons for medical disputes are:

- 1) Unclear and incomplete information: Information about the patient's illness and alternative options is not conveyed clearly and comprehensively.
- 2) Timing of information provision: Information should ideally be provided before the commencement of therapy, especially in the case of high-risk medical procedures with the possibility of expansion in therapy or medical procedures.
- 3) Unsatisfactory information delivery: Patients feel dissatisfied with the way information is communicated, as they believe they are not receiving honest, complete, and accurate information orally from their attending doctor.
- 4) Lack of opportunity for patient choice: Patients feel they are not given the opportunity to choose or explore alternative treatments that have been applied to them, thus neglecting

the patient's right to determine their own course of action by the doctor (Zacher et al., 2023).

- 5) Information solely from nurses (paramedics): Sometimes, patients only receive information from nurses (paramedics), whereas according to the law, the doctor responsible for the patient is the one authorized to provide information.
- 6) Neglect of patient self-determination: Patients feel that their right to self-determination is disregarded by the doctor. Occasionally, patients only receive information from nurses, although, according to the law, the doctor handling the patient is the one entitled to provide information (Isyfyandarye: 2006).

When looking at the elements of medical procedure consent (informed consent) that serve as reasons for medical disputes, these issues can actually be avoided if the information provided by the doctor is truthful. This is because the information that should be provided includes both the risks and benefits of the medical procedure to be undertaken, whether diagnostic or therapeutic.

The completeness of informed consent is crucial for the provision of healthcare services because through informed consent, an agreement is formed in the healthcare field. This agreement can be a determining factor and foster a sense of security and comfort for doctors or healthcare professionals in carrying out their duties as healthcare providers (Hidayat et al., 2022).

Effective communication from doctors or hospitals regarding patients' health issues is essential, providing comprehensive and detailed information. This ensures that patients comprehend their health conditions and the legal rights safeguarding them. Another advantage of clear communication is that patients can understand the extent of their health status or the severity of their illnesses, as well as the doctor's ability to address their issues based on the current conditions.

Concerning legal protection in medical cases between patients and doctors, it requires careful attention and resolution. An increase in legal cases in the medical field can adversely impact the reputation of healthcare services, escalate service costs, and erode public trust in healthcare.

The significance of informed consent in medical procedures is valuable for doctors as a preventive measure in the face of potential risks. Therefore, the examination of informed consent is justified as one of the legal protection measures for doctors performing medical procedures.

Based on the identified issues, the research questions can be formulated as follows: (1) What is the role of Informed Consent in legal protection for doctors during medical procedures? (2) What legal actions can doctors take in case of errors during medical procedures?

METHOD

In this study, the author employs the juridical-empirical research method. Juridical-empirical research involves a field study approach, observing real-world occurrences, and applying regulations related to the research in practice within the community. To support this empirical research, normative research is also utilized through a legal approach, which involves examining legislation related to informed consent (Moleong, 2017; Sugiyono, 2017).

The juridical-empirical research, also known as field research, examines the legal provisions and their actual implementation in society (Soekanto, n.d.). According to Abdulkadir Muhammad,

juridical-empirical research focuses on the enforcement or implementation of normative legal provisions in action during specific legal events occurring within the community (Muhammad, n.d.).

This research is descriptive-analytical, meaning it is aimed at describing and analyzing research in a descriptive manner. Descriptive-analytical research aims to accurately depict individuals, situations, phenomena, or specific groups, or to determine the frequency of certain phenomena within the community (Mamudji, 2015). The specification of this research with descriptive analysis involves providing a specific overview based on systematically collected data (Marzuki, n.d.). In this study, the researcher specifies primary data related to the role of Informed Consent as a legal protection effort for doctors in medical procedures (Brennan et al., 2023).

RESULT AND DISCUSSION

1. The Role of Informed Consent as a Legal Protection Measure for Doctors in Conducting Medical Procedures (Komalawati, n.d.)

Informed consent is the agreement or permission granted by a patient or their family to a doctor to perform medical procedures on the patient, such as physical examinations and other diagnostic procedures, administering medication, injections, assisting in childbirth, administering anesthesia, performing surgery, undertaking follow-up procedures in case of complications, and so forth. The term "informed" is related to information or explanation (King-Kallimanis et al., 2023). Therefore, it can be concluded that informed consent is an agreement or permission granted by the patient or their family, allowing the doctor to perform medical procedures after providing comprehensive information or explanation about the procedure.

The concept of Informed Consent involves the patient agreeing to medical interventions proposed by the doctor after receiving information about the medical efforts that can be undertaken to assist them, including information about potential risks (Komalawati: 2002). Receiving comprehensive explanations is a right granted to patients by the law; hence, in other words, informed consent is an agreement following thorough explanations (Lorenzini et al., 2023). The objectives of informed consent include:

- a) Protecting patients from any medical procedures conducted without their knowledge;
- b) Providing legal protection against unforeseen and negative consequences, such as unavoidable treatment risks, even if the doctor has made every effort and acted with extreme care and precision (Guwandi, n.d.).

In medical treatment, hospitals create informed consent forms detailing the patient's identity, age, the patient's statement granting authority to the doctor or hospital, information provided by the doctor about the planned procedures and explanations of associated risks, a declaration that the patient has understood all the information provided by the doctor regarding the procedures and risks, and the date of the medical procedure's consent. The Informed Consent form articulates the intentions of both parties, with the patient expressing agreement with the proposed medical procedures and both parties signing the consent form. This mutual agreement is binding and cannot be revoked by either party without the consent of the other.

Informed Consent does not have an expiration date; however, it remains valid as long as the patient is undergoing treatment or is still under the doctor's care. The consent form is stored along with the patient's medical records during this period.

In the execution of their professional duties, doctors are protected by Law No. 17 of 2023 concerning Health and Law No. 29 of 2004 concerning Medical Practice. Articles 273 to 279 of Law No. 17 of 2023 concerning Health state that Medical and Health Professionals are entitled to legal protection in accordance with professional standards and ethics, patient health needs, protection of safety, occupational health, and safety, as well as protection against treatment that does not conform to human dignity, morals, ethics, and socio-cultural values. Furthermore, Article 50, letter a, of Law No. 29 of 2004 concerning Medical Practice states that "Doctors or dentists, in carrying out medical practice, have the right to legal protection as long as they carry out their duties in accordance with professional standards and operational procedures."

Therefore, if a doctor has provided medical services or medical practice in accordance with professional standards and operational procedures, the doctor or dentist cannot be sued administratively, civilly, or criminally. This represents a form of legal protection provided by the state for the medical and dental professions.

Some actions that doctors need to take to avoid legal claims include:

- 1) **Informed Consent:** Informed Consent is an obligation that must be fulfilled by a doctor. It consists of two words: "informed," which conveys the meaning of explanation or information, and "consent," which means agreement or permission.
- 2) **Medical Records:** In addition to informed consent, doctors are also obligated to create "Medical Records" for every healthcare activity involving their patients. Medical records are regulated by Article 46, paragraph (1), of Law No. 29 of 2004 concerning Medical Practice. It states that "Medical records are files containing records and documents about the patient's identity, examinations, treatments, procedures, and services provided to the patient. Medical records are created for various purposes, including patient treatment, improving service quality, education and research, financing, health statistics, as well as evidence for legal, disciplinary, and ethical matters."

There are several reasons providing protection to doctors, making them immune to legal consequences. These reasons include:

- 1) **Treatment Risks:** Treatment risks include:
 - a. **Inherent or intrinsic risks:** Every medical procedure performed by a doctor inherently carries risks. Therefore, doctors must practice their profession according to applicable standards. Inherent risks may include side effects such as hair loss due to chemotherapy with cytotoxics.
 - b. **Hypersensitivity reactions:** Excessive immune responses to foreign substances (medications) are often unpredictable.
 - c. **Sudden and unforeseeable complications:** Sometimes, a patient's prognosis may seem positive, but suddenly their condition worsens, or even leads to death without an apparent cause. For example, the occurrence of amniotic fluid embolism.
- 2) **Medical Accidents:** Medical accidents are often considered equivalent to medical malpractice, as these situations cause harm to the patient. Both situations should be distinguished because, in the medical field, doctors aim to heal rather than harm patients. If a medical accident occurs, the doctor's liability depends on how the accident happened or whether the doctor can prove the occurrence of the accident.

- 3) **Contribution Negligence:** Doctors cannot be blamed if they fail or are unsuccessful in treating a patient if the patient does not honestly disclose their medical history or medications used during illness or does not follow the doctor's instructions or refuses agreed-upon treatment. This is considered the patient's fault, known as contribution negligence, where the patient is also at fault. Honesty, compliance with advice and instructions from the doctor are considered the patient's obligations to the doctor and themselves.
- 4) **Respectable Minority Rules & Error Of (in) Judgment:** Medicine is a highly complex field, and there are often disagreements or differing opinions about suitable therapy for specific medical situations. Medical science is both an art and science matured through experience. Therefore, approaches to a disease may differ among doctors. However, all must be based on accountable knowledge. Based on the above situation, a legal theory called the "respectable minority rule" arises, stating that a doctor is not considered negligent if they choose from one of the recognized medical treatment alternatives. The doctor's error in choosing a medical action for their patient introduces a new theory called error of (in) judgment or medical error, meaning a doctor's medical action choice based on professional standards may still be wrong.
- 5) ***Volenti Non Fit Iniura* or Assumption of Risk:** *Volenti non fit iniura* or assumption of risk is an old legal doctrine applicable to medical law. It involves a prior assumption of the high medical risk by the patient if a medical procedure is performed on them. If a detailed explanation is provided, the patient or family agrees, and this is strengthened by informed consent, and the anticipated risk occurs, the doctor cannot be held responsible for their medical actions. This doctrine can also be applied to cases of premature discharge (leaving voluntarily before being officially discharged by the doctor). In such cases, doctors and hospitals are released from legal claims.
- 6) **Res Ipsa Loquitur:** The Res Ipsa Loquitur doctrine is directly related to the burden of proof, involving a shift of the burden of proof from the plaintiff (patient or their family) to the defendant (medical professional). For certain clear negligence, apparent and known, understandable to laymen or based on common knowledge among laymen, medical professionals, or both, that a defect, injury, or fact is clearly evident from the consequences of medical negligence, this does not require proof from the plaintiff, and the defendant must prove that their actions do not fall into the category of negligence or error.

In conclusion, it is evident from the above explanations that doctors enjoy several protections within their profession. However, the most significant protection is provided by informed consent. Doctors can present informed consent as evidence of an agreement between them and the patient before conducting medical procedures. Informed consent serves as a regulation to be adhered to by both parties. If a doctor is proven to be negligent or deviates from what was agreed upon in the informed consent, they may be deemed negligent in the practice of their profession. However, if a doctor performs actions in line with the agreed-upon terms in informed consent, the doctor cannot be presumed guilty and may not be held responsible for their medical treatment. Thus, informed consent offers legal protection to doctors in the event of legal claims from patients or their families.

2. Legal Efforts That Can Be Taken by Doctors in Case of Errors in Medical Actions(Wiratama et al., 2023).

The Supreme Court, through its Circular Letter (SEMA) in 1982, has provided guidance to judges that the handling of cases involving doctors or other healthcare professionals suspected of negligence or errors in medical actions or services should not immediately go through the legal process but should first seek the opinion of the Indonesian Medical Ethics Honor Council (MKDKI). Currently, MKDKI's function is replaced by the Indonesian Medical Disciplinary Honor Council (MKDKI), an independent institution under the Indonesian Medical Council (KKI).

Law Number 17 of 2023 concerning Health, Article 310 states that "In the event that Medical Personnel or Healthcare Personnel are suspected of making mistakes in carrying out their profession resulting in harm to the Patient, disputes arising from these mistakes must be resolved first through alternative dispute resolution outside the court."

From this law, it is evident that the resolution of disputes arising from conflicts in the medical field is prioritized to be resolved through non-litigation or alternative dispute resolution outside the court. The resolution of non-litigation medical negligence disputes is a new breakthrough in the resolution of medical disputes in Indonesia, resolved through mediation and the Indonesian Medical Disciplinary Honor Council (MKDKI). MKDKI is a state institution authorized to determine whether there has been an error committed by a doctor or dentist in the application of medical or dental discipline and to impose sanctions on doctors or dentists found guilty.

The procedures for handling cases by MKDKI have been regulated in the Indonesian Medical Council Regulation Number 2 of 2011 concerning Procedures for Handling Cases of Alleged Violations of Doctor and Dentist Disciplinary Ethics. The handling of alleged violation cases is carried out after receiving a complaint. The requirements for complaints are outlined in Article 3 of Perkonsil Number 2 of 2011. After the complaint is registered with MKDKI/MKDKI-P, the complainant can provide supporting data, such as evidence owned and a statement about the truth of the complaint. Subsequently, clarification will be carried out by a special officer from MKDKI/MKDKI-P. The process then moves to the Preliminary Examination stage.

The preliminary examination stage is discussed in Articles 13-18 of Regulation Number 2 of 2011. In this stage, MKDKI examines whether the complaint is accepted, not accepted, or rejected. If the complaint is accepted, the Chairman of MKDKI forms the Disiplinary Examination Council (MPD). Members of MPD come from MKDKI. MPD can decide that the complaint is not acceptable, rejected, or the examination is terminated. The Disiplinary Examination Council then conducts an investigation to gather information and evidence related to the reported incident. After the investigation, a disciplinary examination session is conducted.

If the disciplinary examination session for a doctor or dentist is completed, the MPD will decide on the accused doctor. The decision can be: 1) Declared not to have violated the doctor's or dentist's discipline. 2) Imposition of disciplinary sanctions, such as: a. Written warning, b. Obligation to attend education or training. 3) Recommendations for revocation of STR or SIP, which can be: Temporary for a maximum of 1 (one) year, Permanent or forever, Restriction of specific medical care actions in a certain field of medical or dental science in the practice of medicine.

If proven to have violated discipline, the accused doctor or dentist can file an objection to the MKDKI decision with the Chairman of MKDKI within 30 days since the decision was read or received, providing new evidence supporting the objection.

Alternative dispute resolution in medical cases, as mandated by the latest Health Law, Law Number 17 of 2023, seeks to overcome the increasing backlog of litigation cases and provide

justice for both parties, doctors, and patients. However, this alternative dispute resolution still has some shortcomings, such as doctors being liable for litigation, and the compensation process between doctors or hospitals and patients is not regulated by Indonesian law.

CONCLUSION

The role of Informed Consent in legal protection for doctors during medical procedures is evident as a documented agreement between the doctor and the patient before any medical intervention. Informed Consent serves as a binding regulation between the two parties, establishing a commitment within an agreement. This measure is essential for obtaining legal protection while performing duties in accordance with professional standards and operational procedures. Thus, the presence of Informed Consent plays a crucial role in safeguarding doctors during medical procedures in the event of unforeseen circumstances.

Legal recourse available to doctors in case of errors during medical procedures involves the pursuit of alternative dispute resolution. This aligns with the mandate of Law Number 17 of 2023 concerning Health, as stated in Article 310. In situations where medical or healthcare professionals are suspected of making errors in their professional duties resulting in harm to patients, disputes arising from such errors are initially resolved through alternative dispute resolution outside the courtroom.

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