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The Role of Informed Consent in Medical Disputes at State University Hospitals

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ABSTRACT

The research aims to understand how informed consent functions in the context of medical disputes at state university hospitals in Indonesia. The main benefit of the study is to provide an overview of how informed consent offers legal protection to the medical profession, particularly in resolving disputes that may arise in the hospital setting. The research utilizes a normative legal research method, focusing on the examination of written laws, regulations, and legal materials applicable in Indonesia. The research concludes that the thoroughness of informed consent documentation is crucial, especially for medical procedures that carry high risks. This thoroughness serves as a legal safeguard for medical professionals, ensuring their protection in case of disputes. Enhanced attention to the completeness of informed consent is necessary to mitigate the risks for doctors and provide legal security within the medical field at state university hospitals.

Keywords: Legal Protection, Informed Consent, Medical Actions, State University Hospital

INTRODUCTION

A hospital is one of the public facilities used by the Indonesian community in the field of health. Hospitals provide several types of services, including medical services, supporting medical services, nursing services, rehabilitation services, prevention and health promotion, as places for medical education and training, as places for research and development in the field of health science and technology, and to avoid health risks and disturbances as intended, thus requiring the management of the hospital environment's health according to health requirements. A hospital is a health service institution that provides comprehensive individual health services, including inpatient, outpatient, and emergency care.[1] Service is any effort organized individually or collectively within an organization to maintain and improve health, prevent and cure diseases, and restore the health of individuals, families, groups, or communities.[2]

The State University Hospital is one of the hospitals in Indonesia owned by a university and is under the Ministry of Research, Technology, and Higher Education, which carries out the Tri Dharma of Higher Education. For that reason, the State University Hospital strongly supports

[1]Ella Mayasari, Nihayatul Munaa, Lailatul Kodriyah, Ida Herawati, Ronal Surya Aditya, (2020)."Keputusan Masyarakat Dalam Pemilihan Rumah Sakit Untuk Pelayanan Kesehatan Di Wilayah Malang Raya", *JKEP*, Vol.5, No.2. p. 115

[2]*Ibid.* p. 166 – 117.

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the implementation of research, education, and community service. As part of its realization, it is necessary to continuously enhance research and innovation in the field of health to improve sustainable healthcare services to the community.

State University Hospitals play an important role in improving the degree of public health in Indonesia, so the quality of service provided to patients must continuously be improved. The high demand for healthcare in the community will certainly impact the quality of services provided, thus an indicator is needed as a reference to maintain service quality. This is important considering that healthcare services involve patients as recipients of services who are very vulnerable to dissatisfaction if they do not receive optimal service according to the applicable procedures and have the potential to cause medical disputes in hospitals.

One of the efforts to enhance the quality of healthcare services in hospitals is by implementing stricter regulation of medical record management. Medical records, as defined by Minister of Health Regulation No. 24 of 2022, serve as critical documents containing comprehensive information about the patient's identity, diagnosis, treatments, procedures, and other healthcare services provided. These records are vital for ensuring administrative order and continuity of care.[3] Every doctor is required to fill out medical records as written evidence of all the services provided to patients, thereby creating administrative order. One of the inseparable parts of medical records is informed consent, which embodies the therapeutic transaction in hospital healthcare services and serves as the legal aspect of the medical actions taken, as well as legal protection in case of future medical disputes. Medical disputes are prone to occur considering that medical actions carry various risks, both high and low, which can threaten a person's life or cause material and immaterial losses.

Komalawati defines informed consent as "An agreement or consent from the patient regarding the medical efforts that will be undertaken by the doctor after the patient receives information from the doctor about the medical efforts, accompanied by information about all possible risks."[4] In Article 45 paragraph 1 of Law Number 29 of 2004 concerning Medical Practice, it is stated that every medical or dental action to be performed by a doctor or dentist on a patient must obtain consent, which is further regulated in Article 274 of Law Number 17 of 2023 concerning Health, which explains that medical and health personnel in their practice must obtain consent from the patient or their family. Article 276 states that patients have the right to obtain information about their health, receive adequate explanations about the health services they receive, and refuse or consent to medical actions, except for medical actions necessary for the prevention of infectious diseases and the control of outbreaks or epidemics.[5] This is also stated in Article 3 paragraph 1 of the Regulation of the Minister of Health of the Republic of Indonesia Number 290 of 2008 concerning Medical Action Approval, which explains that every medical action that involves high risk must obtain written approval signed by the authorized person.[6] The consent is given after the patient receives a complete explanation that at least includes: diagnosis and medical procedure, the purpose of the medical procedure, alternative actions along with their risks, possible risks and complications, as well as the prognosis of the action taken.

The government has established various regulations to govern the implementation of informed consent; however, in reality, issues of incomplete informed consent documentation are still frequently encountered in hospitals, including state university hospitals. In fact, informed consent can be used as one of the basic aspects of proof when a medical dispute arises involving

[3]Menteri Kesehatan RI, (2022). *Peraturan Menteri Kesehatan Republik Indonesia nomor 24 tahun 2022 tentang Rekam Medis*. Jakarta.
[4]Anny Isfandyarie, (2006). *Tanggung Jawab Hukum dan Sanksi bagi Dokter Buku I.* Jakarta: Prestasi Pustaka,p.127.
[5]Undang-Undang Nomor 17 Tahun 2023 tentang Kesehatan.
[6]Peraturan Menteri Kesehatan Republik Indonesia Nomor 290 Tahun 2008 tentang Persetujuan Tindakan Kedokteran.

a doctor as the service provider and the patient. If it is found that the patient's informed consent is not fully documented, there is a possibility that the doctor did not provide clear information and/or did not obtain consent from the patient or the patient's family regarding the medical actions taken, which could potentially lead to legal issues.

Medical actions that carry high risks certainly have the potential to result in the loss of someone's life if there is a breach of duty or malpractice, leading to a medical dispute that will have implications for the doctor and the hospital where they work if there are claims from parties who feel aggrieved by the medical actions. As stated in Article 359 of the Criminal Code, it is explained that anyone who, due to their negligence, causes another person to die, shall be punished with imprisonment for a maximum of five years or detention for a maximum of one year. Article 360 paragraph 1 explains that anyone who, due to their negligence, causes another person to suffer serious injuries, shall be punished with imprisonment for a maximum of five years or detention for a maximum of one year. Article 360 paragraph 2 explains that anyone who, due to their negligence, causes another person to suffer injuries that result in illness or hinder their ability to perform their job or work for a certain period, shall be punished with imprisonment for a maximum of nine months or detention for a maximum of six months or a fine of up to four thousand five hundred rupiah.[7]

Based on the description of the problem above, it is deemed necessary to conduct research on the role of informed consent in medical disputes at State University Hospitals. This is done to examine the legal aspects of informed consent as a form of legal protection for the medical profession and to explore the legal sanctions that can be imposed if disputes arise due to the incompleteness of informed consent documentation at State University Hospitals.

METHOD

The research method employed in this study is the normative (doctrinal) legal research method. This approach views law as a set of positive rules that apply universally (*law in abstracto*) within a specific jurisdiction and timeframe. These rules are established and promulgated by a recognized source of legitimate political authority, commonly referred to as national law or state law.

Data collection in this study involved an in-depth examination of the application of legal principles and norms embedded in various written regulations and legal materials applicable within the jurisdiction of Indonesia. The focus was on interpreting and analysing the relevant statutory provisions, case law, and other authoritative legal sources to understand the legal framework and its practical implications.

ANALYSIS AND DISCUSSION

The Role of Informed Consent

Informed consent is one of the important aspects in medical records. Based on Article 1 paragraph 1 of the Minister of Health Regulation No. 290/MENKES/PER/III/2008 concerning Medical Action Consent, it is explained that informed consent is the approval given by the patient or close family members after receiving a complete explanation regarding the medical or dental actions to be performed on the patient. Literally, informed consent comes from two words, namely informed and consent. Informed means having received an explanation or information, and consent means approval, so informed consent can be interpreted as the

[7]Indonesia Criminal Code (KUHP)

approval given by the patient or family to the doctor to perform a medical action after the patient or family receives complete information regarding the condition and medical actions to be performed on the patient.

Consent must be obtained from the patient or family, either in writing or verbally, considering that all medical actions carry both high and low risks. In general, forms of consent can be distinguished as follows: a. Explicit consent, which consists of verbal and written consent; b. Implicit or tacit consent, which consists of normal and emergency consent.[8]

Verbal consent is used when a medical procedure is considered low-risk or has predictable outcomes. It can be conveyed through Verbal agreement, Non-verbal cues such as nodding, blinking, hand gestures, maintaining eye contact or even silence, provided the patient fully understands the procedure and its implications. The key requirement is that the patient must be adequately informed and aware of the situation. On the contrary, Written consent is necessary for procedures that involve high risks or have uncertain outcomes. It is obtained after the patient or their legal representative receives a thorough explanation from the healthcare provider. This consent is documented on a formal, pre-prepared consent form, ensuring that: The patient understands the procedure, its risks, and potential outcomes, The agreement is clearly recorded for legal and medical purposes. However, there are circumstances where medical actions can be taken without the patient's explicit consent. This typically occurs when the patient is unconscious or incapacitated and no family members or legal representatives are present to provide consent. In such cases, if immediate medical intervention is necessary to address a life-threatening condition or prevent serious harm, healthcare providers are legally and ethically authorized to proceed with treatment under the principle of implied consent. This exception, however, must still comply with applicable regulations considering that the informed consent form is one of the important aspects of the patient's medical record and has legal implications.[9]

In state university hospitals, the implementation of informed consent becomes very important, considering that the position of state university hospitals is as educational hospitals that not only provide health services but also serve as educational facilities for students. In Article 4, paragraph 1 of the Government Regulation of the Republic of Indonesia Number 93 of 2015 concerning Educational Hospitals, it is explained that in carrying out the service functions in the fields of medicine, dentistry, and other health as referred to in Article 3, Educational Hospitals are tasked with providing integrated health services by prioritizing good clinical governance, the development of medical, dental, and other health sciences and technologies based on evidence, while considering professional ethics and health law aspects; and in Article 2, it is explained that services in the fields of medicine, dentistry, and other health as referred to in Article 1 are carried out according to the medical needs of patients/clients, service standards, and prioritizing patient/client safety.[10]

Based on that article, state university hospitals have the obligation to implement good clinical governance by considering professional ethics and health law in every healthcare service activity so that patients feel safe when receiving treatment at the hospital. The implementation of informed consent in accordance with regulations can be one of the indicators for hospitals in achieving good clinical governance, as patients have the right to obtain information about their health, receive adequate explanations about the healthcare services they receive, and refuse or consent to medical actions, except for medical actions necessary for the prevention of infectious diseases and the control of outbreaks or epidemics as stated in Article 276 of the Republic of Indonesia Law Number 17 of 2023 concerning Health.

[8]Guwandi,(2008), *Informed Consent Cetakan Ulang*, Jakarta: Balai Penerbit FKUI, p. 20.
[9]Desriza Ratman, *Aspek Hukum Informed Consent dan Rekam Medis Dalam Transaksi Terapeutik Cetakan Ke-2.* (Bandung: CV. Keni Media, 2018), p.48-49.
[10]Peraturan Pemerintah Republik Indonesia Nomor 93 Tahun 2015 tentang Rumah Sakit Pendidikan..

The information in informed consent at a minimum includes the diagnosis and medical procedure, the purpose of the medical procedure being performed, alternative actions along with their risks, potential risks and complications, the prognosis of the procedure, and the estimated costs arising from the medical procedure, which must be communicated to the patient or the patient's family before the medical procedure is performed. However, in practice, there are still instances of incomplete informed consent documentation by doctors, which could potentially lead to problems in the future.

Informed Consent for Legal Protection of the Medical Profession

In the therapeutic agreement between a doctor and a patient when providing healthcare services in a hospital, informed consent serves as a legal aspect of the medical actions taken and provides legal protection in the event of a medical dispute arising from the medical actions performed. Medical disputes are prone to occur considering that medical actions carry various risks, both high and low, which can threaten a person's life or cause material and immaterial losses to the patient. The incomplete writing of informed consent still often occurs in hospitals, potentially leading to problems in the future if there is a legal claim against a doctor deemed incompetent in providing healthcare services to patients, especially if the medical action taken results in the loss of someone's life.

The lawsuit is a medical risk that often looms over doctors working in hospitals, even though it arises not because the service process did not meet standards and procedures, but rather because the patient's condition was already unsalvageable. However, patients or their families often consider that the medical actions taken do not meet the standards and procedures, indicating a breach of contract or even malpractice because the patient's condition worsened after the medical intervention, even leading to disability and death. This can certainly be exacerbated if the patient or the patient's family previously claimed that they did not receive information and did not consent to the medical procedure, as evidenced by incomplete informed consent documentation, making it difficult for the doctor to defend themselves in the medical dispute.

Prosecutions against doctors related to their medical actions often arise from perceived losses experienced by one of the parties involved in the therapeutic relationship, typically the patient. The consent to medical actions from a criminal law perspective must adhere to the principle of legality. The principle of legality is the principle that determines that every criminal act (offense) must first be regulated by a legal rule before the person performs a medical action. The application of the principle of legality provides legal protection for patients and doctors in the execution of medical actions. Anselm von Feuerbach, a German criminal law expert, stated the principle of legality in Latin, namely: *"Nulla poena sine lege":* no punishment without a legal provision, '*Nulla poena sine crimine'*: no punishment without a criminal act. *"Nullum crimen sine poena legali":* no criminal act without a punishment according to the law. This formulation is summarized in one sentence, namely *"nullum delictum, nulla poena sine praevia lege poenali,"* which means there is no crime, there is no punishment, without prior legal provision. The principle of legality is upheld to strengthen legal certainty. Informed consent as a legal aspect of medical procedures can have criminal implications in cases of malpractice.[11]

Informed consent is a crucial part of the medical practice, ensuring that patients are fully aware of the risks, benefits, and alternatives of a medical procedure. If a doctor fails to properly inform a patient, especially when the procedure involves significant risks, the doctor may be

[11]I Gede Made Wirabrata, I Made Wirya Darma. (2018). "*Tinjauan Yuridis Informed Consent Dalam Perlindungan Hukum Bagi Pasien Dan Dokter*". Jurnal Analisis Hukum Volume 1 No. 2 (2018): 2620-3715

held legally responsible if complications or harm arise. If a patient suffers severe injury or death due to a lack of informed consent, it may form the basis for a legal dispute, where the doctor's negligence could be a central issue. The criminal responsibility of the negligence of a doctor regulated in numerous articles of Indonesia Criminal Code. Article 359 addresses cases where a person's negligence causes another person to die. If a doctor is negligent in obtaining informed consent or carrying out a procedure and this leads to a patient's death, the doctor could face up to five years of imprisonment or a shorter detention term, depending on the circumstances. Article 360, Paragraph 1 applies when negligence causes serious injury to another person. In the medical context, if a doctor's negligence leads to significant harm (e.g., permanent disability or other serious consequences), the doctor may face up to five years of imprisonment or a detention term. Article 360, Paragraph 2 relates to cases where negligence causes harm that results in illness or limits the patient's ability to carry out their usual work or activities for a period of time. This could be relevant if a medical procedure or action leads to moderate injury, leading to a fine or detention.

Furthermore, if there is an error in the medical service provided to the patient that causes harm or loss, the patient is entitled to claim compensation based on an unlawful act under Article 1365 of the Indonesian Civil Code (Kitab Undang-Undang Hukum Perdata, or KUHPerdata). This article establishes that any unlawful act causing loss to another person obligates the person who caused the loss to compensate for it. In cases of medical malpractice, the actions of the doctor or medical institution can be classified as an unlawful act if they deviate from the standard of care or violate professional medical norms, resulting in harm to the patient.

The liability in such cases can either be based on a contractual default, as explained in Articles 1236 and 1239 of the Civil Code, or an unlawful act (tort). While the default liability requires an existing agreement between the doctor and the patient, the liability based on an unlawful act can arise even without a direct contract, as long as the act itself causes harm. In terms of remedies, the patient may seek compensation for the actual losses (e.g., medical costs, loss of income), as well as for damages resulting from the malpractice. In cases of unlawful acts, the compensation is intended to restore the patient to the position they would have been in had the malpractice not occurred. Moreover, the law also allows for claims of interest on the amount owed as compensation from the moment the loss occurred. It is important to note that the lawsuit based on default can only be directed against the parties involved in the agreement. Thus, if the patient entered into a treatment agreement with a medical institution, that institution may be held liable. In contrast, if the loss was caused by an act of negligence or fault by an individual doctor, that doctor may be held personally accountable. However, the damages awarded in such cases must be proportional to the actual losses suffered by the patient, as stated in the applicable civil provisions.

However, principles are foundational in understanding how health law handles cases involving negligence and medical malpractice. In health law, negligence is a critical issue that pertains to the failure to exercise the standard of care expected in a particular situation, leading to harm or injury. There are two legal doctrines—*de minimis non curat lex* and *res ipsa loquitur*—that are important concepts in determining when and how negligence applies, especially in healthcare settings. *De Minimis Non Curat Lex*: This principle, meaning "the law does not concern itself with trifles,"[12] is indeed applied in health law, particularly when the negligence is so minor that it does not result in any harm to the patient. For example, if a healthcare provider makes an insignificant error that doesn't cause any harm to the patient, the law may not consider it as actionable. However, it's important to note that while trivial

[12]Max L. Veech & Charles R. Moon, (1947), DE MINIMIS NON CURAT LEX, 45, *MICH. L. REV*. 537. Available at: https://repository.law.umich.edu/mlr/vol45/iss5/2, p. 358.

matters may not attract legal attention, the standard of "triviality" must be defined based on the specifics of each case. The principle doesn't excuse negligence if harm occurs, even if the act itself seems minor. *Res Ipsa Loquitur* means "the thing speaks for itself." In the context of malpractice cases, it refers to situations where the evidence of negligence is so obvious that it doesn't require additional proof. In other words, the mere occurrence of the event is enough to raise the presumption of negligence. Under this principle, the burden of proof may shift to the defendant (the healthcare provider) to explain the incident, rather than requiring the plaintiff (the patient) to prove negligence.[13]

CONCLUSION

The basis of all medical actions in this hospital is the therapeutic agreement between the doctor and the patient, which serves as the foundation of medical practice and ensures a legally valid relationship between both parties. The implementation of informed consent is not merely a procedural formality, but rather a crucial legal instrument that protects patients and healthcare professionals. Hospitals have an obligation to ensure that informed consent is meticulously fulfilled, and the consequences of failure in this regard are very serious, reflecting the importance of maintaining high standards of care and professionalism in the medical field. The thoroughness of informed consent documentation is crucial, especially for medical procedures that carry high risks. This thoroughness serves as a legal safeguard for medical professionals, ensuring their protection in case of disputes. Enhanced attention to the completeness of informed consent is necessary to mitigate the risks for doctors and provide legal security within the medical field at state university hospitals.

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Regulations

Kitab Undang- Undang Hukum Perdata *(*Indonesian Civil Code*)*

Kitab Undang-undang Hukum Pidana (Indonesian Criminal Code)

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