

The Role of Informed Consent as Patient Protection in Medical Procedures at Kotapinang Regional General Hospital (A Research Study at Kotapinang Regional Public Hospital)

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ABSTRACT

Informed Consent, an essential aspect denoting consent based on comprehensive information, stands as a pivotal right for patients and embodies a distinct rapport between physicians and patients. This relationship serves as a safeguard, as mandated by Law Number 36 of 2009 concerning Health. The research methodology employed is normative legal research, which fundamentally scrutinizes laws construed as societal norms or guidelines influencing individual conduct. The study reveals several critical points: firstly, the alignment of informed consent execution in emergency care with Minister of Health Regulation No. 290 of 2008. Secondly, instances where medical professionals' oversight in obtaining informed consent entails the hospital's liability. Thirdly, the utilization of mediation in resolving medical disputes at Kotapinang Regional Public Hospital. Lastly, there remains a deficiency in adequately disseminating regulations concerning complaints, summons, and medical disputes within the Kotapinang Regional Public Hospital setting.

Keywords: Informed Consent, Patient Protection, Medical Procedures, Kotapinang Regional General Hospital.

INTRODUCTION

Every medical procedure carrying high risks necessitates consent from the patient or their family. This consent, commonly referred to in the medical field as 'Informed Consent,' is

vital. The Republic of Indonesia Law Number 29 of 2004 concerning Medical Practices delineates medical practice as a series of activities performed by physicians in their efforts to provide healthcare to patients. This law was established to regulate medical practice with the aim of safeguarding patients, upholding and improving medical service quality, and ensuring legal certainty for the public.

Beni Satria and Redyanto Sidi Jambak (Beni Satria, Redyanto Sidi Jambak, 2022. 2-3) cited the opinion of Micheal Daniel Mangkey:

“The medical profession, in its pursuit of healthcare, does not encompass solely measurable sciences. Doctors do not guarantee a cure to patients because health exhibits highly individualistic characteristics influenced by numerous factors, including one's immune system, age, gender, and medical risks that are not always predictable. Consequently, when the same illness affects two or more patients and is treated with identical medication and methods, the treatment outcomes may not always be the same.”

The relationship between doctors and patients, doctors and hospitals, and patients and hospitals, viewed from a legal perspective, involves a mutual agreement to bind themselves in carrying out medical treatment, known as a contract. This is

outlined in Article 1313 of the Civil Code, where an agreement is an act in which one or more persons commit themselves to one or more others. Furthermore, Article 1233 of the Civil Code states that contracts arise from agreements or by law. It was Novekawati (Novekawati, 2019. 34) who quoted Salim HS's opinion that: *“An obligation is a legal principle that governs the legal relationship between legal subjects, where one legal subject is entitled to a performance while the other is obligated to fulfill that performance within a specific field.”*

Minister of Health Regulation Number 585/Menkes/Per/IX/1989 officially used the term 'Informed Consent for Medical Procedures.' However, with the issuance of Minister of Health Regulation Number 290/Menkes/Per/III/2008, the term “Informed Consent for Medical Procedures' was replaced with the term 'Informed Consent for Medical Acts.’”

Specifically, there is no law that explicitly explains informed consent. Nonetheless, there are regulations from the Ministry of Health that reinforce how the implementation and administration of informed consent should occur. This is articulated in Minister of Health Regulation No. 290 of 2008 regarding Informed Consent for Medical Acts.

In general, Informed Consent (formerly referred to as Informed Consent for Medical Procedures) occurs based on a patient's right to information about their illness, available treatment alternatives, and the right to consent to actions taken concerning their health. Therefore, Informed Consent represents a patient's right to consent after receiving comprehensive information.

Patients or their families have the right to give consent or refuse medical procedures after receiving clear information from the doctor. This serves as a form of protection for both parties, as stated in Article 56 (1) of Law Number 36 of 2009 regarding Health, which asserts that 'Every person has the right to accept or refuse in whole or in part the assistance that will be given to them after

receiving and understanding complete information about such actions.'

Kotapinang Regional Public Hospital (RSUD Kotapinang) is a government hospital in the South Labuhanbatu District of North Sumatra Province, slated to be the primary healthcare center in the region. RSUD Kotapinang continuously improves its standards in providing facilities, management, and other support services, including enhancing employee understanding of hospital standards and quality. Consequently, the influx of patients is expected to significantly increase, posing a challenge to the hospital's sustainability for changes and improvements to remain competitive. Hence, a legal agreement for medical service procedures (Informed Consent) between medical personnel and patients is essential.

A male patient named Sahrudin, 21 years old, arrived at RSUD Kotapinang at 12:45 PM. He presented with complaints of a torn wound at the back right side of his head and the front of his face above the right eye. The tear measured 3 cm at the back of the head and continuously bled.

Upon observing the bleeding, the emergency room doctors and nurses at RSUD Kotapinang administered anesthesia to the wound, and the patient already had an intravenous drip from an external clinic. The anesthesia procedure was carried out as per protocol, and once successfully administered, resulting in reduced pain, the ER doctor and nurse proceeded to clean the wound from the outer to the inner layers.

During the deeper cleaning of the wound, active bleeding occurred, leading the ER doctor to discontinue the cleaning. Subsequently, the ER doctor summoned the patient's family members and explained that the wound was temporarily sutured due to uncontrollable bleeding. Additionally, it was detailed to the family that the stitches were temporary, and a more intensive cleaning would be done in the operating room or in better-equipped facilities like the CT-Scan available at Rantau Parapat.

To further clarify the patient's wound condition, the ER doctor recommended a referral to RSUD Rantau Parapat, and this information was relayed to a specialist surgeon beforehand. However, the offered referral was not accepted by the patient's family, and the patient opted to depart on another ambulance without an RSUD Kotapinang nurse accompanying them and without a referral letter.

Several days later, around June 23, 2022, an update appeared on social media (Facebook) by Gustiana Harahap, who claimed to be Sahrudin's 21-year-old brother, stating that Sahrudin had been treated in the Emergency Room at RSUD Kotapinang on March 18, 2022, at 12:45 PM. The wound treatment was only situational, and he was not willing to be referred.

Based on the narrative on social media by Gustiana Harahap, comments surfaced criticizing the ER doctors and nurses at RSUD Kotapinang for their subpar performance, albeit without further explanation. Following this social media post, RSUD quickly reassembled the team who handled the patient, gathering medical records as supporting documentation for their treatment. Unexpectedly, during the medical record examination, it was discovered that the Informed Consent was not filled out (left blank), adding another layer of complexity to the patient's case.

In the end, on June 27, 2022, a mediation process took place between both parties: the first party, Sahrudin Harahap, and the second party, RSUD Kotapinang's Dr. Ahmad Ridwan Ritonga, resulting in a mutual settlement agreement. In this agreement, the first party agreed not to pursue the case further legally and to delete the status on Facebook. Meanwhile, the second party pledged to provide intensive care to the first party by performing a minor surgery on his head in the operating room, handled by a specialist at RSUD Kotapinang. This agreement was signed on a stamp paper and witnessed by four individuals.

Several studies related to the above phenomenon include Wibowo's (2021)

research on Alternative Dispute Resolution in Medical Cases at Private Hospitals (Case Study: Hospital X in Jakarta). The analysis concluded that although mediation mechanisms were utilized, the actual mediation process was incomplete due to factors or obstacles hindering its progress, thus impeding mediation.

Ummah's (2019) study on Mediation in Medical Dispute Resolution Between Doctors and Patients revealed that while litigated mediation failed, it served as a deterrent to doctors and hospitals to prevent recurring disputes. Additionally, the doctor's practice license was revoked, preventing their return to practice, influencing societal judgment and resulting in a negative image of the doctor, reflecting their mistake causing harm to another person's life.

MATERIALS & METHODS

The type of research here is descriptive, involving an approach focused on natural phenomena or occurrences. Qualitative research is fundamental, naturalistic, and cannot be conducted in a laboratory but rather in the field, studying societal issues, norms, specific situations, including relationships, activities, attitudes, perspectives, ongoing processes, and influences of a particular phenomenon. (Zuchri Abdussamad, 2021. 30). This research type is classified as normative legal research. Normative legal research examines and analyzes literature or secondary data. This type of legal research is also known as library-based legal research or theoretical/dogmatic legal research. Hence, the materials studied in normative legal research are literature or secondary data, sourced from primary and secondary sources. (Ishaq, 2017. 66-67).

RESULT AND DISCUSSION

Alternative Dispute Resolution for Medical Disputes at Regional Public Hospital Kotapinang

Dispute resolution processes can be pursued through two avenues: litigation (the court system) and non-litigation/consensual/non-

adjudicative methods. Non-litigation dispute resolutions encompass various types and methods, one of which is mediation. Seeking dispute resolution through mediation aims to achieve reconciliation, allowing parties the opportunity to propose suggestions based on their interests. (Muhammad Afiful Jauhani, 2020).

From the research findings, it's evident that the Regional Public Hospital Kotapinang has diligently endeavored to prevent legal issues or court proceedings for medical professionals, including doctors, nursing staff, and the management. They've swiftly addressed complaints by coordinating with the Public Relations department and involving all relevant departments/units, facilitated by a Mediator internal to the hospital. This approach has expedited the resolution of complaints. However, the researcher needs to re-examine how the concept of implementing mediation aligns with the legal regulations, specifically by scrutinizing Health Mediators from various aspects:

1. As stipulated in Article 23 paragraph (1) of the Supreme Court Regulation Number 1 of 2016 concerning Mediation Procedures in Court: "With the assistance of a certified mediator, parties who successfully settle disputes outside of court through a peace agreement may file the peace agreement with the competent court to obtain a peace deed by filing a lawsuit." This provision allows the possibility of reaching an agreement outside of court. Meanwhile, the rules regarding Mediators are stated in Article 13 paragraph (1) of the Supreme Court Regulation Number 1 of 2016 concerning Mediation Procedures in Court: "Every Mediator must have a Mediator Certificate obtained after completing and passing the Mediator certificate training organized by the Supreme Court or an institution accredited by the Supreme Court." Mediators are neutral third parties, and based on the content from the

Indonesian Mediation Association Training, crucial aspects during the Mediation process within the scope of hospitals with Health Mediators include: Introduction, Statement of Parties, Schedule, Caucus, Parley, Agreement/Settlement. (Zahra, H. M., & Marpaung, D. S. H. (2022). 9(2), 889-897)

2. Article 1 paragraph (10) of Law Number 30 of 1999 concerning Arbitration and Alternative Dispute Resolution states that "Alternative Dispute Resolution is a dispute resolution or disagreement settlement institution through procedures agreed upon by the parties, namely settlement outside the court by means of consultation, negotiation, mediation, conciliation, or expert assessment."
3. In Article 29 of Law Number 36 of 2009 concerning Health, it is stipulated that "In the event health workers are suspected of negligence in carrying out their profession, such negligence must first be settled through Mediation." From the aforementioned regulation, the researcher observes medical disputes, which involve healthcare services provided by Doctors, Nurses, and other Healthcare Professionals to Patients, their Families, or the Community regarding healthcare services.

In this relationship, it is based on an agreement termed as the Therapeutic Agreement between the Doctor and the Patient, which establishes a legal relationship with rights and responsibilities for both parties. This agreement aims to determine the most suitable therapy for the patient by the doctor. Here, the object of the agreement is not a promise or a guarantee of the patient's recovery but an effort to find the appropriate treatment for the patient's recovery. The Therapeutic Agreement is governed by the Indonesian Civil Code. Concerning healthcare examinations, within the Therapeutic Agreement, Article 1320 of the Indonesian Civil Code stipulates:

1. The existence of an agreement binding the involved parties
2. The capacity to enter into an agreement
3. Relating to a specific subject matter
4. permissible cause

From the regulations outlined in letters a to e, the Researcher found that although there isn't a specific regulation governing the alternative resolution of medical disputes in terms of explicitly mandating that medical disputes are resolved through Non-Litigation Mediation outside of the Court, the Researcher discovered that medical disputes could potentially arise due to the relationships among Doctors, Nursing, and other Healthcare Professionals bound by the Therapeutic Agreement, which falls under Civil Law. Consequently, these disputes can be resolved through alternative dispute resolution, guided by the aforementioned regulations.

The Position of Informed Consent in Legal Aspects

Informed Consent is the most crucial part of a doctor's medical practice, as the absence of consent is recognized as a legal violation, not only in civil law but also in criminal law, categorized as medical malpractice.

1. Position of Informed Consent in Criminal Aspects

Muntaha (Muntaha, H. (2022) in his book "Criminal Law Malpractice" cites Roeslan Saleh stating that according to criminal law, a person can be held accountable for criminal acts if they meet the following criteria: 1) Committing a criminal act; 2) Being accountable or responsible; 3) Acting intentionally or negligently; and 4) Absence of justifiable reasons.

Facing criminal charges from patients and their families who feel aggrieved by a doctor's actions, a practicing physician usually faces two concurrent responsibilities, namely professional responsibility. Teguh Sulistia and Aria Zurnetti also express their opinions on this responsibility.

"Professional responsibility is based on errors in carrying out professional duties

according to medical professional regulations, namely the ethical code arising from obligations in carrying out the medical profession. As for legal responsibility, it is based on applicable regulations."

Determining the basis for claims and proving the existence of errors and negligence in a doctor's malpractice in carrying out their professional duties as a healthcare professional seems to be still very difficult. This is mainly due to the lack of measures, standards, and parameters, even though medical records have been suggested.

For example, malpractice cases that occur, especially in Indonesia, are still often debated as to whether malpractice is an issue of medical ethics with the doctor's obligation to provide assistance for someone's suffering, or whether there is a juridical factor in the form of legal violations causing someone to become physically and mentally disabled or experiencing death, and exacerbating the patient's condition. The lack of clarity in these measures will further complicate the proof of a medical action performed by a doctor, whether it has indications of deviation or legal violations, and therefore legal claims based on malpractice can be made.

2. The Position of Informed Consent in Civil Law

In relation to contract law, in Article 1320 of the Civil Code, it is essential to have an agreement between both parties, namely the doctor and the patient. This implies that there must be sufficient information from both parties. Juridically, informed consent does not fulfill Article 1320 of the Civil Code in conjunction with Article 1338 of the Civil Code.

Informed consent has violated the provisions found in Article 1320 of the Civil Code, which embodies the principle of freedom of contract. Article 1338 of the Civil Code establishes that "Every agreement/contract made lawfully is binding upon those who make it, like law."

The agreement reached within informed consent is an imperfect agreement and

contradicts the principle of consensualism. The implied consensualism principle in Article 1320 of the Civil Code means that a contract is already in place and thereby binds the parties within the contract since there is a mutual agreement on the essential elements of the contract. In other words, a contract is valid once there is an agreement on its essential elements, and no specific formalities are required. This principle is observed concerning the formation of agreements.

Furthermore, Article 1321 of the Civil Code stipulates that: "There is no valid agreement if that agreement is given under a mistake, or obtained by force or fraud." In other words, if there is an element of coercion in the contract, among other things, then the agreement specified in Article 1320 of the Civil Code is considered void.

If an agreement does not occur, the contract is deemed to lack the requirements for validity as stipulated in Article 1320 of the Civil Code. Article 1321 of the Civil Code involves an imperfect or defective agreement due to coercion. As informed consent does not meet the five freedoms inherent in the principle of freedom of contract, according to the requirements of being binding as law, it cannot be declared binding for the parties involved.

Informed consent involves an element of undue influence by the contracting parties. This condition aligns with the condition of coercion as informed consent does not meet the requirements of mutual consent required for a valid contract under Article 1320 of the Civil Code. In other words, based on Article 1320 in conjunction with Articles 1321, 1323, and 1338 of the Civil Code, informed consent does not comply with the principles of consensualism, freedom of contract, and binding as law.

3. The Position of Informed Consent in Administrative Aspects

Recognizing that not all patients can comprehend information from doctors, alongside the possibility that the patients themselves might not be able to articulate

their complaints due to their condition, there are four groups of patients who do not need to receive information, namely: 1) Patients who are not yet adults; 2) Patients who are mentally incapacitated due to illness; 3) Patients who would be harmed by hearing such information, for example, due to a weak heart that might endanger their health; and 4) Patients who will undergo treatment with a "placebo" (dummy drug). Placebo is a pharmacologically inactive compound used as a comparison drug or for suggestion (suggestive therapeuticum).

If a patient is unconscious to the extent that a doctor cannot provide information, then the doctor may act or perform medical procedures without the patient's consent as an action based on *zaakwaar neming* or voluntary representation according to Article 1354 of the Civil Code." (Reni Agustina Harahap, 2018, 39-40).

CONCLUSION

The description of the implementation of non-litigation mediation outside the Court in resolving medical disputes at the Regional General Hospital of Kotapinang can be outlined as follows:

1. Efforts have been made to resolve medical disputes through non-litigation mediation outside the Court at the Kotapinang Regional General Hospital by Internal Mediators.
2. Mediation has not yet been conducted by Health Mediators who are Neutral Parties, as they still originate from within the Kotapinang Regional General Hospital or legal services acting as general mediators.
3. The final resolution of Medical Dispute issues by Internal Mediators and the assistance of Lawyers/Legal Consultants at the Kotapinang Regional General Hospital has not been documented in a Peace Agreement Minutes, only a peaceful agreement document signed by both parties, and minor re-surgeries (wound care) in the operating room handled by expert medical personnel.

4. The peaceful agreement document has not been filed as a Lawsuit in the Court to obtain a Peace Act as a legal guarantee that the issue has been resolved.

It is suggested that the Kotapinang Regional General Hospital appoint a Health Mediator from Neutral Parties as the Implementation Team for Handling Complaints, along with the assistance of Lawyers/Legal Consultants, as the mediation is still being conducted by Internal Mediators, directly led by the Director of the Kotapinang Regional General Hospital. Furthermore, it is hoped that the authority will soon be granted to Health Mediators to issue a Peace Act if the non-litigation mediation of medical disputes outside the court, as stipulated in Supreme Court Regulation Number 1 of 2016 Article 36 Paragraph (1), is successful in reaching a Peace Agreement. The lack of effective communication regarding Regulations related to Complaints, Notices, and Medical Disputes within the Kotapinang Regional General Hospital is apparent. There is still a low level of awareness among parties, including patients/families, the community, as well as medical and hospital management staff regarding their respective positions in the therapeutic relationship concerning healthcare services, leading to potential medical dispute issues arising from the contractual/agreement relationship embedded within the Therapeutic relationship.

Declaration by Authors

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