



The Legal Power of Informed Consent as A Valid Evidence in Cases of Alleged Malpractice in Terms of Civil Law

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Abstract

Patients have rights that must be fulfilled when informed consent. Patient information rights are often ignored. There are at least two kinds of information, namely: first, the risks and complications that may occur, and the prognosis for the actions taken. Providing clear information at the time of informed consent will provide a sense of security and for the patient will understand the actions during the rehabilitation period. A medical action is an action that is full of risks. In legal norms any medical action that results in harm to a patient can be called medical malpractice if it fulfills certain elements in both civil and criminal law. Based on the above background, the problem is how the function of informed consent in evidence in court is related to efforts to find the truth and how is the strength of proving informed consent for judges against alleged malpractice in terms of civil law. For this purpose, research was carried out using a normative juridical approach, the research specifications used were descriptive analytical, the data used in this study were secondary data, namely data obtained through library research. The data technique used is literature. The analysis used is normative qualitative. Based on the results of the analysis of the patient's rights as Article 45 paragraph 1 of Law Number 29 of 2004 concerning Medical Practice says that the operation must obtain the patient's consent, If the patient's condition is an emergency, then the approval of the family. If it is not possible, the operation can be carried out by the hospital authority, Article 56 paragraph (1) of Law Number 36 of 2009 concerning Health states that everyone has the right to accept or reject part or all of the relief measures that will be given to him after receiving and understanding information regarding the action is complete. And based on Article 45 paragraph (3) of Law no. 29 of 2004 concerning Medical Practice explains that risks, complications and prognosis must only be given before surgery. So that normatively informed consent has a legal position as evidence of letters and instructions in cases of malpractice. However, this evidence must be supported by other evidence, such as expert testimony, but if it is related to the teaching of the law, the evidence must still be adjusted to the requirements of the evidence, namely: 1) Allowed by law, 2) Reability, 3) Necessity, and 4) Relevance. Thus, the value of the power of proving informed consent is not fully binding on the judge but depends on the conviction and accuracy of the judge.

Keywords: Informed consent, Evidence, Malpractice

A. Introduction

The state is an organization that has a purpose. In the context of the Indonesian state, the goals of the state are stated in the fourth paragraph of the Preamble to the 1945 Constitution, which identifies that Indonesia is a legal state that adheres to the concept of a welfare state. As a state of law that aims to realize the general welfare, every activity in addition to having to be oriented towards the goals to be achieved must also be based on the applicable law as the rules for state, government and social

activities.¹The essence of the understanding of law is that the essence of law is to be a means for the creation of a just rule of society.²

Today the law plays an important role in various aspects of social and state life. To realize an optimal health degree for everyone, which is an integral part of welfare, legal support is needed for the implementation of various activities in the health sector.³Doctors as one of the main components of providing health services to the community have a very important role because they are directly related to the provision of services and the quality of health services provided.

The main basis for doctors to be able to perform medical actions for others is the knowledge, technology, and competencies they possess, which are obtained through education and training. The knowledge possessed must be continuously maintained and improved in accordance with advances in science and technology.

Doctors with their scientific tools have unique characteristics. This peculiarity can be seen from the justification given by law, namely the permissibility of taking medical action against the human body in an effort to maintain and improve health status. Efforts to improve quality in the health sector are very broad and comprehensive efforts, these efforts include improving health, both physical and non-physical. In line with technological and socio-cultural developments, the provision of health services is not only an effort to cure disease, but is more comprehensive, integrated and balanced including efforts to improve health (promotive), disease prevention (preventive), cure disease (curative),⁴

At first the legal relationship between doctors and patients was vertical or paternalistic, doctors were considered the most superior (father know best), but along with the development of the times, including the increasing field of education and public legal awareness, recently this form of legal relationship shifted towards a form of legal relationship. which is more democratic, namely a horizontal contractual legal relationship, an equal legal relationship between the patient and the doctor.⁵When a patient comes to the doctor for a check-up, the legal relationship that occurs between the patient and the doctor is essentially a service-buying relationship that is identical to the relationship between producers and consumers. Patients are located as consumers of health services, while doctors or health workers are sellers of health services. This engagement relationship is known as a therapeutic agreement or therapeutic transaction. In therapeutic transactions, patients have the same position as doctors or health workers. The patient has the right to determine what medical actions may and may not be performed on his body.⁶

Health workers who are dealing with Patients such as doctors and nurses, in carrying out their duties must respect the rights of patients, what is meant by patient rights

¹Juniarso Ridwan, Achmad Sodik Sudrajat, State Administrative Law and Public Service Policy, Nuansa Cendekia, Bandung, 2014, p. 11

²Theo Huijbers, Philosophy of Law, Kanisius, Yogyakarta, 1995, Pg. 75

³ibid

⁴Bahder Johan Nasution, Doctors' Liability Health Law, Rineka Cipta, Jakarta, 2005, Pg. 87

⁵Syahrul Mahmud, Law enforcement and legal protection for doctors suspected of committing medical malpractice, CV Mandar Maju, Bandung 2008, page 27

⁶Vicia Sacharissa, [https://www. Hukumonline.com/berita/baca/lt5caacd2490e88/hasil-ketiadaan-iinformed-consent-i-menurut-perspektif-law-perdata-oleh--vicia-sacharissa/](https://www.Hukumonline.com/berita/baca/lt5caacd2490e88/hasil-ketiadaan-iinformed-consent-i-menurut-perspektif-law-perdata-oleh--vicia-sacharissa/), accessed on August 14, 2019

include, among others, the right to obtain information, the right to give consent, the right to medical secrets, and the right to a second opinion.

In relation to the rights of these patients, especially the right to give consent, sometimes doctors are negligent in acting, resulting in the action taken or given by the doctor is categorized as malpractice if it is not in accordance with the patient's expectations to get a cure, even if the patient experiences bad things, especially if the patient dies.⁷

Lately, the medical profession has received a lot of attention from the public, which is a sign that some people are not satisfied with the services and dedication of the health profession. In general, this dissatisfaction is due to the gap between expectations and the reality they get. The reduced public trust in doctors, the rampant lawsuits filed are often identified with the failure of healing efforts carried out by doctors. The term malpractice is a familiar term. Malpractice cases filed by the public in the medical profession are increasing. This condition is actually an encouraging picture.⁸

This condition is reflected in the cases of alleged malpractice that occurred recently, namely:⁹

1. A malpractice case that had caught the attention of the Indonesian people occurred at the end of October 2015. At that time, the victim named Falya Raafan Blegur, the second child of the couple Ibrahim Blegur and Eri Kusrini died due to allegations of malpractice by a doctor at Awal Bros Hospital, Bekasi. Falya had been treated in the ICU since Thursday, October 29 2015, before finally taking his last breath on Sunday November 1 2015. The family felt something was odd, so they could not accept the doctor's statement that their second child was dead. In fact, a few days earlier, the hospital diagnosed Falya with mild dehydration. According to Ibrahim's confession, his second child was already cheerful and started playing with his brother. In fact, he could already run. But unfortunately, before being allowed to go home, a doctor reportedly injected fluids into his IV. After the injection, Falya's condition was suddenly critical. His whole body turned blue, freckles appeared, and foam came out of his mouth.
2. The case that befell Ayu Tria (7 years) which must receive the full attention of the medical parties. At the end of 2012, Ayu was reported to have died after being rushed to the Harapan Kita Hospital because her condition suddenly dropped. After arriving at the hospital, Ayu was immediately taken to the Emergency Room (ER) to be treated by the hospital. He was then transferred to the ICU on the advice of a doctor. The transfer process was delayed for about 15 minutes because the road from the ER to the ICU was apparently interrupted by the equipment for shooting a wide-screen film. Ayu Tria was immediately given an IV and fitted with a pacemaker when she entered the ICU. But unfortunately, a few

⁷Mikhaela FL Tapada, The Position of Informed Consent (Agreement on Medical Action) Between Doctors and Patients in Indonesian Criminal Law, *Lex Crimen* Vol. VII/No. 3/May/2018, Pg. 154

⁸Diah Widi Astuti, Legal Status of Medical Records and Informed Consent as Evidence in Malpractice Cases, Thesis, Indonesian Islamic University, Yogyakarta, 2009, p. 2

⁹Dimas Andhika Fikri, 3 Malpractice Cases Shocking Indonesia, <https://lifestyle.okezone.com/read/2018/10/20/481/1966555/3-case-malpractice-menggemparan-indonesia-salah-cut-gender-to-suntik-mati>, Accessed on August 14, 2019

- hours later, the doctor declared that Ayu had died. According to the Daily Executive of the Indonesian Consumers Foundation (YLKI), Tulus Abadi,
3. The unfortunate incident happened to Sriah's mother, who underwent surgery to remove the uterus which caused her stomach to hurt and she could not pass urine due to obstruction of urine with the impression of intra-abdominal bleeding and fluid in the abdomen.¹⁰

This phenomenon shows that there is an increasing public awareness of the law, especially people who are victims of their rights. Patient dissatisfaction with the performance of the medical profession continues to grow. The public's demand to bring cases of suspected medical malpractice to court is understandable given the very small number of cases of medical malpractice that are settled in court. Either by civil law, criminal law or by administrative law.

Law Number 29 of 2004 concerning Medical Practice does not contain provisions regarding medical malpractice. Article 66 Paragraph (1) contains a sentence that contains a medical practice error, namely "Everyone who knows or his interests have been harmed by a doctor's actions in carrying out medical practice can make a written complaint to the Chairman of the Indonesian Medical Discipline Honorary Council". This article only provides a legal basis for reporting doctors to their professional organizations if there are indications of a doctor's actions causing harm, not a basis for claiming compensation for the doctor's actions. This article only has meaning from the point of view of the administrative law of medical practice. Article 54 paragraph (1) of Law Number 23 of 1992 concerning Health, formulate a clearer sentence from the term that the doctor's interests are harmed by the action of the doctor with the term "...does a mistake or negligence in carrying out his profession..." but does not explain what the meaning and contents are so that the criteria are not clear. Moreover, the norm of that article is dead because Article 85 of Law Number 29 of 2004 concerning Medical Practice has been nullified, while Article 29 of Law Number 36 of 2009 concerning Health contains the term negligence, namely "In the event that a health worker is suspected of being negligent. In carrying out his profession, the negligence must first be resolved through mediation. Article 46 of Law Number 44 of 2009 concerning Hospitals also contains the term negligence, namely "The hospital is legally responsible for all losses caused by negligence committed by hospital health personnel". With the existence of Law No. 44 of 2009, it has provided a legal basis for the public to ask for legal responsibility for hospitals in the event of negligence that causes harm to patients. Of the four laws, it is not enough to provide the meaning, content, limitations of medical malpractice, while in the Criminal Code (Criminal Code) it is known as "negligence", in the KUHPdt (Civil Law Book) it is known as the terms "default" and "loss". Law Number 8 of 1999 concerning Consumer Protection provides legal remedies for victims to demand justice through court or out of court.

Regulation of the Minister of Health Number 585/Menkes/Per/IX/1989 concerning Approval of Medical Actions, Regulation of the Minister of Health Number 512/Menkes/Per/IV/2007 concerning Licenses for Practice and Implementation of Medical Practices, Regulation of the Minister of Health Number 269/Menkes/Per/III/2008 concerning Medical Records provides technical arrangements for patients and doctors in the event of a loss in medical services.

The consent of the patient before the doctor performs medical services or medical action on the patient is a must or obligation. This is reflected in the provisions of Article 45 paragraphs 1 and 2 of the Law on Medical Practice which states the following:

¹⁰Decision No. 08/Pdt.G/2014/PN. Kdr

1. Every medical or dental action to be performed by a doctor or dentist on a patient must obtain approval;
2. The approval as referred to in paragraph (1) is given after the patient has received a clear explanation.

Approval for medical treatment is reaffirmed in the Regulation of the Minister of Health of the Republic of Indonesia No. 290/Menkes/Per/III/2008 concerning Approval for Medical Action which states that Informed Consent is the consent given by the patient or his closest family after receiving a complete explanation regarding the medical procedure or dentistry performed on patients. in Article 39 of the Law on Medical Practice Number 29 of 2004 that;

"Medical practice is carried out based on an agreement between a doctor or dentist and a patient in an effort to maintain health, prevent disease, improve health, treat disease and restore health."

From the point of view of civil law, the legal relationship between doctors and patients is in a legal agreement (*verbinten*) which binds one legal subject to another legal subject to do something or not to do something or to give something called achievement. This raises the rights and obligations of each party that forms legal liability. For the doctor, the achievement of doing something or not doing something in *casu* not doing anything wrong or wrong in medical treatment which is solely for the benefit of the patient's health is a very basic legal obligation in the agreement.¹¹

Informed consent has legal force for patients who feel their interests have been harmed. If in medical treatment there are errors or omissions that deviate from the consent, the patient has the right to demand compensation. As regulated in Article 1239 of the Civil Code, if a patient or his family considers that the doctor or dentist is not carrying out his contractual obligations, the patient can sue on the grounds of default and demand that they fulfill these conditions.¹²

Civil Procedure Law is a formal law that regulates how to defend material civil law through the mediation of a judge. Violations of rights resulting in harm to others can be prosecuted through courts based on law.

According to Sudikno Mertokusumo, the Civil Procedure Code regulates how to file a claim for the right to examine and decide and implement the judge's decision.¹³

In the Civil Procedure Law process, the judge has the role of applying the law of evidence in 4 (four) classifications, namely establishing the actual legal relationship between the two parties to the dispute, imposing proof to one or both parties, providing an assessment of the evidence with respect to the above. the legal relationship between the parties, finding the law between the two parties' disputes.¹⁴

¹¹Adami Chazawi, *Medical Malpractice*, Sinar Graphic, Malang, 2007, Pg. 41

¹²Syahrlul Mahmud. *Law enforcement and legal protection for doctors suspected of committing medical malpractice*, CV Mandar Maju , Bandung 2008, page 53

¹³Ridwan Syahrani, *Book of Basic Civil Law Materials*, PT Citra Adhya Bakti, 2000, Pg 2

¹⁴Pangabean, *Law of Proof of Theory-Practice and Indonesian jurisprudence*, PT Alumni, Bandung, 2014, Pg 7

B. Method

The research method is very important in order to obtain satisfactory and accurate research results, therefore the authors conduct research based on the following methods:¹⁵

1. Approach Method

Referring to the title and formulation of the problem, this research uses a normative juridical approach, namely research conducted by examining library materials or secondary data in the form of primary legal materials, secondary legal materials, and tertiary legal materials. The materials are arranged systematically, studied, then a conclusion is drawn in relation to the problem under study.

2. Research Specification

The research specifications used are descriptive analytical which aims to accurately describe,¹⁶ namely to obtain a comprehensive and systematic picture of legal theories and practice of implementing positive law concerning the issue of the legal force of informed consent as legal evidence in cases of alleged malpractice.

3. Sources and Data Collection Techniques

The data used in this study are secondary data, namely data obtained through library research which includes primary legal materials, secondary legal materials and tertiary legal materials. Primary legal materials are legal materials whose contents have binding power to the community, such as basic norms, statutory regulations, unwritten law and jurisprudence. The primary legal materials used in this research are statutory regulations such as the 1945 Constitution, Law No. Medical Practice Law, Permenkes No. 1419/ Menkes/Per/X/2005 concerning the Implementation of Medical Practice and the Minister of Health of the Republic of Indonesia No. 749a/Men.Kes/Per/XII/1989 concerning Medical Records, Decree of the Minister of Health of the Republic of Indonesia No. 585/Men.Kes/Per/IX/1989 concerning Medical Approval which was later linked to the Civil Procedure Code as the law that applies generally to the proceedings in civil cases. Secondary legal materials are legal materials whose contents provide an explanation of legal materials primary consists of draft laws and regulations, works of scholars - doctrine, papers - Journals, research results in Tertiary legal materials are works that do not directly discuss the research material.

4. Analysis Techniques

In analyzing the study data related to the research conducted by the author, qualitative normative analysis was used.¹⁷ Normative because this research stems from existing regulations as positive legal norms and is related to problems.¹⁸ While qualitative because all data are compiled and presented systematically, then analyzed in a form to describe in words and do not use calculations or mathematical formulas.

¹⁵Rony Hanitjio Soemitro, *Legal Research Methodology*, Jakarta, Ghalia Indonesia, 1990, Pg. 98

¹⁶Amiruddin and Zainal Asikin, *Introduction to Legal Research Methods*, Jakarta, Raja Grafindo Persada, 2003, Pg. 25

¹⁷Suharsimi Arikunto, *Research Procedures A Practical Approach*, Jakarta, Rineksa Cipta, 2002, Pg. 9

¹⁸Winarno Surakhmad, *Introduction to Introduction to Basic Scientific Research and Engineering*, Bandung, Tarsito, 1998, Pg. 140

C. Results and Discussion

1. Analysis of the Legal Strength of Informed Consent as Legal Evidence in Cases of Alleged Malpractice Judging from Civil Law

a) The Function of Informed Consent in Evidence in Court Is Connected with Efforts to Find the Truth

Based on the Regulation of the Minister of Health of the Republic of Indonesia Number 585/Menkes/Per/IX/1989 concerning Approval of Medical Actions, informed consent is the consent given by the patient or his family on the basis of an explanation regarding the medical action to be performed on the patient.

These actions include examination, giving injections, surgery or writing prescriptions. The doctor's action can be classified as an engagement to do something. Whatever the doctor's action in this connection is with the main aim of providing benefits to the recipient of the action, even though all the actions taken, often pose a high and low risk, the risk is relative and the risk lies with both parties.¹⁹

The function of informed consent in the evidence in the decision no. 08/Pdt.G/2014/PN. Kdr Plaintiff argues that the unlawful acts committed by Defendants I and II as formulated in Article 1365 of the Civil Code which stipulates that "every act that violates the law, which causes harm to another person, obliges the person who because of his mistake to issue the loss, compensates for the loss".

That what is meant by unlawful acts as formulated in Article 1365 of the Civil Code must contain the following elements:

- 1) There is an action
- 2) This act is against the law
- 3) There is an error on the part of the perpetrator
- 4) There is a loss for the victim
- 5) There is a causal relationship between actions and losses.

Whereas based on jurisprudence what is meant by unlawful acts are actions (or not doing) that meet the following criteria:

- 1) Contrary to the legal obligations of the perpetrator or
- 2) Violating the subjective rights of others or
- 3) Violating the rules of etiquette or
- 4) Contrary to the principle of propriety, thoroughness and caution that a person should have in his association with fellow citizens or against other people's property;

Setiawan said that because the four criteria use the word "or" thus for the existence of an unlawful act, it does not require the existence of the four criteria cumulatively, but with the fulfillment of one of the criteria alternatively the conditions for an unlawful act have been fulfilled.

That there are other conditions that must be met that an act that is contrary to the legal obligations of the perpetrator is seen as an act against the law, namely:

- 1) Whereas with the violation the interests of the Plaintiff are threatened;
- 2) Whereas the interests of the Plaintiff are protected by the rules being violated (schul normtheorie);

¹⁹CST Kansil, Introduction to Health Law, Rineka Cipta, Jakarta, 1991, Pg. 234

3) That there is no legal justification.

Whereas the essence of the Plaintiff's lawsuit is basically based on an argument that the Defendants have made a mistake for which they are responsible because of the medical action against the Plaintiff, it is deemed to have violated the law due to lack of caution. Therefore, it is important to consider the essential element of the occurrence of an unlawful act, namely the element of guilt on the perpetrator. Therefore, it is necessary to consider that in the current development of judicial practice, the problem of wrongdoing in unlawful acts that arise is based on the legal relationship of a doctor with his patient in certain events. its value often becomes less important, because there is a tendency for error elements to be "imagined", "presumed" or "objectified" (de schuld fictie), (deschuld vermoeden) (de schuld objectivering.)²⁰

In addition to doctors and dentists who can be sued because they are deemed to be in default, the doctor or dentist can also be sued by the patient or his family if the result or action of the doctor or dentist has resulted in harm to the patient due to committing an unlawful act as regulated in Article 1365 of the Civil Code. This can be done if there are facts that support the patient's loss due to the actions of a doctor or dentist. Therefore, the following conditions must be met:²¹

- 1) The act is an unlawful act (onrechmatige daad)
- 2) There must be an error
- 3) There must be a loss caused
- 4) There is a causal relationship between the act and the loss.

According to Guwandi, what is meant by malpractice are:²²

1. Doing something that should not be done by health workers.
2. Not doing what should be done or neglecting obligations (negligence).
3. Violating a provision according to or based on statutory regulations.

Whereas in addition, prudence must be considered in its relevance to the principle of good faith, which is related to the principle of duty of care, namely an obligation to act carefully which is sometimes also formulated as an obligation or obligation recognized by law, which requires so that a person acts according to a certain standard of conduct "a certain standard of conduct" in order to protect others against a risk which, according to common sense, does not actually need to occur (unreasonable risk).

That there are 2 (two) measures that can be used to determine whether a person has acted carefully which might harm others, namely in accordance with the principle of "the neighbor principle" (our fellow human beings) and "the area of risk principle" (the principle of space). scope) in which both principles contain certain standard measures of behavior that must be met, namely humans always act according to reason, someone acts according to common sense, the standard measure of behavior desired by society, must be an objective measure and not constitute an objective measure. something subjective. Individual judgments, the good and bad qualities of the

²⁰Flower Compound About Medical Malpractice Theoretical Description of Medical Malpractice With Legislation, Study Team of the Supreme Court of the Indonesian-Dutch Legal Cooperation Project, Jakarta, 1991, Pg. 3

²¹Syahrl Machmud, Op. Cit, hlm. 55

²²Guwandi, Medical Negligence, FK UI Publishing Center, Jakarta, 1994, Pg. 20

perpetrator are not a determining factor, because that measure, as far as possible is the same and applies to everyone,²³

According to Munir Fuady, what is meant by informed consent in the field of health law is an agreement from the patient's side (or from the patient's family if it is not possible for the patient to give consent) freely and reasoning on the actions to be taken by the doctor on his body or on diagnostic, therapeutic and palliative matters. (relieve pain), which is done by the doctor, the consent is given by the patient after the patient has been given sufficient information in a language that the patient can understand (so that the patient can make the right decision) about everything related to the action to be taken. by the doctor, including information about the aims and objectives of diagnostic, palliative and treatment, all important facts, the risks and side effects or complications that may occur, the disadvantages and benefits of treatment in this way, other available alternatives, the amount of costs that will be incurred, the percentage of failure, conditions after treatment and the experience of the doctor.²⁴

Whereas furthermore Defendant I and Defendant II denied the Plaintiff's arguments or exceptions which are basically as follows:

1. Plaintiff's lawsuit lacks parties

In consideration, the Panel of Judges said that based on "Civil Procedure Law in Theory and Practice" Retnowulan Sutantio and Iskandar Oeripkartawinata stated that the Plaintiff was a person who "felt" that his rights had been violated and took the person who was deemed to have violated his rights a defendant in a case before the court and the Plaintiff felt that only Defendant I and Defendant II had violated their rights, so that related to the lack of parties in this lawsuit, it was deemed unreasonable, so that the exceptions of the Defendants who stated that the Plaintiff's lawsuit lacked parties should be rejected.

2. Plaintiff's lawsuit is vague (eceptio obscur libel)

Whereas Defendant I argued that the petitum of the Plaintiff's claim was not supported by the a quo claim posita. In its consideration, the Panel of Judges explained that the ambiguity of the lawsuit may include:

- a) The object of the lawsuit is not clear, if the size of the object of the lawsuit listed in the lawsuit is not the same as actually controlled by the defendant, the lawsuit can be declared vague.
- b) Whereas the posita and petitum are contradictory, it means that there is no attachment between the posita and petitum;
- c) Against the petitum of the lawsuit, namely the petitum or the plaintiff's claim that is not clearly and definitely detailed, it results in the claim being blurred.

Whereas it appears that there is a relationship or synchronization between the posita and the petitum, there is no difference because the Plaintiff clearly states what his claim is. Whereas petitum number 7 as a complement to the petition for a decision is immediately alternative in nature, so that it is not included in the claim posita does not make the Plaintiff's claim obscure so that this petition is rejected. Considering that the claim for compensation in an unlawful act may not be detailed, and material and

²³Decision No. 08/Pdt.G/2014/PN. Kdr

²⁴Kiagus Ferry Soufjan, The Role of Midwives in Informed Consent Pre-C-section as a Form of Respect for Patient Autonomy, Thesis, Bandung Islamic University, 2011, hlm. 24

immaterial damages can be demanded without a certain standard of Article 1365 of the Civil Code, in contrast to the claim for compensation for Defaults calculated from the time of negligence (1237 of the Civil Code), including losses incurred experienced and the benefits to be obtained (Article 1236 and Article 1243 of the Civil Code). Weigh, that the Panel considers that the events described by the Plaintiff in their lawsuit show that there is a legal relationship that forms the basis of the claim, without having to explain in detail and at length the basis and storyline or the history of the incident, because it can be stated in the trial and evidence (Individualization theory). . This is in accordance with Jurisprudence No: 547K/Sip/1971 "which states that the brief formulation of material events in the lawsuit has fulfilled the requirements". Considering, that based on the foregoing the Panel of Judges is of the opinion that the exception to the lawsuit stating that it is not detailed and unclear is rejected. without having to explain in detail and at length about the basis and course of the story or the history of events, because it can be stated in trial and evidence (Individualization theory). This is in accordance with Jurisprudence No: 547K/Sip/1971 "which states that the brief formulation of material events in the lawsuit has fulfilled the requirements". Considering, that based on the foregoing the Panel of Judges is of the opinion that the exception to the lawsuit stating that it is not detailed and unclear is rejected. without having to explain in detail and at length about the basis and course of the story or the history of events, because it can be stated in trial and evidence (Individualization theory). This is in accordance with Jurisprudence No: 547K/Sip/1971 "which states that the brief formulation of material events in the lawsuit has fulfilled the requirements". Considering, that based on the foregoing the Panel of Judges is of the opinion that the exception to the lawsuit stating that it is not detailed and unclear is rejected.

Whereas Defendant I works at Baptist Hospital and has a Specialist Doctor's license to practice No. 446/280/419.41/2011 dated November 29, 2011 from the head of the Health Office of the City of Kediri as presented at the trial, namely evidence T-1 and has a doctor's registration certificate no. 711 130 121 108 5602 dated October 3, 2011 from the Indonesian Medical Council as presented at the trial, namely evidence T-2.

Whereas in the consideration of Judges Defendants I and II provided evidence in the form of informed consent as one of the evidences (exhibit T.1-3, evidence T.1-4) and was confirmed by witness Ani Kristina Priyanti (employee of Kediri Baptist Hospital) and witness Sa'adiyah Meilina (an employee of Kediri Baptist Hospital) revealed by Defendant 1 to strengthen and prove the arguments for her refutation.

Approval of medical action is a mandate from Permenkes No. 290 of 2008 concerning Approval of Medical Action which is the implementation of Law no. 29 of 2004 concerning Medical Practice Article 45. Permenkes PTK Article 2 paragraph (1) states that all medical actions to be carried out on patients must obtain approval. This regulation is a representation of the state's efforts to prevent the occurrence of arbitrariness of doctors which allows violations of patient rights.²⁵

Whereas based on expert witnesses, namely:

1. dr. Paraton Day, Sp. OG (K) explained under oath as follows:

²⁵ <https://www.kompasiana.com/tammysiarif/5bbb275dc112fe45f6106a09/persecepat-aksi-kedokteran-informed-consent?page=all#>, accessed on October 9, 2019

- a. That abnormal uterine bleeding, uterine myoma and ovarian cysts are part of the competence of obstetrics and gynecology specialists;
- b. Whereas in the case that the initial treatment, both conservative and surgical, is SpOG's competence, if it turns out to be a malignancy, then the follow-up therapy is referred to a sub-specialist/oncology consultation;
- c. Whereas the steps of the procedure that must be carried out by obstetrics and gynecology specialists (obstetrics and gynecology) in establishing the diagnosis of their patients, in particular the diagnosis of Abnormal Uterine Bleeding, Uterine Myoma and Ovarian Cysts;
- d. That a good history can help about 80% of diagnosis, physical examination, general gynecological examination, special examination (USG, kurtage if needed);
- e. That the general complaints or symptoms felt by patients suffering from Abnormal Uterine Bleeding, Uterine Myomas and Ovarian Cysts are:
 - a) Abnormal uterine bleeding: bleeding outside the menstrual cycle (metrorrhagia, meno-metrorrhagia), excessive menstruation;
 - b) Myoma Uteri: bleeding outside the menstrual cycle (metrorrhagia, meno-metrorrhagia), excessive menstruation (menorrhagia) sometimes accompanied by pain. If myoma is large > 10 cm, it can be accompanied by symptoms of frequent urination (BAK) or difficulty defecating (BAB). These symptoms are closely related to the location and size of the myoma;
 - c) Ovarian cysts: functional cysts do not give real symptoms, sometimes there can be a delay in the menstrual cycle. Pathological cysts depending on the size and type, Endometriosis cysts often give symptoms of difficulty conceiving and pain during menstruation. Pathological cyst large > 10 cm gives symptoms of pressure in the lower abdomen sometimes pain during strenuous activities;
- f. Whereas what is meant by total hysterectomy / total abdominal hysterectomy and left salpingo oophorectomy (TAH – SOS):
 - a) Total abdominal hysterectomy (TAH), a procedure through the abdomen (abdominal wall) to remove the uterus/hysterectomy/womb, the term total is used when the entire uterus is removed including the cervix/mouth of the womb;
 - b) Salpingo oophorectomy sinistra (SOS), a procedure to remove the salping/fallopian tube/oviduct and ovary/ovary together (Sinistra = left side);
- g. Whereas in terms of the field of science and obstetrics, usually the risks and complications of the TAH-SOS action are:
 - a) Risks due to general / regional anesthesia:
 - b) Impaired consciousness
 - c) Lung disorders;
 - d) Infections of the CNS;
 - e) temporary paralysis;
 - f) Risks due to drugs:
 - g) Allergy ;

- h) Anaphylaxis;
- i) Risks due to surgery:
- j) Bleeding;
- k) Injuries: intestines, blood vessels, ureters, bladder, nerves;
- l) surgical site infection;
- m) Complications depend on the current situation:
- n) Heavy bleeding: anemia;
- o) Vascular injury: hematoma + anemia + pain;
- p) Ureteral injury: urinary obstruction, leakage; Bladder injury: leakage;
- h. That the normal size of the uterus (uterus) in adult women: 6-8 cm x 3-5 cm;
- i. Whereas the nurse who is an operating assistant is competent to sew the skin of the patient's abdomen after the procedure is completed by the obstetrician and gynecologist;
- j. Whereas the operation is an activity carried out by a team, consisting of anesthesiologists, anesthesiologists, assistants I – II (doctors, nurses, DM), instrument nurses, general assistants and operators. Assistance operations are permitted as long as the actions are known and on the orders of the operator;
- k. Whereas in the TAH-SOS action there was bleeding and after the action the patient's urine did not come out, it is already if the obstetrician and gynecologist gave drinking (water) to the patient with the intention of replacing body fluids;
- l. Whereas in post-TAH-SOS cases if bleeding is suspected or occurs, the following actions are taken:
 - a) Determine the source of bleeding;
 - b) Improve general condition, rehydration fluids to stabilize the patient's hemodynamics;
 - c) Ensure the diagnosis by physical examination, laboratory or imaging or certain tests;
- m. That if a few hours after the TAH-SOS procedure, the patient complains of bloating and no urine comes out even though drinking and appropriate therapy have been given, and based on the physical examination, the doctor suspects that there are abnormalities in the organs in the patient's abdomen after the TAH-SOS procedure. , then the procedure to identify and handle the complaint is as follows:
 - a) After the TAH – SOS procedure, there was bloating, possibly intestinal motility disorders (ileus), internal bleeding;
 - b) Confirmed by physical and laboratory examination, if the Hb level drops, blood pressure drops and pulse increases, then there is a possibility of bleeding due to surgery (surgical bleeding);
 - c) Bleeding conditions, especially if there is a state of shock, can result in oligoruria or anuria (not coming out of urine);
 - d) If the Hb level is stable, blood pressure and pulse are stable, then there is a possibility of injury to the ureter or bladder;

- e) The action that must be taken is to assess and improve the general condition of the patient, ultrasound examination can be done to add diagnostic information. If ureteral injury is suspected, re-opening/re-operation is the option;
- n. That if all stages have been passed in order to handle the patient's complaints after surgery for flatulence and urine does not come out, the operating doctor may refer to a specialist in internal medicine because:
 - a) In such circumstances, referrals should be made to colleagues, internal medicine specialists, anesthesiologists and surgeons/urologists, radiology doctors;
- o. That if a few hours after the patient underwent the TAH – SOS procedure by the Obstetrics and Gynecology doctor, the patient complained of flatulence and no urine output, then an ultrasound radiological investigation was carried out which showed inflammation of the kidneys and a picture of intra-abdominal bleeding and the presence of fluid in the abdomen. , then it is appropriate if the Obstetrics and Gynecology doctor performs an exploratory relaparotomy on the patient in order to find or cause the ultrasound image because it is re-opened or relaparotomy for exploration and ascertaining the source of the disturbance is the right choice to be made;
- p. That ureteral injury is a risk and complication of the TAH – SOS procedure in the form of a TAH surgical procedure, the possibility of ureteral and bladder injury is 0.5% - 30%, the size of the risk or complication depends on the anatomical abnormality of the uterus, the tissues around the uterus, and variations in the anatomy of the ureter. . Ureter comes from the kidney to the bladder/bladder across the uterus/womb at the level of the isthmus/cervix with a distance of 1-2 cm laterally;
- q. That after an exploratory relaparotomy, it turned out that the patient had ureteral injury, so whether to refer the patient to a general surgeon to repair the injured ureter due to the TAH - SOS medical procedure, it was appropriate for the Obstetrics and Gynecologist and also the general surgeon to be competent to perform the procedure. Ureteral repair due to ureteral injury can be treated by general surgeons or urological surgeons. Bladder/bladder injuries can be treated by specialists in Obstetrics and Gynecology (obstetrics and gynecology), general surgeons and urology specialists;
- r. That if there is a risk / complication of ureteral injury after the TAH - SOS procedure, then repair of the ureter has been carried out according to the indications, the impact that usually occurs to the patient after the procedure is that a DJ stent is usually installed, a catheter is placed in the ureter to help smooth urine from the kidneys down into the bladder / bladder, reducing ureteral contractility so that healing can be fast;
 - a) If the bowel movements are smooth, there are no complaints, healing of the ureteral injury has occurred, then the DJ stent is removed;
 - b) There is a risk of urinary tract infection while using a DJ stent;

- s. That each removal of body tissue is carried out by pathological anatomy examination to ensure conformity with clinical diagnosis, detect other pathological abnormalities;
- t. There was a complaint that the patient could not eat after TAH – SOS surgery and repair of the ureter, there was no relationship with being able to eat because Post TAH – SOS involved the genital tract, repair of ureteral injury involved the urinary tract. While the function of eating involves the intestinal tract and oropharynx. Each tract has its own characteristics and functions;
- u. That if after the second operation, the patient may move to another doctor because the patient's rights are highly respected, if the doctor has moved the responsibility of the operator is cut off That based on evidence T.II – 10 witnesses always see if they want to do surgery and fill in the information in the consent form for medical action (especially risk) must always be associated with it;
- v. Whereas the witness as an expert has been an OG doctor since 1989 and if there is abnormal bleeding, the first thing to do is conservatively with existing medicines, if it doesn't work, then surgery;
- w. Whereas after the operation the first time urine does not come out, the doctor Sp.OG may perform a second operation and every nurse is competent to sew up the post-surgery and sew up the ureter;
- x. That to open the abdomen of the SPOG doctor, to sew the ureters by a surgeon or a urologist;
- y. That the ureter is hidden behind a layer for that risk of cutting, suturing up to 30% and that is not the negligence of the operator;
- z. That those who have the right to explain the risk of Sp.OG doctors can, ordinary surgeons or anesthesiologists can also;
- aa. That after suturing the ureters, a DJ stent should be placed within 1 – 3 months and the responsibility of releasing the surgeon or urologist is required;
- bb. That at the time of surgery the doctor can hold the intestine and then it will come back by itself;
- cc. That the risk must be notified before the doctor performs and every medical/medical action has a risk;
- dd. That the first responsibility of the operator to know early after surgery, secondly if complications occur, they must immediately deal with other sub-specialists if necessary and any risks are not malpractice;
- ee. Whereas the one who stated that the operator doctor's actions were wrong was the accidentiel team and if it is proven that the competence related to it is revoked;
- ff. That surgery for cysts, uterine myomas is included in the category of major surgery, but for regional anesthesia it can also be total;
- gg. That for follow-up actions must be conveyed to the patient and
- hh. The risk agreement signed by the patient regarding the follow-up action must be conveyed wisely, because because it is conveyed as it is, no patient will dare to be operated on;

- ii. Whereas the development of the times, especially in Europe, currently there is a request for surgery signed by the patient, while in Indonesia IDI is still revising Law No. 36 of 2009 concerning Health.

2. Witness Dr. Ari Purwadi, SH., M. Hum explained under oath as follows:

- a. Whereas the witness explained that the definition of unlawful acts in detail did not exist, there were only elements including losses, mistakes and causal relationships;
- b. That the relationship of the claim for compensation is related to Article 1365 BW, especially the patient suing the doctor, is:
 - a) Aspects of civil law concerning a patient's lawsuit against the doctor who handles it are almost all problems of claiming compensation.
 - b) Article 1365 BW stipulates that every act against the law, which causes harm to another person, obliges the person who, because of his fault, issued the loss, to compensate for the loss;
 - c) Acts against the law (onrechtmatigedaad) in its development were expanded into 4 (four) criteria, namely: First, violating the rights of others, Second, contradicting the legal obligations of the perpetrator, Thirdly violating the rules of morality, Fourth, contradicting propriety, accuracy and caution should be owned in association with fellow citizens or the property of others;
- c. Whereas the method of proving the element of an unlawful act in Article 1865 BW is about the burden of proof, if you postulate a loss, you must prove the cause of the loss;
- d. That the relationship between unlawful acts and the profession, especially medicine, is not easy to determine when there is a professional error, in daily practice there are three criteria: First, the obligation of doctors to provide medical services for their patients, the starting point of the possibility of professional errors that cause harm. for other people, it is an obligation on doctors who perform medical actions or medical services for their patients, obligations here which are subject to contract law or have some special characteristics, the professional scope they have is only for the efforts to be carried out, not for the final result; Second, there is a violation of a doctor's obligation to his patient, in accordance with the definition of obligation as stated above.
- e. Whereas if there is a lawsuit on suspicion of medical negligence, the Default Article can use Article 1239 BW. This article can be used if the legal relationship formed between a doctor and a patient is a result-oriented agreement (resultaatsverbentenis);
- f. Whereas negligence, using Article 1366 BW: "Everyone is responsible not only for losses caused by his actions, but also for losses caused by negligence or carelessness";
- g. Whereas the measure of unlawful acts committed by doctors is contrary to legal obligations;
- h. That inform concern includes a written agreement;

- i. That in every doctor's action the risk must have been explained by the doctor and the patient has understood it can be said to be in agreement because verbal agreement is allowed;
- j. That the expert opinion regarding malpractice related to legal contracts is that it must refer to our positive law, namely the Health Law and Medical Practice Regulations, and in these two regulations there is no term malpractice, the existence of bad practice is related to the size of professional standards, if professional standards are met there is no malpractice;
- k. Whereas according to the expert in Article 1365 BW regarding joint and multiple liability, joint responsibility is not recognized in an unlawful act. Thus, that an unlawful act committed by two or more persons is guilty of "to what extent is the responsibility of the role and the burden of the loss";
- l. Whereas if there is only one element, it cannot be said to be against the law;
- m. Whereas if there is an error in the action of the doctor during the operation so that the doctor concerned is unable to then refer to another doctor, it is difficult to say that it violates the law or its norms;
- n. Whereas the expert opinion regarding risk-responsive doctors is related to professional standards, if there is a risk but it has been explained previously it cannot be said to be negligent or the doctor is risk-responsive in practice and has carried out standard operating procedures (SOPs);
- o. That when entering the hospital there is an operating approval, further approval is not necessary, while regarding the responsibilities it must be sorted out, which are the responsibilities of the hospital and which are the responsibilities of the doctor.

The presence or absence of written informed consent does not change the magnitude of the doctor's responsibility for the actions or consequences of the medical actions he takes. Doctors must comply with professional standards, including that their actions must be based on informed consent, even though every medical action must be with the patient's consent, but the determination of the need for a medical action is in the hands of the doctor as a professional, so that the doctor remains responsible for the actions or consequences of the medical actions he takes.²⁶

Whereas in determining the existence of the error, it turns out that the "imagined" error (de schuld fictie) is the most gross, so it is called dogmatic (een dogmatische dwaasheid) even though it can achieve the correct result, while with the "presupposed" error (deschuld vermoeden), a judge to certain things can twist/shift the burden of proof. That is, the perpetrator must prove that he is innocent. In "deschuld objectivering" errors, concrete actors are abstracted. The measure used is no longer subjective individualitis but is associated with normal humans in general.

That based on the Supreme Court's Decision No. 117k/SIP/1956 dated June 12, 1957 said that taking into account the responsibility of jinawab in the trial process of this case, it turns out that the Defendants have acknowledged the existence of a legal relationship between the Plaintiff and Defendant I and Defendant II as patients with hospitals and or doctors who perform medical actions, however denied that he had

²⁶Veronica Komalawati, Ibid, Pg. 181

made a mistake in providing medical services, because all of his actions were based on standard medical services according to his expertise and or did not violate the provisions of the legislation, so that in this case there was a confession accompanied by an addition that had nothing to do with the confession. that, which doctrine and jurisprudence call "gekwalificeerde bekenenis", acknowledgment can be separated from the addition. That an unlawful act violates another person's subjective rights must be interpreted when the act has violated a person's subjective rights, namely a special authority of a person recognized by law, which is given to him for his interests including material rights, in casu regarding acts to provide medical services. inherent in the Plaintiff, as a party who has legal standing and legal capacity and has the right to provide medical services for the Plaintiff, as a patient of Defendant I and Defendant II. In addition, the argument that the Defendants have acted carelessly must be tested with the teachings of unlawful acts, which in one of the criteria is that the actions of the perpetrators are contrary to the principle of propriety, thoroughness and careful attitude that a person should have in his association with fellow members of the community or towards other people's property. If the doctor only takes actions that are contrary to medical ethics, the plaintiff must prove 4 (four) elements as follows:²⁷

- 1) There is an obligation for doctors to patients;
- 2) The doctor has violated the medical service standards that are commonly used;
- 3) The Plaintiff has suffered damages that can be claimed for compensation;
- 4) In fact the loss was caused by substandard actions.

That in accordance with the main scope of the problem in this case, to determine whether the actions of the Defendants were an unlawful act that harmed the Plaintiffs, of course, apart from paying attention to the elements and criteria as well as the conditions for the existence of an unlawful act as already considered at the beginning of this Decision, the main thing is and what must be considered is the existence of a reciprocal and balanced obligation between the Plaintiff as a patient and therefore entitled to the agreed medical services, whether they have carried out their duties in good faith and with full sense of responsibility, in relation to with the actions of the Defendants who have provided medical services to the Plaintiffs, as a derivative action born from a primary right as a party with an interest in the recovery of the Plaintiff.

In essence, informed consent is a tool to enable self-determination, namely the value, goal in informed consent. Concretely, the requirement for informed consent is for every action, both diagnostic and therapeutic. According to Thiroux, informed consent is an approach to the truth and involvement of patients in decisions about their treatment.²⁸

Whereas based on the juridical facts that were revealed at the trial based on jinawab answers and or the evidence submitted by the parties of Defendant I and Defendant II, the panel of judges concluded that the medical actions taken by Defendant I and Defendant II on the Plaintiff were in accordance with the standards. the profession that Defendant I has owned and carried out so far as an expert doctor in charge of the medical action. In addition, the medical action was also in accordance with the applicable provisions, because Defendant I had also previously explained the risks posed to both the Plaintiff and his family, and Defendant I had tried and made

²⁷M. Jusuf Hanafiah, *Medical Ethics and Health Law*, EGC Medical Book, Jakarta, 1999, Pg. 89

²⁸Veronika Komalawati, *Ibid*, Pg. 106

maximum efforts, so that the Plaintiff as a patient received the expected recovery. . Likewise, Defendant II as the Hospital has also prepared all the facilities needed by the Plaintiff properly. Therefore, there is no element of error in the unlawful acts that are argued against the Defendants, and or the actions of the Defendants, do not conflict with the legal obligations of the perpetrators or do not conflict with the principles of propriety, thoroughness and caution that a person should have in dealing with the law. association with fellow citizens or the property of others.²⁹

A doctor is a person who has professional expertise as a service provider, on the other hand, a patient, a person who requires assistance from the professional services of a doctor as a recipient of services. The relationship between the two parties began when the patient first came to the doctor's office with a complaint of pain. After hearing complaints from the patient, the doctor took the initiative to take certain actions aimed at curing the patient.³⁰

Health service is a service commodity that has special characteristics and is not the same as other service industries, such as transportation services, telecommunications services, and banking services. Consumers who use health services are usually sick, concerned, panicked and tense in uncertainty, this means that consumers face an element of compulsion.³¹

People with medical or health professions take actions or actions against patients in the form of efforts that are not necessarily successful, because therapeutic transactions are essentially transactions of parties, namely doctors and patients to seek the most appropriate therapy by doctors in an effort to cure the patient's illness. This therapeutic transaction relationship is called *inspanings verbintenis* and not *verbintenis resultaat* as the patient's perception judges from the results. The patient also never has the thought that any actions or actions taken by doctors and or other health workers have been based on the patient's consent, which in the literature is referred to as informed consent or approval of medical action.³²

Informed consent basically has an ethical and legal basis, so the responsibility for its implementation can also be seen from an ethical and legal perspective.³³

Informed consent in a medical action serves as the basis for eliminating the crime, in addition to being based on the proper aims and objectives of the medical action.³⁴As Arrest HR (10-2-1902) in his legal considerations said that if causing injury or pain to the body is not a goal but a mere means to achieve a proper goal then there is no persecution.³⁵

Obtaining informed consent if to achieve improper goals then medical action is still persecution. Medical action without informed consent in an urgent situation, in fact still constitutes persecution. Not being punished for losing the nature of being

²⁹Court Decision No. 08/Pdt.G/2014/PN. Kdr

³⁰cst. Kansil, Introduction to Indonesian Health Law, Rineka Cipta, Jakarta, 1991, Pg. 234

³¹Z Umrotin K Susilo and Puspa Swara, Consumer Tongue Connector, YLKI, 1996, Pg. 63

³²Hermien Hadiati Koeswadji, Law for Hospitals, PT. Citra Aditya Bakti, Bandung, 2002, Pg. 60

³³Veronika Komalawati, The Role of Informed Consent in Therapeutic Transactions, Citra Aitya Bakti, Bandung, 2002, Pg. 117

³⁴Diah Widi Astuti, Legal Status of Medical Records and Informed Consent as Evidence in Malpractice Cases, Thesis, Indonesian Islamic University, Yogyakarta, 2009, p.

³⁵Soenarto Soerodibroto, KUHP and KUHP Equipped with the Jurisprudence of the Supreme Court and Hoge Raad, PT. Raja Grafindo Persada, Jakarta, 1994, Pg. 212

against the law. As for the conditions in an urgent or emergency situation, it is left to the considerations of medical science and law. From the point of view of medical science, the consideration is that if you don't get medical help immediately, it will be fatal or die.

There must be written informed consent signed by the patient before certain medical actions are carried out, carried out in health facilities, namely in hospitals for documentation in the form of medical records. So the hospital must meet the standard of medical services as regulated in the Decree of the Minister of Health no. 436/Men.Kes/SK/VI/1993 concerning the enactment of hospital service standards, medical service standards in hospitals. Thus the hospital is also responsible if the informed consent requirements are not fulfilled. If the medical action is carried out without informed consent, the doctor concerned may be subject to administrative sanctions in the form of revocation of the practice license as stipulated in Article 13 of the Regulation of the Minister of Health no. 585/Men.³⁶

That the presence or absence of informed consent does not change the magnitude of the doctor's responsibility for the actions or consequences of the medical actions he takes. Doctors must comply with professional standards, including actions that must be based on informed consent. Because the determination of the need for a medical action is in the hands of the doctor as a professional, so the doctor remains responsible for the action or consequences of the medical action he takes. Even if the written informed consent is not signed by the patient. Therefore, if the communication in the treatment interview is carried out in accordance with professional standards, then signing the consent form is only a technical administrative action.³⁷

In law, that someone who is able to help others who are in danger of death without endangering himself, does not help because without being given help the person dies. Thus, the person who does not help is legally responsible for that person's death. This is as regulated in Article 531 of the Criminal Code which states that: "Whoever witnesses himself a person in a state of mortal danger, neglects to provide or provide assistance to him while that assistance can be given or carried out without worrying that he himself or others will be in danger. , is sentenced to a maximum imprisonment of three months or a maximum fine of Rp. 4.500, - if the person who needs to be helped dies".

Medical action in an emergency that ignores informed consent can also be justified on the basis of the subsidiarity principle. The law provides a way to defend conflicting legal interests, meaning that it cannot defend both. So that what must be chosen is a greater legal interest (for example: risk of death) than maintaining a smaller legal interest (the interest of doctors getting legal protection against malpractice claims due to the absence of informed consent). This provision can be used as a basis for doctors to take emergency medical actions without informed consent either verbally or in writing in urgent circumstances in order to save the patient from a fatal risk, namely death. Therefore, if it is related to the position of informed consent as evidence when an action is suspected of being malpractice, the presence or absence of informed consent cannot necessarily be used as evidence in determining the occurrence of malpractice. To be able to be used as adequate evidence in cases of

³⁶Veronika Komalawati, Ibid, Pg. 180

³⁷Veronika Komalawati, Ibid, Pg. 181

malpractice, informed consent must be in accordance with the legal theory of evidence, namely:

- a. Allowed by law, in this case informed consent is an obligation that must be made by a doctor who has been stipulated by the Law on Medical Practice;
- b. Reliability, ie the evidence can be trusted for its validity (eg: not fake). Informed consent must be obtained after the patient fully understands the information that has been submitted along with the risks after agreeing to the action to be taken and must comply with the provisions contained in Article 45 paragraphs (1) to (6) of the Medical Practice Act. In this study, it was found that although the doctor had tried to give an explanation before taking a medical action, he was not completely sure that the patient could understand the whole explanation.
- c. Necessity, namely the evidence is needed to prove a fact.
- d. Relevance, ie the evidence has relevance to the facts to be proven.

The relationship between patients and doctors cannot be seen as something that stands alone, but as part of the overall legal relationship between health services and the community.³⁸

In book III of the Civil Code, an engagement is a legal relationship between two people that gives one the right to demand something from the other, while the other person is obliged to fulfill that demand.³⁹

In Article 1313 of the Civil Code, it is stated that consent is an act by which one or more people bind themselves to one or more persons which gives rise to an agreement to perform certain services, then at the time of the approach taken between the recipient of health services and the service provider. In health, there is a legal relationship that can give birth to legal consequences between each party.⁴⁰

Agreements in performing certain services between doctors and patients, the parties are equal, the nature of the work is in accordance with the profession as a doctor and the object is about the safety of people so that in the service a relationship is required for a high sense of humanity, honest, voluntary, and non-discriminatory in distinguishing ethnicity, race or ethnicity.⁴¹

Viewed from the aspect of civil law, medical actions carried out by doctors are the implementation of engagements in the form of therapeutic transactions between doctors and patients. The agreement between a doctor and a patient is called a therapeutic agreement, which is an agreement made between a doctor and a patient to seek or find therapy as an effort to cure the patient's illness by the doctor. Therapeutic agreements as part of private law are subject to the rules specified in the Civil Code as the basis for an engagement.⁴²

Therapeutic transactions occur between doctors and patients which result in the emergence of rights and obligations for both parties. In the therapeutic agreement between the doctor and the patient, a medical relationship has been established in the form of medical action which automatically also results in the formation of a legal relationship.⁴³

A patient who asks a doctor about diagnosis and treatment and the doctor answers

³⁸HJJ Leenen and PAF Lamintang, *Health and Legal Services*, Bina Cipta, Bandung, 1991, Pg. 62

³⁹Subekti, *Principles of Engagement Law*, PT. Intermasa, Jakarta, 2003, Pg. 16

⁴⁰Abdul Kadir Muhammad, *Indonesian Civil Law*, PT. Citra Aditia Bakti, Bandung, 1999, Pg. 224

⁴¹Abdul Djamali and Lenawati Tedja Permana, *Legal Responsibilities of a Doctor in Handling Patients*, Abardin, Bandung, 1998, Pg. 93

⁴²YES Triana Ohoiwutun, *Anthology of Health Law*, Bayu Media Publishing, Malang, 2007, Pg. 12

⁴³YES Triana Ohoiwutun, *Ibid*, Pg. 8

that he agrees, then a direct verbal agreement occurs, if there is no explicit agreement then there is a tacit agreement based on the behavior of the patient and doctor.⁴⁴

Therapeutic transactions between patients and doctors have an agreement, namely the agreement given by the patient which is always based on the information provided by the patient which is always based on the information provided by the doctor (informed consent). Informed consent is an agreement given by the patient or his family on the basis of an explanation regarding the handling in performing health services to be performed on the patient along with the risks that may arise as a result of the health service actions to be provided, therefore providing information on drug prescriptions to patients regarding the amount of goods and or services is one of the obligations of doctors in performing health services. The important therapeutic agreement is the existence of information from both parties which is the rights and obligations of each as the basis for carrying out medical actions. Doctors in carrying out medical actions that have a high risk, such as surgery, need to give informed consent to the patient in advance about the medical action that will be carried out. The hospital provides a refusal form for medical treatment if the surgery is not approved by the patient or his family.⁴⁵

The obligation to carry out informed consent by this doctor will result in sanctions if this obligation is neglected. This sanction was given to the doctor because he had made a mistake in carrying out his medical profession. In many cases of medical malpractice and medical negligence in Indonesia, most of it is caused by the absence of sufficient information from doctors to their patients about the medical actions that will be carried out by doctors. So that the patient does not have sufficient information or information and can be used as a basis for determining whether to give consent or not to give consent to the doctor.⁴⁶

By being informed of the medical action that will be carried out by the doctor, the patient can then exercise his right to choose, approve or reject the medical action in question. In this case, having chosen one therapy in seeking his recovery and agreeing to therapy in the form of certain medical actions, which he chose based on complete and accurate information, the patient can no longer blame the doctor. Because certain medical actions to be taken have been approved according to their independence without any outside influence.⁴⁷ However, as in Article of the Minister of Health No. 290/Menkes/Per/III/2008 concerning Approval of medical action that granting approval for medical action does not eliminate legal liability in the event that it is proven that there was negligence in carrying out medical actions that resulted in harm to the patient. Therefore, patients who feel aggrieved have the right to sue the doctor who made a mistake or negligence even though the prior informed consent has been implemented if the doctor does not take action in accordance with medical professional standards and or operational standards.⁴⁸

The relationship between doctors and patients is actually between subjects and subjects regulated by the rules of civil law and fulfills the relationship that regulates the rights and obligations of the parties. As in Government Regulation Number 32 of 1996 concerning Health Workers Article 32 paragraph (1) states that certain types of health

⁴⁴Soerjono Soekanto, *Aspects of Patient Rights and Obligations*, Mandar forward, Bandung, 1990, Pg. 3

⁴⁵Yuan Andrayani, *Responsibilities of Doctors in Fulfilling Patients' Rights to Information in Post-operative Care in Hospitals Based on Law Number 29 of 2004 concerning Medical Practices Juncto Law Number 36 of 2009 concerning Health*, Thesis, UNPAD, Bandung, 2013, p. 73

⁴⁶Putri Chairina Ahari, *The Urgency of Informed Consent Regarding Criminal Liability in Medical Negligence*, Thesis, University of North Sumatra, Medan, 2019, Pg. 48

⁴⁷Putri Chairina Ahari, *Ibid*, Hlm. 50

⁴⁸ ⁴⁸Putri Chairina Ahari, *Ibid*, Hlm. 51

workers in carrying out their professional duties are obliged to:

- a) Respect patient rights;
- b) Maintain the confidentiality of the patient's identity and personal health data;
- c) Provide information relating to conditions and actions to be taken;
- d) Request approval of the actions to be taken;
- e) Create and maintain medical records.

Leenen and Van Der Mij, argue that in carrying out their profession, a health worker needs to adhere to three general standards, namely:⁴⁹

- a) Authority;
- b) Average ability; and
- c) General accuracy;

A piece of evidence can be accepted in court, the evidence must be relevant to what will be proven.⁵⁰Evidence becomes relevant when the evidence has a sufficient relationship with the problem to be proven. Informed consent is possible to be used as evidence of letters or instructions in accordance with Article 184 of the Criminal Procedure Code, but informed consent does not have full binding power in proving cases of malpractice. In accordance with the evidentiary system adopted in Indonesia, namely the theory of evidence based on the law in a negative way, in addition to valid evidence, the judge's belief in the evidence is also required.

Based on Law Number 29 of 2004 concerning Medical Practice, the failure of a medical action that has gone through a standard operating procedure (SOP) is considered as a form in the event of an indication of failure in providing medical efforts by a doctor. For the medical community, this is not a form of error, because the doctor has taken action according to the SOP. Therefore, the Government established the Indonesian Medical Discipline Honorary Council (MKDKI) whose function is to enforce discipline for doctors and dentists in carrying out medical practice as regulated in Article 55 of Law Number 29 of 2004.

Based on Article 9 paragraph (1) of the Minister of Health Regulation Number 290/MENKES/PER/III/2008 concerning Approval of Medical Actions, it is explained that the explanation prior to approval of medical action is given in full in easy-to-understand language or in other ways that aim to facilitate understanding.

The problem of delivering information by doctors to patients affects the quality of health services and also the implementation of treatment, especially the impact on patients.⁵¹

Based on Article 56 paragraph (1) of Law Number 36 of 2009 concerning Health, it is stated that everyone has the right to accept or reject part or all of the assistance that will be given to him after receiving and fully understanding the information regarding the action. Article 58 of Law Number 36 of 2009 concerning Health provides a legal basis for legal prosecution for prosecutors in the matter of compensation. This is regulated in the BW as a generally applicable rule, in this case, directly or indirectly there is protection of the patient's rights by the negligence of the doctor, the doctor's error in carrying out his profession in the case of a therapeutic agreement including errors relating to obligations arising from the agreement. .

b) The Power of Informed Consent Evidence for Judges Against Alleged Malpractice Judging From Civil Law

⁴⁹Adami Chazawi, *Medical Malpractice*, Bayumedia, Malang, 2007, Pg. 29

⁵⁰Munir Fuady, *Theory of Criminal and Civil Evidence Law*, Citra Aditya Bakti, Bandung, 2012, Pg. 25

⁵¹Veronica Komalawati, *The Role of Informed Consent in Therapeutic Transactions*, PT. Citra Aditya Bakti, Bandung, 1999, Pg. 55

Subekti is of the opinion that proof is a process of how evidence is used, proposed or defended by an applicable procedural law.⁵²

Evidence aims to obtain the truth of an event or a right submitted to the judge. In civil law, the truth sought by judges is formal truth, while in criminal law, the truth sought by judges is material truth. In judicial practice, a judge is actually required to seek the material truth of the case he is examining, because the purpose of the evidence is to convince the judge or provide certainty to the judge about certain events, so that the judge makes decisions based on the evidence.⁵³

Andi Hamzah, who gives almost the same definition of evidence and evidence, is as follows:⁵⁴

Evidence is something to convince the truth of a proposition, position or accusation. Evidence means an effort to prove through tools that are allowed to be used to prove the arguments, or in criminal cases of charges in court, for example, the defendant's testimony, testimony, expert testimony, letters and instructions, in civil cases including allegations and oaths.

Informed consent is an agreement to take medical action which contains an agreement or agreement of the patient on the medical efforts that will be carried out by the doctor against him after the patient has received information from the doctor regarding medical efforts that can be taken to help him along with the risks that may occur. Therefore, informed consent has legal force, where a letter signed with self-awareness without coercion from any party can be used as evidence in filing a lawsuit to the court. In addition, informed consent is one of the prevention of malpractice actions and malpractice claims.⁵⁵

Based on contract theory, informed consent is the main requirement that must be met for a contract to occur so that a contractual obligation arrangement for services can be determined along with their rights and responsibilities. In this case, written informed consent can be used as written evidence of the occurrence of a therapeutic contract. Meanwhile, undertaking theory does not question the existence of informed consent if a doctor voluntarily provides assistance even without the knowledge of the patient he is helping to provide professional services. then written informed consent is not intended as an effort to avoid risk, nor as an effort to facilitate the implementation of a certain medical action.⁵⁶

Evidence in cases of alleged malpractice is an attempt to find the proper truth through examination and legal reasoning about whether or not the incident occurred. The purpose of this proof is to seek and find material truth.

Informed consent has a special function when an event is suspected of being malpractice. Informed consent is an agreement on the actions taken by the doctor against him after sufficient information has been carried out regarding all possible risks. Informed consent can be used as evidence but cannot prove the whole truth of

⁵²Subekti, *Law of Evidence*, Pradnya Paramita, Jakarta, 1991, Pg. 7

⁵³Abdul Manan, *Application of Civil Procedure Law in Religious Courts*, Preneda Media Group, Jakarta, 2005, Pg. 228

⁵⁴Andi Hamzah, *Legal Dictionary*, Ghalia Indonesia, Jakarta, Pg. 99

⁵⁵Putu Eka Trisna Dewi, *The Existence of Informed Consent in the Implementation of Medical Actions From a Legal Agreement View*, Journal, Ngurah Rai University, 2016, Pg. 145

⁵⁶Veronika Komalawati, *Ibid*, Pg. 183

the occurrence of malpractice events, therefore expert testimony from medical colleagues is still needed.

Informed consent can be used as valid evidence only if it is made based on actual facts and has the power of proof in terms of formality. Thus, to prove a case of alleged malpractice, it is not enough to use evidence in the form of informed consent, but other evidence and the judge's conviction are also needed, for example, corroborated by the testimony of expert witnesses, as witness dr. Hari Paraton, Sp. OG (K) and witness Dr. Ari Purwadi, SH., M.hum in case No. 08/Pdt.G/2014/PN. Kdr. The essence of expert testimony/expert witnesses is in the form of opinions based on scientific theory and not directly related to the case being examined. Expert testimony is neutral and does not side with anyone, but is expected to help find a causal relationship.⁵⁷

Informed consent, although there are no explicit rules that state it as evidence, but informed consent made on the basis of the theory of self-determination says that in principle doing an act on one's body without the consent of the owner of the body is an act that violates ethics, civil law and law. criminal acts, and even violates human rights so that formally informed consent can be used as evidence when a case is suspected of being malpractice.

In civil cases, evidence aims to give confidence to the judge about the events or the arguments put forward by the parties.⁵⁸In civil procedural law, the certainty of the truth of the events presented at the trial is highly dependent on the evidence carried out by the parties by submitting valid evidence specified in the HIR/Rbg. As a consequence, the truth is said to exist or is achieved if there is a match between the judge's conclusion from the results of the process and the events that have occurred. If what happens is the opposite, it means that the truth has not been achieved.⁵⁹

The act of proving has the intention of growing or adding confidence to the judge, therefore there are some general guidelines for judges to decide on the evidence presented in court. These guidelines include:⁶⁰

- a) A person proves that he has the right (Article 163 HIR)
- b) A person proves to strengthen his rights (Article 163)
- c) Someone proves to refute the rights of others (Article 163)
- d) Someone proves the existence of an event (Article 163 HIR)
- e) Because what needs to be proven is a disputed issue, which is not denied by the opposing party, it does not need to be proven;
- f) Facts that are known to the public (notoir facts) do not need to be proven;
- g) Because proving is to grow the judge's confidence, everything that the judge has seen in court does not need to be proven again.

Evidence in the trial at the Court of Medical Ethics Honorary Council recognizes the types of evidence consisting of:⁶¹

- a) Evidence documents

⁵⁷Abdullah, Legal Considerations of Court Decisions, Postgraduate Program at Sunan Giri University, Sidoarjo, 2008, Pg. 61

⁵⁸Elisabeth Nurhaini Butarbutar, Law of Evidence Analysis of the Independence of Judges as Law Enforcers in the Evidence Process, CV. Nuanasa Aulia, Bandung, 2016, Pg. 162

⁵⁹Elisabeth Nurhaini Butarbutar, Ibid

⁶⁰Munir Fuady, Ibid, Hlm. 43

⁶¹Syaiful Bakhri, The dynamics of the law of evidence in the achievement of justice, Raja Grafindo Persada, Depok, 2018, Pg. 227

- b) Medical record
- c) Drug or drug part
- d) Medical devices
- e) things
- f) Document
- g) Testimonials
- h) Expert testimony
- i) Instructions that are directly related to professional service or the doctor-patient relationship, each of which becomes the complainants or the parties.

The provision of information to postoperative patients developed in hospitals is to help sick people or patients so that they can overcome their health problems, especially speeding up healing of their disease. From a psychosocial point of view, people who are sick or their families are in a state of discomfort, pain, worry, anxiety, confusion and so on. Therefore, they really need help, not only treatment but also other assistance such as information, advice and instructions from hospital staff related to the problems they are experiencing.⁶²

Postoperatively, it is necessary to have perioperative nursing care to support medical actions. Perioperative nursing care, including nursing provided before (preoperative) during (intraoperative) and after surgery (postoperative). Perioperative nursing is carried out based on the nursing process and nurses need to determine strategies according to individual needs during the perioperative period so that patients get convenience from arriving until the patient is healthy again, so continuous nursing care is needed. Optimal nursing interventions and active participation of patients are expected to prevent postoperative complications so that patients can return to their best possible body level.⁶³

In the Declaration of Lisbon (1981) and the Patient's Bill of Rights (American Hospital Association, 1972) which essentially explains that patients have the right to accept and refuse treatment and the right to receive information from their doctor before giving consent. This relates to the right to self-determination as the basis of human rights and the right to information held by patients about their illness and what medical action the doctor wants to take with him.⁶⁴

In the therapeutic agreement, the hospital is responsible for unlawful acts committed by health workers who carry out health services. Likewise, doctors who in carrying out their professional practice are assisted by subordinates consisting of nurses, assistant doctors and so on. Therefore, for mistakes made by their subordinates, hospitals and doctors can also be held accountable for these mistakes based on Article 1367 paragraph (3) of the Civil Code.⁶⁵

According to Arrest Hoge Raad (January 13, 1919) unlawful acts include the notion of doing or not doing something that violates the rights of others and is contrary to legal obligations or decency or decency in society, both to oneself or to other people's objects.

⁶²Notoatmodjo, Health Promotion, EGC, Jakarta, 2005, Pg. 24

⁶³Potter and Perry, Fundamental Of Nursing, EGC, Jakarta, 2006, p. 102

⁶⁴Jusuf Hanafiah & Amri Amir, Medical Ethics and Health Law, EGC, 1999, Pg. 67

⁶⁵Veronika Komalawati, Ibid, Pg. 102

Based on the Civil Code, the alleged occurrence of civil malpractice is related to the implementation of a therapeutic agreement allegedly carried out by a doctor. Thus, a claim can be made:

- a. Default lawsuit based on Article 1239 of the Civil Code;
- b. A lawsuit against the law based on Article 1365 of the Civil Code;
- c. Claims for negligence causing losses based on Article 1366 of the Civil Code;
- d. The lawsuit for neglect of obligations under Article 1367 of the Civil Code.

Based on Article 1865 of the Civil Code, the problem of proof in civil law for a lawsuit states that anyone who argues that he has a right or to affirm his own rights or refutes the rights of others shows in an event that he is required to prove the existence of such rights or events.

Evidence that can be submitted according to civil law consists of written evidence, evidence accompanied by witnesses, suspicions, confessions and oaths as stipulated in Article 1866 of the Civil Code.

Sanctions for health workers who do not provide information to patients based on Article 19 paragraph (2), namely that administrative actions can be in the form of verbal warnings, written warnings, up to the revocation of practice licenses. Therefore, it is important for hospitals to make SOPs for health workers to provide information for patients. Thus, it has fulfilled the rights of patients and helped doctors to provide optimal services.

D. Conclusion

1. Whereas Informed consent is a standard agreement or standard in the form of a form, normatively it can be used as evidence to reveal suspected cases of medical malpractice, both as documentary evidence and as evidence in accordance with the Criminal Procedure Code Article 187 paragraph 4 letter b and Article 188 paragraph 2 and 3. Informed consent can be used as evidence in cases of malpractice, but from the legal teachings of evidence, it still has to be seen again regarding the requirements for something to be made into evidence, namely: (1) Allowed by law, (2) Reliability, namely the evidence its validity can be trusted, (3) Necessity, namely the evidence is indeed needed to prove a fact and (4) Relevance, namely the evidence has relevance to the facts to be proven. Informed consent as evidence is not only determined by the formal legal requirements but also depends on the judge's conviction.
2. The perception obtained from the judges is that informed consent can be used as evidence in the form of letter evidence. Doctors also mentioned that informed consent can be used as evidence in proving malpractice cases, although not all of them specifically mention the type of evidence. Both of these professions both consider that informed consent is not a stand-alone piece of evidence, but they still need other evidence to clarify existing medical facts.

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