The Function of Informed Consent in Therapeutic Transactions as a Form of Efforts to Prevent Malpractice Claims in Indonesia

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Abstract. The relationship between the patient and the doctor will create what is called a therapeutic transaction, which is an agreement that occurs between a doctor and a patient in the field of medicine (something that contains elements or value of treatment) which includes the fields of diagnostic, preventive, rehabilitative, and promotive. In this relationship, informed consent will be obtained, namely consent, permission given by the patient, freely and rationally, after hearing and understanding information about the medical action that should be taken. Informed consent has a role as a form of autonomous right to personal freedom. The relationship between the patient and the doctor does not always run smoothly and smoothly, there are times when problems occur, one of which is the emergence of alleged malpractice claims due to the patient not being satisfied with a therapy, this is where the role of informed consent is as an instrument in solving these problems. This legal research is normative, that is, it focuses on norms and legal materials. In this paper, we will discuss the function of informed consent and its application as an effort to prevent and minimize malpractice claims. In this study, the results showed that informed consent as a vital thing in maintaining a therapeutic transaction relationship, informed consent as an engagement between a doctor and a patient or a patient's guardian with a doctor's note that the doctor had implemented procedures and steps according to the medical code of ethics and medical steps.

Keywords: Informed Consent · Therapeutic Transactions · Malpractice

1 Introduction

Treatment activities in curing disease have been carried out by humans since ancient times, humans have always tried to find out the cause of disease and how to cure it. In the course of the history of life, medicine has created a relationship between the patient and the healer, in today's world we know the relationship between the patient and the doctor. The relationship between the patient and the doctor is based on a sense of trust, this is called a therapeutic transaction [1]. With the development of community dynamics, the relationship between patient and doctor has changed into a horizontal

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contractual relationship, namely a relationship that gives birth to legal aspects. The legal aspect is a legal relationship between 2 (two) legal subjects, namely between patients and doctors who are equal in nature resulting in the creation of rights and obligations of the parties concerned [2]. This legal aspect protects the parties from attempts to violate the law.

In guaranteeing the rights and obligations of patients and doctors, various procedures emerge in handling a medical action activity, one of which is called informed consent. In short, according to J. Guwandi informed consent is consent, permission given by the patient, freely and rationally, after hearing and understanding information about medical actions that should be taken [3]. In this context, doctors have an obligation to provide all information to patients about medical actions that should be carried out and their causes, and patients are given autonomy over their bodies to determine medical actions rationally and freely. In the Indonesian regulations regarding informed consent, it is mentioned in several regulations, one of which is Article 8 of Law Number 36 of 2009 concerning Health, hereinafter referred to as UUK, which stipulates "Everyone has the right to obtain information about his/her health data including actions and treatments that have been or will be received from health workers" (Health Law Number 36 Year 2009).

The relationship between patients and doctors does not always run smoothly and smoothly, there are times when problems occur in relation to this writing taking an example of problems in providing information before medical action is taken. In cases in Indonesia, it often happens that medical cases are given action information to immediately take severe medical action against competent people, both to patients who are aware, husband/wife, or parents about actions that must be taken immediately, but then between the parties start asking when it is felt that there are irregularities or discrepancies in the medical actions taken as an example of the patient being unconscious after surgery, these problems can lead to disputes.

There is another example of a problem. Based on the data, it is stated that in recent years there have been widespread reports of malpractice claims being reported to MKEK (Medical Ethics Honorary Council) since 2000. Prior to 2000, there were only 7–13 malpractice reports to MKEK. In 2000–2001 this number increased rapidly to 20–30 cases per year. The malpractice case that got attention was the case of Dr. Ayu cs who was sentenced by the Supreme Court for causing the patient Sisca Makatey to die, where in the trial it was proven that before performing a cito secsio cesarean operation on the victim, they did not convey to the victim's family about the possible outcomes. happened to the victim [2].

2 Formulation of the Problem

Based on the description of the background above, so that the discussion can be studied in a structured manner, the formulation of the problem can be described as follows:

1. How does informed consent function in therapeutic transactions?
2. How is informed consent as an effort to prevent malpractice claims?

3 Research Methods

Research methods are needed to find the truth, namely to solve legal issues that are being faced, so it takes the ability to identify problems, legal reasoning, analyzing legal problems so as to provide answers and solutions to problems. At the time of writing this research is included in the type of normative legal research that focuses on norms and legal materials. The nature of this research is descriptive analytical that is legal material can be described and described. Legal materials use primary legal materials, namely laws and regulations in force in Indonesia and secondary legal materials as supporting materials that provide explanations for premier legal materials including books, research results, legal opinions, and other documents related to the problem.

4 Discussion

4.1 Aspects in Research

Medical Aspect. In article 5 of the Indonesian Code of Ethics, it is stated that "every act or doctor's advice that may weaken psychological or physical endurance, must obtain the consent of the patient/family and only given for the benefit and good of the patient". The medical aspect in terms of informed consent is related to medical actions carried out by doctors including preventive, diagnostic, therapeutic, rehabilitative and invasive actions that have a high risk of requiring approval of medical action or informed consent. It is different with emergency/emergency events or government programs, medical aspects are carried out in relation to maintaining life or life saving, which does not require approval for medical action.

Ethical Aspect. In terms of ethical aspects, informed consent is closely related to biomedical ethical principles in the medical field. There are 4 principles of biomedical ethics, namely doing good (beneficence), not harming (non maleficence), respecting patient autonomy (autonomy), and fair (justice). Informed consent is a procedure that is in accordance with the principle of autonomy, that is, a person has the right and freedom to act and make medical decisions for himself. With the condition that they must be competent in choosing actions and making decisions against themselves so that they can be said to be individual autonomy. The Medical Ethics Code contains aspects related to the principles of autonomy and informed consent. Informed consent is an ethical procedure regulated by law and is closely related to daily health services. Important components required in informed consent are competent patient/family consent/refusal, clear and detailed information regarding the medical action to be taken, as well as information that consent was given without coercion [4].

Juridical Aspect. Every action that will be taken in the implementation of the Medical Action Agreement is guided by the existing laws and regulations, based on the standard medical action approval form. Medical Action Approval is regulated in various laws and regulations, namely Law no. 36 of 2009 concerning Health, Law no. 44 of 2009 concerning Hospitals, Law no. 29 of 2004 concerning Medical Practice, the Civil Code (KUH Perdata), Permenkes No. 290/Menkes/Per/III/2008 concerning Approval of Medical Actions. Informed consent from the legal principle of the agreement serves as

the fulfillment of the principle of consensualism which implies that since an agreement (consensus) is reached between the parties regarding the main contents of the agreement, the agreement has occurred. Both parties have been bound since the agreement was reached, to fulfill the obligations arising from the agreement and obtain their rights in accordance with the agreement or according to the applicable legal provisions [5]. However, there is a slight difference, namely the agreement is not the result of the service but the treatment of the medical best efforts carried out by the doctor. Therapeutic transactions are juridically defined as legal relationships between doctors and patients in professional medical services based on appropriate competencies based on certain expertise and skills in the health sector.

4.2 Functions of Informed Consent in Therapeutic Transactions

Article 39 of Law Number 29 of 2004 concerning Medical Practice stipulates "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." Medical practice in the regulation is a series of activities carried out by doctors and dentists for patients in carrying out health efforts. In medical practice will result in therapeutic transactions. The relationship between doctors and patients and sufferers which is carried out in an atmosphere of mutual trust (confidential), and is always filled with all emotions, hopes and concerns of human beings is the meaning of a therapeutic transaction. The legal relationship between a doctor or dentist and a patient in medical practice arises because of an agreement between the two parties, or is based on an agreement between them [6].

With the therapeutic transaction, an agreement or agreement arises which will later be called informed consent, the consent is given after the patient has received a complete explanation at least including the diagnosis and procedures for medical action, the purpose of the medical action taken, other alternative actions and risks, risks and complications that may occur as well as the prognosis of the action taken [5]. In short, according to J. Guwandi Informed consent is consent, permission given by the patient, freely and rationally, after listening to and understanding information about medical actions that must be taken [3]. For Guwandi, an important element in informed consent is a reciprocal communication process between doctors and patients [7].

According to the Indonesian Medical Council (KKI), [8] KKI emphasizes that informed consent is a unilateral statement from the patient or his legal representative, the contents of which are approval of a medical or dental action plan proposed by a doctor or dentist, after receiving sufficient information to be able to do so. make approval or rejection. In KKI, the essence of informed consent is holding detailed discussions with patients and documented in the medical record. There are 2 types of informed consent, namely according to J. Guwandi 1995 stated clearly (express), orally (oral) or in writing (written) and considered given (implied or tacit consent) under normal circumstances (normal) and in an emergency (emergency). If the patient experiences an emergency/emergency event or a government program, medical aspects are carried out to maintain life or life saving, no medical approval is required.

In the patient's medical record file at the hospital there is one sheet, namely the medical action approval sheet. This sheet will be filled out/approved by the patient or his/her

family after receiving an explanation from the health worker. The process of giving this explanation is referred to as informed consent [9]. The patient has the right to informed consent, which is to give an agreement to all diagnostic, therapeutic actions that are carried out on him after receiving the information, so he has the right to make decisions on getting information, has the right to choose various diagnostic/therapeutic actions for himself after receiving the information and have the right to refuse a therapeutic action [10].

The functions of informed consent according to Guwandi [3] include, (1) promoting individual autonomy rights, (2) self-protection of patients and subjects, (3) preventing fraud or coercion, (4) stimulating the medical profession to conduct self-introspection, 5) promotion of rational decisions, and (6) community involvement in promoting the principle of autonomy as a social value and exercising oversight in biomedical investigations. Of these six functions, Guwandi [3] describes two purposes of informed consent, namely: (a) to provide patient protection against doctor's actions that are not actually needed and there is no medical justification for doing it without the patient's knowledge; (b) provide legal protection to doctors against a failure and is negative, because modern medical procedures are not without risks and in every medical action there is a risk attached.

In Article 44 paragraph 1 points j and k of Government Regulation Number 47 of 2007 concerning the Implementation of the Hospital Sector, it is stated that the patient's right to receive information which includes diagnosis and procedures for medical treatment, the purpose of medical action, alternative actions, risks and complications that may occur, and prognosis on the actions taken as well as the estimated cost of treatment, giving approval or refusing the actions to be taken by the health worker for the disease he is suffering from; So it can be concluded that the patient has the right to obtain information, the right to obtain answers, the right to choose other alternatives, and the right to refuse.

It can be concluded that informed consent in a therapeutic agreement is the fulfillment of the principle of consensualism that fulfills the law of the agreement where based on article 1320 of the Civil Code it is stated that an agreement will occur when both parties reach an agreement. restoration of the patient's health [2]. According to Adami Chazawi, informed consent has a dual role, namely for doctors, informed consent is to make a sense of security in carrying out medical actions on patients, as well as informed consent acts as a means of self-defense against a possible claim or lawsuit from the patient or the patient's family if unexpected causes arise. desired, while for patients informed consent is an acknowledgment of their rights regarding the autonomy of their bodies by doctors and can be used as a reason for a lawsuit against a doctor if there is a deviation from a medical action by a doctor from the intention of giving approval or it is not in accordance with medical ethical procedures [6].

4.3 Informed Consent as a Form of Efforts to Prevent Malpractice Claims

The therapeutic agreement has its own characteristics that are different from the agreement in general, which is found in the object of the agreement. The object of this agreement is in the form of an effort or therapy for healing the patient. According to the law, the object in the agreement in a therapeutic transaction is not healing the patient, but seeking the right effort for the patient's recovery [5]. The therapeutic agreement between

the patient and the doctor does not include a resultaats agreement (an agreement that provides tangible results in accordance with the agreement) [11] because the agreement is not the result of medical services but the behavior and treatment of medical services. The patient and doctor agreement is included in the inspanningsverbintenis agreement (ie an effort agreement which means agreeing to make maximum efforts to realize what was promised) [11], because the doctor tries his best for the patient's recovery with records in accordance with medical ethics, procedures that can be accounted for.

In the development of community dynamics in the global era, the medical profession is a very complex community service. The ethics of the medical profession, which was originally able to maintain the image of doctors in carrying out their professional duties, seems to be getting weaker so that the government believes that it needs to be supported by legislation that is more binding on doctors [2]. The problem that often arises in medical business activities is malpractice lawsuits. Malpractice can occur when the results of medical action, medical actions that are not successful can occur due to forced circumstances or overmatch or caused by doctors who are not in accordance with the standards of the medical profession, another term is called negligence, this is the beginning of the term malpractice. The failure factors can be described as follows: (1) there is an element of negligence (2) there is an element of wrongdoing (3) there is an element of violation of professional or legal rules and (4) there is an intentional act that can cause harm [12].

The frequent occurrence of malpractice lawsuits, one of which is caused by people who do not understand or are unfamiliar with medicine and tend to focus on the results of medical actions, the public must know the legal basis of the agreement previously described regarding the inspanningsverbintenis agreement. It can be said that if all patients sue doctors with malpractice lawsuits, there is injustice in the medical profession considering the nature of the doctor-patient agreement is an inspanningsverbintenis agreement.

It is undeniable that the medical actions carried out by the doctor have medical risks because the patient's recovery rate is not always influenced by the doctor's performance, but also other factors such as God's will. In medical risk, the subject who is responsible is the patient. It is the patient who has to bear the loss. This obligation to bear is based on the fact that doctors have carried out medical actions in accordance with medical professional standards [2]. Medical procedures which include health maintenance, disease prevention, health promotion, disease treatment, and health recovery in accordance with professional service standards, professional standards, standard operating procedures, and health needs of health service recipients with results that are not optimal in the sense of death cannot be called malpractice.. That's where the important role of informed consent as an engagement between doctors and patients or patient guardians. The explanation of the informed consent given to the patient or the patient's family has been regulated in detail in the Minister of Health Regulation number 290/Menkes/Per/III/2008 concerning Approval of Medical Actions where in article 7 it is regulated as follows: (1) Explanation of medical actions must be given directly to the patient and/or closest family, whether requested or not. (2) In the event that the patient is a child or an unconscious person, an explanation is given to the family or the accompanying person; (3) The explanation of the medical action as referred to in paragraph (1) shall at least include: Diagnosis and

procedures for medical action; The purpose of the medical action performed; Alternative courses of action, and their risks; Risks and complications that may occur; and Prognosis of the actions taken; and Estimated financing.

Therefore, it is necessary to implement an informed consent mechanism as an effort to prevent malpractice claims due to ignorance and layman in the medical world. The purpose of informed consent is so that the patient gets sufficient information to be able to make a decision on the therapy or treatment that will be carried out. Informed consent also means making joint decisions. The patient's right to determine his fate can be perfectly fulfilled if the patient has received all the information he needs so that he can make the right decision [2]. Informed consent is also an embodiment of the right to self-determination, namely the final decision on one's own destiny according to complete information about all advantages and disadvantages taken in medical action.

5 Conclusion

1. That informed consent in a therapeutic agreement is the fulfillment of the principle of consensualism that animates the law of the agreement where based on article 1320 of the Civil Code it is stated that an agreement will occur when both parties reach an agreement, which is included in the inspanningsverbintenis engagement, namely an effort agreement which means agreeing to make maximum efforts to realize what was promised. Informed consent plays a role as a maker of security in protecting the rights and obligations between all parties concerned because it contains a) Diagnosis and procedures for medical action; b) The purpose of the medical action taken; c) Other alternative actions, and their risks; d) Risks and complications that may occur; and e) Prognosis of the actions taken f) Estimated financing.
2. Implementation of the informed consent mechanism as an effort to prevent malpractice claims due to ignorance and layman in the medical world. Because the purpose of informed consent is so that the patient gets enough information to be able to make a decision on the therapy or treatment that will be carried out. For doctors as a means of self-defense against a possible claim or lawsuit from the patient or the patient's family if undesirable causes arise. The important role of informed consent as an engagement between a doctor and a patient or a patient's guardian with a doctor's record has implemented procedures and steps according to the medical code of ethics and medical steps.

Suggestion

1. Providing understanding to the community that the relationship between the patient and the community is an agreement that does not refer to the results of healing but as a health service, behavior seeks maximum healing in accordance with the agreement based on a medical code of ethics, steps or procedures that are in accordance with medical medical actions so that it does not cause all harm. anything if there is no cure is considered malpractice.

2. Mutual awareness of the role of informed consent between doctors and patients is a right and obligation that is upheld. In an effort not to cause problems that can be detrimental in the future and can harm all parties.
3. Improved communication between patients and doctors, because communication is the main key in mutual awareness of the approval of medical action, so that it can run well, by improving better communication it will minimize the risk of malpractice demands in the medical field.

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