



The Role of Informed Consent in Therapeutic Transactions

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Abstract. The 1945 Constitution of the Republic of Indonesia (UUD 1945) in Article 28H stipulates that health is a right for every individual and all citizens are entitled to health services. In an effort to obtain health services or treatment, someone hereinafter referred to as the patient will be faced with health service providers, namely health workers, especially medical personnel (doctors). Therapeutic transactions basically contain various things related to healing efforts carried out by doctors for patients in health care facilities, where these efforts are based on the expertise and competence of a doctor. However, the current situation is no longer the same as it used to be where doctors have more space to carry out actions that are considered right without consent and even without the patient knowing what and how the healing efforts will be carried out. Along with the development of the times and the amount of information that can be accessed by the public, in the end it raises awareness of the existence of legal elements in the implementation of health services, which some individuals then make as objects to plunge health workers who are actually health service providers into the realm of law.

Keywords: Informed consent · Therapeutic Transactions

1 Introduction

The government's continued efforts in health development are aimed at raising knowledge of and motivation for leading healthy lives so that everyone can achieve optimal health levels. According to Law Number 36 of 2009 concerning Health, being in a condition of health permits one to live a socially and economically productive life and is also a state of being physically, psychologically, spiritually, and socially healthy. Article 28H of the Republic of Indonesia's 1945 Constitution (UUD 1945) states that everyone has a right to good health and access to medical care.

Healthy is an absolute necessity for everyone because healthy is the main capital to face the future and there is no future if it is not healthy [1]. To maintain and maintain one's health, a person will do various ways, but when he is not healthy or sick, the thing he always does is go to a health care facility to get treatment. In an effort to obtain health services or treatment, someone hereinafter referred to as the patient will be faced with health service providers, namely health workers, especially medical personnel (doctors).

Doctor as one of the energy health is obliged to seek, maintain, and improve health in a promotive, preventive, and rehabilitative manner by providing health services as stipulated in Article 51 of Law Number 29 of 2004 concerning Medical Practice regarding the obligations of doctors.

When a patient first visits a clinic or medical facility with a health problem, their relationship as patients and recipients of individual health services officially begins. Anamnesis, a type of initial examination that a doctor will undertake, is followed by a physical examination that results in a patient diagnosis. What type of medical intervention a patient need is determined by the findings of the diagnosis [19].

The therapeutic transaction is then used to describe the interaction between the clinician and the patient. Generally speaking, this therapeutic agreement is presented as a contract between a doctor and a patient that permits the doctor to take out actions to provide patients with health services based on the doctor's knowledge and expertise [2]. In carrying out their authority, doctors do not necessarily have the right to take any action that is in accordance with their authority and knowledge of the patient even though this is done in the context of healing. On the basis of a therapeutic agreement or contract that has occurred between a doctor and a patient which then causes the creation of a legal relationship followed by the fulfillment of rights and obligations.

The legal relationship between health professionals and patients is based on an agreement, which is also known as a therapeutic agreement or what is commonly referred to as an inspanning verbitenis agreement, wherein what is demanded in this situation is not an agreement of results but rather that the doctor will do his best to relieve the patient's suffering. Or resultaat verbitenis, but what is needed is the doctor to do his or her very best effort [10].

Not a few cases of medical disputes with allegations of malpractice which eventually arise due to lack of information received by patients and families regarding the steps for handling, any treatment and the risks of handling actions taken for the disease they are suffering from.

Before the therapeutic agreement can be put into practise, the patient's activity must first be approved by the health professional, doctor, or dentist. This is known as informed consent [5]. Along with the development of the times and the amount of information that can be accessed by the public, in the end it raises awareness of the existence of legal elements in the implementation of health services, which some individuals then make as objects to plunge health workers who are actually health service providers into the realm of law.

Based on the background that has been stated, the formulation of the problem in this paper is:

1. What is the Role of Informed Consent in Therapeutic Transactions
2. How are the ethical aspects of informed consent in health services
3. How is the juridical aspect of Informed Consent in health services

2 Discussion

2.1 Informed Consent in Therapeutic Transactions

The relationship between doctor and patient initially adhered to an established therapeutic relationship model, namely a paternalistic (family) relationship on the basis of trust. Such a relationship model certainly has a comparative advantage over a relationship model based solely on legal principles. However, if there is a conflict, the relationship model has a less clear concept of settlement [13].

The medical profession or other health workers in carrying out health services, both curing disease (curative), disease prevention (preventive), health recovery (rehabilitative), and health improvement (promotive), actually there has been a transaction or agreement between two parties in the health service sector that referred to as a therapeutic transaction, but this is sometimes not widely understood by health workers [6].

Therapeutic transactions basically contain various things related to healing efforts carried out by doctors for patients in health care facilities, where these efforts are based on the expertise and competence of a doctor. However, the current situation is no longer the same as it used to be where doctors have more space to carry out actions that are considered right without consent and even without the patient knowing what and how the healing efforts will be carried out.

Providing information about the overall condition and treatment plan that will be received by the patient must be given before the patient finally gives consent or refusal. According to Article 56 Paragraph 1 of Law Number 36 Year 2009 concerning Health, "Everyone has the right to receive or refuse part or all of the relief measures that will be given to him after receiving and fully understanding the information regarding the action, this is based on the fact that it is the duty of a doctor to communicate information regarding all matters pertaining to the patient, which is also his/her right that must be fulfilled.

The results of the process of providing information from doctors regarding medical efforts that can be done, including regarding all risks that may occur to give birth to an agreement/approval from the patient [1].

This agreement is then written in a document or sheet that is signed by the patient and or the family and the doctor who performs the treatment. This agreement is hereinafter referred to as the informed consent and documented in a file unit called a medical record where this medical record is the main door in health services, as a measure of patient satisfaction. This medical record unit will later be responsible for the management, data collection, processing and presentation of patient data into health information that is useful for decision making [15].

The development of informed consent in Indonesia cannot be separated from the development of similar problems in other countries. The Declaration of Lisbon (1981) and the Patient Bill of Right (American Hospital Association, 1972) essentially state that patients have the right to accept and refuse treatment and the right to receive information from their doctor before giving consent for medical treatment. This is related to the right to self-determination as the basis of human rights and the right of patients to obtain clear information about their illness and the actions and alternative actions to be taken. From this point of view, informed consent can actually be seen as a respect among health

workers for the patient's right to autonomy. Furthermore, this can also prevent or prevent fraud or coercion or from another point of view it can also be said that informed consent is a limitation of the doctor's authorization to the interests of the patient [12].

In accordance with Article 7 paragraph (3) explanation of the activity, authorisation of medical action from the patient is necessary in cases when a sickness necessitates specific medical care, according to Minister of Health Regulation Number 290/MENKES/PER/III/2008. Medicine contains the diagnosis, the method for taking medical action, the goal of that activity, any alternatives, potential risks and problems, the prognosis for that action, and an estimate of the cost. This authorization may be expressed verbally or in writing. This is based on the extent of the danger posed by the medical intervention made.

In addition to the laws and regulations, the implementation of Informed Consent has also been regulated by the Indonesian medical council where it is stated that there are several types of Informed Consent. Informed consent orally or in writing (Stated) or expressed consent An agreement that is given either orally or in writing through or signing a form of action approval document. Written informed consent is required for several procedures that are high risk and can significantly affect the patient's health. As stated in Chapter II Article 2, Regulation of the Minister of Health Number 290 of 2008 concerning Approval of Medical Actions that every surgical procedure (Operation) and other high-risk actions, must be with a written agreement signed by the person who wants to give consent while the implied informed consent or deemed to have been given (Implied Consent) Not done in writing or verbally but can be seen from the patient's movements or behavior which indicates that the patient agrees with the action to be taken without having to sign a written document.

Informed consent in health services is very important considering that the level of public knowledge is currently getting higher, medical procedures that have risks, both risks that arise that are unpredictable and the associated risks that will occur with respect to the actions taken, should be known by the patient and or his family. In addition to fulfilling the rights and obligations of both parties who are bound, the informed consent can be used as legal evidence if a dispute occurs. However, this informed consent does not necessarily protect health workers from legal entanglements.

Informed consent can protect health workers if what is stated in the informed consent has been carried out in accordance with standard operating procedures and professional standards, if in a medical dispute the health worker is deemed to have committed negligence and is proven to have caused harm to the patient, other provisions will apply such as administrative sanctions compensation, to revocation of practice licenses and registration certificates by the competent authorities after mediation has been carried out beforehand, as explained by doctors who have carried out their duties in accordance with professional standards, service standards and standard operating procedures are entitled to legal protection.

In order to protect themselves from lawsuits in the event of suspected malpractice, clinicians must comply with informed concentration and medical records requirements when practising medicine [18].

2.2 Ethical Aspects of Informed Concentration in Therapeutic Transactions

Health professionals and their patients have a therapeutic connection that gives rise to informed consent, which then attaches the rights and obligations of each party that must be honoured. The obligation of one party to contribute will come into conflict with another's right to receive, and vice versa. The interaction between rights and obligations is what gives birth to legal relations that will and must be regulated by law so that the function of law, namely the achievement of order (certainty) and order in human life in society can be realized. The rights of patients as users of health services will relate to the obligations of health workers to fulfill their rights [14].

In practicing health services, health workers, both doctors and other health workers, must always adhere to the code of ethics and professional standards in accordance with their expertise. Doctors as a health profession that was previously known to have a history where doctors are known to have some basic or fundamental qualities such as good and wise qualities, namely divinity, purity of intentions, nobility, humility, seriousness of work, scientific and social integrity, and colleagues who do not no doubt.

However, along with the times and science, it has the impact of increasing one's knowledge, but it cannot be denied that sometimes knowledge and knowledge that are already qualified are not accompanied by a person's behavior and ethics will be better and in accordance with the provisions of the grip on the philosophy of life of the Indonesian nation, namely Pancasila and the constitution. 1945, therefore Indonesian doctors, both professionally incorporated in the Indonesian Doctors Association, and functionally bound in organizations in the fields of service, education and health and medical research, issued the Indonesian Medical Ethics Code (KODEKI). Beneficence, non-maleficence, autonomy and justice.

The medical code of ethics is one of the non-penal efforts for the medical profession in carrying out medical practice [9]. A patient has the absolute right to receive accurate, unambiguous, and honest information, according to the rules set forth in the code of ethics and doctor's oath. It is specified in articles 7c and d of KODEKI. In addition to upholding the patient's confidence, a doctor must respect the rights of his patients, his colleagues, and other healthcare professionals. The rights in question are to the patient's ability to obtain information, agree or disagree with a course of action that will be conducted against him in accordance with article 7d. Every doctor must constantly be mindful of his duty to preserve human life. Information on the patient's condition and the proposed course of treatment should be provided.

The use of informed consent is another method of upholding patients' inherent human rights, specifically the degree to which medical professionals respect each patient's decision to accept or reject a medical procedure that will be performed on him freely, without coercion or pressure, and without fear. For the choices he had made. Even if the patient declines the medical treatment the doctor will administer, this does not compel the doctor to relinquish control or make an arbitrary decision regarding the nature of the legal relationship. A doctor is required by his doctor's oath and a medical code of ethics to perform his medical obligations in a way that upholds the dignity of the medical profession and is honourable and ethical.

2.3 Juridical Aspects of Informed Consent in Therapeutic Transactions

Legally speaking, the doctor-patient relationship is a therapeutic contract. In the world of medicine, both patients and doctors are usually aware that it is difficult for medical professionals to promise that attempts to treat patients will always be effective in accordance with the patient's or his family's intentions. The information they have acquired and their experience in treating diseases only allow doctors to use the maximum amount of care and caution.

A valid contract is one that satisfies the requirements set forth by law in order to be regarded as a legally binding agreement [10]. A legitimate agreement must meet the requirements of Article 1320 of the Civil Code, which are as follows:

- There is an agreement of will between the parties to the agreement (consensus);
- There is the ability of the parties to make an agreement (capacity);
- There is a certain subject matter;
- There is a legal cause.

If the provisions in Article 1320 of the Civil Code are applied in the context of a therapeutic agreement relationship, it can be explained that the agreement of will between the parties making the agreement (consensus) is the awareness of the patient going to the doctor at the health care facility to get treatment then the doctor with his competence seeks to perform healing. There is the ability of the parties to make an agreement (capacity) a doctor who has clear competence and a patient who has met the qualification requirements or is an adult (21 years old, married even though he is not yet 21 years old) or if he does not meet the qualification requirements then a representative must be represented. By his guardian, There is a certain thing (a certain subject matter) namely an attempt to heal and there is a lawful cause (legal cause) where the healing effort or action to be taken by the doctor is an action that does not conflict with the regulations.

The implementation of informed consent is closely related to the fulfillment of rights and obligations between doctors and patients. As a nation that upholds and recognises human rights, Indonesia guarantees public health rights in Article 28 H paragraph (1) of the 1945 Constitution, which reads, "Everyone has the right to live in physical and spiritual prosperity, to live in and obtain a healthy environment, and to have access to health services" [8].

The 1945 Constitution's provisions on the right to self-determination are governed by Article 28 A, which states that everyone has the right to life and the right to self-defense, while the provisions on the right to information are governed by Article 28 F, which states that everyone has the right to seek out, acquire, possess, and store information for the purpose of enhancing their personal and social environments.

The implementation of informed consent is an obligation that must be obeyed by doctors in every implementation of medical practice, especially in terms of giving certain medical actions to patients. Informed Consent is an initial requirement that must be met before carrying out a medical action, so that the actions taken by doctors are considered valid by law and can provide legal protection for doctors.

Some of the legal rules that form the basis for the implementation of the Informed Consent are, among others:

- Article 45 paragraph (1) of Law Number 29 of 2004 concerning Medical Practice which states that “Every medical or dental action to be carried out by a doctor or dentist on a patient must obtain approval”.
- Article 37 paragraph (1) of Law Number 44 of 2004 concerning Hospitals which states that “Every medical action performed in a hospital must obtain the consent of the patient or his family”
- Article 56 paragraph (1) of Law Number 36 Year 2009 concerning Health which 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 fully understanding the information regarding the action.”
- Article 58c of Law Number 36 of 2014 concerning Health Workers states that “Health workers in carrying out their practice, obtain approval from the recipient of health services or their families for the action to be given”
- Article 2 paragraph (1) of the Minister of Health of the Republic of Indonesia Number 290/Menkes/Per/III/2008 concerning Approval of Medical Actions states that “All actions to be carried out on patients must obtain approval”

Informed Consent according to the applicable laws and regulations as well as those outlined by the Indonesian Medical Council in the Medical Action Approval Manual has requirements so that it can be considered valid, and then it can be used as legal responsibility, including granting permission for operative actions on patients, namely:

The Patient Himself with a Note, the Patient is Considered Competent in the SENSE that:

- Able to receive information given to him in a clear way, using simple language and without overly technical terms;
- Able to trust the information provided;
- Able to maintain an understanding of the information for a long time and be able to analyze it, use it, to make decisions independently;

In the event that a patient is considered to have fluctuating competence or a patient whose competence is missing, the information provider/doctor must provide all the necessary assistance and record or document all decisions made when the patient is considered competent and re-assures that the decisions taken are consistent.

Closest family.

In an emergency situation (emergency), to save the patient’s life and or prevent disability, it is not necessary to consent to the patient’s actions if the patient is accompanied by the closest family, then approval can be requested from the next of kin in the following order:

- Legal Husband/Wife,
- Biological children,

- Biological father or mother,
- Siblings Or
- The defender.

With the signing of the consent form for medical action, there will be consequences, namely what is called the agreement of the parties who have bound themselves, there is an agreement to carry out medical action [11].

According to civil law, an agreement is a promise made by one person to another or a commitment made by two people to one another. The agreement is composed of a string of verbal or written pledges and takes the shape of a series of sentences. Another name for a contract is an agreement. As a result, every agreement constitutes a legal contract that is governed by the Civil Code. According to Article 1233 of the Civil Code, every engagement is created either through consent or by legal decree. In the doctor-patient relationship, the doctor makes a commitment to provide results in the form of the best medical care, and the patient makes a commitment to give accurate information or follow the doctor's instructions, among other commitments [6].

The condition of the patient under certain circumstances is sometimes unpredictable, if the patient is unconscious so that it is impossible for the doctor to provide information, the doctor can act or make medical efforts without the patient's permission as an action based on voluntary representation or according to the provisions of Article 1354 of the Civil Code called *Zaakwaarneming*. The definition of *zaakwaarneming* in Article 1354 of the Civil Code is to assume a person's responsibility until that person can once again take care of themselves. According to Article 1354 of the Civil Code, if a person voluntarily represents another person without being directed to do so, either with that person's knowledge or not, he has secretly agreed to continue and settle the matter so that the person whose interests are represented can conduct the business themselves. If someone is given explicit authority to act by a power of attorney, he is also required to fulfil all of his other obligations.

In situations that require immediate treatment which if not done will threaten the patient's life or emergency the doctor is obliged to take action even without the patient's consent. The best interests of the patient, and after the patient regains consciousness, the doctor is obliged to provide information about the medical actions that have been carried out and about all the possibilities that arise from these actions [18] In the engagement, the next action depends on the consent of the patient concerned.

According to Adam Chawazi, *Zaakwaarneming* is a form of legal engagement born by law, as is the case with *onrechtmatige daad*. *Zaakwaarneming* is not the cause of medical malpractice, in contrast to *onrechtmatige daad*, which gave rise to civil malpractice of doctors. Medical malpractice may result from failures to uphold a doctor's legal obligations resulting from *zaakwaarneming* if those failures result in patient losses. The patient in this situation is unconscious, perhaps as a result of a major accident, thus the action is done out in an emergency. Whereas in these situations, the patient needs immediate attention and cannot wait. When the patient's life is in danger as a result of delaying treatment, for example, the requirement to acquire informed consent can be lifted [4].

The formal legal relationship that develops between a doctor and a patient as a result of the legislation requiring doctors to treat patients. This indicates that there is

no requirement for initiative or even patient involvement, such as could be the case in an emergency, in order for this legal connection to exist. Because the patient lacks initiative or even participation, a legal relationship between a doctor and a patient that results from the law is unlikely to result in resultaat verbintenis (outcome engagement). The involvement that results from this is called inspanning verbintenis (commitment effort/effort).

In an agreement, in general, if there is a violation of the contents of the agreement from one of the parties, it is said to be a default, which then raises the question whether this happens in the context of a medical worker taking action but there is a risk that the medical agreement can be said to be in default or can it be equated that the act is a default because the work task has been carried out, then it cannot be said to be in default, but it can be said to be a default if the execution of the work is not in accordance with standard procedures [6]. Default if described in the view of the general public is identical to malpractice.

Not a few cases of medical disputes with claims for malpractice. Because the agreement that underlies the therapeutic agreement is a healing effort, it does not necessarily mean that doctors and health workers are said to be malpractice when the healing efforts are not in accordance with what the patient expects.

Informed consent belongs to the field of Medical Law, as a branch of Legal Science, so that Medical Law must also follow the legal system in general. In Law, there are three kinds of sanctions, namely administrative sanctions, civil sanctions (compensation), and criminal sanctions (corporate law, fines). And there are still sanctions in the field of Ethics and Discipline which include the authority of internal professional organizations that are not interfered with by law. If a doctor does not get approval for a legal medical action, then the impact is that the doctor will be in trouble [7].

- Criminal Law Touching or acting on a patient without consent can be categorized as an “assault”. This can be a reason for the patient to report the doctor to the police investigator, although this kind of case is very rare.
- Civil Law In order to file a claim or claim for compensation against a doctor, the patient must be able to show that he was not forewarned of a certain end result of the action in question even though if he had been warned beforehand then he certainly would not have done it, or show that the doctor has taken the action without consent (unlawful act).
- Discipline by the MKDKI If MKDKI receives a complaint about a doctor or dentist doing this, the MKDKI will try it and may impose medical disciplinary sanctions, which can range from a warning to a recommendation for the revocation of the Registration Certificate.

In law enforcement against health service providers, doctors and health workers are also not necessarily snared with punishment in accordance with the demands, health workers also get legal protection from the state as stated in article 29 of Law number 36 of 2009 concerning health which states “In the event that a health worker is suspected of negligence in carrying out his profession, the negligence must be resolved first through mediation”. From this article, it is hoped that in carrying out their noble duties as public health workers, they can better understand that in carrying out their duties a health worker will not do things that endanger the patient’s life, especially if this is done intentionally,

because in carrying out his duties there is a burden. Morals and ethics that are carried out by each health worker.

3 Conclusion

- The importance of an informed consent which is not merely a step to fulfill the rights and obligations of service providers and patients as stated in the legislation, informed consent which is carried out in accordance with the provisions, and actions in accordance with standard procedures and professional standards can also be protect health workers in the event of a medical problem or dispute.
- The legal relationship between doctors and patients occurs because of a relationship based on a contract, namely Therapeutic Transactions and Relationships by law. On the basis of this, both doctors and patients have rights and obligations that are jointly imposed to carry out. The form of the relationship because the contract can be due to a real contract (expressed contract) or an implied contract (implied contract). The achievements of the therapeutic contract in the doctor-patient relationship are not results achieved or healing (resultaatsverbintenis), but a genuine effort, maximum effort (inspaningsverbintenis).
- The relationship between doctors and patients must be established in such a way that there is no distance between doctors and patients for the sake of health service efforts that are burdened with rights and obligations that must be fulfilled. Doctors should build interactive communication while still upholding medical ethics towards patients or the relationship between the two is more as a partner so that patients feel more comfortable and treatment can be more optimal.
- Medical actions carried out without the approval of a valid medical action will have an impact in the event of a medical dispute, medical or health personnel will be threatened with sanctions, namely Administrative sanctions, Civil sanctions (compensation), and Criminal sanctions (corporate law, fines) and sanctions in the field of Ethics and Discipline which includes the authority of internal professional organizations that are not interfered with by law.

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