Informed Consent as Fulfillment of Rights and Obligations in Therapeutic Transactions Indonesian Medical Services

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Abstract- The informed consent principle functions to protect the autonomy and integrity of individuals who have the right to make their own choices freely for treatment to be carried out by doctors/medical personnel. According to MKDKI 80% of the 135 cases reported were caused by poor communication between doctors and patients. This study aims to analyze informed consent in therapeutic transactions as a fulfillment of rights and obligations for doctors and patients. The research was conducted in a normative juridical method, emphasizing the norms in legislation, theories, and doctrines related to health law, especially the study of informed consent. The data obtained is analyzed by the logic of deduction, taking into account the legal concept in the system of legislation. The results of the study find that urgency of informed consent is to protect and increase patient autonomy, protect patients and prevent manipulative and coercive actions and increase the attitude of self-awareness of the medical team. Therefore, medical personnel must be rational as both medics and moralists. Medical personnel needs to pay attention to the implementation of informed consent and standard professional practice in accordance with applicable regulations.

Keywords- Informed Consent, Patient Rights, Medical Services

I. INTRODUCTION

Indonesian society is a religious society, where Therapeutic transactions are an agreement carried out in the context of therapy, in this case therapy which is not only about health but also concerns all aspects of health, which are related to promotive, preventive, curative and rehabilitative. The term therapeutic transaction can be found in the Preamble of the Indonesian Medical Ethics Code (KODEKI) contained in the Decree of the Minister of Health of Republic of Indonesia Number 434/Men.Kes/ X/1983 concerning the entry into force of the Indonesian Medical Ethics Code which includes the following therapeutic transactions: referred to as therapeutic transactions is a legal relationship between doctors and sufferers carried out in an atmosphere of mutual trust and always overwhelmed by all the emotions, hopes and concerns of human beings. Therefore, it is explained, detailed or confirmed the enactment of a code of ethics to protect doctors and patients. Therapeutic transactions position the position of doctors and patients, on equal relationships with the hope that they will be able to provide legal protection for the parties, but in reality these norms have not been able to provide legal protection. [1].

According to the law, the relationship between doctors and patients is a relationship that originates from an agreement, whose object is in the form of medical services or healing efforts, known as therapeutic transactions. As in the general agreement, the therapeutic transactions also apply the general provisions of the Engagement Law as stipulated in Chapter III of Burgerlijk Wetboek/Civil Code [2]. The relationship between the doctor and the patient according to the law is a relationship between the business agreement (inspannings verbintenis) means that the doctor will try his best to provide medical services to the patient, and the doctor does not guarantee that he will always succeed in providing medical services [3]. In relation to therapeutic transactions, the position of the patient who was originally only as a party depends on the doctor in determining how to cure (therapy), has now turned into an equal party with the doctor. Doctors should no longer ignore consideration of the opinions of patients in choosing treatment methods, including whether to determine the need for surgery or not [4]. Although in reality on a therapeutic contract, the doctor is in a superior position compared to the patient, because of the “professional power” that affects the psychological and physical condition of the patient, the protection of this patient is built by heeding the principles of vulnerability. The criteria for determining someone is categorized in a vurnerable person, involving several aspects such as biology, economics, culture and so on. This vulnerability can be caused by disability, environmental problems, social injustice, gender, and unbalanced relations so that a person is not able to freely defend himself.

Even so in practice the implementation of informed consent problems arise such as a mother who is admitted to the ICU (Intensive Care Unit) in one private hospital because of experiencing "coma" and shortness of breath, thus requiring a breath aid called a ventilator. Where the doctor explained the use of the tool and the risk of not using the tool. But the doctor does not provide an explanation of how long and how much the cost will be borne by the patient's family related to the use of the ventilator. Notification (information) of medical action followed by informed consent, and even in one of the
hospitals in Semarang, mostly given and signed by the patient's family (85%) even though the patient is mature and in a conscious state, this is the same as research related to the medical record survey conducted in one of the private hospitals in the city of Semarang which showed that informed consent was mostly signed by the patient's family [5]. The case of Ratna Suminar complained about a hospital in the city of Cimahi, West Java because her son, Sepia Rizkiani, had suffered blindness for 18 months after receiving an IV in the forehead, even though Ratna refused the infusion when her child was treated [6].

According to MKDKI 80% of the 135 cases that were reported were caused by poor communication between doctors and patients, while the reasons for not being optimal were interviews between doctors and patients due to: from the doctor's side due to the busyness and routine work of the doctors, the doctors were less have time to provide all information, the number of patients faced by doctors every day may cause doctors to experience boredom or boredom in providing excessive information, the condition of patients who are both physically and psychologically causing difficulties for doctors, because if patients get too much patient information will be afraid or even shock so it can worsen the healing process, even fear, while giving too little information can cause misinterpretation. Seconds of health, 80 percent of doctors were referred to MKDKI because of miscommunication [7]. Based on the background of the problem, the formulation of the problem to be assessed is as follows:

**First**, how is informed consent in a therapeutic transaction in the field of medical services in Indonesia?

**II. RESEARCH METHOD**

The research method used for this research is normative juridical, by emphasizing the norms in legislation, theories and doctrines relating to health law, specifically the study of informed consent. The research specifications are descriptive. The data used in this study is secondary data with the main material in the form of primary legal material (statutory regulations). The data obtained is analyzed by logic deduction, taking into account the concept of law as positive norms in the national legislation system.

**III. FINDINGS AND DISCUSSION**

Therapeutic transactions begin with the decision of the patient or his family who chooses and visits a doctor based on his competence to treat his illness. The patient's visit is interpreted as an offer (aanbod) and is responded to by acceptance, aanvaarding the doctor through a medical ability that is stated expressly or implicitly, this is in agreement with the initiation of diagnostic actions followed by therapeutic measures. The stages in medical services require communication to obtain correct information on the patient's disease conditions, in fact, in Indonesia communication between doctors and patients is often not maximally utilized by the parties.

Regarding communication between doctors and patients, Steven said:

Information is power. Patients need information in order to make informed decisions about therapeutic and treatment options. The most accepted way of providing information to a patient is through the informed consent process. The patient is provided with the information needed to agree to have a procedure done. In some cases, very little information is needed. This is called simple consent [8].

Furthermore, in the implementation of therapeutic transactions, understand that the therapeutic transaction is a covenant or contract, as used in the term akad nikah which is translated into English as a covenant of marriage [9]. This means that even though the relationship between the doctor and the patient has the characteristics of the transaction as a transaction in general, the relationship is positioned more than the transaction in general. A doctor who accepts sick people as his patients, then the doctor has bound himself to that person, on the other hand the sick person expects certain services from the doctor to fulfill them. The doctor will do his best to cure the patient and the patient will follow the doctor's instructions (such as about medication), besides paying off the doctor's account directly or through insurance.

Informed consent is a matter that is very urgent/important to be implemented in accordance with the provisions that apply as a form of legal protection for doctors and patients. In the health world informed consent is a means of legitimacy for medical personnel to conduct medical interventions that contain medical risks and consequences, so that informed consent is not only useful for doctors but also useful for patients. For patients, informed consent is an appreciation of their rights and can be used as a reason for a lawsuit against a doctor in the event of a doctor's deviation from the intention of giving the medical action agreement.

Article 16 Regulation of the Minister of Health Number 290/Men.Kes/Per/III/2008 regulates the patient's refusal of medical action after the patient has received an explanation of the medical action to be performed and the procedure for rejecting the medical action. However, regarding the revocation and limits of the permissibility of an informed consent that has been granted by the patient does not yet have a legal rule. As is known that informed consent as a form of autonomy from individuals who give it and informed consent is given unilaterally, meaning that there is no obligation either from the agreement or from the law for the patient to give it. Therefore, giving informed consent is the right, even the absolute right of the patient so that if it cannot be revoked, then it is an injustice.
Informed consent is one pillar of modern clinical practice [10] [11]. In relation to health care, it is a general legal and ethical principle that valid consent must be obtained before commencing an examination, starting treatment or physical investigation, or providing care [12] [13]. Consent is the master concept that defines the law of contracts in the United States. First, consent expresses the primacy of individualistic values in our culture. To say that one cannot be bound by a promise that one did not voluntarily and knowingly make is to say that the individual should be the author of her own undertakings, that a genuine respect for her dignity requires a broad deference to her choices. Second, consent is instrumental to economic efficiency, a cherished value in American culture. According to neoclassical theory, which continues to dominate most academic thinking, a transaction increases one's welfare (and indirectly, social welfare) only when it results from one's informed, voluntary choice to engage in the transaction, or when it accurately mimics the choice that one would have made under those ideal conditions [14].

Meanwhile, Lokeh P. Nijhawan said:

The informed consent is described in ethical codes and regulations for human subject’s research. The goal of the informed consent process is to provide sufficient information to a potential participant, in a language which is easily understood by him/her, so that he/she can make the voluntary decision regarding “to” or “not to” participate in the research study [15].

In Indonesia informed consent emphasizes more on its sociality, namely the relationship between someone with the family and the surrounding community, so that when surgery or other medical actions are needed in the hospital, those who are asked to sign a permit are family and not the patient itself. At present informed consent has been accepted as a basic principle in health services, even though the context is often different. In the field of treatment processes and prospects for healing, doctors generally communicate with families, this condition is accepted by patients and families as a matter of course. Even though informed consent cannot be forced, if the patient demands his right so that the doctor provides information directly to him.

The function of informed consent is to protect and increase patient autonomy, protect patients and research participants, prevent manipulative and coercive actions, increase the attitude of self-awareness of the medical team, improve rational decision making, and involve the public in developing autonomy as social values and control of biomedical research. These functions are based on a number of moral principles, namely the principle of autoimmunity, beneficentia, nonmaleficentia, and utility [16].

Provisions of Article 56 and Article 57 of Law Number 36 of 2009 concerning Health, in Article 56 paragraph (1) which states that every person has the right to accept or reject part or all of the assistance measures that will be given to him after receiving and understanding information about the action complete, while paragraph (2) states that the right to accept or reject as referred to in paragraph (1) does not apply to: (a) sufferers of diseases whose disease can be quickly transmitted into the wider community; (b) the condition of someone who is unconscious; or, (c) severe mental disorders. Paragraph (3) states that the provisions concerning the right to receive or reject as referred to in paragraph (1) are regulated in accordance with the provisions of the laws and regulations. Article 57 paragraph (1) states that every person has the right to the secret of his personal health condition that has been stated to the health service provider, while paragraph (2) states that the provisions regarding the confidentiality of personal health conditions as referred to in paragraph (1) do not apply in case: (a) law orders, (b) court orders, (c) permits concerned; (d) community interests; (e) the interests of the person.

If it is associated with Law No. 29 of 2004 regarding Medical Practice, Information consent was directed to:

a. Respecting the dignity and dignity of the patient through the giving of information and approval of the actions to be taken,
b. Raising awareness, willingness and ability to live healthy,
c. Growing positive and good attitude, as well as professionalism in the role of physician (and dentist) in view of the importance of the dignity and dignity of the patient,
d. Maintain and improve service quality according to applicable standards and requirements [17].

As it is known that the law is needed as a means to balance the interests of the parties, because the legal purpose is to create order and justice. In the field of legal certainty health on physician and patient relationships in a therapeutic transaction will provide certainty in the implementation of a medical service, so it is not exaggerated if in a physician and patient relationship, the parties are required to understand and understand their rights and obligations respectively. One of the success of the health system development is the health service that can accommodate the doctors and patients' rights and obligations in a manner that will create harmonious health services [18]. Therefore, the culture of mutual respect and respect for the position of each party must be developed. Physician and patient relationships embodied in therapeutic transactions based on partnership principles are therapeutic transactions based on the equality of positions, transparency and mutual benefit between the parties.

IV. CONCLUSION

Informed consent in health services is to protect and enhance the patient's autonomy, protect the patient and
prevent manipulative and coercive actions, improve the self-esteem of the medical team. The protection of the right of the patient is to protect and enhance the individual autonomy, that in good relations between the physician and patient will prevent the occurrence of ignorance which inhibits the autonomy of the patient and/or his family to decide, which ignorance can come from lack of information or misunderstandings about such information. On the other hand, the informed consent function is to protect patients and subjects of research conducted by physicians/medical personnel on the diagnosis of a patient's illness; and provide protection in preventing the loss of the patient, especially unconscious patients, children, mental retardation and so forth.

Looking at the importance of informed consent in health services, in the event of a patient/family rejection to give approval then medical personnel should be rational as medics as well as ethical morally by considering the patient's condition, especially medical action categorized as extraordinary means

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