The Anatomy of Informed Consent that Provides Legal Protection for every Party

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Abstract — a doctor-patient relationship relies on two kinds of basic individual rights; right of self-determination and right to healthcare. These basic rights derive from patients’ rights to get information about their medical condition. This study discusses the importance of informed consent for any parties engaged in a therapeutic agreement. It resulted in several findings. First, informed consent is useful to provide legal protection for any parties that give medical services. Second, hospitals in Indonesia, particularly in Airlangga Hospital along with its stakeholders may have better understanding on their rights and obligations in respect to providing medical treatment to their patients, as well as making decisions. This study is a normative legal research. As a normative research, it uses statute and case approaches. The data resources to be used here is primary and secondary materials, which collected through library research on legal references that related to this study. This study concluded that informed consent can be defined as the recognition on the principle of equality between doctor and patient; The procedures of providing informed consent begins since the doctor provides information about medical treatment will be given to the patient or another legal relative; and they may approve or, otherwise, refuse the medical treatment.

Keywords — informed consent, therapeutic contract, legal protection.

I. INTRODUCTION

Health is one element of public welfare, and thus, the issue of healthcare is classified into national problem that should be immediately solved, given that people may not optimally do their activities when they suffer from either physical or mental illness. Therefore, having healthcare is one basic right that every individual should have.

The more advanced a nation comes more needs of a good healthcare. Looking into the national constitution of Indonesia, healthcare is the right for every people and it is assured by the constitution. The assurance on healthcare is based on Hippocratic and called therapeutic transaction [3]. This article mentions that every individual has the right to live well both physically and mentally, having a good place to live, and having a good and healthy living environment, as well as the right to get healthcare.

Having a healthy physical body is everyone’s dream. To get a healthy body, many ways are used, such as implementing a healthy lifestyle (as a preventive effort) and having medical treatment from appropriate doctors due to illness (as a repressive effort). Recently, medical treatment by doctors is an option for an individual (i.e., patient) suffering from an illness with a hope that they may get recovery from the illness they suffer through the doctors’ treatment [1].

Organizing medical practices is the core of medical treatment and healthcare by doctors, and it should correspond to the standard of medical profession and have very high moral ethics, the authority and competence as experts, certifications, license, and etc. It is consistent to H. J. J Leneen that:

“De formulering van de norma voor de medische professionele standard zou dan kunnen zijn: zorgvuldig volgens de medische standard handelen als een gemiddelde bekwaam arts van gelijke medische die in redelijke verhouding staan tot het concreet handlingsdoel” [2].

Parties that get engaged in healthcare involve doctors, patients, and hospitals. Those three components are the legal subjects in relation to both medical treatment and legal relationship. The object among those parties is healthcare itself. Doctors and hospitals provide medical treatment, while patients as the recipients of that treatment. The implementation of such relationship among those parties is organized in harmony through several regulations.

In the context of juridical field, a doctor-patient relationship is a kind of written agreement signed by patients as their consent. Otherwise, it indicates a surreptitious agreement.

A legal relationship between doctor and patient derives from a paternalistic relationship which progress involves some stages for the sake of medical treatment and based on Hippocratic and called therapeutic transaction [3]. In relation to doctor-patient relationship, it relies on two kinds of basic rights with individual nature, including the right of self-determination and the right to healthcare. Those rights carry on patients’ rights to get information on their medical condition [4].

After having complete and honest information about their medical condition along with particular medical treatment they may get, patients may give their consent to get particular medical treatment from doctor, and it is called informed consent. It has been set under the Regulation of Health Ministry No. 290/MENKES/PER/III/2008 about the Consent for Medical Treatment (later called Permenkes No. 290 Year 2008), particularly Article 2 that every medical treatment implemented to patients should be under the
In accordance to the introduction, the research problems of this study are as follow.
1. Informed consent in providing legal protection for any parties.
2. The procedures of providing informed consent to patients in hospitals.

II. RESEARCH METHOD

This study is a normative legal research (doctrinally legal research). As a normative research, it uses statute and case approaches, therefore it didn’t use any qualitative, quantitative, or mixed instrument for data collection. The data resources to be used here is primary and secondary materials which data collection is through library research on legal references that relate to this study. Library research is an instrument of collecting legal materials through written ones using content analysis [7].

This study uses deductive logics as data analysis technique. It process the legal materials in deductive way by explaining general things to take more specific conclusion.

III. RESULT AND DISCUSSION

A. Informed consent in providing legal protection for any parties

In relation to the doctor-patient relationship, the earliest model used in this relationship is paternalistic or paternal model [8]. In this models, the doctor ensures that patients receive the interventions that best promote their health and well-being, by using their skills to determine the patient’s medical condition and their stage in the disease process and to identify the medical test and treatment most likely to restore patient’s health condition. This model widely knowns to justified during the emergencies when the time to take the informed consent might irreversibly harm the patient, however, to this present this model rarely adopted by the doctor in doctor-patient interaction as an ideal for their interaction routine. As the development of the type of doctor-patient relationship, the current model that commonly used is deliberative model utilizing the informed consent by the patient or any parties on behalf of the patient considering the medical treatment given to the patient [9].

The definition of informed consent is actually a kind of communication relationship between doctor and patient in a hospital in relation to providing information by doctor to patients as their recovery effort. This definition is also lies a therapeutic relationship between doctor and patient into a framework of doctor-patient relationship and the emphasis on medical profession in conducting their medical treatment toward their patients.

Informed consent reveals based on a doctor-patient relationship in a therapeutic agreement. Each of the contracting parties has their own rights and obligation to fulfill. It indicates that doctors have an obligation to do diagnosis and provide the most appropriate medical treatment under their consideration, and patients along with their family have rights to decide which medical treatment to be implemented on their body [10].

A contractually legal relationship between doctor and patient does not begin when the patient come to see the doctor as everyone expects, otherwise, it begins since the doctor is available to give medical treatment through either oral or
Indeed, the theory of economy claims that human’s primary needs involve three aspects including food, clothes, and housing. However, health is another one. Without being healthy, people may not do their activities. Thus, in very broad meaning, health is considered as a human right which deals with social rights [15]. Following John Locke in his book entitled Second Treaties of Government: humans carry on principles as their innate rights within [16]. This book argues that the right of health is a basic right and may not be interrupted by anyone, including the state. This John Locke’s argument is consistent towards Bill of Rights in Britain which was very influential for civilized society.

Therefore, the classification of human rights actually consists of two parts. First, it refers to rights that directly derives from humane aspects in an eternally universal life and be tightly related to their dignity. Second, it refers to non-basic rights that derives from interpersonal aspects which is likely to be different and classified based on particular place, time, and condition.

The principle of informed consent doctrine is that patients have an autonomy right to decide what they want for medication [17]. In short, patients have the right to either accept or refuse any medication, and the right to get information from the doctor before they give their consent on any medical treatment they may get. It is related to human rights. Therefore, informed consent is associated to two human rights, as follow.

1) The right to self determination

After the doctor provided information that dealt with patient’s medical condition, the patient may give his/her consent. This consent is a manifestation of the right to self-determination. Based on the Regulation of Health Ministry of the Republic of Indonesia No. 585 Year 1989, the parties that give the consent are: a) legal-age patients in conscious condition and mentally good; b) the parents or relatives of under-age patient; c) the relative or curator of legal-age patient who is under amnesty; d) the parents or relative or curator of legal-age patient with mental illness; and e) the closest relatives of under-age patient and orphans, or the family is unavailable to give consent.

Patients do not have to agree with any medical treatment their doctor offers, as they have the right to refuse. However, the refusal is often due to particular factors such as their incompetence to pay the bill or the patients are afraid of the medical treatment they are going to have. Responding to such refusal, doctors have no right to force their patient. In this case, they should appreciate the patient’s right to self-determination.

2) The Right of Information

In this case, the one who is responsible to provide information to the patients about their medical condition along with its treatment is doctors. It means that doctors should provide their patients’ medical information, whether requested or not. The Regulation of Health Ministry No. 290/MENKES/PER/III/2008 about the Informed Consent, especially in Article 1 subsection (a) that informed consent for medical treatment is a consent the patient or the closest family of the patient gives after having a complete information about particular medical/dental treatment the patient will have. And,
Informed consent is basically a process of sustainable communication [20]. In addition to communication, informed consent seems abstract and ideological. In ethical context, informed consent is the attempt to implicitly ask the patients’ consent, and with their autonomy, the patients accept that the aim of medical treatment conducted to them is their own choice, not under other’s pressure. In this case, informed consent shifts the paradigm of making decision from doctor-oriented to patient-oriented. It requires a disclosure, and thus, doctors should get very clear information by, for instance, tracking the medical record of patient’s family.

A doctor-patient relationship is never apart from the process of transparent communication. Technically, however, it is not as expected due to distortion on language and culture. In this case, patients are passive ones with no good and systematic communication. Therefore, doctors may feel difficult to give appropriate answers as expected. When this happens, the doctors will ask for help from the patients’ family. However, it seems ineffective since, in particular culture, it is still taboo to share the history and medical condition of family member transparently to others (including doctors), and it is assumed as an intervention from private domain.

These facts show that not all patients are available to give information about their family and relatives. Understanding and realizing this problem, misunderstanding between doctor and patient can be avoided, and the final decision of this communication always relies on the ethics of medication. On the other hand, there is another objection against informed consent. Onora O’Neill, from Newnham College in Britain, argues that informed consent is only for patients who are physiologically and psychologically mature [21]. Toward the public policy in health sector, O’Neill argues that informed consent may inhibit the legislation for health sector since the policy should be publicly applied rather than personal. Whereas, informed consent should actually be personally applied.

Essentially, the difference between doctor-patient relationship and others is in the juridical nature. This relationship is a kind of agreement (i.e., verbintenis) which characteristics involve (1) consensual or agreement, that both parties (doctor and patient) agree to one another on medical treatment, and (2) fiduciary; this relationship is trust-based to one another [22], and thus, informed consent is classified into agreement.

Due to this categorization, informed consent leads to organizing a contract. An agreement is considered legal if it satisfies the terms and condition set under regulation, as mentioned in Article 1320 BW, otherwise, it may not be recognized by law although all the contracting parties has dealt with that. Based on the provision of Article 1320 BW, the terms that make an agreement legal involve (1) consent among parties, (2) proficiency, (3) particular issue, and (4) rightful cause.

Responding to this inequal condition between doctor and patient, it may take the principle of proportionality into account as the basic position between both parties. According to Agus Yudha Hernoko, the principle of proportionality in the process of organizing and implementing commercial business contracts has several functions. First, in the process of pre-contract, the principle of proportionality gives chances for negotiation among parties to do fair exchange on their rights and obligation. Therefore, we need to avoid any negotiation with no good
faith. Second, in the process of organizing a contract, the principle of proportionality ensures that the equality of rights and freedom to define/set the proportion of rights and obligations among parties can be fairly implemented. Third, in the implementation of contract, the principle of proportionality ensures the realization of exchanging rights and obligations based on the consensus within. Fourth, in case of a contract failure, it should be seen proportionally whether the failure is fundamental (i.e., fundamental breach) that disturbs the implementation of contract in most part or merely trivial one (i.e., minor important). Therefore, a test on the principle of proportionality is a determinant factor to define the proposition of contract failure. Hence, it should not be misused by one of the contracting parties to take benefits from such condition (i.e., the failure of the contract) for the sake of their personal interest which may violate another party. Fifth, in case of contract dispute, the principle of proportionality is useful to set the proportion of fault as the attempt to solve the dispute based on the principle.

The concept of proportionality as discussed above, the pattern of position between doctor and patient is proportional. Patients as ones that need doctors’ skills and expertise. This proportional position between doctor and patient corrects the contractual relationship between them, as it should be equal.

The content of a therapeutic agreement contains the statement of consent from patients or their family with full of consciousness and without any coercion toward particular medical treatment on them. The statement clarifies that the patient has been informed by the doctor about the characteristics, goal, risks, and the importance of a medical treatment the doctor will conduct to the patient. In addition, the pertinent parties (i.e., patient/the family, doctor, and hospital) should also sign the consent. It is to get the legality of the agreement for conducting medical treatment toward the patient, clarifying that both parties; doctor and patient, agree to what is contained in the consent.

The fixed procedures of implementing informed consent in hospitals contain several conditions [23].

First, in prior to the process of consent, the doctor should provide information to the patient/the family/the legal relatives that represent the patient about a set of medical treatment he is going to conduct, including diagnosis, the basis of diagnosis, medical treatment, the indication of the treatment, the goal, procedures, the risk of complication, prognosis, and another alternative risk.

Second, the explanation or information should be provided by the doctor that conducts the examination and treatment using a simple language with less technical terms in order to make sure that he will get an appropriate consent.

Third, the patient or the legal relative of the patient who gives the consent should be competent, 18 years old or more and married, physically and mentally healthy, capable to understand, analyze, and use the information to make decision.

Fourth, the informed consent should be independently provided without any pressure from anyone, including the medical staff, siblings, friends, police, insurance company, and etc.

Fifth, the competent patient has the right to refuse any medical treatment although the decision seems unreasonable. Therefore, it needs to check whether the patient sees his/her medical condition, the medical treatment and therapy that he/she should get along with any possible risks and side effects.

Sixth, the informed consent for implementing a medical treatment can be postponed by the patient or the legal relative due to various reasons. For instance, there are still some members of the family that do not agree, it deals with financial condition or the schedule of implementation.

Seventh, the informed consent for medical treatment remains legal until it is taken off by the provider of the consent. Patients may abrogate their consent whenever they want by making a written statement of abrogation of the agreement for medical treatment. The statement should be filed before the treatment begins to conduct, and the patient should be informed that he/she should be responsible to any consequence of the abrogation.

Eighth, the informed consent for medical treatment is provided in a form of informed consent and it should be signed by the patient or his/her family or legal relative and the doctor who gives the treatment and takes a set of medical conduct, and also other witnesses if necessary.

Ninth, in a condition of medical emergency and it is impossible to ask for the patient’s consent, and none of the family or relatives are available, the doctor may do a set of medical treatment for the patient’s interest without having any consent before, given that the information will be provided later.

The following figure briefly presents the procedures of informed consent, as follow:
Fig. 1. The Procedures of Informed Consent in Bahasa

IV. CONCLUSION

Informed consent can be defined as the recognition on the principle of equality between doctor and patient. This recognition of equality does not merely deal with private (individual) relationship, but also reaching a broader context that emphasizes the government’s participation in the implementation of health programs to reach higher level of health. Hence, informed consent does not only put the responsibility of medical professionality in individual manner, but also in relation to the consistency of government’s responsibility that corresponds to the constitutional mandate which is attempting to reach the assurance of equality in healthcare as the basic right of every people of Indonesia.

The procedures of providing informed consent begins since the doctor provides information to the patient or another legal relative that represent the patient about a set of medical treatment he is going to conduct including: diagnosis, the basis of diagnosis, medical treatment, the indication of the treatment, the goal, procedures, the risk of complication, prognosis, and another alternative risk. After having information from the doctor, patients and/or the family may approve or, otherwise, refuse the medical treatment. This is not apart from the basic principle of an agreement that puts the principle of proportionality in front as the basis of making an agreement, and both pertinent parties may have an equal position within.

REFERENCES


[9] Ibid., h. 2225


[13] Ibid.


