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Informed Consent in Indonesia

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Abstract
This study aims to determine the relationship between malpractice prevalence and patient's ignorance of the right to information, as well as obstacles that affect the implementation of the right to information, including how alternatives can be used to overcome obstacles in order to protect the interests of patients as recipients of health services and provide legal certainty to paramedics/doctors who provide health services. This research is normative legal research which is descriptive-analysis by using statute approach, comparative approach and conceptive approach. The results of the study found that therapeutic transactions were agreements between physicians and patients in the form of legal relationships that gave birth to rights and obligations for both parties. Information on medical action should be given to the patient, whether requested or not requested by the patient. Holding information should not, unless the physician judges that the information may harm the health of the patient. While the legal protection for the patient in relation to one of the rights of the patient that is the right to information of the patient can be found in some of the provisions in force in Indonesia, among others; Law of the Republic of Indonesia Number 8 Year 1999 regarding Consumer Protection, Decree of the Executive Board. IDI Number 319/PB/A4/88, Government of the Republic of Indonesia Regulation Number 32 Year 1996 regarding Paramedics, and Law of the Republic of Indonesia Number 29 Year 2004 regarding Medical Practice. Constraints in the delivery of information is a problem of language use difficult to understand by the patient, the limit on the amount of information that can be given is not clear.
Keywords: Informed Consent, Malpractice, Patient Information Right, Paramedics, Legal Protection

I. Introduction

The hospital as a health facility plays an important role to improve public health status. But sometimes the noble efforts of this hospital can bring havoc which ultimately deals with the courts. One important aspect of this relation is the relationship of patients to hospitals with an emphasis on ethical and legal aspects.

Basically, the relationship between physicians and patients in care approval rests on 2 kinds of human rights, ie:

1. The right to self determination
2. The right to information.

The right to self-determination is an important principle because it provides a position for every health care. The right to information in physician relationships with patients is reciprocal. Information should start from patients who explain well, clear and complete and answer questions from the doctor about complaints. Information has an influence on the quality of the diagnosis. Before the consent is given by the patient to the physician to take medical action against him the doctor first provides information relating to the illness suffered, and from the information a patient can determine whether he agrees or does not approve of medical actions that will be done by the doctor against him. It can be said that the information needed or given to the patient about his illness is crucial to the action to be performed by the dick against him. With information, a patient can determine what will be done related to his illness.

In the case of information given to patients, there are things that can be informed. Information given to the patient among others:

1. What illness suffered by the patient,
2. What medical actions will be performed related to the illness suffered by the patient,
3. Benefits to be gained from the medical action performed on the patient,
4. What alternatives will be done,
5. What is likely to happen if medical action is not taken against the patient,
6. The amount of cost required and problem solving if the patient is constrained on the cost issue (Wiradarma: 1996)

The information submitted to the patient is truthful, true information and do not cause confusion for the patient which will further increase the difficulty for the patient.

In turn, the physician based on the diagnosis should provide information clearly and adequately in a language that the patient can understand about what action to take, what risks, the likelihood of an unexpected outcome, what if the action is not performed, the prognosis etc.

It is intended that the patient based on the information provided will obtain a clear picture so that he can consider the proposed treatment from the doctor and decide whether or not to agree to treat. Approval for care without information concerning anything related to his illness is not lawful.

Legal protection for both those who receive and for those who provide health care becomes highly relevant. Doctors and hospitals need to be careful because with the growing health services and the increasing awareness of community law, masyarakatpun increased awareness about rights and obligations in the field of health services. Problems encountered often stem from the actions taken in health services by medical personnel that can cause harm to the recipient of health services. Doctors can be sued if the services provided cause fatal consequences. In order to avoid this undesirable thing, it is necessary to create a relationship arrangement of patients and doctors/hospitals.

The legal relationship between a doctor and a patient performed with a patient's sense of confidence in a doctor is termed a therapeutic transaction. Legal protection of the rights of patients in relation to medical information needs to be strengthened. This is because:

1. Absence of special provisions governing the rights of the patient.
2. The occurrence of medical malpractice by doctors
3. Patient's right to information in care approval.

Although legislation on health has been widely disbursed, it is unfortunate that Indonesia does not currently have a Medical Law which is the most important part of the Health Law.

Today Medical and Health Laws are still used interchangeably, as if they are synonyms. But if we look at the definition of the Netherlands seems clear difference. Health Law is broader than Medical Law.

Definition of Health Law:

"Black's Law Dictionary 5th ed., 1979 formulates: Health Laws are laws, ordinances or rules governing health standards, designed to protect public health".

According to Fred Ameln, Leenen formulated:

Health Law as "all legal provisions directly related to the maintenance of health and the application of civil law, criminal law, and administrative law in the relationship. In addition, International guidelines, customary law and jurisprudence related to health care, autonomous law, science and literature, become sources of health law" (Fred Ameln :1991).

Van der Mijn, in the book Fred Ameln formulated: The Law of Health as:

"A set of rules directly related to the provision of care and also its application to civil law, criminal law and administrative law".

And the Law of Medicine as "the science of studying the juridical relationship in which the physician becomes one party, the law of Medicine is part of the law of health".

From this definition, it can be deduced that Health Law (*gezondheidsrecht*) is wider than Medical Law.

If the scope of health law is concerned, it includes:

- Medical law,
- Nurse law,
- Hospital law,
- Environmental law,
- The law on industrial waste,
- Laws on pollution (noise, smoke, dust, toxic gas),
- Foods that damage health, equipment that can damage health, for example contain X-rays,
- Safety laws, and other regulations that are directly related and which may affect human health,
- Existing health laws that lie in the areas of criminal law, civil law and administrative law, whose application, interpretation and judgment of the fact lies in the medical field. Herein lies the difficulty of health law, because it implies 2 disciplines.

There is a field that deals with the laws of medicine, namely the so-called Justice Medicine. It should be distinguished between the medical judiciary (*gerechtelijke geneeskunde*) which includes medical discipline, and medical law (medical law) which includes the discipline of law.

Medical law material relies on 2 (two) principles, that is:

- The right to health care,
- The right to self-determination.

Health law in Indonesia is still weak so it's time to develop. This is considering the growing world of medicine on the one hand and the consciousness of society for their rights concerning health issues.

Problems such as malpractice events can not only be resolved through ethical or professional lines but also need legal aspect.

In addition, public complaints against health services, especially doctors lately tend to increase. Although the patient still shows his dependence and complete surrender to the doctor, but the doctor is regarded as a human being who cannot be separated from negligence and mistakes. And when we discuss the legal responsibilities of hospitals and doctors, it automatically correlates with the rights and obligations of hospitals

and doctors to patients. They are in essence a reciprocal relationship between patient and physician that is very unique and cannot be separated from human rights. Each patient has similar rights, obligations and responsibilities.

The relationship between doctors and patient is generally a contractual relationship. There is a contractual agreement between the physician's relationship with the patient and the contractual relationship occurring in the civil law arrangements, namely that the contractual relationship between the two parties is done legally to decide on a mutually agreed attitude. In conducting therapy between physicians to patients there is a direct bonding contract. Patients want to be treated and doctors agree to treat. For a valid contractual agreement there must be understanding and cooperation of the parties involved in the agreement. The patient has the right to refuse the examination, postpone approval and even cancel approval. If the patient refuses to take a medical action, the physician is obliged to provide information about the good of the action to the patient.

The doctor's relationship with the patient is a therapeutic relationship, which in the law is said to be an agreement to perform certain services. With this agreement is intended to get the results of a particular goal that the patient expected. The legal status of a physician in practicing his profession with practice is a very complex issue (Komalawati, 1999). In terms of medical law, the relationship between physician and patient can be included in the contract group. A contract is a meeting of minds of two people on a matter (*sollis*). The first party binds to provide services while the second receives service delivery. The agreement does not guarantee the patient's cure or benefit the patient, but the doctor will make every effort to provide the best service according to his or her ability to provide the best service for the patient. With this agreement it is hoped that the parties, both doctors and patients, understand their rights and obligations, so as not only to protect patients from the abuse of doctors, but also to protect doctors from the abuse of patients who violate the boundaries of law and legislation (malpractice). This form of agreement is now known as the approval of a medical act or Informed consent.

The term informed consent is commonly used in the legal world and for those who work in medical or healthcare settings, is generally familiar with informed consent and everything related to it. But it turns out there are still many people who do not know, even those who work in health care environment though. This becomes something that needs to be socialized properly and intensively, even people working outside the health care environment need to know it, because every human is almost certain to ever and will be in touch with health services. Informed Consent or approval of medical action, usually imagined and often we confuse with forms that must be signed by the patient or his family. It's as if the meaning is the same, but it does not mean that. In essence the Consent is a “Communication Process”. Not a form (Rozovsky). The form is merely a mere embodiment, confirmation or documentation of what was agreed upon first, when the patient is examined and where there is a dialogue between the doctor and the patient.

The fact is that in society not all understand about this informed consent, most people only know that informed consent is a form that must be signed if operation will be done only there, even among hospitals and health workers own understanding more or less almost that too. There is even an opinion that the medical personnel can be free from important lawsuits form informed consent has been signed. From such misunderstandings resulted in the phenomenon of the emergence of various malpractice demands of doctors that we see and witness in print and electronic media that most of the subject matter is derived from the ignorance of the public regarding the consent or informed consent and may also be exacerbated by the lack of explanation from the medical personnel themselves the approval. The purpose of this research is to know the application of approval of medical action.

II. Reseacrh Method

A. Approach Method

The approach method used in this research is normative legal research which is descriptive analysis by using statute approach, comparative approach and concept approach.

The method or procedure used to solve the research problem by researching the secondary data first, to then proceed with conducting primary research in the field. This research is supported by library research, that is researching secondary data. The juridical factor, is a set of rules of contract law in general and regulations relating to health or medicine law, which is actually a branch of jurisprudence and closely related to this research. While the empirical factor, is the patient at the Central General Hospital (RSUP) Dr. Wahidin Sudirohusodo Makassar as the party concerned in the implementation of this medical action agreement.

B. Population and Sample

The population in this study were patients treated at Makassar Hospital. In this study random sampling technique is used because the sample members can be selected randomly from the population that has been determined. It is also used Respondents that is by taking the subject based on a particular purpose. Respondents who became the source of data in this study were patients treated at Makassar Hospital.

C. Types and Data Sources

types and sources of data used in this study are primary data and secondary data. Primary data obtained directly

from the first source in the field through research, namely by distributing questionnaires. Also through official document documents, books, research results in the form of reports, diaries and so on that can be obtained from the research location. While secondary data in legal research consists of primary law and secondary law. Primary legal materials, in the form of binding legal materials in the form of laws and other implementing regulations that are the rules of the treaty laws and regulations in the field of medicine related to the approval of the act of medicine. Secondary legal materials, which provide explanations of primary legal materials, such as law books of treaties and engagements, and medical or medical law books, magazines, papers and others relating to the approval of medical action.

D. Data Collection Technique

Data collection will be done by conducting structured interview with question guide to the respondent. This is a data collection technique done by giving a set of questions that have been prepared to respondents to answer it.

E. Processing and Analysis of Data

After all the data collected by structured interview technique with question guide, then performed data processing by grouping data obtained from questionnaires that have been filled by the respondent according to the scope of the problem so that facilitate data analysis that will be presented as the result of research. Data analysis in this study was conducted qualitatively, that is from the data obtained then arranged systematically and analyzed qualitatively to achieve clarity of the issues discussed (Sugiyono, 2006). Qualitative data analysis is a method of research that produces descriptive data analysis, that is by explaining and interpreting logically and systematically data obtained from the research. Logical and systematic shows the way of deductive-inductive thinking and following the order in writing the reports of scientific research.

III. Result and Discussion

In connection with the provision of information to patients, should be noted several things:

1. Information should be provided, whether requested or not.
2. Information should not use medical term because it is not understood by ordinary people.
3. Information should be provided in accordance with the level of education, condition and situation of the patient.
4. Information should be provided in a complete and honest manner, unless the physician judges that the information may harm the interests or health of the patient or the patient refuses to be informed (KODEKI, Article 5)
5. For surgical measures (surgery) or other invasive measures, information should be provided by the doctor who will perform the surgery. If the physician concerned does not exist, then the information should be provided by another doctor with the knowledge or guidance of the responsible doctor.

The doctor's duty relating to information is to provide adequate and honest information to the patient about the need for the relevant medical treatment and the risks it may incur (KODEKI, Article 7b). One of the hospital's obligations to the patient is to provide an explanation of what the patient suffered and what action to take (KODERSI, Chapter III Article 10).

Article 52 of Law of the Republic of Indonesia Number 29 Year 2004 on Medical Practice, the patient shall have the right to have a full explanation of the medical treatment to be received whereby the explanation shall at least include:

1. Diagnosis and procedure of medical action,
2. The purpose of the medical action performed,
3. Alternative actions and risks,
4. Risks and complications that may occur,
5. Prognosis of the action taken. (Article 45, paragraph 3)

Implementation of Legal Protection of the Patient from Malpractice Medic

Basically the provisions governing the protection of the law for the consumer can be found in Article 1365 *Burgerlijk Wetboek* (BW) which contains the following provisions:

> "Every act against the law that brings harm to another, obliges the person because of the wrong to replace the loss".

Patients as health consumers have legal protection from possible irresponsible health care efforts such as neglect. So, the patient is also entitled to safety, security and comfort to the service he receives. The relationship between physician and patient can be regarded as the relationship between business actors and consumers which are generally regulated in Law of the Republic of Indonesia Number 8 Year 1999 on Consumer Protection. As a consumer, a patient has another right that is the right to be heard.

In Article 4 paragraph c of Law of the Republic of Indonesia Number 8 Year 1999 stated that the Right to Information is true, clear and honest, and from this article we know that the legal protection of the Right to Information of Patient has not been regulated explicitly in legislation. However, the legal protection associated

with it is regulated in several laws.

In the Medical Code of Ethics and Doctor's Oath are listed if a patient has the fullest right to obtain correct, clear and honest information. It is also contained in article 45 of Law of the Republic of Indonesia Number 29 Year 2004 on Medical Practice, concerning the need for consent of the patient prior to the conduct of a doctor's action in which the consent is provided by the patient both orally and in writing after obtaining an explanation or information about the medical action to be performed by the doctor. This provision does not represent all the provisions on the Right to Information of Patients, but it can be used as a reference in order to obtain legal protection against all matters relating to the right information.

A patient usually desperately needs honest and proper information from a doctor, but sometimes an obstacle in the delivery of information is a problem of language difficult to understand the patient, the limit on the amount of information that can be given is not clear, the problem of third-party interference.

Even the guarantee of legal protection can be seen in Law of the Republic of Indonesia Number 36 Year 2009 on Health, i.e.:

1. Everyone shall be entitled to compensation due to errors or omissions committed by health personnel
2. The compensation as referred to in paragraph (1) shall be carried out in accordance with prevailing laws and regulations.

From the rules of the article we can see about the right of patients to demand compensation for errors or omissions committed by health personnel, in the form of mistakes in providing information or omission by not giving advance information to the patient about the medical action that will do. The granting of a right to compensation is an attempt to provide protection for each person for any consequences arising, whether physical or non-physical due to errors or omissions of medical personnel. This protection is very important because the consequences of negligence or error may cause death or cause permanent disability. What is meant by physical loss is the loss or malfunction of all or some of the body's organs, whereas non-physical losses are related to one's dignity.

If a person as a consumer engages in a legal relationship with another party violates a mutually agreed agreement, then the consumer is entitled to challenge his/her opponent based on a default. If there is no agreement beforehand, the consumer still has the right to prosecute civil, namely through the provisions of the act against the law.

From these provisions are given the opportunity to sue as long as the four elements are fulfilled, ie there is an act against the law, there is a mistake made by another party or the defendant), there is a loss (suffered by the plaintiff) and a causal relationship between the error and the loss. According to Regulation of the Minister of Health of the Republic of Indonesia Number 290 Year 2008 Article 1, Approval of Medical Measures is the consent given by the patient or his family on the basis of an explanation of the medical action to be performed on such patient. In practice, often the term informed consent is equated with an operating license (SIO) provided by a health worker to the family before a patient is operated on, and is considered a written consent. Informed consent must be done every time will take medical action, no matter how small the action. According to the Ministry of Health of Health of the Republic of Indonesia (2002), the existence of informed consent is very important, because it contains a moral idea, such as responsibility (autonomy is inseparable from responsibility). Once the importance of this informed consent to the Government, in this case the Ministry of Health of Health of the Republic of Indonesia, issued the Regulation of the Minister of Health of Health of the Republic of Indonesia Regulation Number 290/MENKES/PER/III/ 2008 concerning Approval of Medical Measures. According to Minister of Health of the Republic of Indonesia Regulation Number 290/MenKes/Per/III/2008 Article 1 and Act No. 29 of 2004 Article 45 and the 2008 KKI Medical Action Agreement Manual, the Informed Consent is the approval of the medical action provided by the patient or his immediate family after obtaining an explanation complete on the medical action to be performed on the patient.

IV. Conclusion

1. Right to Information Patients are already widely regulated in various provisions in force, but there are still many irregularities committed by doctors. This is due to patient's patience with medical information. Information which, according to the Medical Practice Act, must be submitted by the physician to the patient, most of the information has been communicated to the patient either directly or through the question of the patient concerned. If there is a question of the patient or his family, then the doctor or hospital official tends to answer by dodging or by using medical terms that are difficult to understand by the layman. This means that the doctor's information to the patient has been given even though not fully in accordance with the provisions of Article 45 paragraph (3) of the Law of Medical Practice.
2. Legal protection for patients there have been regulatory provisions, but in practice many are constrained. Suppose that every case, there is always a problem in the proof.
3. Today, people are increasingly aware of their rights as health consumers. So often they critically questioned

about the disease, examination, treatment, and actions to be taken with regard to the disease, even if they rarely seek second opinion. It is a right that should be respected by the health service provider.

References

Guwandi J. (1993). *Tindakan Medis dan Tanggungjawab Produk Medis*, Penerbit Fakultas Kedokteran Universitas Indonesia, Jakarta.

Ilyas Amir. (2014). *Pertanggungjawaban Pidana Dokter dalam Malpraktik Medik*, Rangkang Education, Yogyakarta.

Isfandyarie Anny. (2006). *Tanggung Jawab Hukum dan Sanksi Bagi Dokter*, Prestasi Pustaka, Jakarta.

Soewono Hendrojono. (2007). *Batas Pertanggungjawaban Hukum Malpraktek Dokter Dalam Transaksi Terapeutik*, Srikandi.

Wiradarma. (1996) Hukum Kedokteran. Jakarta.

Rules:

Minister of Health of the Republic of Indonesia Regulation Number 290/ Men.Kes/Per/III/2008 on Approval of Medical Measures.

Decree of the Executive Board. IDI Number 111/PB/A.4/02/2013 about Implementation of the Indonesian Code of Conduct

Law of the Republic of Indonesia Number 29 Year 2004 on Medical Practice.

Law of the Republic of Indonesia Number 36 Year 2009 on Health.

Law of the Republic of Indonesia Number 36 Year 2014 on Paramedics