INFORMED CONSENT IMPLEMENTATION AT LEONA HOSPITAL IN KUPANG CITY

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ABSTRACT

Informed Consent is a patient's approval on medical action that will be performed on one after one has received a complete explanation of it. It is done to protect patients against all medical actions that are carried out without the patient's knowledge and at the same time provide legal protection to doctor against unexpected negative consequences, for example against the risk of inevitable treatment even though the doctor has tried his/her best and acted circumspect. Therefore, the principle of informed consent doctrine is a patient's autonomy right to himself to decide what is desired in the matter of treatment. It is an empirical legal research or non-doctrinal legal research. The data required is primary data obtained directly from respondents/informants, and secondary data obtained from the literature with data collection techniques are in the form of observations, interviews, document studies and group discussions. This study resulted in information regarding informed consent implementation at the Leona Hospital, Kupang City, and the obstacles faced in the informed consent implementation in the form of patient/patient's family being heterogeneous groups patient's perceptions of her/his illness, doctors' explanations contain medical technical terms, and the limited time. This study suggests that doctors are still obliged to provide information to patients either orally or in writing form and that doctors need to improve their communication skills with patients from different backgrounds so that the goal of delivering information to patients is achieved.

Keywords: Informed Consent, Doctor, Patient, Constraint

PRELIMINARY

Nowadays, many areas of life have been touched by law. It also has touched the field of health services in the form of its specialization, namely health law and medical law. This shows the importance of a legal provision and the function of health law, including medical law, in common life.

According to Fred Ameln, the functions of health law are[1]:

1. Legal certainty for providers and recipients of health services;
2. Legal protection for providers and recipients of health services.

Legal certainty for health service providers (health providers) in this case is doctors. There is legal certainty that doctors may carry out medical activities according to their expertise, and legal certainty for health service recipients (health receivers), legal certainty that those who carry out medical actions. These are health workers (doctors) who are really capable of doing it. Legal protection for service providers lasts as long as service providers carry out their professional duties in accordance with their respective professional standards and health service recipients need to receive legal protection even though they are in a position of ignorance of medical science.

Regarding health services, there is a legal relationship between doctors and patients. It is usually called a therapeutic transaction or a medical transaction[2]. The relationship is correlative, giving rise to the rights and obligations of both parties. Patients have rights including the right to information and the right to give consent. Article 8 of Law Number 36 Year 2009 concerning health, states: "Everyone has the right to obtain information about his health data including actions and treatments that have been or will be received from health workers". Furthermore, Article 45 paragraphs (1) and (2) of Law Number 29 of 2004 concerning Medical Practices, states:

(1) Every medical or dental action to be performed by a doctor or dentist on a patient must obtain approval.
(2) The approval as referred to in paragraph (1) is given after the patient has received a complete explanation.

That the doctor-patient relationship has the same goal, namely the patient's recovery. However, in reality the doctor - patient relationship, is asymmetrical[3]. Doctors have a higher relationship than patients due to they have medical knowledge while patients are laymen in the medical field and in need help/help from doctors. This does not mean that the patient understands everything that is suggested by the doctor, but rather that the patient believes that the doctor knows everything he is doing for the good of the patient[4].

In health law, the patient's right to information and the right to approve is called *informed consent*. *Informed consent* issue needs to be studied in depth through a study because it is an important part of a therapeutic transaction or medical transaction among doctors and patients. In fact, many *informed consent* issues are related to medical malpractice issues as well as medical treatment consent forms. This underlies the author to examine it through scientific research related to Informed Consent Implementation at the Leona Hospital, Kupang City.

[1] Fred Ameln in Husein Kerbala, Segi-Segi Etis dan Yuridis Informed consent, Sinar Harapan, Jakarta, 1993. P.24.
[2] Mukadimah, Indonesian Medical Code of Ethic.
[3] Irfan, Position of Informed Consent in Doctor-Patient Relations, De Lege Lata: Journal of Law, UMSU Faculty of Law, Volume 3 Number 2, July December 2018
[4] Solita Sarwono, Sociology of Health, Gadjah Mada University Press, Yogyakarta, 1993. P. 46

STATEMENT OF THE PROBLEM AND METHOD

Based on the background, then studied and analysed related to the implementation of informed consent, and the obstacles faced in the implementation of it at the Leona Hospital, Kupang City. Therefore, the urgency of this study is that the patient's right to information and to give approval (informed consent) is part of respecting everyone's right to self-determination, including the right to one's body integrity body as well as part of efforts to carry out legal functions that guarantee certainty and protection for providers and recipients of health services. Research strategies, namely textual studies, documents and field studies. Primary data sources are obtained directly from the results of field studies on doctors and patients in the implementation of informed consent, as well as the obstacles faced. Secondary data was obtained through reviewing the results of previous studies, document data of legislation regarding informed consent in the form of primary, secondary and tertiary legal materials. Data was collected by means of observation, in-depth interviews and focus group discussions.

THEORETICAL PERSPECTIVE

Relationship Between Doctor and Patient

The doctor-patient relationship is a trust relationship. Patients come to the doctors due their believe that the doctors are able to treat or cure their illness.

According to Thiroux as cited by Veronica Komalawati, there are three views of doctor-patient relationship: paternalism, individualism, and *reciprocal* or *collegial*[5]. According to paternalism, doctors must act as parents to patients or their families. It is because doctors have superior knowledge about treatment, while patients have limited knowledge, so they must trust doctors and should not interfere in the treatment they recommend. According to individualism view, patients have absolute rights over their own bodies and lives. In this view, any and all decisions regarding the care and treatment of patients, including the provision of health information are in the hands of the patient because the patient fully has the right to himself. According to the reciprocal or collegial view, patients and their families are the core members of the group, whereas doctors, nurses and other health professionals work together to do what is best for patients and their families. In this view, the professional ability of doctors is seen according to their knowledge and skills, and the rights of patients to their bodies and lives are not seen as absolute but must be given top priority. In this case, especially regarding the patient's right to obtain information about each procedure be based on consent after being given sufficient information.

According to Schepers and Nievaard as quoted by Solita Sarwono that based on the type of disease or patient's health condition, the doctor-patient relationship in general can be divided into three models: active-passive, leader-follower, and equal relationship[6]. The active-passive relationship model occurs when the patient is in a condition that does not allow reacting or participating in the relationship. In this case, the patient is really an object who only accepts whatever is given to him. The leader-follower relationship model will occur if the patient has an acute illness or infection, the doctor gives instructions while the patient obeys the instructions. The equal relationship model exists when the doctor helps the patient to help himself. The doctor gives advice/advice that the patient discusses in this relation, so that the patient is expected to actively decide what to do for his own healing and good.

The three models above, the leader-follower relationship model is often considered as a model that marks the doctor-patient relationship in general, and it is even suspected that it is still found in many doctors' practices in Indonesia[7].

Informed Consent

Definition

Literally, *Informed Consent* consists of two words informed and consent. Informed means having received information/explanation, while consent means giving approval/permitting. Therefore, informed consent means giving consent on the basis of previously obtained information.

According to Veronica Komalawati, informed consent is an agreement/approval of the patient on the medical efforts that the doctor will take against him after the patient has received information from the doctor regarding the medical efforts that can be taken to help him along with information about all the risks that may occur[8].

The Minister of Health Regulation of the Republic of Indonesia Number 290/Menkes/Per/III/2008 concerning Approval of Medical Actions, in Article 1 point 1 it is emphasized that the approval of medical action is the approval given by the patient or next of kin after receive a complete explanation of the medical or dental procedures to be performed on the patient.

Right to Information

One of the patient's rights is the right to information. In the relationship doctor-patient, it is the duty of the doctor to provide information/explanation to the patient, whether requested or not.

Article 7 The Minister of Health Regulation Number 290/Menkes/Per/III/2008 stipulates:

1. An explanation of the medical action must be given directly to the patient and/or closest family, whether requested or not.
2. In case the patient is a child or an unconscious person, an explanation is given to the family or the accompanying person.
3. The explanation of the medical action as referred to in paragraph (1) shall at least include:
   a. Medical diagnosis and procedures;

[5] Veronica Komalawati, The Role of Informed Consent in Therapeutic Transactions (Agreement in Doctor-Patient Relations) A Juridical Review, PT. Citra Aditya Bakti, Bandung, 1999. Pp. 46-47.
[6] Solita Sarwono, Op. Cit. Pp. 46-47.
[7] Hariman Siregar, Our Provider is Still Paternalistic (In Prisma No. 6 Year XIX), Jakarta. Pp. 71-73.
[8] Husein Kerbala, Op. Cit. P. 57.

b. The aim of the medical action performed;
c. Other alternative actions and their risks;
d. Risks and complications that may occur;
e. Prognosis of the actions taken;
f. Estimated financing.

Information function for patients is as a basis for giving approval to doctors, as well as protection for the patient to determine his own destiny (*the right to self-determination*). As for doctors, it can help smooth the medical actions, reduce the incidence of side effects and complications, can speed up the recovery and healing process of disease, can improve service quality, and can protect doctors from lawsuits[9].

Although the patient has the right to information, it is relative in certain case which means that there are exceptions. Those who are excluded from the right to information: patients who are not yet mature (not yet 21 years old), mentally ill patients, patients who are in an unconscious state (emergency). For such a patient, the information is given to parents, next of kin or the accompanying person.

Right to Consent

The information submitted by the doctor will be the basis for patient to considerate in giving consent or refusing to give consent. Therefore, doctors can only perform medical actions to the extent agreed by the patient.

The consent given by the patient can be in written or oral form. Written approval is used if the medical action carried out contains a high risk (Article 3 paragraph (1) of the Minister of Health Regulation Number 290/Menkes/Per/III/2008). Thereby, *a contrario*, any lower risk medical action is sufficient with verbal consent.

It is said that the right to give approval for medical/medical action is an adult patient who is conscious and mentally healthy (adult patient referred to here is 21 years old or married). Thus, for patients who are immature, unconscious (emergency), mentally ill or patients who are under guardianship, the consent is given by parents or next of kin, or those who deliver).

Theory About Informed Consent

Veatch puts forward three theories about informed consent in relation to experiments on humans in the field of medicine: the theory of benefits for patients, the theory of benefits for social life, and the theory of self-determination[10].

a. Benefit Theory for Patients (*Het nut voor de patient als theory over informed consent*) Experiments in medicine field are an integral part of patient service and care, which are systematically planned with the aim of acquiring medical knowledge. It means, any experimental carried out not in the patient's interests must be prohibited. The view of what is good and beneficial for particular patient is different one to another, because it really depends on the personal situation and condition as well as the values held by the patient concerned. In this regard, the provision of information to patients must be carried out in such a way that patients can participate in the process of designing and making decisions, even patients actively master it, so that the maximum benefit can be obtained.
b. Theory of Benefits for Socialization (*Het nut voor de samenleving als theory over informed consent*)
This theory focuses on utility view: the greatest benefit to the greatest number. The experiments implementation is permitted if based on certain considerations that the are more benefits than the disadvantage; and at the same time this experiment as a whole produces more benefits than the possibilities generated by the application of other methods.
c. Theory of Self-Determination (*de selfbeschikkings theory over informed consent*)
Eventhough, *informed consent* can sometimes increase the benefits for the patient, or for social life, the real purpose is more than that. Therefore, the existence of an individual's right to self-determination makes informed consent important for all actions taken on the body, even for violations of the private life atmosphere. Therefore, the self-determination right provides an autonomous basis for the informed consent requirement.

Constraints in the Implementation of Informed Consent Indeed

An Important element in the doctor-patient relationship regarding the implementation of informed consent is communication. According to Solita Sarwono, things that often hinder doctor-patient communication are the use of symbols (medical or scientific terms that are interpreted differently or are not understood at all by patient); pseudo-communication (continuing to communicate fluently when in fact the patient does not fully understand or has a different perception of what is being said); and non-verbal communication (face expressions, tone of voice, movements that affect understanding of the message/ information given).

DISCUSSION AND ANALYSIS

Informed Consent Implementation at Leona Hospital, Kupang City

In the previous section, it has been mentioned that informed consent is actually the approval of a medical action given by the patient on the basis of the information/explanation provided by the doctor. In this regard, communication amongst doctors and patients is very important.

[9] Ibid, Pp. 63-65
[10] Veronica Komalawati, Op. Cit. Pp. 111-112.

Table 1. Respondent Answers (Doctor) of Who Started the Conversation

Number	Started the Conversation	Frequency	Percentage (%)
1.	Doctor	4	66.7
2.	Patient/Patient's Family	-	-
3.	Sometimes Doctor/Patient or Patient's Family	2	33.3
	Total	6	100

Source: Primary Data, processed.

Table 1 data shows that 4 (66.7%) respondents are doctors who initiate conversations and 2 (33.3%) respondents answered that sometimes doctors and sometimes patients/patients' families initiate conversations, this means that both doctors and patients aware that information in doctor-patient communication is very important for the benefit of treatment and patient healing. That is, the patient/patient's family provides information about the disease and the doctor provides an explanation according to the examination result.

Table 2. Information Provision by Patients/Patient's Families (N=20)

Number	Respondent's Answer	Frequency	Percentage (%)
1.	Providing information to doctors	20	100
2.	Not giving information to the doctor	-	-
	Total	20	100

Source: Primary Data, processed.

The data in Table 2 states that 20 (100%) of the patient/patient's family respondents answered giving information about their illness to the doctor during the treatment interview. This respondent's answer supports the researcher's statement that information is significant in doctor-patient communication. Regarding the informed consent implementation, especially regarding the provision of information/explanations by doctors to patients can be seen in the following table.

Table 3. Respondents Answers (Doctors) in Providing Information/Explanations (N=6)

Number	Respondent's Answer	Frequency	Percentage (%)
1.	Giving information/explanation	6	100
2.	Does not provide information/explanation	-	-
	Total	6	100

Source: Primary Data, processed.

Table 4. Respondents' Answers (Patients/Patient's Families) in Providing Information/Explanations (N=20)

Number	Respondent's Answer	Frequency	Percentage (%)
1.	Get information/explanation	20	100
2.	No information/explanation	-	-
	Total	20	100

Source: Primary Data, processed.

The data in Table 3 and Table 4 show that 6 (100%) doctors answered giving information/explanations to patients/patients' families, as well as 20 (100%) respondents from patients/patients' families who answered that they received information/explanations from doctors. Therefore, it can be said that the doctor carried out his obligation to provide information/explanation for the patient/patient's family. In other words, the patient has received information/explanation from the doctor.

Furthermore, what things are informed/explained by the doctor to the patient/patient's family?

Table 5. Doctor Information/Explanation

Number	Items Informed/Explained	Frequency	Percentage (%)
1.	Diagnosis and procedures for medical action;	6	100
2.	The purpose of the medical action taken;	6	100
3.	Alternative actions;	6	100
4.	Risks and complications that may occur;	6	100
5.	Prognosis of the action taken;	6	100
6.	Estimated financing.	6	100

Source: Primary Data, processed

The data in Table 5 shows that 6 (100%) doctor respondents have attempted to provide information/explanation to patients regarding the matters regulated in Article 7 of the Minister of Health Number 290/Menkes/Per/III/2008 concerning Approval of Medical Actions: Diagnosis and Management method of medical action; The purpose of the medical action performed; Other alternative actions; Risks and complications that may occur; Prognosis of the actions taken; Estimated payment. The problem arises is, is the patient / patient's family understands well what the doctor explanation? Considering which explanation will be the basis for the patient in giving consent. The following is the response of patient respondents/patient families regarding the doctor explanation.

Table 6. Respondents Responses (Patients/Patient's Families) to Doctor's Explanations (N=20)

Number	Respondent's Answer	Frequency	Percentage(%)
1.	Understand	12	60
2.	Lack of understanding	5	25
3.	Do not understand	3	15
	Total	20	100

Source: Primary Data, processed

The data in Table 6 shows that 12 (60%) patients/patient families understand what the doctor explained, 5 (25%) stated that they did not understand, and 2 (15%) did not understand. The doctor's information/explanation becomes the basis for the patient in making a decision to approve or reject the medical treatment offered by the doctor. If the patient agrees, then the doctor can only carry out medical actions according to or limited to what the patient agrees. There are two forms of consent, namely written consent and verbal consent. What is the The basis for consideration of the patient / patient's family in giving consent, can be seen in the following table.

Table 7. Basis for Patient/Family Consideration in Giving Consent (N=20)

Number	Respondent's Answer	Frequency	Percentage (%)
1.	Doctor's explanation	12	60
2.	Patient Healing	8	40
	Total	20	100

Source: Primary Data, processed

Table 7 shows that 12 (60%) patients/patient families respondents answered that the doctor explanation is the basis for their consideration in giving consent. Meanwhile, 8 (40%) answered that the patient's recovery is the basis for consideration. If it is related to the data in Table 6, it can be said that even though the explanation is the basis for the patient/patient's family in giving consent, there are still patients/patient's family who do not understand or do not understand what is explained, they still give their consent. Their reason is the patient's recovery is the most important, not a matter of explanation. This was also stated by Mr. Andereas (Patient) and Mrs. Fitriningsi (Patient's Family) that "the doctor gave an explanation, but we did not understand everything, we have no idea about medicine. Thereby, we follow anything said by the doctor since the most important thing is the patient recovery"[11].

Furthermore, who gave the approval? The result revealed that normatively the patient has the right to give consent because he has the right to the integrity of his body, the right to self-determination.

Table 8. Respondents' Answers (Doctors and Patients/Patient's Families) in Giving Consent (N=26)

Number	Approving	Frequency	Percentage (%)
1.	Patient	26	100
2.	Patient Family	26	100

Source: Primary Data, processed

The data in Table 8 shows that both doctor and patients/patient families respondents (100%) stated that the patient's family had the right to give consent, but they also stated that consent could also be given by the patient's family. This can be accepted or justified because normatively those who have the right to give consent are adult patients who are conscious and mentally healthy because they have right to their body integrity. However, this patient's rights are not absolute in certain cases, means that they are relative because there are exceptions. Those who are excluded from the right to give consent are: Patients who are not mature yet (under 21 years old and unmarried), consent is given by parents or guardians or family; Adult patients who are under care (*curatele*), approval is given by curator; An unconscious state or in an emergency situation patients, if they are not accompanied by their families, approval is unnecessary and taken over by the doctor; Adult patients who suffer from mental disorders, consent is given by parents or guardians or family[12].

[11] Mr. Andereas' interview results on Saturday, November 3, 2018 and an interview with Mrs. Fitriningsi on Thursday, November 22, 2018
[12] Compare, Y. A. Triana Ohoiwutun, Anthology of Medical Law, Bayumedia Publishing, Malang. 2007, p. 41 and Husein Kerbala, Op. cit. Pp. 78-81.

The consent given can be in written or oral form. The data in Table 9 illustrates that if the medical action to be carried out is a high-risk or invasive medical procedure, written consent must be obtained. On the other hand, verbal consent is sufficient for non-high-risk medical procedures.

Table 9. Respondents' Answers About Forms of Consent (N=6)

Number	Medical Action	Approval Form	Frequency	Percentage(%)
1.	High risk	Written	6	100
2.	Not high risk	Oral	6	100

Source: Primary Data, processed

The written approval is given by signing a statement in the form of a prepared form, while verbal approval is given in the form of an agreement or a nodding head gesture which can be interpreted as an agreement.

Constraints Faced in Implementing Informed Consent at Leona Hospital Kupang City

Actually, *Informed consent* emphasises on two patient rights: the right to information and the right to give consent. In a correlative legal relationship, it will rise rights on one party and obligations on the another. Likewise, the doctor's legal relationship with the patient, the patient has the right to information, the doctor is obliged to provide information/explain. The *informed consent* implementation is not as easy as turning the palm of the hand, especially regarding the information/explanations giving. This is also revealed from the answers of doctor respondents in Table 10.

Table 10. Doctor Respondents' Answers about Informed Consent Constraints (N=6)

Number	Difficulties in terms of	Frequency	Percentage (%)
1.	Giving Information/Explanation	6	100
2.	Granting of approval	-	-
	Total	6	100

Source: Primary Data, processed

Table 10 shows that all doctor respondents stated that in implementing informed consent, the obstacles faced were related to providing information/explanations for patients/patient families and those from doctors, as:
1. The patient/patient family is a heterogeneous group;
2. The patient's perception to his disease;
3. Medical technical terms used in explanation;
4. Limited time.

Patients or patients' families are a heterogeneous group, in the sense that they come from different backgrounds such as education, age, occupation, and disease.

Table 11. Education Level of Patient /Patient's Family Respondents (N=20)

Number	Education Level	Frequency	Percentage (%)
1.	Doctorate (S3)	-	-
2.	Master (S2)	3	15
3.	Bachelor (S1)	5	25
4.	SMA/SMK	8	40
5.	Middle School	2	10
6.	SD	2	10
	Total	20	100

Source: Primary Data, processed

Table 12: Age of Patient/Patient's Family Respondent (N=20)

Number	Age	Frequency	Percentage (%)
1.	60-70 Years	3	15
2.	50-59 Years	6	30
3.	40-49 Years	4	20
4.	30-39 Years	2	10
5.	20-29 Years	3	15
6.	10-19 Years	1	5
7.	0-9 Years	1	5
	Total	20	100

Source: Primary Data, processed

The data in Tables 11 and 12 illustrate that the patient/patient family is a heterogeneous group. This condition is seen as one of the obstacles in the *informed consent* implementation, especially regarding giving information/explanations to patients/patients' families. It is said that, highly educated patients who have broad insight usually ask as much detail as possible about the patient's illness. On the other hand, low education patients who have lack of understanding of the doctor's explanation, usually surrender to the situation and thought of patient's recovery is the most important thing than the doctor's explanation (see also Table 7).

Another obstacle is the patient's perception of his illness[13], patients who have the perception that their illness will sooner or later lead to death, tend to agree to invasive and operative actions. The doctor's information/explanation will have not much influence on the patient's attitude to decide on the operation. Meanwhile, patients who give no attention to the disease while according to the doctor the disease is at a severe stage will not approve of invasive or operative actions.

Furthermore, the obstacle due to the using of medical technical terms in explanation. In providing information/explanations to patients, doctors sometimes use medical technical terms which cause patients understand nothing from his explanation. According to Rofinus (a patient with prostate), what was informed/explained by the doctor was not yet fully understood or understood because sometimes the explanation used medical terms. Furthermore, he said that although we could not understand well the doctor explanation, my family and I still gave our approval for the operation, solely for the sake of my recovery[14].

Another obstacle is the limited time. Regarding to informed consent, the doctor is obliged to provide a complete explanation regarding the diagnosis, therapy and alternative therapy along with the risks and benefits, prognosis, financing and others. Therefore, it takes 45 to 60 minutes to explain. Meanwhile, many patients are waiting (queuing) to be served.

CONCLUSIONS AND RECOMMENDATIONS

Informed consent implementation at the Leona Hospital of Kupang City has taken into account the applicable laws and regulations, such as Law Number 36 of 2009 concerning Health, Law Number 29 of 2004 concerning Medical Practice, and Law Number 44 concerning Hospitals, and has followed the mechanism stipulated in the Regulation of the Minister of Health of the Republic of Indonesia Number 290/Menkes/Per/III/2008 concerning Approval of Medical Actions.

Whereas, in the implementation of informed consent at Leona Hospital, there are several obstacles in terms of providing information/explanations to patients. They are: patients/patient families are heterogeneous groups which means that they come from different backgrounds in terms of education, age, occupation, disease; the patient's perception of the disease; explanations using medical technical terms; limited time thereby explanation is not fully explained.

Patients have rights, including the right to information and the right to give consent. Therefore, it is recommended that whether requested or not by the patient, the doctor is still obliged to provide information/explanation to the patient.

Consent for medical treatment given by the patient can be in written and oral forms. In this regard, it is recommended that the information/explanation from the doctor is not only delivered orally, but for certain diseases (casuistic) a short-written explanation is required.

Considering that the patient or patient's family is a heterogeneous group (different educational backgrounds, age, occupation, type of disease), the limited time to communicate with patients, doctors need to improve communication skills with patients so that the purpose of delivering information/explanations can be achieved.

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Law Number 29 of 2004 concerning Medical Practice

Minister of Health Regulation Number 290/Menkes/Per/III/2008 concerning Approval of Medical Action

[13] Ibid, P. 61.

[14] Interview results on Wednesday, November 21, 2018.

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