RESEARCH ARTICLE

INFORMED CONSENT IN HEALTH SERVICES: HOW ARE THE PATIENTS' RIGHTS PROTECTED?

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ABSTRACT

This study aims to analyze the rights of patient in medical services case on Batara Siang Hospital. This study was triggered by various problems regarding the privacy rights of patients in health services. Informed consent is an explanation by the doctor related to the condition of the patient's illness and the medical action that the doctor will take to cure the patient and then from the explanation explained by the doctor get the consent of the patient or the patient's family. Before giving emergency measures, the Batara Siang Hospital also applies an informed concentration Republic of Indonesia Health Minister Regulation Number 585/MEN.KES/PER/X/1989. This study revealed that Batara Siang Hospital always applies Informed Consent before taking medical or medical measures, but for emergency cases it is excluded because it concerns the lives of patients.

Keywords: Informed Consent, Patient Rights, Health Services, Privacy Rights

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INTRODUCTION

Law No. 44 of 2009 concerning Hospitals has been emphasized that hospital is a health service institution that conducts complete individual health services that provide inpatient, outpatient and emergency services, one of which is to provide protection to patient, community, hospital environment and human resources at home sick by continuing to improve quality and maintain hospital service standards. The relationship between doctors and patients formed in the community is a relationship that has been known since the BC era which is known since the discovery of Codex Hammurabi where the discovery regulates the obligations between doctors and patients (Ramadianto, 2017; Hidayati, 2018). A medical emergency is a condition that occurs unexpectedly and requires prompt treatment so as not to cause more severe damage. In this situation, the doctor has an obligation to immediately provide health efforts for the safety of his patients. However, in certain cases, medical emergencies require quite a risky treatment so that there must be responsibility for the patient. Therefore, medical approval is needed or known as informed consent.

Informed Consent comes from two words, namely *informed* which means that it has received an explanation or information and *consent* which means approval or giving permission (Nurrobhika, 2015). Doctors have an obligation to immediately provide health efforts for the safety of their patients. However, in certain cases, medical emergencies require quite a risky treatment so that there must be responsibility for the patient. Therefore, medical approval is needed or known as informed consent. Informed Consent comes from two words, namely informed which means that it has received an explanation or information and consent which means approval or giving permission (Nurrobhika, 2015: 28). Doctors have an obligation to immediately provide health efforts for the safety of their patients. However, in certain cases, medical emergencies require quite a risky treatment so that there must be responsibility for the patient.

Therefore, medical approval is needed or known as informed consent. Informed Consent comes from two words, namely informed which means that it has received an explanation or information and consent which means approval or giving permission (Nurrobhika, 2015). Informed Consent is a tool to determine the patient's own fate in medical action, so that patients can only give concrete approval if the patient can receive and understand the contents of information about the actions to be given (Komalawati, 2002). Approval of medical action is used as a form of guarantee or responsibility for an action and the consequences arising from the actions of doctors in providing health care to the patient concerned. Doctors in providing a health effort in medical emergencies require a legal basis to protect the doctor itself.

Approval of medical treatment is used as proof that the patient's family has agreed on the health efforts to be undertaken by the doctor in handling his patients. The agreement is made after the patient gets a complete explanation from the doctor about the diagnosis and procedures for medical treatment, the purpose of the medical action taken, other alternative actions and risks, risks and complications that may occur and the prognosis for the actions taken (Hanafiah, 2008). In diagnosing patients, doctors are required to provide explanations/information about matters relating to health problems experienced by patients correctly and honestly (Bertens, 2013). The principle of informed consent is made to respect human dignity that is free and autonomous where each human being is free to determine for themselves what will be done or will not be made as emphasized by Jackson (2009) the purpose of the medical action taken, alternative other actions taken (Hanafiah, 2008).

In diagnosing patients, doctors are required to provide explanations or information about matters relating to health problems experienced by patients correctly and honestly (Bertens, 2013: 141). The principle of informed consent is made to respect human dignity that is free and autonomous where each human being is free to determine for themselves what will be done or will not be made (Jackson, 2009) the purpose of the medical action taken, alternative other actions and risks, risks and complications that may occur and the prognosis for the actions taken (Hanafiah, 2008). This study analyzes the informed consent implementation in Batara Siang Hospital. Batara Siang Hospital is a regional hospital on Jl. Sultan Hasanuddin No. 7 Pangkajene, Padoang Doangan, Pangkajene, South Sulawesi. Batara Siang Hospital has a slogan committed to improving the quality of public services that focus on patient safety. Service facilities owned by Batara Siang Hospital include: emergency room, inpatient, outpatient, surgical, labor and perinatology, radiology, clinical pathology, physiotherapy, pharmacy, nutritional installation, laboratory, medical checkups.

One of the legal basis for approval of medical action or Informed Consent is contained in the Regulation of the Minister of Health of the Republic of Indonesia Number 290/Menkes/Per/III/2008 concerning Approval of Medical Action. In the event of a medical emergency, where there must be a risky treatment, Batara Siang Hospital carries out health efforts preceded by an approval of medical action or Informed Consent in accordance with the Regulation of the Minister of Health of the Republic of Indonesia Number 290 / Menkes / Per / III / 2008 Concerning Approval of Actions Medical. A doctor is very important to know Informed Consent, because the lack of doctor's knowledge related to the legal consequences of Informed Consent can lead to a lack of doctor's compliance in carrying out informed consent. Doctors who have good knowledge of the rule of law and the provisions of the application of informed consent, will consciously obey implement the Informed Consent (Khasna, 2016: 46). The full medical consent or informed consent will be explained in this journal.

THEORETICAL BASIS

Therapeutic agreements are agreements made between doctors and health workers and patients, in the form of legal relationships that give birth to rights and obligations for both parties (Cecep, 2010). Whereas Informed Consent is an agreement given by a patient or guardian who is entitled to the doctor to perform a medical action against the patient after obtaining complete information and who understands about the action (Haryani & Wen, 2016). In order for agreements made by doctors and patients to be legal according to the law, an Informed Consent is needed (Achmad, 2018). The implementation of invasive medical procedures must obtain the consent of the patient or family, manifested in the form of an Informed Consent document (Azwar, 1996).

In general the risks raised are those that can be understood by the patient in deciding a choice with other alternative medical measures, so only the risks and benefits that can be understood by the patient must be stated (Achmad, 2006). Approval of medical measures is needed to prevent something undesirable and to ensure legal certainty. The need for consent from the patient and to avoid having one of the injured parties, the doctor must provide information as clearly as possible so that patients can consider what will happen to him (Suprapti, 1994). Law No.29 of 2004 concerning medical practices listed in article 45 paragraph (1) states that "every medical or dental action to be performed by a doctor or dentist on a patient must obtain approval". Form of approval of medical treatment (Amril, 1997), namely:

- *Implied Consent* (considered given)
 In general, implied consent is given under normal circumstances, which means the doctor can catch the approval of the medical action from the cues given / carried out by the patient.
- b. *Expressed Consent*(stated) can be stated in oral or written form. In medical actions that are invasive and contain risks, doctors should obtain written approval, or what is generally known in hospitals as operating licenses.

Medical personnel who are in the position of service providers (medical providers) and patients as recipients of services (medical receivers) have the rights and obligations that must be respected, so, there needs to be an Informed Consent (Sakir, 2017). The purposes of the Informed Consent as highlighted by Guwandi (2005), are:

- a. Protect the patient against all medical actions carried out without the patient's knowledge
- b. Providing legal protection against unforeseen and negative consequences, for example against risk of treatment that is impossible to avoid even if the doctor has tried as much as possible and acted very carefully and thoroughly.

Furthermore, Pratita (2013) explained the procedure for providing Informed Consent information is as follows:

- a. The purpose of the informed consent is getting enough information to make a decision on the action to be carried out. The patient's right to determine his destiny can be fulfilled perfectly if the patient has received all the necessary information so that the patient can make a decision.
- b. The doctor has an obligation to inform the patient of the condition, diagnosis, differential diagnosis, supporting examinations, therapies, risks, alternatives,

prognosis and expectations. Doctors should not reduce the material to force patients to immediately make a decision.

- c. Not all patients may give statements, both agree and disagree. The patient must be an adult, with the age of 21 years, patients under 21 years in a conscious state, can be invited to communicate naturally and smoothly and in a healthy state of mind.
- d. The form of consent must be based on all elements of true informed consent, namely knowledge and competence. Some hospitals and doctors have developed for approval that summarizes all information and also permanent records, usually in the patient's medical record.
- e. All information must be received by the patient before the planned medical action is carried out. Providers of this information should be objective, impartial, and without pressure, after receiving all the information patients should be given time to think and decide on a balance.
- f. The process of providing information and requesting approval for medical action may not be carried out by a doctor, if the patient is in an emergency condition. In this condition, the doctor will prioritize actions in saving the lives of patients. However, the procedure for saving lives of patients is still carried out in accordance with service standards accompanied by high professionalism.

METHOD

This study uses qualitative methods, where this research is exploratory with a phenomenological approach. Qualitative methods are research procedures that produce qualitative data, about the person's own expressions, or notes or their observed behavior (Bogdan, 1993). This study allows researchers to obtain in-depth answers about people's opinions and feelings (Samino, 2014). The informant in this study was Dr. Annas Achmad, SpB is the Director of Batara Siang Hospital which was held on February 12, 2020.

INFORMED CONSENT (APPROVAL OF MEDICAL MEASURES) IN THE HEALTH LAW PERSPECTIVE

I. INFORMED CONSENT IN THE REGULATION OF THE MINISTER OF HEALTH ON APPROVAL OF MEDICAL MEASURES

Therapeutic agreement is an agreement between a doctor and a patient that gives the authority to the doctor to carry out activities to provide health services to patients based on the expertise and skills possessed by the doctor. In the Preamble of the Indonesian Medical Ethics Code which is attached to the Decree of the Minister of Health of the Republic of Indonesia Number 434 / Men.Kes / X / 1983 concerning the Applicability of the Indonesian Medical Ethics Code for Doctors in Indonesia, states about therapeutic transactions as follows:

> "Therapeutic transactions are the relationship between doctors and patients and sufferers carried out in an atmosphere of mutual trust (confidential), and are always overwhelmed by all the emotions, hopes and concerns of human beings".

Article 1 paragraph 1 of the Regulation of the Minister of Health of the Republic of Indonesia Number 290/Menkes/Per/III/2008 explaining Informed Consent or approval of medical action is approval given by the patient or immediate family after obtaining a complete explanation of the medical or dental action that will be performed on the patient (Permenkes, 2008). Approval of this procedure is aimed at competent patients (adults) or the immediate family/guardians of patients where these people are people who are entitled to approval of medical procedures. The patient's family in question is the husband or wife of the patient, the father or biological mother of the patient, the biological children and siblings of the patient as well as those who care for the patient concerned. Article 1 paragraph 6 of the Regulation of the Minister of Health of the Republic of Indonesia Number 290/Menkes/Per/III/2008 explained medical or dentist actions in this regulation are in the form of preventive, diagnostic, therapeutic or rehabilitative medical actions performed by doctors or dentists on patients. Doctors or dentists who deal with patients in this regulation are doctors, specialists, dentists and dentists who have graduated from medical or dental education both domestically and abroad that are recognized by the government of the Republic of Indonesia in accordance with statutory regulations (Permenkes, 2008).

All actions taken by a doctor on a patient must obtain approval where the consent is written or oral and before the consent is given, the patient or family must be given an explanation of the need for medical action. In cases where the patient's condition must be given a high-risk medical treatment, it can be in the form of oral consent in the form of an agreement or nodding head which is interpreted as a statement of agreement. However, if it is considered doubtful, written approval can be sought.

Approval of medical treatment is not necessary for situations where the patient is in an emergency, where the doctor acts to save the patient or prevent disability. Approval of medical action can also be canceled or withdrawn by the decision maker before the medical action starts where the one responsible for all impacts arising from the cancellation of the action is what invalidates the medical action.

Regulation of the Minister of Health of the Republic of Indonesia Number 290 / Menkes/Per/III/2008 concerning approval of medical measures, Article 7 (paragraph 3): Explanation as referred to in (paragraph 2) at least includes:

- a. Diagnosis and procedure of medical treatment;
- b. The purpose of the medical action carried out;
- c. Other alternative actions, and risks;
- d. Possible risks and complications; and
- e. Prognosis of actions taken.
- f. Estimated financing

The Authors added that related to the completeness in filling out the Informed Consent form. Quoting Herfiyanti's opinion, which states that completeness of completing the Informed Consent surgical form consists of: patient identity (patient's name, age, gender, address, medical record number), patient's family identity information (name of consent, age, sex, address, relationship with patient, date of consent), type of action, type of information (occupational diagnosis, differential diagnosis, medical action, indication of action, procedure, goals, risk of action, complications, prognosis, alternatives and risks, etc.), and authentication information which includes the name and signature of the doctor, the name and signature of the patient or family of the patient, and the names and signatures of witnesses (Herfiyanti, 2015). The function of the completed Informed Consent sheet can be used for various purposes. These requirements include as evidence in lawsuits, research and education materials and can be used as a tool for analysis and evaluation of the quality of services provided by hospitals (Oktavia, 2020).

II. INFORMED CONSENT IN BATARA SIANG HOSPITAL PERSPECTIVE OF THE REGULATION OF THE MINISTER OF HEALTH ON APPROVAL OF MEDICAL MEASURES

Informed Consent it is very important for the patient and the patient's family because Informed Consent is used as a guide or guide to the legal procedures of every medical action performed on the patient. This was stated by Dr. Annas Achmad, SpB.

> "Informed Consent is very important as a guide for legal procedures for every medical action performed. IC is a legal standing in performing medicinal measures on a patient both small and large procedures" (Personal Interview 12 February 2020 at 21.31 WIB)

How to deliver Informed Consent on Batara Siang Hospital services according to Dr. Annas Achmad, SpB. has been carried out according to existing standards that is in accordance with the rules of the Regulation of the Minister of Health of the Republic of Indonesia Number 290 / Menkes / Per / III / 2008 Regarding the Approval of Medical Measures in accordance with those stated namely:

> "The way to deliver informed consent to patients and families is to provide a form that has been set according to the standard, provide an explanation according to the request form, ask the patient and family to ask if there are still things to be known. IC is performed by doctors to patients and families where if the patient has agreed to the action taken, the patient or family, the doctor and two witnesses must provide a signature as proof of the purpose of the action. Likewise, if you refuse action" (Personal Interview 21 February 2020 at 21:25 WIB)

Dr. Annas Achmad, SpB. as the Managing Director of Batara Siang Hospital always applies Informed Consent before taking medical or medical measures, but for emergency cases it is excluded because it concerns the lives of patients. This was stated by Dr. Annas Achmad, SpB.

> "Informed Consent must be carried out before medical treatment except in emergency cases where if it is not done immediately then the patient is confirmed to be medically dead, for example such as cases of respiratory arrest and cardiac arrest" (Personal Interview 12 February 2020 at 21.35 WIB)

The exception of the Informed Concent is also justified in the rules of the Regulation of the Minister of Health of the Republic of Indonesia Number 290 / Menkes / Per / III / 2008 Regarding the Approval of Medical Measures as stipulated in article 4 paragraphs (1) and (2) where in article 4 paragraph (1) it reads "In an emergency, to save a patient's life and / or prevent disability there is no need for approval of medical measures" and article 4 paragraph (2) which reads "The decision to take medical action as referred to in paragraph (1) is decided by a doctor or dentist and recorded in the medical record" (Permenkes, 2008).

Medical record makers must also have competence where Medical recorder competence must be able to determine disease codes and actions appropriately in accordance with the classification in force in Indonesia (ICD-10 and ICD-9-CM), perform duties in providing high-quality medical records and health information services with due regard to laws and ethics applicable profession, managing medical records and health information to meet the needs of medical services, administration, and health information needs as material for decision making in the health sector (Ministry of Health RI, 2007). However, competence must not only be possessed by medical personnel, but also includes patients. A patient is said to be competent if he is able to understand the procedure, consider the risks and benefits, and make decisions according to his understanding and his personal values and goals (Kusmaryanto, 2015; Jafar 2020). In this regard, the responsibility of medical records for treating doctors is, among others, responsible for the completeness and correctness of the contents of the medical record (Suprapti, 2001).

Dr. Annas Achmad, SpB. As the Managing Director of Batara Siang Hospital has not found conflict because of handling emergency cases without Informed Consent as stated:

"I have never found a conflict due to handling emergency cases without Informed Consent" (Personal Interview 12 February 2020 at 21.40 WIB).

The special requirements for doctors who deliver Informed Consent are doctors who take the Informed Consent action themselves because the doctor has an understanding of what will be done and the impact that will be caused, as stated by Dr. Annas Achmad, SpB as follows:

> "Special requirements for doctors who deliver ICs are doctors who will immediately carry out the action themselves so that they

understand what and what if the action is carried out" (Personal Interview 12 February 2020 at 21.53 WIB)

The implementation of medical emergency we know that doctors have legal protection in carrying out their medical actions. How is the doctor's responsibility or what action is taken if the doctor negligence? Doctor in carrying out a medical action are responsible for what they do. The doctor's responsibility is to save patients who are in emergency cases that the doctor is holding on toStandard Operating Procedure (SOP) or Permanent Procedure (SOPAP). In accordance with stated byDr. Annas Achmad, SpB:

"The doctor's responsibility is to take medical action according to known standards or procedures. In every emergency case, anyone especially the doctor who is able to carry out compulsory actions to carry out medical help without IC because it involves the safety of someone who if not done, the patient will die immediately"(Personal Interview 12 February 2020 at 21.53 WIB).

The legal strength of the approval of medical action lies in the implementation of the approval of medical measures as stipulated in the law. If the approval of medical action is in accordance with the rule of law, then the approval of medical action will provide legal certainty for doctors (Amin, 2019: 10). Protection is not only for doctors, but also for patients because this informed consent will provide legal protection to patients and protect health workers / doctors from disproportionate demands from the patient (Hanafiah & Amri, 2012).

CONCLUSION

This study highlighted and concluded that therapeutic agreement is an agreement between a doctor and a patient that gives the authority to the doctor to carry out activities to provide health services to patients based on the expertise and skills possessed by the doctor. Preamble to the Indonesian Medical Ethics Code which is attached to the Decree of the Minister of Health of the Republic of Indonesia Number 434/Men.Kes/X/1983 concerning the Applicability of the Indonesian Medical Ethics Code for Doctors in Indonesia, stating the therapeutic transaction as Therapeutic transaction is the relationship between doctor and patient and patient carried out in an atmosphere of mutual trust (confidential), and is always overwhelmed by all the emotions, hopes and fears of human beings. In the context of Batara Siang Hospital,

this hospital has been running an Informed Consent in accordance with Permenkes RI Number 585/MEN.KES/PER/X/1989. Based on the statement from Dr. Annas Achmad, SpB. as the Main Director of Batara Siang Hospital, that the Batara Siang Hospital always applies Informed Consent before taking medical or medical measures, but for emergency cases it is excluded because it concerns the lives of patients. This is done to ensure the existence of legal certainty and prevent something that is not desirable.

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