

Written Informed Consent to Ensure the Rights of Patients in Medical Treatment in Indonesia

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ABSTRACT

Background: Recently, informed consent in medicine is increasingly necessary, a necessity made by doctors before carrying out medical actions, planned although exceptions are making informed consent before medical action, in certain circumstances.

Aim: To analyze written informed consent to ensure the rights of patients in medical treatment in Indonesia.

Methodology: This study using normative juridical research. The definition of normative juridical is a type of research that emphasizes more on library research, where the materials used will be obtained from laws, literature, mass media, which are related to writing materials.

Conclusion: The results showed that by using written informed consent, it is hoped that the patient will have guaranteed health assurance. This guarantee can be implemented in all hospitals in Indonesia, consider written informed consent to be necessary. At the very least, the hospital needs to have a standard written draft to provide informed consent and the proper procedures and workflow in terms of implementing informed consent.

Keywords: Informed Consent, Written Agreement, Protection of Patient Rights.

INTRODUCTION

As the most basic need for every human being, health is an essential factor in national development¹. For this reason, the government has made various efforts to improve public health status by fulfilling health facilities and providing health services fairly and equitably; this is explained in Article 4 of Law Number 36 of 2009 concerning Health (from now on referred to as the Health Law) which states that: "Everyone has the right to obtain safe, quality and affordable health services"².

Doctor and patient are two legal subjects related to medical law, both of which form both a medical relationship and a legal relationship³. The medical relationship and the legal relationship between doctor and patient are a relationship whose object is the maintenance of health in general and health care. In carrying out the relationship between doctor and patient, the implementation between the two is always regulated by specific rules, resulting in harmony in implementation⁴.

Patients as parties who need health services fully surrender their pets and health care to a doctor on the other side. When a patient comes to the doctor and states his complaint and is willing to listen to the patient's complaint, there is already an engagement relationship between them⁵. The arrival of a patient to a doctor's office, hospital, or another health facility can be interpreted as an attempt to offer the doctor help to overcome the complaint he or she is suffering. Vice versa, doctors will also perform medical services in the form of a series of medical diagnosis and treatment actions. This legal relationship is called a transaction, which in civil law is called an agreement, and in health services, it is called a "therapeutic agreement" or a therapeutic transaction⁶.

The legal relationship between doctors and patients, which is carried out with the doctor's trust, is called a therapeutic transaction. In the agreement law, there are 2 (two) types of agreements, namely⁷:

1. VerbintenisInspanning, namely an effort agreement, meaning that both parties promise or agree to make maximum efforts to realize what was agreed.
2. Verbintenis Resultaat, namely an agreement that will provide tangible results following what was promised.

Lately, the existence of informed consent in medicine is increasingly becoming a necessity, a necessity made by doctors before carrying out medical actions, planned although there are exceptions to making informed consent before medical action in certain circumstances⁸. However, it is still felt that not all doctors have implemented it according to existing provisions, perhaps due to the unavailability of an informed consent form containing the contents according to the needs of specific medical disciplines or not taking the time to make it⁹. The two main topics in informed consent, namely information and consent, have wide variations and are somewhat complex, involving various doctor-patient-family elements¹⁰.

The absence of informed consent can lead to doctors' malpractice, especially if there is harm or intervention in the patient's body¹¹. Common laws in many countries state that the consequences of not having informed consent are equivalent to negligence. However, in some cases, the absence of such informed consent¹². Equivalent to an act of deliberate action, so that the degree of error by the doctor who acted was higher. Therefore, written informed consent is needed as part of the confirmation of what has been previously agreed¹³. The purpose of a complete explanation is for the patient to make his own informed decision. Therefore, patients also have the right to refuse recommended medical treatment¹⁴. Patients also have the right to ask other doctors' opinion (second opinion) and the doctor who treated them¹⁵. From the problems above, this study aims to analyze written informed consent to ensure the rights of patients in medical treatment in Indonesia.

MATERIAL AND METHODS

In this study, normative juridical research was used. The definition of normative juridical is a type of research that

emphasizes more on library research, where the materials used will be obtained from laws, literature, mass media, which are related to writing materials. Besides the data obtained from the literature, the authors will also be described in this study's results. After getting the data using normative juridical, then the writer describes it in words into the research¹⁶.

RESULTS AND DISCUSSION

In the development of health development so far, there has been a change in orientation, both in values and thoughts, especially regarding efforts to solve problems in the health sector that are influenced by political, social, cultural, defence and security factors science and technology¹⁷. This change in orientation will affect the process of implementing health development. Health development must be carried out comprehensively or integrated and continuously in order to achieve optimal results¹⁸. Health development includes health promotion or promotion, disease prevention or prevention, disease cure or curative and health recovery or rehabilitative¹⁹.

To achieve the above goals, the availability of medical personnel (doctors and dentists) who are reliable and who understand well their rights and obligations is one of the determining factors in achieving the expected direction of health development. However, in carrying out the medical or health profession so far, there is one thing that is rarely realized by medical personnel, that when he accepts a patient to overcome health problems, either cure disease (curative), prevent disease (preventive), restore health (rehabilitative) as well as health promotion (promotion) there has been a transaction or agreement between two parties in the health sector²⁰.

Medical personnel understand that if they already have a certificate, they can practice and be ready to provide health services under the certificate they have. Primarily, if it is assigned to a hospital, puskesmas or other health service centre, there is only one in mind that must carry out the profession according to the assigned mission. It did not occur that there had been a transaction in the field of medicine (therapeutic)²¹.

Today, the relationship between doctor and patient has developed, which was previously a paternalistic relationship, leading to a balanced relationship between the two parties. This situation makes the relationship between doctor and patient a contractual relationship²². In a state balanced, patients have the freedom to make decisions and have the same position as doctors. This situation will be bound by an agreement established by both parties where each party concerned is required to carry out its roles and functions following each's rights and obligations²³.

The patient has a tremendous opportunity to take advantage of the patient's right to know all the procedures that the patient will undergo. In this era, the doctor-patient relationship is undoubtedly different from the paternalistic nature of the previous dominant relationship where patients only follow the decisions given by doctors and undergo planned procedures. Patients have the right to submit and obtain as much information as possible before deciding to follow a doctor's plan of action²⁴.

Through informed consent, it is hoped that the patient will have a guaranteed health assurance. In general, informed consent can be defined as a patient's consent to a doctor for a medical action to be performed after obtaining precise information about the action. According to the Minister of Health Regulation No.585 / Menkes / Per / IX / 1989, Informed Consent is the consent given by a patient or his family based on an explanation of the medical action to be performed on the patient. The objectives of informed consent, according to J. Guwandi, are:

1. To protect patients against all medical actions carried out without the patient's knowledge.
2. Providing legal protection to doctors against unexpected and negative consequences, for example, against the unavoidable risk of treatment even though the doctor has tried their best and has acted very carefully and carefully.

In an example of a lawsuit that occurred due to informed consent in an emergency measure, it was stated that in a hernia operation, the medical personnel found that the patient's left testicle was heavily infected²⁵. For a successful hernia operation, a heavily infected (unwillingly or unwilling) testicle must be removed. Medical personnel were sued in court because there was no explicit consent to an extended operation. The medical staff's advocate said that the operation's expansion was necessary for the patient's health and justified his survival²⁶. The removal of the testicles is only done for the patient's benefit and is a logical measure to postpone the operation. In that case, the judge confirmed the medical personnel's actions because the decision to remove the testicles was in the patient's best interests. It is not true that the medical personnel does nothing in these situations and conditions²⁷.

Problems regarding the consent to medical action or informed consent that occur in Indonesia include Nina Dwi Jayanti, a patient at CiptoMangunkusumo Hospital Jakarta who has been operated on without the consent of her family. Initially, this 22-year-old girl complained that she could not defecate, then came to the hospital on 15 February 2009²⁸. Then, the doctor gave her medicine to smooth her bowel movements. However, the drugs did not work. The doctor then estimated that Nina's complaint was appendicitis. A doctor also carried out the operation without asking the consent in the family's accordance with the procedure for performing surgery²⁹. After the operation, it turned out that the doctor's suspicion was wrong. Nina does not have appendicitis. The doctor then decided, based on the diagnosis, that Nina was suffering from a bladder leak. Then the doctor operated again without asking the family's consent as before. You can see that Nina's surgery marks; there are about ten stitches on Nina's stomach. The family can only surrender and ask the hospital to take responsibility. Nina's father, who works at the hospital, will report this case to the Minister of Health and is ready to lose his job. Finally, the court decided that the CiptoMangunkusumo Hospital pay compensation of one billion rupiahs.

In Minister of Health Regulation No. 585 / Men. Kes / Per / IX / 1989 article 11 states that only patients who are unconscious or unconscious are the only exceptions. Nevertheless, some experts criticize if the patient is

conscious but in an emergency. In Minister of Health Regulation No. 290 / Menkes / Per / III / 2008 article 4 paragraph (1) clearly and clearly that "states In an emergency, to save a patient's life and / or prevent disability, approval of medical action is not required". In addition to the provisions stipulated in Law No.29 of 2004 concerning Medical Practice and Regulation of the Minister of Health No.209 / Menkes / Per / III / 2008, if the patient is in an emergency so that the doctor may not submit an informed consent, then based on the Civil Code article 1354 medical treatment without patient consent is permitted. This action is called *zaentukarnerning* or voluntary guardianship, which is "If someone volunteers without being asked after taking care of other people's affairs, either with or without the person's knowledge, then he has secretly tied himself up to continue the matter so that the person is able to take care of it himself". In such circumstances, the engagement that arises is not based on a patient's consent but based on an act according to law; namely, the doctor must take care of the patient's interests and possible. So the doctor is obliged to provide information about the medical action he has done and all the possibilities that arise from that action.

Patients have individual fundamental rights in the field of health (the right to self-determination). The same fundamental, but the right to health services is often considered in the doctor-patient relationship; the patient is relatively weak, incapacitated. Patients to defend their interests in health care situations create a need to challenge patients' rights in dealing with professionals health³⁰.

Information that must be provided to patients or their closest relatives is regulated in Article 7 paragraph 3 of Regulation of the Minister of Health Number 290 of 2008 concerning Approval of Medical Action, which at least includes: (a) Diagnosis and procedures for medical action; (b) The purpose of the medical action being performed; (c) Other alternative actions, and their risks; (d) Risks and complications that may occur; and (e) Prognosis of action taken (f) Estimated financing³¹.

When a patient comes to the doctor for a check-up, the legal relationship between the patient and the doctor is essentially a service buying and selling relationship that is identical to the relationship between producers and consumers. Patients have status as health services consumers, while doctors or health workers are sellers of health services. This engagement relationship is known as a therapeutic agreement or therapeutic transaction³².

In therapeutic transactions, patients have the same position as doctors or health workers. The patient has the right to determine what medical actions can and should not be done on his body. The patient's right to his own body is one of the human rights, in which Munir Fuady classified it as one of the rights under the umbrella of the right to self-determination or the right to self-determination. No matter how great a doctor is, it is still not permissible to take medical action against his patient if he does not get approval³³.

In deciding whether to approve the medical action or medical procedure, the patient needs to get sufficient information from the doctor. The process of providing information by the doctor, which is then followed by the

patient's medical action's approval, is known as informed consent. Its existence is one of the elements in the occurrence of therapeutic transactions, and as an agreement, therapeutic transactions are subject to the provisions of civil law³⁴. The absence of informed consent from the aspect of civil law can be seen from three sides:

1. The absence of informed consent which results in not fulfilling one of the terms of the agreement according to Article 1320 of the Civil Code
2. The absence of informed consent, which is classified as default.
3. The absence of informed consent is classified as an unlawful act based on Article 1365 of the Civil Code.

First, the absence of informed consent, which results in not fulfilling one of the terms of the agreement according to Article 1320 of the Civil Code. Therapeutic transactions are not explicitly regulated in the Civil Code, but according to the provisions of Article 1319 of the Civil Code, all agreements, both nominate and innominate agreements, are subject to Chapter I Book III of the Civil Code and are sourced from Chapter II Book III of the Civil Code. If the legal terms of the agreement according to Article 1320 of the Civil Code are further elaborated and linked to informed consent, the following is the explanation³⁵.

1. Their agreement which binds themselves (*toestemming van degene die zichverbinden*): an agreement to exchange information mutually between the parties that will be involved written in the form of informed consent. With informed consent, it means that between the patient or his representative and the health worker concerned there has been an agreement to do or not do something;
2. The ability to make an engagement (*bekwaamheid om eeneverbintenis aantaan*): this is related to the patient's ability to give consent concerning the ability to act so that their guardian can represent patients who are not eligible for an agreement, husband or wife. , father or mother, adult brother or sister, adult child or party who has been given a power of attorney. Meanwhile, doctors and health workers must have the skills required by patients, which can be proven by a relevant certificate or letter.
3. A particular subject (*eenbepaaldonderwerp*): it means that informed consent creates rights and obligations that each party needs to fulfil. The need for rights and liabilities related to legal actions that can be taken in the event of a dispute - with the rights and obligations that arise, the injured party can sue because the opposing party has neglected to carry out its obligations.
4. A reason that is not prohibited (*geoorloofdeoorzaak*): that informed consent is not given for things that violate the law, such as abortions that are against the law.

Second, the absence of informed consent is classified as default. If it is related to default, the absence of informed consent can be further broken down into the following four forms:

1. Not fulfilling performance: for example, in a therapeutic transaction, the patient and doctor have agreed to remove a cyst at two points on the patient's body. It turned out that only one was appointed, not following

what the patient agreed to, and causing the patient to suffer losses.

2. Fulfilled the achievement, but not as promised: for example, the patient and doctor have agreed to perform an appendix removal operation with the latest method that does not require major surgery, but it turns out that in the end, the appendix removal was carried out by conventional surgery which was not following the patient's consent and harm the patient.
3. Fulfilled the achievement, but it is too late: for example, the patient and doctor have agreed to operate on the day and date that has been determined, but on the day when the patient is ready, the doctor turns out to be late, the operation is postponed to the detriment of the patient.
4. Doing what is promised not to be done: for example, a patient gives consent to take a specific type of drug and refuses other medicine types to be prescribed by a doctor. However, doctors still write down drugs that patients reject, which result in side effects that the patient does not want.

Third, the absence of informed consent is classified as an act against the law or *onrechtmatigedaad* following Article 1365 of the Civil Code. This article states that "Every act that violates the law and brings harm to others, obliges the person who caused the loss due to his mistake to compensate for the loss."³⁶

In order to file a lawsuit based on an unlawful act, it is necessary to fulfil the requirements contained in Article 1365 of the Civil Code, namely:

1. The patient must suffer a loss
2. There is an error
3. There is a causal relationship between error and loss
4. The act is against the law

Regarding the criteria for what actions can be classified as illegal acts, since the *Lindenbaum Cohen Arrest Hoge Raad* case on January 31, 1919, jurisprudence has stipulated four criteria for an illegal act, namely:

1. The act is contrary to the legal obligations of the perpetrator;
2. The act violates the rights of others;
3. The act violates the moral code of conduct;
4. Such actions are contrary to the principles of propriety, thoroughness, and caution that a person should have in his interactions with fellow citizens or other people's property.

If the theory above is applied to the causal relationship that occurs in the absence of informed consent, then the patient must be able to prove the following matters:

1. That between the patient and the doctor or health worker, there is a legal relationship; 2. Whereas the doctor or health worker failed to fulfil the informed consent.
2. Whereas patients experience losses due to doctors or health workers failing to fulfil informed consent.

It can be concluded that the absence of informed consent only creates legal problems if the doctor's actions cause harm to the patient. The losses in question have a reasonably broad scope; both material losses such as pain or scars that interfere with daily life or psychological losses such as violations of particular beliefs or religions can also be used as a basis for controversy.

Informed consent is regulated in the Minister of Health Regulation No. 290 / MENKES / PER / III / 2008 concerning Approval of Medical Action. Informed consent or consent to medical action is the patient's consent or immediate family after receiving a complete explanation of the medical or dental action to be performed on the patient. The party responsible for conveying the patient's explanation is the doctor who carries out the medical action. However, if the doctor concerned is unable to convey an explanation, the explanation can be represented by another doctor with the knowledge of the doctor concerned. Delegation of authority to nurses is only justified if the medical action is not a surgical or other invasive procedure.

Based on Article 7 and Article 8 of the Minister of Health Regulation Number 290 / MENKES / PER / III / 2008 concerning Approval of Medical Action, the explanation submitted must be easy to understand and revolve around the following main points:

1. Explanation of the diagnosis and procedure of action medicine, which includes: (1) clinical findings from the results of medical examinations to date; (2) a diagnosis of disease, or in the case that it cannot be established, then at least a working diagnosis or a differential diagnosis; (3) the indication or clinical condition of the patient requiring medical action; (4) prognosis if action is taken and if action is not taken; and (5) procedures for implementing what actions the patient will experience during and after the procedure, as well as any side effects or discomfort that may occur.
2. A description of the medical action's objectives to be carried out, covering the objectives of the medical action, which can be in the form of preventive, diagnostic, therapeutic, or rehabilitative.
3. A description of the other available alternative medical treatments and their respective risks, including: (1) other alternative treatments and their advantages and disadvantages compared to the planned action; (2) risks and complications that may occur in each alternative action; (3) expansion of possible measures to deal with emergencies resulting from these risks and complications and other unforeseen circumstances.
4. A description of the risks and complications that may occur, including: (1) risks and complications that have become common knowledge; (2) risks and complications that occur very rarely or are very mild; and (3) unforeseeable risks and complications.
5. A description of the prognosis of the disease if the medical action is carried out or not carried out, including (1) prognosis of life and death; (2) prognosis about its function; and (3) prognosis about recovery.
6. Estimated Payment.

Informed consent can be expressed verbally and in writing. Oral consent is where the patient expresses the patient's consent which is expressed verbally and does not sign in a written form, whereas written consent is required in cases of extensive interventions involving risks where anaesthesia or sedation is used as a restorative, invasive or surgical procedure, drug administration risk high-. The

Minister of Health Regulation Number 290 of 2008 concerning Approval of Actions Medical In articles 2 and 3, it is stated that all medical actions to be carried out against patients must obtain consent, consent, as referred to in paragraph (1), can be given in writing or orally. Article 3 states that every medical action that carries a high risk must obtain a written consent signed by the person entitled to consent.

Even though regulations regulate many medical actions, high risk and medical services performed by doctors or other medical personnel are malpractices reported by the public but not legally resolved; this is due to the absence of an agreement between the doctor and the patient and the absence of written evidence that the patient has in demanding damages in the event of malpractice by the doctor³⁷. According to the results of research conducted by Herwanda at a hospital in the city of Banda Aceh, it was found that two people (0.8%, sometimes 45 (17.4%) did not use oral medical consent (0.8%, sometimes 45 people (17.4%) Approval of oral medical treatment as many as 212 people (81.9). From the study results, it can be concluded that the majority of research subjects at RSGM Unsyiah used informed oral consent.

Besides, there are still arrangements in the hospital procedures that are not yet appropriate with the law and standards accreditation hospital, so that doctors in implementing informed consent are not under the existing legislation and service standards. Some doctors do not know about the permanent informed consent procedure because the socialization of the procedure has not been held again after all this time, as for monitoring and sanctions given by the hospital is still limited to checking the completeness of the informed consent sheet and giving sanctions to complete the informed consent sheet; this can lead to a lack of compliance and a doctor's sense of responsibility in carrying out informed consent. For this reason, it is necessary to develop organizational policies to improve physician compliance in implementing informed consent and monitoring and sanctions for the implementation of informed consent. Management's role is also needed to complement existing routines to comply with laws and hospital accreditation assessment standards. Besides, it is necessary to disseminate regular procedure organizational policies, monitor and sanction informed consent, and increase physician compliance in implementing informed consent.

The explanation above shows that there are still a few hospitals and doctors who consider the importance of written informed consent. While this is very important in order to anticipate unexpected things, a statement can be added that the patient agrees:

1. Expansion measures, if deemed necessary.
2. Removal of organs or tissue that can no longer be maintained (for example: cutting the intestine).
3. A photo or video camera is taken with the condition that the identity is not disclosed;
4. The use of remaining tissues or organs for educational and or research purposes.

In the future, the existence of written informed consent must be present in any medical action; at the minimum, it must contain:

1. Recognition that the patient or person entitled to represent has been explained:
 - a. The reasons for the need for medical action.
 - b. The nature of medical action (experimental / non-experimental).
 - c. The purpose of medical action.
 - d. Risk of medical action.
 - e. Adverse effects that are not pleasant.
 - f. Whether or not there are alternative medical measures.
 - g. The consequences that will be experienced if he refuses medical action.
2. Recognition that he has understood the information
3. Statement that he agrees to medical action.

Besides, the influence of the hospital's organizational policy has a significant effect on doctors' compliance and responsibility in implementing informed consent. For example, the application of fixed procedures aims to make doctors work following the procedures and work flow, which is the implementation of informed consent. Apart from regular procedures, there is also monitoring and sanctions applied by the hospital to evaluate the implementation of informed consent and increase doctors' compliance and responsibility in implementing informed consent according to existing regular procedures.

From the provisions above, it can be concluded that written consent is required for medical actions that contain high risks, while for medical actions that do not contain high risks, verbal consent can be given. Informed consent as an agreement is a form of agreement that must meet the agreement's legal requirements as stipulated in the provisions of Article 1320 of the Civil Code, namely: agreeing that those who bind themselves are competent to make an engagement, a sure thing, a legal cause. Agree is an agreed statement of will (overeenstemendewilsverklaring) between the parties regarding the agreement's subject. To reach an agreement in agreeing, both parties must have freedom of will in agreeing. The parties do not get pressure which causes defects for the realization of this will. Defect of will can occur if, in agreeing, there is an error, coercion, fraud, or abuse of circumstances.

In granting Approval of Medical Actions by families/government agencies responsible for patients with mental disorders at Grhasia Hospital, it is carried out after obtaining complete information about the medical actions that will be carried out on the patient, so for the good conditions of the agreement related to the agreement of the parties have been fulfilled; this means that consent is given after the party giving the consent has a clear understanding of the medical action to be taken and determines the decision independently which in his opinion is best for the patient. Therefore, if the family/government agency responsible for the patient does not agree with the medical action was taken against the patient, rejection of medical action can be done by filling in the Rejection of Medical Action sheet. Wila Candra Supriadi explained that the patient has the right to refuse treatment for the patient, although this can be a dilemma for the doctor because, on the one hand, the doctor has a moral obligation to help the patient, while on the other hand, the doctor must respect

the patient's rights, including refusing to give consent. However, if the patient refuses medical treatment even though he has been given information about the possibility of recovery and the risks, the doctor cannot force them to consent if no medical action is taken.

CONCLUSION

The patient has a tremendous opportunity to take advantage of the patient's right to know all the procedures that the patient will undergo. Patients have individual fundamental rights in health (the right of self-determination); although it is the same fundamental, the right to health services is often considered essential. In the doctor-patient relationship, the patient is relatively in a weak position. Through written informed consent, it is hoped that the patient will have guaranteed health assurance. This guarantee can be implemented in all hospitals in Indonesia, consider written informed consent to be necessary. At the very least, the hospital needs to have a standard written draft to provide informed consent and the proper procedures and workflow in terms of implementing informed consent. Some doctors are not aware of the permanent informed consent procedure because the procedure's socialization has not been held again after a long time.

Meanwhile, the hospital's monitoring and sanctions are still limited to checking the completeness of the informed consent sheet and giving sanctions for completing the informed consent sheet; this can lead to a lack of compliance and a doctor's sense of responsibility in carrying out informed consent. For this reason, it is necessary to develop organizational policies to improve physician compliance in implementing informed consent and monitoring and sanctions for the implementation of informed consent. Approval is given after the party giving the consent has a clear understanding of the medical action to be performed and determines the decision independently, which is best for the patient. Therefore, if the family/government agency responsible for the patient does not agree with the medical action was taken against the patient, rejection of medical action can be done by filling in the Rejection of Medical Action sheet.

Acknowledgments: Thank you to Universitas Lampung for supporting this research.

Conflict of Interest: No

Funding Source: Author.

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