URGENCY OF INFORMED CONSENT IN RELATION BETWEEN PATIENTS AND DOCTORS IN MEDICAL MALPRACTICE

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ABSTRACT

Human life dynamics needs protection particularly fulfillment of health for society should be offset with legal instruments which is appropriate. This research combining between library and empirical research. Based on law, the regulation on medical practice refer to Law No 29 of 2004 on Medical Practice and Law No 20 of 2013 on Medical Education. The aforementioned regulations is basic for doctors of in conducting medicine for public with the aim of providing help or providing assistance to patients. This relationship creates what is called a therapeutic transaction. Informed consent itself regulated by Regulation of the Minister of Health of the Republic of Indonesia No 290/Monkes/PER/III/2008 on Approval of Medical Measures as a translation of Article 45 of Law No 29 of 2004 on Medical Practice. That regulation is only to clarify informed consent procedures related to the approval of Medical Measures but not explaining the legal sanctions.

Key Words: Informed Consent, Patients, Doctors, Medical Malpractice

Background

The word of informed consent was adopted and translated into a treaty of medical treatment, which is the consent of a patient to the doctor for a medical action to be performed, after obtaining information affirmatively about the action (Guwandi 1995: 17). Semantically informed consent means not only the consent of medical action, but also a process whereby one activity is executed and performed by the doctor to the patient after the consent and agreement. Information (informed intact) and consent (action) is more philosophical because implicitly it contains which is broad and involves the social issues of humanity, law and conventions that apply in the institution of society.

Guwandi said that it is not uncommon for patients or families to consider informed consent merely a formality that must be met (Guwandi, 2006: 3). This is a process of requesting the signature of the patient/guardian on the form as a permit of a medical action or a specific procedure, whereas informed consent is a very important stage in the relationship between doctor and patient. Therefore, both are required to actively engage in what has been informed about the procedures, risks and benefits in the implementation of medical action. A thorough understanding by the patient about the information already submitted will greatly assist in the implementation of subsequent procedures in medical practice and then resulting in therapeutic transactions.

Discussion of informed consent can not be separated from medical malpractice within the therapeutic contractual framework between doctor and patient as it is closely related to law and ethics (Guwandi, 1995: 2). Therapeutic contracts, in the relationship between doctors and patients, are part of the legal aspect because the substance of the relationship is legal relations (rechtsbetrekking) and not just social relationships.

It is basically difficult to determine whether the doctor is malpractice, in intent or by negligence. In the 4th edition of the Black's Law Dictionary it is mentioned that malpractice, in Latin mala praxis, is unskillful management or treatment. Particularly applied to the neglect or unskillful management of a doctor, surgeon, or apothecary. Two important things according to Black in the definition is the management and handling are not trained or unprofessional. A similar opinion is said by Emanuel, "lack of skill in the practice of a profession. Usually, but not always, applied to medical practitioners and their associates, the term denotes neglect or lack of reasonable skill in treatment or advice to a patient or client (Lazar Emanuel, 1999: 229). According to both, malpractice occurs usually in activities related to medicine.

Implementation of medical actions that occurred in Indonesia, not infrequently ignore the rights of patients and some of them indicated malpractice. Until the year 2009 there were at least 387 cases of alleged malpractice in Indonesia (Agus Budianto, 2009: 40). According to the report of the Central Health Legal Aid Institute, there were 405 reports of medical problems from various parts of Indonesia and as many as 73 cases of which were reported to the police (Dedi Afandi, 2009: 189). In many cases, fewer wins are won by the patient and even if they occur then the general execution of the court decision is also unclear. Many parties then throw responsibilities such as whether the responsibility is on the doctor's side or the hospital. Moving on from the background that has been raised in advance, the main review of this paper is How is the arrangement of informed consent in Indonesian Legislation and How is the Impact or Implication of Informed Consent and Medical Malpractice in Legislation in Indonesia?
Materials and Method
This research was conducted to identify the concepts and legal principles used to regulate health, especially those used as the basic framework in Law Number 36 Year 2009 on health. In relation to this normative research, several approaches are used: statute approach, conceptual approach and case approach.

Normative law research uses normative case studies of legal behavioral products, such as reviewing laws. The subject of the study is the law which is conceptualized as the norm or rule that is in society and becomes the reference of everyone’s behavior. Thus normative legal research focuses on the inventory of positive law, legal principles and doctrines, the discovery of law in the case of concreto, systematic law, the level of synchronization, comparative law and legal history (Abdul Kadir Muhammad, 2004: 52). In accordance with the above concepts, then the source of data needed are some cases related to medical crime which resulted in the malpractice of medicine. The primary data needed here is data on cases that have occurred in Indonesia.

Discussion
1. Urgency of Informed Consent Arrangement in Indonesian Laws and Regulations
Talk about health law issues, it will speak the patient's right in informed consent. This informed concentration is the first right in the health sector which is regulated the first time SK PB-ID1 Number 319 / PB / A.4 / 88 in 1988 made by Indonesian Doctors Association (IDI) about informed consent. It was then confirmed by Regulation of Health Minister No. 290 of 2008 on Approval of Medical Measures or Informed Consent. However, before the birth of Regulation Of Health Minister, the government has issued a regulation on medical practice as outlined in Law No. 29 Thun 2004 indirectly in it contains the existence of informed consent. Article 45 paragraph (1) to (6) states:

1. any act of medicine or dentistry to be performed by a doctor or dentist on a patient must be approved
2. the approval referred to in paragraph (1) shall be provided after the patient has a full explanation.
3. The explanation as referred to in paragraph (2) shall at least include:
   a) Diagnosis and procedure of medical action;
   b) The purpose of the medical action;
   c) Alternative other actions and risks;
   d) Risks and possible complications; and
   e) Prognosis of the action taken.
4. approval as referred to in paragraph (2) may be given either in writing or orally.
5. any high-risk medical or dental treatment shall be granted with a written consent signed by the person who has the right to give consent
6. provisions concerning procedures for approval of medical or dental action as referred to in paragraph (1), paragraph (2), paragraph (3), paragraph (4) and paragraph (5) shall be stipulated by Ministerial Regulation.

The implication of the birth of the regulation is that every medical action must be approved by the patient as regulated in Article 2 paragraph (1) of Regulation Of Health Minister Number 290 Year 2008, which reads: All medical actions to be performed on the patient must be approved. Informed consent approval is interpreted as recognizing the principle of similarity between patient and doctor, disarming compiling and executing programs in order to create a better health degree, the consistency of the state describes the recognition that raises the obligation to seek equal health protection.

Approval of medical action is the consent given by the patient or immediate family. After obtaining a complete explanation of the medical action to be performed on the patient, the consent of medical action between patient and doctor is in the form of:

1. all medical measures to be taken against the patient must be approved;
2. approval may be given in writing or orally; and
3. the consent provided the patient gets the necessary explanation of the need for medical action to take place.

According to Regulation of health minister No. 290 / MenKes / Per / III / 2008 and Law Number 29 Year 2004 Article 45 and Manual of Approval of Medical Action of KKI in 2008, it is stated that Informed Consent is the approval of medical action given by the patient or his immediate family after getting explanation in Complete on the medical action to be performed on the patient.

Furthermore, according to the attachment of SKB IDI Number 319 / P / BA / 88 and Regulation of health minister Number 290 / Men.Kes / Per / III / 2008 concerning Approval of Medical Action Article 4 paragraph 2 mention in giving information to patient / family, the presence of a nurse / paramedik Others as witnesses are important. In legal relations, the practitioners and users of medical acts (doctors and patients) act as "legal subjects" ie persons with rights and obligations, while "medical treatment services" as "legal objects" are something of value and benefit to persons as Legal subjects, and there will be a legal act that is an act which consequently is regulated by law, either by one party or by two parties.

The doctor as a medical practitioner, besides being bound by the Indonesian Medical Code of Ethics (KODEKI) to the doctor, can not escape the provisions of civil law, criminal law or administrative law, as long as it is applicable. In the conduct of medical action, ethical and civil law issues, the benchmark used is "small error" (culpa levis), so that if a minor error occurs in a medical action that harms the patient, then it can be legally accountable. This is because the civil law generally applies adagium "whosoever harms others must give compensation".

The benchmark used in criminal law issues is "grave error" (culpa lata). Therefore, a small (light) error on the implementation of medical action can not be used as a benchmark to impose criminal sanctions. Aspects of Civil Law, a medical action performed
by a medical practitioner without consent from the user of a medical (patient) service, whereas the patient is fully aware and able to give consent, the doctor as the medical practitioner may be blamed and was sued for committing an offense (onrechtmatige daad) under Article 1365 BW. This is because the patient has the right to his body, so the doctor should respect him.

In relation to the criminal law aspect, "informed consent" absolutely must be fulfilled with the existence of article 351 of the Criminal Code concerning the persecution. An invasive act (eg surgery, invasive radiology) performed by a medical practitioner without the consent of the patient, the medical practitioner may be prosecuted for committing a criminal act of maltreatment of a violation of Article 351 of the Criminal Code.

As one of the implementers of medical services the doctor should be aware that informed consent can really ensure the implementation of legal relations between the patient and the doctor, on the basis of mutual fulfillment of the rights and obligations of each party is balanced and accountable. Informed consent is relative, for example, is not easy to determine whether an information has been or not enough given by the doctor. It is difficult to establish and the theoretical basis of the juridical is also not strong, so a more in-depth review of the legal issues concerning this informed consent is required.

Informed consent essentially is an engagement, civil provisions will apply and it is closely related to professional accountability regarding treatments treaties and therapeutic agreements. The civil aspect of informed consent when it is associated with the Law of Engagement which in Article 1320 BW contains 4 (four) terms of validity of an agreement namely: the agreement of the parties, free from coercion, error and fraud, the parties are competent to make engagement, the existence of a cause Legitimate, justified, and not prohibited by laws and regulations, and is a reasonable cause to be fulfilled.

The first requirement is an agreement between both parties (between health care workers and patients), then it means there should be sufficient patient complaints information from both parties. On the part of the officer must be informed of the patient's complaints to be honest, so also from the patient side must get the diagnosis and therapy that will be done. There are several rules that must be considered in preparing and providing informed consent for the law of this engagement is not legally flawed, such as (Adami Chazawi, 2007: 5):

1. Not fooling (fraud);
2. Not attempting to press (force);
3. Does not create fear (fear).

The consent signed by the patient or his immediate family, does not relieve the doctor of the charges if the doctor carries out the negligence. Medical action taken without the consent of the patient or his immediate family, may be classified as an act of maltreatment under Article 351 of the Criminal Code. Medical actions performed without patient consent, can be classified as an act of maltreatment under Article 351 of the Criminal Code (trespass, battery, bodily assault).

In Article 5 of Regulation of health minister No 290 / Menkes / PER / III / 2008, the approval of medical action may be canceled or withdrawn by the consent, prior to the commencement of action (paragraph 1). Cancellation of approval of medical action shall be made in writing by the consent (paragraph 2). According to Regulation of health minister No. 290 / MenKes / Per / III / 2008 and Law Number 29 Year 2004 Article 45 and Manual of Approval of Medical Action of KKI in 2008, it is stated that Informed Consent is the approval of medical action given by the patient or his immediate family after getting explanation in Complete on the medical action to be performed on the patient.

Furthermore, according to the attachment of SKB IDI Number 319 / P / BA / 88 and Regulation of health minister Number 290 / Men.Kes / Per / III / 2008 concerning Approval of Medical Action Article 4 paragraph 2 mention in giving information to patient / family, the presence of a nurse / paramedik Others as witnesses are important. In legal relationships, the practitioners and users of medical acts (doctors and patients) act as "legal subjects" ie persons with rights and duties, while "medical treatment services" as "legal objects" are something of value and benefit to persons as Legal subjects, and there will be a legal act that is an act which consequently is regulated by law, either by one party or by two parties.

In relation to the doctor's "informed consent" as a medical practitioner, in addition to being bound by the Indonesian Medical Code of Ethics (KODEKI) for doctors, it can not escape the provisions of civil law, criminal law or administrative law, as long as it is applicable. In the conduct of medical action, ethical and civil law issues, the benchmark used is "small error" (culpa levis), so that if a minor error occurs in a medical action that harms the patient, then it can be legally accountable. This is because the civil law generally applies adagium "whosoever harms others must give compensation".

2. The Implications of Informed Consent to Medical Malpractice in Indonesia

Doctor and patient relationship in therapeutic transactions (medical agreement). Therapeutic is a translation of therapeutic meaning in the field of medicine, this is not the same as therapy or therapy which means treatment.224 Therapeutic agreement is an agreement that occurs between doctors and patients not only in the field of medicine alone but more broadly, including diagnostic, preventive, Rehabilitative and promotive (Salim HS, 2006: 45).

Article 2 of Regulation of health minister No 290 / Menkes / Per / III / 2008 expressly states that all medical actions to be performed on the patient shall be approved. Such consent may be given in writing or verbally from the patient after the patient is informed and explanation of the need for medical action is taken. Implementation of the provisions is implemented by providing information and get approval of medical actions to be performed by doctors against patients commonly called Informed Consent.
In the provisions of Article 7 paragraph (3) No 290 / Menkes / Per / III / 2008 also provides that in the explanation of medical measures 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 possible complications;
5. Prognosis of action taken;

The existence of clear standards and procedures related to medical action, it is expected that medical actions performed by health personnel and doctors can run well and accompanied by a sense of responsibility by medical personnel to patients. However, not all patients understand and understand the existence of informed consent and vice versa, so that many feel harmed by the medical action. Civilly it can be accounted for.

The responsibility in the informed consent, in this matter to the parties in the field of health, there are other parties related to the field of health, not doing what has been agreed, one of the parties neglect or neglect or one of the parties violate what he promised Or one party conducts or acts in accordance with which it is not permitted, the offending party may prosecute and the offender or breach of such pledge is liable to a civil law which is often called "accountability" (civiel rechtelijke aansprakelijkheid).

The legal basis governing accountability in the Civil Code is Articles 1243, 1239, 1365, 1367, 1370 and 1371. In civil law, errors or omissions include (Soerjono Soekanto, 1986: 8):

1. Performing a default or an injury to an appointment (Articles 1239 and 1243 of the Civil Code);
2. Performing unlawful acts or onrechtmatige daad (Article 1365 Civil Code);
3. Carry out negligence resulting in loss (Article 1366 Civil Code);
4. Making negligence in the work as a person in charge of a particular job (Article 1367 Civil Code)

This legal protection is very important because the result of negligence or error may cause death or permanent disability. What is meant by physical loss is the loss or malfunction of all or any part of the body, whereas non-physical losses are related to the dignity of a person.253 With this liability, the patient may take legal action when harmed as a result of medical treatment by a doctor has resulted in permanent injury, death etc. Efforts as a legal action that can be taken patients to the doctor.

Informed consent is important in enforcing patient rights in the relationship of medical action between patient and doctor. Many cases of medical malpractice occurred, one of which did not follow the procedure of informed consent ignored by the doctor. Several court decisions, related to medical malpractice, refer to the Medical Practice Law relating to criminal acts of negligence, and consumer protection in relation to the protection of patients' rights to health services by doctors, or the hospitals. In relation to some cases included in the judiciary, malpractice is more in the act of negligence by doctors to patients.

with regard to informed consent The patients' rights are not clearly illustrated, that there are stages of procedure that must be passed before taking medical action between patient and doctor. This condition illustrates that the provisions of informed consent are not as legally binding as the treaties provided in civil law, that agreement or agreement by both parties (in this case the patient and the doctor) remembers the medical action to be taken.

Meantime if there are errors, defects, permanent disability, even death of the patient, do not give deterrent effect on the offender in this case the doctor to meet the existing procedures. The absence of strict sanctions in relation to informed consent in the existing legislation of various fields related to health, which does not expressly set criminal provisions in its arrangement.

In a variety of incident practices, many disadvantaged patients, even no legal protection in the health sector, are related to medical treatment performed by a doctor. Things like those in various court decisions, whether at the first level, appeal, satisfaction, and review, still place the patient in a weak and unprotected position in a doctor's medical practice.

The existing legal provisions, however, have not been clearly set about informed consent as an important part in the legal protection effort in the field of health for patients. Therefore, efforts to place informed consent as a legal principle in a legislation in the field of health is time to assess that informed consent as a soul in a norm in the legislation in the field of health. The following describes an analysis of court decisions related to informed consent that have implications for medical malpractice in patient and doctor relationships.

Informed consent implicated in medical malpractice can be explained here from the relationship between informed consent and the implications of medical malpractice. Understanding the implications of medical practice should be interpreted lexically from "implication is" that is (1) something that is suggested without being said directly; (2) something that is implied; (3) the fact or state of being involved in or connected to something (such as a crime); (4) the fact or state of being implicated in something.

Errors in taking medical action will have the potential for malpractice. Malpractice itself in legal understanding, adopted from Latin, is a mala praxis which means "unskilful management or treatment. Particularly applied to the neglect or unskilful management of a doctor, surgeon, or apothecary.
In 2 (two) important terms according to Black in the definition is the management and handling of unstructured or unprofessional. A similar opinion is said by Emanuel, "lack of skill in the practice of a profession. Usually, but not always, applied to medical practitioners and their associates, the term denotes neglect or lack of reasonable skill in treatment or advice to a patient or client (Lazar Emanuel, 1999: 229). Malpractice occurs usually in activities related to medicine. In practice, the discussion of informed consent can not be separated from medical malpractice within the therapeutic contractual framework between doctor and patient as it is closely linked to law and ethics. Therapeutic contracts, in the relationship between doctors and patients, are part of the legal aspect because the substance of the relationship is legal relations (rechtsbet-rekking) and not just social relations. Therefore, there should be clarity regarding the legal rights and obligations for both parties with a view to making clarity of settlement in case of a dispute in the future. The implications in this regard are understood as the possibility of default.

**Conclusion**

Informed consent is essential for all elements of doctors, health workers and the public. Juridically, the issue of informed consent is governed by several regulations, both the law and the ministerial regulations, but the regulation does not yet contain strict sanctions against the non-disclosure of informed consent by doctors to patients.

**References**


