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The critical role of informed consent for doctors and patients in the community

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ABSTRACT

Introduction: Malpractice and medical case disputes are commonly found in the community. It was caused by misperception between patients and doctors on a medical case. Therefore, the informed consent role is essential for patients and doctors. This paper aims to describe the role of informed consent for patients and doctors.

Methods: This is a narrative literature review. Literature was taken from PubMed, Google Scholar, and Science Direct. The selected journals were published within 10 years.

Results: Informed consent is a sign of approval for any medical procedure that might cause disputes. On the doctors' side, informed consent is a legal protection. On the other side, informed consent is an explanation for the patient in helping decide on approval or rejection of any medical procedure. An informed consent paper has legal protection for the attending physician. Doctors must give accurate and complete information about the procedure before it is done. Patients have the right to have an explanation, give consent, or rejection regarding any procedure. When a doctor does a medical procedure before giving informed consent, it is considered malpractice. Informed consent is related to human rights fulfillment. Patients have the right to accept or reject any medical procedure after the doctors explain thoroughly about the procedure.

Conclusion: In conclusion, the role of informed consent for doctors is legal protection and obligation. Meanwhile, the role of informed consent for the patients is to fulfill human rights.

Keywords: Doctor; informed consent; malpractice; legal protection, patient.
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INTRODUCTION

Malpractice in Indonesia is not something new, but this incident continues even though the legal instruments in force in Indonesia are in line with the needs of the community as consumers of health services. Several cases indicating malpractice in Indonesia can be found in various mass media, but not all cases are brought to justice. The malpractice cases that have occurred include, among others, the case of patient Anna Marlina at Persahabatan Hospital which occurred in 2013, the case of an RFB baby in Bekasi who died allegedly due to negligence by the Awal Bros Hospital Medical Team, which occurred in 2015. The case of a paralyzed boy in Kediri allegedly occurred after receiving immunization. Every medical procedure such as immunization needs parental approval even though they come from outside the city. Doctors must ask about the child's condition before receiving immunization treatment. Meanwhile, the Indonesian Medical Disciplinary Honorary Council, or MKDKI for short considers that the actions taken by doctors so far are limited to alleged disciplinary violations.[1]

Health workers (doctors) and consumers (patients) need to be protected at the same level according to the law (legal) aspect. However, malpractice and disputes in medical cases are commonly found nowadays. It was caused by misperception between patients and doctors on a medical case. Therefore, informed consent is needed to prevent any malpractice and disputes. Informed consent is a sign of approval for any medical procedure that might cause disputes. On the doctors' side, informed consent is a legal protection. On the other side, informed consent is an explanation for the patient in helping decide on approval or rejection of any medical procedure.[2]

Humans as social creatures, need interaction with other humans. Interaction among people includes legal aspects and the patient-doctor relationship. Relationships between doctors and patients might end with disputes. Therefore, informed consent given before any procedure has some essential roles for patients and doctors in the community.[3] Informed consent is a part of the educational process between doctors and patients/family for reaching the best decision.[4]

An informed consent paper has legal protection for the attending physician. Doctors have the obligation of giving true and complete information about the procedure before it is done. Patients have the right to have an explanation, give consent, or rejection regarding any procedure. When a doctor does a medical procedure before giving any informed consent, it is considered malpractice. Informed consent is related to human rights fulfilment. Patients have the right to accept or reject any medical procedure after the doctors explain thoroughly about the procedure.[5]

Informed consent is one of the important elements that affect health law dynamics. When there is a dispute or malpractice, the court decisions are

Table 1. Summary of the selected articles

Number	Author, publication year	Summary point of view
1	Syafruddin and Rohman, 2019	Cases of malpractice in Indonesia
2	Amirthalingam, 2019	Legal protection for doctor and patient (informed consent)
3	Susilowati et al., 2021	Essential roles of informed consent
4	Vikas et al., 2021	Roles of informed consent
5	Kasiman et al., 2023	Legal protection meaning of informed consent
6	Cioffi and Zaami, 2020	Informed consent in psychiatric patients
7	Vergallo and Spagnolo, 2019	Informed consent role in legal aspect for doctor and patients
8	Sutarno and Maryati, 2021	The crucial role of informed consent to prevent malpractices and disputes
9	Asharib et al., 2022	The importance of giving informed consent before surgery
10	Wuryanto and Khodijah, 2016	The obstacles between doctors and patients regarding the understading of informed consent given
11	Jennie and Lestari, 2019	Patient has the right to refuse unclear informed consent
12	Hanson and Pitt, 2017	The role of family member in delivering the informed consent to the patient
13	Nauta et al., 2022	The role of informed consent in AI era
14	Hassija et al., 2024	The role of informed consent in AI era
15	Bouderhem, 2024	The role of informed consent in AI era

analyzed with regulations. Therefore, the final result depicted the judge's assessment regarding the informed consent implementation. The result of the study by Syafruddin and Rohman in 2019 revealed that judgment is based on medical action, except in emergency cases in which patient approval is not necessary due to safety reasons. Protecting patient uses the reverse proof (i.e. informed consent).[1] Therefore, the informed consent role is essential for patients and doctors. This paper aims to describe the role of informed consent for patients and doctors.

METHOD

This is a narrative literature review. Literature was taken from PubMed, Google Scholar, and Science Direct. The selected journals were published within 10 years. There were 15 selected articles. The selected articles were summarized and narrated. Article were selected based on the title, abstract and full text content. Title and abstract must contain three of the five keywords as follows: informed consent, doctor, patient, legal protection, practice, or malpractice. Meanwhile, full text content was screened based on the depth of the topic. The selected articles were summarized in table 1.

RESULT

Doctors, patients, and hospitals are three legal subjects in the healthcare system. Doctors include dentists, doctors, and specialists, who graduated from local or international medical faculty that are considered by the Indonesian government based on the law. Patients are anyone who has a health consultation and service directly or indirectly at the hospital. Informed consent implementation in every country might be different based on the law. For example, in USA, England, and France, the countries use the Anglo-Saxon law. This law implements the legal system based on the common law and role of law (jurisprudential or based on the judge's decision).[3]

Content of informed consent

Informed consent is a consent from patient for any medical procedure after the patient gets sufficient information from the attending physician. The procedures include preventive, diagnostic, therapeutic, and rehabilitative procedures. A high-risk procedure is a procedure that in certain probability could cause disability or death such as an invasive procedure or surgery. Informed consent can be stated or implied, oral or written. Written consent is applied for a high-risk procedure. Meanwhile, implied consent is done by showing a body gesture of permitting a medical procedure. For example, a patient is permitted to take a blood sample by rolling his/her arm shirt for supporting diagnostic procedures. Only the competent patient can give full permission according to the law. Competent means mature and healthy in physical and spiritual condition, and the patient should not be a child. A competent patient is also a married/ever-married person, not in a disturbed physical awareness, and shows a normal communication ability. It means the patient has no mental decline/illness. Patients have to make a decision freely without any force from any parties. When the patient is in a fluctuating competence state, the informed consent process cannot be done at once, but it should be repeated when the patient is competent and consistent. Otherwise, the consent will be accomplished by other authorized persons after getting sufficient information and explanation. Other people who have the right are other people in the family (father, mother, wife, husband), and next of kin (children). Meanwhile, grandfather, grandmother, grandson, granddaughter, uncle, aunt, nephew, and cousin are not considered a close family. Giving information is the longest part of the informed consent process.[3]

A psychiatrist should determine at best when the patient is in an optimal condition to give valid informed consent. However, this is very difficult. The doctor might get some medico-legal consequences for wrong choices of time in delivering the informed consent. On the other side, the patient might not fully understand the information given by the psychiatrist.[6]

The standard operational procedure for giving informed consent:[3]

a. The hospital provides medical records and operation resumes based on the medical record number
b. The surgery nurse provides the medical operation sheet report.
c. After the surgery, the doctor writes the details of the surgery,
d. The surgery report contains the following data: name, age, room number, registration number, operation date, the name of the in-charge surgeon, assistant 1, assistant 2, instrumentation, anesthesiologist, anesthesiologist assistant, pra-surgery diagnosis, post-surgery diagnosis, the tissue/secretion that is taken for diagnosis procedure, length of operation time (include the start time and the finish time), length of anesthesia time (the starting time, the finish time, and length), type of operation (clean, clean-contaminated, contaminated, dirty, also minor/major operation)
e. Urgency of the operation (emergency, elective)
f. The amount of blood loss and the blood transfusion needed during the operation
g. Complication of operation
   The summary of the operation includes pre-operation, the position of the patient, disinfection, skin incision, the opening of the operation site, what is done, closing of the operation site, complications of the operation, the procedure of the operation, the excision of the organ/tissue, conclusion, also date, surgeon name, and time of signature
h. The anesthesiologist nurse rechecks the completeness of the summary of the surgery report.

Common mistakes in filling out the informed consent form

Doctors often forget to explain the side effects of the anesthetic medicine. Surgeons often neglect to complete the informed consent file, where the doctor only writes the diagnosis and the doctor's signature, the other details are written by the nurse and/or anesthesia nurse.

The Role of informed consent for patients

Based on Law Number 44 Section 32 in 2019 about hospitals, it is stated that one of the patient's rights is getting an effective and efficient medical service to prevent physical and material risks. Patients also have the right to be given any information regarding diagnosis, medical procedure, alternative of the procedure, complication, prognosis of the procedure, and costs.

Patients have the right to give any permission (consent) or objection to the upcoming medical procedure by the health workers regarding their diseases. Therefore, patients and their families might sue the hospital or health workers if they conduct any malpractice during the procedure.[3]

Role of informed consent for doctors

Based on Law number 36 of 2014 regarding health workers, health workers are defined as anyone who devotes himself/herself to health sectors, and based on the knowledge, skill, and/or education, conducts health efforts. Thus, medical staff understand the aim of giving informed consent before doing any procedure to prevent suits and disputes.[3]

The Role of Informed Consent in Medical Dispute Prevention Efforts

The role of informed consent could be fully accomplished when there is compliance of medical staff in applying informed consent based on the existing standard operational procedure.[3]

Some common mistakes in filling out informed consent forms are forgetting to write the patient's name/identity, and signing the informed consent themselves. In this case, when there is a dispute or malpractice sue, this false informed consent form could be used as proof of the misconduct.[3]

DISCUSSION

Procedures for Implementing Informed Consent

Operational Report is the act of writing on the patient's medical record sheet which must be carried out by the surgical operator after carrying out the operation, which includes specific details of the surgical action, complications or absence of complications, bleeding, and medical devices used (implants, drains, etc.).[3]

Common mistakes in asking for informed consent from the patient

When doctors cannot communicate well, there might be a misunderstanding. Doctors should try to have effective communication with patients to prevent complaints. The worst things and complications that might happen must be told to the patients and the families as completely as possible. Nevertheless, patients might complain directly to legal authorities or institutions. Several cases that have entered the realm of law and been handled by courts related to medical malpractice are Decision Number 46 K/Pdt/2006, Decision Number 90/Pid.B/2011/PN Mdo, and Decision Number 1110 K/Pid.Sus/ 2012. Some of these cases are representative of the implementation of law enforcement in the health sector in Indonesia.[1]

The sanctions contained in the laws and regulations in the health sector themselves do not seem strict, because the judge refers more to the provisions in the Criminal Code regarding negligence. The judge should be able to refer to the informed consent regulations in the Minister of Health Regulation Number 290/MENKES/PER/ III/2008 concerning Approval of Medical Procedures. Moreover, this regulation is an implementation of Article 45 of Law Number 29 of 2004 concerning Medical Practice.[7] The aspect of informed consent and the existence of a therapeutic transaction is the basis for a doctor to carry out medical procedures. If aspects of informed consent and therapeutic transactions are ignored, in criminal law this is considered negligence in medical procedures. Criminalize a doctor who performs a medical procedure without prior informed consent and therapeutic transactions to be criminalized, the authorized party must be able to prove it. Without the aspect of informed consent in a medical procedure, this could constitute an element of error by the Article 359 of the Criminal Code. Juridically, the binding basis of Minister of Health Regulation Number 290/MENKES/PER/III/2008 concerning Approval of Medical Procedures do not provide sanctions in

the event of ignoring informed consent which has harmed the patient. Of course, this harms the implementation of the human right to health which is mandated by the Constitution. In medical procedures, the patient and the doctor/health worker should be in a balanced position, that is, the legal relationship between the patient and the doctor/health worker is contractual and each other is equal in law. This must be understood in medical procedures, so that actions that are suspected of medical malpractice against patients can be avoided. It should be remembered that consent to medical procedures that involve high risks must require written consent signed by the party giving the consent. Medical procedures that do not pose a risk can be given with verbal consent. The essence of informed consent in medical procedures is agreement between the patient and the doctor/health worker. In line with J Guwandi, disclosure of information relating to risks takes into consideration the nature of the risk, the importance of the risk, the possibility of the risk arising, and whether or not the risk will arise soon. Therefore, informed consent takes into account the facts of the court decision. It is suspected that medical malpractice can be minimized by providing informed consent for everyone's rights. By placing informed consent as a right that is inherent in a person, whether patient, doctor/health worker, a relationship pattern will be maintained balanced, and parallel to each other. Respect for patient rights by placing the right to informed consent as a patient's right which must be respected, appreciated, and given strict sanctions if it is not carried out. Judges in assessing cases are absolute, because judges must assess expressed consent as a condition for actions to be carried out by doctors or health workers, unless the patient is in an emergency then the patient's consent is no longer needed. This is because patient safety is the highest law by the principle of agroti salus lex suprema.[7]

First, the influence of informed consent is used as the main basis by judges in assessing the causality of an act. Consent to medical procedures that involve high risk must obtain written consent signed by the person approving. On the other hand, medical procedures that do not involve risks can be given with verbal consent. Second, the model for protecting and fulfilling patient rights at the law enforcement level (court) is to apply the principle of reverse evidence against doctors/medical personnel, because it is more effective and opens up opportunities for patients to obtain justice. This is part of fulfilling the rights of patients. However, the application of this principle must be balanced and not a negative thing.[1]

The Regulation and Implementation of Informed consent in Indonesia

Potential dangers and complications during and after the operation must be told completely to the patients and their families. Patients might get a false perception of the information given by the doctors. Therefore, doctors must communicate clearly regarding the potential complications and the risks of surgery or medical action, including hazards and death. The transparency principle is important to prevent malpractices and disputes. However, the ignorance of the public and medical staff regarding the importance of informed consent makes the regulation of informed consent crucial.[8]

The challenges in giving informed consent might come from two sides. Firstly, physicians try to provide complete information on diagnosis, treatment, complications, and prognosis. However, alternative interventions might not be given. Time constraints of the attending physician could be a challenge. Secondly, the patient's health literacy sometimes is low. They cannot fully comprehend the physicians' information. This condition might induce a dispute later on.[10] Informed consent has a function as legal protection. Therefore, the patient also has the right to refuse the informed consent given if it is not clear enough based on their understanding.[11]

Meanwhile, in emergency cases, informed consent might be excluded, especially when the patients come with no family, and their condition is very critical. On the other side, informed consent should be seen as a medico-legal documentary evidence for the doctors and patients. However, patients from developing countries might see informed consent as a pressure. Signing a document is seen as a suspicious action for people with a lower educational background. There are three components of surgical consent, i.e. disclosure of values, understanding of the procedure and disease, and decision making based on the benefits and risks explanation.[4] The role of the family member is very critical in translating the content of the informed consent form to prevent information loss and reduce the anxiety of the patients.[12]

The role of informed consent in the artificial intelligence (AI) era

Informed consent has some roles in the artificial intelligence era, i.e. in the emergency condition. Informed consent is also needed to protect the patients from the limitations and uncertainties of the AI system[13,14]. Implementing informed consent equals ensuring human rights and values. Patients can make decisions about their well-being and health condition[15].

Limitations of this review

This review was a narrative literature review. The data might not be as complete as systematic literature review. It needs further studies in the future regarding the role of informed consent for patients and doctors in the community.

CONCLUSION

In conclusion, the role of informed consent for doctors is as legal protection and obligation, meanwhile, the role of informed consent for the patients is as a fulfilment of human rights. In the invasive procedures, information has to be very clear and complete. In the emergency, informed consent could be excluded due to patients' safety. In psychiatric cases, a psychiatrist must decide and determine the best moment when the patients are in a good mental condition for understanding the information well. Doctors should be open and transparent in any information, including the possibility of death and complications to prevent any disputes later.

CONFLICT OF INTERESTS

There is no conflict of interest, such as any financial, professional, or personal

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AUTHOR CONTRIBUTION

There was only one author in this paper. Therefore, all of the contribution is made by one person, as corresponding author also.

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