



## Informed consent as a patient's legal protection for high risk anesthesia

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### Abstract

Informed consent to anesthesia has traditionally been considered "implied" after the patient has consented to surgery, with surgical consent stating that anesthesia will be required for surgery and there are risks associated with anesthesia. The problem is often that informed consent, especially in writing, is carried out by a surgeon, when the patient has not met the anesthesiologist. The risk of anesthesia is not always directly proportional to the risk of surgery. High-risk anesthesia depends on the patient's general condition related to disorders of vital organs. This could cause problem if medical or anesthesia accidents happen. Because of this, anesthesiologists should have a role in providing all information to patients regarding their health status and anesthetic risks. Patients are clinical consumers who receive health services there is a needs of legal protection, especially in regards to patient rights after that patient can accept or refuse all the medical service especially in high risk anesthesia. Therefore, Written informed consent should be the main option by the anesthesiologist is a must after the patient has given consent to undergo high-risk anesthesia after the given information about the action plan that will be carried out and the possible risks of anesthesia that may occur.

**Keywords:** informed consent, medical action, high-risk anesthesia

### Introduction

According to Article 28 H of The 1945 Constitution, everyone has the right to live in physical and spiritual prosperity, to have a place to live, and to have a good and healthy living environment and have the right to obtain health services. It is explicitly stated that health services are an important aspect that given to all Indonesian people without exception and their regulation is guaranteed by the highest legislation in Indonesia which is the legal basis for the other Act under it. Act No. 36 of 2009 concerning Health, emphasizes that health is a condition that must be implemented by the state and the state guarantees health for all people in order to achieve the highest degree of public health. In the current era of national health insurance, public awareness of health is increasing. The ease of accessing information and getting access to health is one of the supporting factors. Unfortunately, not all information obtained by patients can be justified. This is the basis for changing the pattern of relationships between doctors and patients into an equal reciprocal relationship, no longer paternalistic as before. This change in relationship makes every healing effort made by doctors to their patients requires informed consent from the patients themselves, because patients have the human right to determine their own destiny, while for doctors, informed consent can function as legal guarantees against possible risks that arise as a result of the medical procedure. In informed consent, it is necessary to explain information about the disease, the actions to be carried out in lay language that is easy for the patient to digest, side effects, alternatives as well as the efforts and possible consequences of these healing efforts so that they can protect the patient while at the same time giving the doctor a sense of calm in taking action. medical. Medical action is an unpredictable endeavor, the results cannot be calculated with certainty, and almost all medical

procedures have risks. The scale of risk, which is a side effect of medical action, can be different for each patient, not infrequently the risk of medical actions that are predicted to not occur in patients. This depends on the condition of the patient at the time of medical action and cannot be separated from how all health workers carry out all medical actions according to standard operating procedures. All risks of medical action will be borne and felt by the patient, so it is logical that the patient himself has the most rights to express his consent before medical action is carried out, especially in high-risk medical actions. One of the high-risk medical procedures is surgery, which in the case of surgery involves anesthesia.

The risk of anesthesia in many cases is not in line with the risk of surgery, surgery that is in the mild risk category may with anesthesia fall into the high-risk category due to many factors related to the different health conditions of each individual. However, there are no laws and regulations in Indonesia that regulate informed consent for high-risk anesthesia apart from surgery and the legal consequences of informed consent. Therefore, it is important to arrange written informed consent for patients under high-risk anesthesia, considering the possible risks that the patient will face. With informed consent, it means that between the patient or their representative and the health worker concerned there has been an agreement to do and/or not to do something. By law, informed consent protects patients from pressure in the form of unwanted medical intervention. As for the doctor, informed consent serves to limit the authority of the doctor to his patient, so that the doctor be more careful in carrying out medical actions, in other words, taking medical action with the consent of the patient.

### Discussion

Informed consent according to the Indonesian Medical Council is the legal consent given by the patient or his/her

representative to obtain medical or dental treatment. Before giving medical action, the doctor must obtain approval from the patient or the patient's closest family, after previously the doctor gave an explanation of the medical or dental action plan (Dezriza Ratman, 2018). In Indonesia Informed Consent regulated by three laws and regulations used as a basic legal reference in the practice of medical services, namely: Act No. 29 of 2004 concerning Medical Practice Article 45 paragraphs (1) to (6), Regulation of the Minister of Health Republic of Indonesia No. 585/Men.Kes/Per/IX/1989 concerning Approval of Medical Actions, Regulation of the Minister of Health of the Republic of Indonesia No. 290/Menkes/PER/III/2008 concerning Approval of Medical Actions.

Informed Consent is basically a subjective condition for the occurrence of therapeutic transactions in health services which are based on two kinds of human rights as basic human rights, namely the right to be informed and the right to decide for himself. According to the Regulation of the Minister of Health No.

290/MENKES/PER/III/2008 concerning Approval of Medical Actions, what is meant by Informed Consent is the approval given by the patient or closest family after receiving a complete explanation of the action that will be done to the patient. The description above explains that Informed Consent aims to protect patients against all medical actions carried out without the patient's knowledge and providing legal protection for doctors against unexpected risks due to medical actions taken. Informed consent can be divided into:

### 1. Written Consent

Consent is given in written form on a special form provided. Written consent is given to:

- a. all medical procedures that contain a high risk;
- b. Actions whose results are difficult to predict (doubtful).

This is intended to anticipate the occurrence of things that are beyond the doctor's intents and predictions which include complications from the procedure, disability and even death (on the operating table). But it should be understood that it does not mean that if the patient has agreed to the action by signing on the form and then something happens that harms the patient, the doctor is free from legal responsibility. All must be examined whether the doctor's actions are in accordance with the indications of illness, whether they are in accordance with their authority, whether they are in accordance with standard operating procedures or whether they are in accordance with professional standards So from here we can understand together that the consent given by the patient/patient's family does not remove liability (legally, both criminal and civil) or in other words does not make doctors immune in the eyes of the law.

### 2. Verbal Consent

Regulation of the Minister of Health No. 290/MenKes/2008 concerning Approval of Medical Actions, if the action given by a doctor or health worker is not a high-risk action, then written approval does not need to be given.

Patients and families can give their consent through body language in the form of:

- a. Confirming with words;
- b. Nodding head;
- c. Wink;
- d. Signaling by hand;
- e. Be silent but the patient is conscious and understands the meaning of the conversation

If the patient or family provides body language as above, it can be considered to have given consent provided that the action given is not a high-risk one.

In a situation the doctor or health worker is going to take an uncertain action the consent shouldn't given orally by the patient with a decreased state of consciousness or if there is a prediction that it will cause a problem in the future, then the consent should be given in written form, even though it does not meet the criteria for written consent.

### 3. Consent in Certain Circumstances

In the course of the disease, a patient may experience a worsening of the condition during the treatment of a doctor. This is not due to the fault or inability of the doctor in treating the patient, but factors from the patient's own body that can cause what happens not as expected. According to J Guwandi, patients and their families must be informed about the development of their condition at any time and when unexpected conditions occur, such as:

#### a. In an Emergency

If the patient's condition is in emergency and requires immediate treatment to save the patient's life, then verbal or written consent does not need to be given, because in this condition the doctor must take action quickly and it is feared that it could endanger the patient if he has to wait for approval.

If after being given emergency assistance something worse happens, the patient and his family cannot sue the doctor or other health workers if it is proven that the health worker has provided assistance correctly according to their capacity and ability. The argument from the above conditions is in accordance with the articles in the related KUHPPerdata, namely: Article 304 of the KUHPPerdata: whoever causes or leaves a person in misery, while he is obligated to provide life, care or support to that person, will be sentenced to imprisonment with longest duration or a fine of -Amount: R. 4,500,-. Article 531 of the KUHPPerdata: whoever witnesses himself a person in danger of death and neglects to provide assistance while he is able to provide such assistance, shall be sentenced to a maximum imprisonment of three months or a maximum fine of Rp. 4.500,- if the person who needs help died. Article 51 paragraph (d) of Act No. 29 of 2004 concerning Medical Practice states that if a doctor does not provide assistance to a patient who falls to an emergency unless at that time there are other people on duty and capable of handling the emergency better than himself, they are threatened with one year imprisonment or a maximum fine of Rp. 50,000,000.

#### b. Pediatric patients or incompetent people in the eyes of law

Consent to a pediatric patient or incompetent in the eyes of the law cannot be considered valid because legally, they are not capable of giving consent, and that act considered to be a violation of law. Then approval must be requested from their guardian or those who have been appointed to

represent. If it is known that the doctor has done an act that harms the patient, the doctor can be sued for the error or negligence. This is because the doctor-patient relationship as the party to the agreement must be subjected to the national treaty law, which follows Article 1320 of KUHPerdata concerning the terms of a valid agreement which states that the parties who gave consent must be legally capable. This will be discussed further in the section of therapeutic agreement.

### c. The patient is fully unconscious

If the patient comes in a state of fully unconscious, the patient cannot be asked for direct consent, but the doctor or medical personnel can ask for approval from the patient's family or a person who is rightful in the eyes of the law to give consent. If at that time there was no competent family and the patient's condition was in an emergency, doctor should give first priority to helping the patient.

According to the Regulation of the Minister of Health of the Republic of Indonesia No. 290/Menkes/PER/III/2008 concerning Medical Approval, informed consent can be submitted directly, either oral or written. The most unquestionable form is written Informed Consent, but oral is also valid unless there are certain legal conditions that require written Informed Consent for certain procedures. In the event that the doctor's actions do not harm or disturb the patient's body, the absence of informed consent will not cause problems. However, if the doctor intervenes on the patient's body, causing injury or pain, so that the patient suffers a loss, then the absence of informed consent can result in the doctor being sued for malpractice because he is considered to have committed an unlawful act.

Basically, explanations in providing information by doctors are much more important than signing written agreements, because this is the basis for determining decisions to be taken by patients and their families, but unwritten agreements will be difficult to prove when unwanted events occur. In criminal law, if a medical action is not preceded by informed consent, then the basis of the lawsuit is Article 351 of Indonesian Criminal Code (Indonesian Criminal Code (hereinafter referred to as the KUHAP)), states: Persecution is punishable by a maximum imprisonment of two years and eight months or a maximum fine of four thousand five hundred rupiah. If the act results in serious injury, the guilty person is threatened with a maximum imprisonment of five years. If it results in death, it is punishable by a maximum imprisonment of seven years. Informed consent in a medical action actually functions as the basis for the elimination of a crime, in addition to being based on the exact intent and purpose of the medical action. Although informed consent is possible to be used as evidence of letters or instructions in accordance with article 184 of KUHAP, it does not have full binding power in proof. In accordance with the evidentiary system adopted in Indonesia, namely the theory of evidence based on the law in a negative way, in addition to valid evidence, the judge's belief in evidence is also required.

### Patient Rights as Consumers

Patients are clinical consumers who receive health services and clinics are business actors who provide health services

to patients. This means that patient as a consumers are in a weaker position when compared to health facilities, in this case the clinic must provide legal certainty guarantees to patients, so there is a needs of legal protection, especially in regards to patient rights. In Act No. 29 of 2004 concerning Medical Practices, especially Article 52, the rights of patients are regulated, which include:

- a. To obtain a complete explanation of the medical action as referred to in Article 45 paragraph 3.
- b. Ask for the opinion of another doctor or dentist.
- c. Get services according to medical needs.
- d. Refuse medical treatment.
- e. Get the contents of the medical record

Act No. 36 of 2009 concerning Health, Article 56 clearly states the main rights of patients that everyone has the right to accept or reject a part or all of the relief measures that will be given to him after receiving and understanding the information. So the right of informed consent (informed consent) is the implementation of the two patient rights. For protection, everyone has the right to accept or reject part or all of the relief measures that will be given to him after receiving and fully understanding the information regarding the medical action. The right to accept or reject as referred to in paragraph (1) does not apply to:

- a. people with diseases whose disease can quickly spread to the wider community;
- b. person with unconscious state; or
- c. severe mental disorder.

Act No. 29 of 2004 concerning Medical Practice Article 1 No. 10 states that a patient is anyone who consults about his health problems to a doctor/dentist to obtain health services as referred to either directly or indirectly. Organizing Informed Consent related to patient (consumer) protection, namely the provisions on consumer rights to correct information, guidance, and health services as stipulated in Article 4 letters c, g, and i, Act No. 8 of 1999 concerning Consumer Protection which states: Consumer rights are: "...c. the right to obtain a correct, clear and honest information regarding the condition and guarantee of fine goods and/or services"; "...g. the right to be treated or served properly and honestly and not discriminatory"; and "...i. the rights regulated in the provisions of other laws and regulations, for example to keep personal data (including medical history) confidential" Violation of the obligation to provide correct, clear, and honest information as well as to maintain the confidentiality of the patient's personal data (health history) including Article 8 letter a of the Consumer Protection Act which states: Article 62 paragraph (1) of the Law with a maximum imprisonment of 5 (five) years or a maximum fine of Rp. 2,000,000,000.00 (two billion rupiah). For this reason, it is clear that the patient's position as a consumer in informed consent must be protected because the services provided by doctors in the form of medical actions in the context of efforts to heal patients must comply with the law as regulated in the consumer protection law. This relates to the position of patients and doctors are equal before the law.

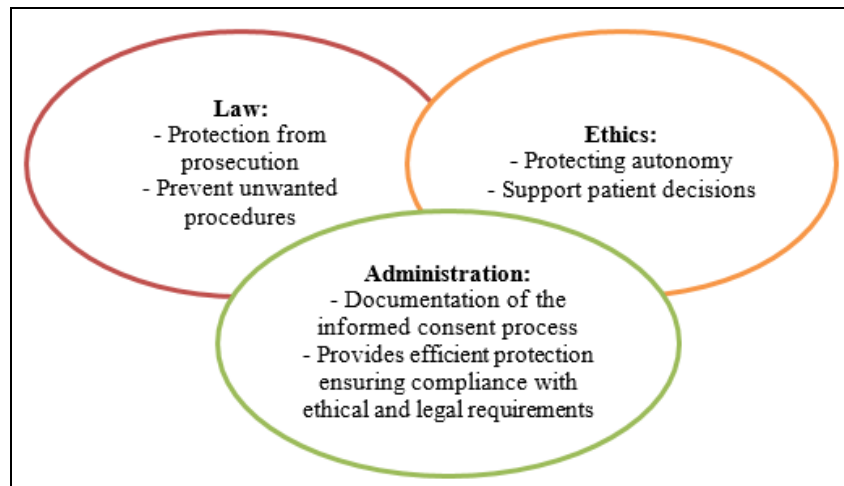


Fig 1

The agreement to exchange information reciprocally between the parties who will be involved is stated in the form of informed consent. Medical action will not be taken if there is no consent from the patient, and does not eliminate legal responsibility if there is negligence in health services as regulated in the Regulation of the Minister of Health No. 290 of 2008 concerning Approval of Medical Actions. With informed consent, it means that between the patient or his/her representative and the health worker concerned there has been an agreement to do and/or not to do something. By law, informed consent protects patients from pressure in the form of unwanted medical intervention. As for doctors, informed consent serves to limit the authority of doctors to their patients, so that doctors will be more careful in carrying out medical actions, in other words, doing a medical intervention with the consent of the patient. The absence of informed consent which results in the non-fulfillment of one of the terms of the agreement according to Article 1320 of the KUH Perdata. The absence of informed consent is classified as an unlawful act based on Article 1365 of the KUH Perdata.

Informed consent can be used as valid evidence only if it is made based on real facts and has evidentiary power in terms of formalities. Thus, proving a case is not enough with evidence in the form of informed consent, but also other evidence and the judge's conviction. Informed Consent that can be used as a means of proof as referred to in Article 13 Paragraph (1) letter b Regulation of the Minister of Health No. 269/MENKES/PER/III/2008 concerning Medical Records states: these records can be used as evidence in the process of law enforcement, discipline medicine and dentistry as well as the enforcement of medical ethics.

### Anesthesia Procedure

Anesthesia is a medical procedure that is inseparable from surgery. This implies that as with surgery, anesthesia is a high-risk medical procedure that must obtain written consent that must be signed by the patient and the patient's family. This is in accordance with the provisions of Article 3 paragraph 1 of the Minister of Health No 290/MENKES/PER/III/2008 concerning Approval of Medical Actions, Article 45 paragraph 5 of Act No. 29 of 2004 concerning Medical Practices and explanation of 37 paragraph 2 of Act No. 44 of 2009. High-risk medical procedures require informed consent, even though in an emergency the main priority is life saving measures.

Anesthesia is an action to help the patient so they didn't feel pain during a medical procedure. Anesthesia is often also referred to as an anesthetic and can be given in various ways, from injection, inhalation, to smearing. The drugs used during the anesthetic process will temporarily numb the nerves. Anesthesia is a high-risk specialty, and the general public is unaware of the risks involved. With the advent of safe drugs, good quality equipment and high standards of monitoring, anesthetic practice has become safe but even so, complications may occur. Due to the commercialization of modern medical practice and limited interaction, there is a lack of trust in the doctor-patient relationship. Thus, whenever a medical accident occurs, patients and staff suspect negligence on the part of the doctor and such cases are brought to court.

Informed consent has become the main paradigm for protecting the legal rights of patients and guiding the ethical practice of medicine.

According to Regulation of the Minister of Health No. 519 of 2011 concerning Guidelines for the Implementation of Anesthesiology Services and Intensive Therapy in Hospitals, Anesthesia services in hospitals include:

- a. anesthesia/analgesia services in the operating room and outside the operating room,
- b. perioperative medical services, acute and chronic pain management,
- c. cardiopulmonary and brain resuscitation,
- d. emergency services and intensive therapy.

Anesthesia is an attempt to relieve pain with the techniques used in surgery. Anesthesia can be done with General Anesthesia (GA), Regional Anesthesia (RA), Local Anesthesia (LA). According to the ASA (American Society of Anesthesiologist) which is also quoted from Regulation of the Minister of Health No. 779 of 2008 concerning Standards for Anesthesiology and Reanimation Services in Hospitals, there is a classification of the health status of patients for whom anesthesia procedures will be performed.

#### a. Physical status 1

Patients who do not have a systemic disease or disorder requiring localized surgery. Example: A healthy man underwent a herniotomy.

#### b. Physical status 2

Patients with mild or moderate systemic disease, due to medical reasons or disorders requiring surgery. Example: a



diabetic patient on oral medication, but no other organ complications.

### c. Physical status 3

Patients with systemic disease that limits their activity. Example: patients with cardiac infarction, with angina pectoris who must be managed with medical care.

### d. Physical status 4

Patients with life-threatening illnesses. Example: a patient with severe heart failure who can only walk a few meters.

### e. Physical status 5

"Moribund" patients who are 50% will die within 24 hours, with or without surgery. Example: patients with strangulation ileus with anuria, coma, blood pressure 70/40 with dopamine infusion.

Physical Status 3 or more can be referred to as high-risk Anesthesia because there is a severe systemic disease in the patient.

The death rate attributable to anesthetic procedures appears to have declined over the past 30 years from one or two deaths per 3000 anesthesia experiences, to a rate of one or two deaths per 20,000 experiences. According to the ASA (American Society of Anesthesiologists), during the 1990s the three leading causes of anesthesia accidents were death (22%), nerve injury (18%) and brain damage (9%) and the probable Physical Status 3 death rate was 7.8 -25.9% and increasing in physical status level. Informed consent for high-risk anesthesia plays a role when "High-Risk Patient" undergoes a complex surgical procedure with multiple severe comorbidities.

To understand critical events during anesthesia, a definite concept of the anesthetic system must be formed. What is meant by "system" here is the unity of components that are interrelated with each other in a certain environment that aims to provide a result, in this case is a safe, efficient and effective anesthesia service. This system can consist of human as well as technical components, which is known as "Man-machine system". In the anesthesia system, the components include anesthesiologists, patients, anesthesia machines, monitoring machines, operating room personnel (surgeons, nurses, Technicians), operating room equipment and other facilities at the discretion of the hospital. All of these components must be considered as a cause for the emergence of factors that can influence or be affected by the system. This concept must always be kept in mind, not only when investigating the occurrence of an anesthetic accident but also more importantly when evaluating the optimal outcome of the system as a whole.

There are several reasons why it is difficult to accurately measure adverse events associated with the outcome of anesthetic procedures, which are also known as anesthesia accidents. It is often impossible to establish responsibility (who is responsible) for a patient's poor outcome, whether due to the patient's inherent disease, surgical procedure, anesthesia or management. In fact, all three can contribute to poor outcomes is also difficult to determine measurably. Death is an obvious endpoint, but death by anesthesia associated perioperatively is extremely rare. However, many studies have attempted to determine the incidence of complications due to anesthesia. Unfortunately, studies that vary in criteria for determining outcomes associated with adverse anesthesia have only used retrospective analyses.

Finally, medicolegal concerns hinder accurate reporting. Consent to anesthesia has traditionally been considered "implied" after the patient has consented to surgery, with surgical consent stating that anesthesia will be required for surgery and there are risks associated with anesthesia. The problem is often that informed consent, especially in writing, is carried out by a surgeon, when the patient has not met the anesthesiologist. Anesthesiologists should have a role in providing all information to patients regarding their health status and anesthetic risks.

A doctor should not impose his will on a patient even though it is in accordance with the knowledge and interests of the patient, because what distinguishes a doctor from a general criminal offense such as persecution is informed consent. For this reason, doctors must be guided by the Minister of Health Regulation No. 290 of 2008 concerning the approval of medical actions which contains how to do informed consent correctly. The obligation to provide sufficient information to the patient plays an important role so that the patient can give a correct and real decision/consent. Informed consent is a manifestation of patient protection in treatment. Approval of medical action does not have to be done so strictly in written or authentic form, it does not mean it cannot be through an authentic deed but is considered unreasonable, excessive, or too bureaucratic because it takes a long time while the patient requires immediate treatment.

A key aspect of informed consent is to provide sufficient information for the patient to accept or refuse the proposed treatment, and avoid deception or coercion. It has long been known that 'Maintaining good relationships with patients often works better than best-informed consent'. This view is consistent with listening to the patient and developing a therapeutic relationship so that it can provide meaningful risk information in a way that enhances rather than hinders the patient experience.

## Conclusion

Informed consent for patients with high-risk anesthesia requires the anesthesiologist to get approval from the patient or the patient's closest family after the anesthesiologist has explained or provided information about the anesthetic action plan that will be carried out and the possible risks of anesthesia that may occur. Written informed consent by the anesthesiologist is a must after the patient has given consent to undergo high-risk anesthesia after the given information about the action plan.

According to the Consumer Protection Act, the consumer has rights to give correct, clear and honest information regarding the condition of their bodies and violations to that act can result in a punishment in form of imprisonment or a maximum fine of two billion rupiahs. Informed Consent as evidence has three parts, namely the legal section, the ethics section and the document section. It is intended that each section will make doctors to work carefully, supports patient decisions and becomes evidence of written legal documents.

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